

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
16-55	C4591001 1011 10111215	1	19OCT2020	Product administration error	DOSE NOT CHANGED	N	N	19OCT2020	N	N
	C4591001 1012 10121103	2	22SEP2020	Product administration error	DOSE NOT CHANGED	N	N	22SEP2020	Y	N
	C4591001 1024 10241002	2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241004	2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1024 10241006	2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1024 10241014	2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241023	2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1024 10241032	1	17AUG2020	Product storage error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001 1024 10241033	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

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	C4591001 1024 10241039	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241040	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241042	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241044	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241046	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241054	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241055	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241061	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241066	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N



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	C4591001 1024 10241067	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241071	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241072	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241074	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241078	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1024 10241084	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241085	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241091	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1024 10241094	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N

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	C4591001 1024 10241100	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1024 10241102	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1024 10241104	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241108	1	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441001	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441015	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441028		24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1044 10441029	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1044 10441031	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N

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	C4591001 1044 10441034	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441037	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441045	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441048		27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441050	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441052	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441054	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441060	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1044 10441063	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N

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	C4591001 1044 10441068	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1044 10441071	1	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441076	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441079	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441088	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441089	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1068 10681002	1	18AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1068 10681003	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681006	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N

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	C4591001 1068 10681010	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681011	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681012	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681013	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681016	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681017	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
		4	08JAN2021	Product administration error	DOSE NOT CHANGED	N	N	08JAN2021	N	N
	C4591001 1068 10681018	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681021	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N

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	C4591001 1068 10681024	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681025	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681026	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681027	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681028	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681031	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681034	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681035	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681036	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N

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		4	08JAN2021	Product administration error	DOSE NOT CHANGED	N	N	08JAN2021	N	N
	C4591001 1068 10681037	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681038	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681042	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681046	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681047	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681052	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681053	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681058	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N

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	C4591001 1068 10681060	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681061	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681064	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681066	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681071	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681072	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681073	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681074	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681076	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N



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	C4591001 1068 10681077	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681080	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681081	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681083	1	01SEP2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1079 10791039	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1079 10791130	1	17AUG2020	Wrong product administered	DRUG WITHDRAWN	N	N	17AUG2020	N	N
	C4591001 1079 10791170	3	25FEB2021	Product administration error	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1079 10791206	1	28AUG2020	Product administration error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1088 10881077	2	11SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	11SEP2020	N	N

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	C4591001 1090 10901334	1	03SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1091 10911005	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001 1091 10911008	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1091 10911014	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1091 10911015	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1096 10961011	3	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961027	3	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961059	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961195	2	21SEP2020	Product administration error	DOSE NOT CHANGED	N	N	21SEP2020	N	N

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	C4591001 1096 10961197	2	21SEP2020	Product administration error	DOSE NOT CHANGED	N	N	21SEP2020	N	N
	C4591001 1096 10961209	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961245	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961246	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1101 11011024	3	28DEC2020	Expired product administered	DOSE NOT CHANGED	N	N	28DEC2020	N	N
	C4591001 1116 11161226	1	11SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	11SEP2020	N	N
	C4591001 1126 11261053	1	20AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1129 11291129	2	08SEP2020	Product administration error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1136 11361027	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N

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	C4591001 1136 11361039	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1136 11361083	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1136 11361084	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1136 11361109	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1141 11411011	2	21AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1141 11411014	1	03AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1141 11411023	2	25AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1141 11411065	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1141 11411068	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N

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	C4591001 1141 11411080	1	14AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	14AUG2020	N	N
	C4591001 1141 11411093	1	18AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1141 11411139	1	27AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1146 11461196	1	03SEP2020	Product administration error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1146 11461338	2	13NOV2020	Product administration error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1161 11611010	1	31JUL2020	Product administration error	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1161 11611015	1	01AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	01AUG2020	N	N
	C4591001 1163 11631006	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N
	C4591001 1163 11631039	1	06AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	06AUG2020	N	N

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	C4591001 1163 11631064	1	07AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	07AUG2020	N	N
	C4591001 1163 11631096	1	12AUG2020	Product administration error	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1163 11631117	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631121	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631124	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631127	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631136	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631142	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631145	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N

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	C4591001 1169 11691033	3	07JAN2021	Underdose	DOSE NOT CHANGED	N	N	07JAN2021	N	N
	C4591001 1169 11691049	2	05OCT2020	Product administration error	DOSE NOT CHANGED	N	N	05OCT2020	N	N
	C4591001 1185 11851017	2	16NOV2020	Product administration error	DOSE NOT CHANGED	N	N	16NOV2020	N	N
	C4591001 1185 11851037	2	16NOV2020	Product administration error	DOSE NOT CHANGED	N	N	16NOV2020	N	N
	C4591001 1212 12121005	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121008	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121013	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121022	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1212 12121031	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N

## 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1221 12211079	1	02DEC2020	Expired product administered	DOSE NOT CHANGED	N	N	02DEC2020	N	N
	C4591001 1230 12301157	2	28OCT2020	Product administration error	DOSE NOT CHANGED	N	N	28OCT2020	N	N
	C4591001 1231 12313428	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313429	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313449	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313456	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313459	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313467	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313469	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N



## 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313479	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313483	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313486	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313487	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313492	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313497	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313498	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313501	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313505	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313506	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313508	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313509	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313512	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313514	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313515	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313517	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313518	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313519	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313528	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313533	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313534	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313537	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313541	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313542	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313546	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313551	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313553	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313554	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313556	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313564	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313567	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1232 12321354	2	13NOV2020	Product storage error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1232 12321373	2	13NOV2020	Product storage error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1232 12321382	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1232 12321385	2	13NOV2020	Product storage error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1232 12321394	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N

## 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
>55	C4591001 1232 12321395	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1269 12691004	1	17AUG2020	Product administration error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001 1269 12691011	1	20AUG2020	Product administration error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1269 12691016	1	20AUG2020	Product administration error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1003 10031120	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1011 10111201	1	19OCT2020	Product administration error	DOSE NOT CHANGED	N	N	19OCT2020	N	N
	C4591001 1024 10241003	2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241031	1	17AUG2020	Product storage error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001 1024 10241037	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1024 10241041	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241049	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241057	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241059	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241065	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241068	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241077	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241081	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1024 10241083	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1024 10241087	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241096	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1024 10241097	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1037 10371356	2	12NOV2020	Expired product administered	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1044 10441002	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441004	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441007	2	05SEP2020	Product storage error	DOSE NOT CHANGED	N	N	05SEP2020	N	N
	C4591001 1044 10441010	2	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441016	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1044 10441018	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441032	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1044 10441036	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441041	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441047	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441049	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441055	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441062	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1044 10441067	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N



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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1044 10441073	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441075	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441080	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441083	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441085	1	05SEP2020	Product storage error	DOSE NOT CHANGED	N	N	05SEP2020	N	N
	C4591001 1044 10441090	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441092	1	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441093	1	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441094	1	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1054 10541024	2	10OCT2020	Wrong product administered	DOSE NOT CHANGED	N	N	10OCT2020	N	N
	C4591001 1068 10681001	1	18AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1068 10681004	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681005	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681007	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681008	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681009	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681014	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681015	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1068 10681019	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681020	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681022	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681023	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681029	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681030	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681032	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681033	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681039	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1068 10681040	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681041	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681043	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681044	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681045	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681050	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681051	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681054	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681055	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1068 10681056	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681057	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681059	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681062	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681063	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681065	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681068	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681069	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681075	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1068 10681078	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681079	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681082	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681084	1	01SEP2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1079 10791038	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1079 10791042	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1079 10791044	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1079 10791207	1	28AUG2020	Product administration error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1081 10811053	2	09SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	09SEP2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1091 10911001	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001 1091 10911004	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001 1091 10911010	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1091 10911012	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1096 10961068	4	26FEB2021	Product storage error	DRUG WITHDRAWN	N	N	26FEB2021	N	N
	C4591001 1096 10961149	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961247	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961324	3	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1121 11211071	1	03SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	03SEP2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1129 11291091	2	01SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1136 11361057	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1136 11361059	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1136 11361079	4	24FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1136 11361105	4	25FEB2021	Incorrect dose administered	DOSE NOT CHANGED	N	N	25FEB2021	N	N
	C4591001 1141 11411066	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1163 11631003	1	31JUL2020	Product administration error	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1163 11631005	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N
	C4591001 1163 11631007	1	31JUL2020	Product administration error	DOSE NOT CHANGED	N	N	31JUL2020	N	N



### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1163 11631008	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N
	C4591001 1163 11631010	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1163 11631011	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1163 11631013	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1163 11631030	1	05AUG2020	Drug therapy	DRUG WITHDRAWN	N	N	05AUG2020	N	N
	C4591001 1163 11631062	1	13AUG2020	Drug therapy	DRUG WITHDRAWN	N	N	13AUG2020	N	N
	C4591001 1163 11631092	1	13AUG2020	Drug therapy	DOSE NOT CHANGED	N	N	13AUG2020	N	N
	C4591001 1163 11631126	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631131	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1163 11631132	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631133	2	10SEP2020	Product storage error	DOSE NOT CHANGED	N	N	10SEP2020	N	N
	C4591001 1163 11631144	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631149	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1177 11771089	2	09SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	09SEP2020	N	Y
	C4591001 1212 12121021†	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1214 12141002	1	22OCT2020	Product administration error	DOSE NOT CHANGED	N	N	22OCT2020	N	N
	C4591001 1231 12311057	1	11AUG2020	Product dispensing error	DOSE NOT CHANGED	N	N	11AUG2020	N	N
	C4591001 1231 12313446	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313461	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313468	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313478	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313480	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313496	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313503	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313511	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313524	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313530	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313536	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313538	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313549	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313562	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313855	4	24FEB2021	Product administration error	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1231 12314669	4	24FEB2021	Product administration error	DOSE NOT CHANGED	N	N	24FEB2021	N	N
	C4591001 1232 12321383	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1232 12321389†	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1232 12321390	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N

### 16.2.5.3 Listing of Medication Errors – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1232 12321398	2	12NOV2020	Product storage error	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1265 12651026	1	31AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1269 12691009	1	19AUG2020	Product administration error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1269 12691019	1	20AUG2020	Product administration error	DOSE NOT CHANGED	N	N	20AUG2020	N	N

Note: † = Human immunodeficiency virus (HIV)-positive subject.  
a. Dose No. = the vaccination visit at which the medication error occurred.  
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_me\_all\_p3

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
16-55	C4591001 1001 10011004^	Immune system disorders	Seasonal allergy	01JUN2010		Y
		Investigations	Human papilloma virus test positive	01JUN2006	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JUN2014	01JUN2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JUN2010		Y
	C4591001 1001 10011005^	Gastrointestinal disorders	Haemorrhoids	01JAN2007		Y
		Infections and infestations	Tooth abscess	01MAR2016	31MAR2016	N
		Investigations	Smear cervix abnormal	01JAN2018	31MAR2019	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
			Insomnia	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2018		Y
	C4591001 1001 10011008^	Gastrointestinal disorders	Aphthous ulcer	01JAN1998		Y
			Diarrhoea	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01MAR1999		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN2012		Y
	C4591001 1001 10011009^	Infections and infestations	Upper respiratory tract infection	25APR2020	05MAY2020	N
	C4591001 1001 10011011^	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1001 10011012^	General disorders and administration site conditions	Swelling face	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cyst removal	01JAN2005	31DEC2005	N
	C4591001 1001 10011013^	Immune system disorders	Allergy to animal	05MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				18JUN2019		Y
			Seasonal allergy	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Eczema	01JAN2017		Y
	C4591001 1001 10011015^	Gastrointestinal disorders	Dyspepsia	01JAN2011		Y
	C4591001 1001 10011017^	Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
			Onychomycosis	01JAN2008		Y
		Injury, poisoning and procedural complications	Joint injury	01AUG2013	31DEC2018	N
		Investigations	Biopsy colon	19SEP2018	19SEP2018	N
			Colonoscopy	01APR2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Back pain	19NOV2012		Y
		Nervous system disorders	Piriformis syndrome	01DEC2012	31JAN2013	N
		Renal and urinary disorders	Nephrolithiasis	01NOV2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
			Transient acantholytic dermatosis	01JAN2019	28FEB2019	N
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Varicose vein operation	01JUL2005	29FEB2008	N
	C4591001 1001 10011019^	Skin and subcutaneous tissue disorders	Dry skin	01NOV2019		Y
	C4591001 1001 10011024^	Psychiatric disorders	Anxiety	01JAN2018	31DEC2020	N
	C4591001 1001 10011026^	Gastrointestinal disorders	Irritable bowel syndrome	30JUN2008		Y
		Immune system disorders	Seasonal allergy	30JUN2010		Y
		Injury, poisoning and procedural complications	Ankle fracture	01FEB2003	28FEB2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Road traffic accident	01FEB2003	28FEB2003	N
		Skin and subcutaneous tissue disorders	Urticaria			Y
		Surgical and medical procedures	Tendon operation	30JUN2003	30JUN2003	N
			Wound closure	30JUN1996	30JUN1996	N
	C4591001 1001 10011028^	Investigations	Arthroscopy	01JAN2009	31DEC2009	N
			Endoscopy upper gastrointestinal tract	01FEB2019	28FEB2019	N
			Vitamin D decreased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JUN2010		Y
		Surgical and medical procedures	Caesarean section	30JUN1997	30JUN1997	N
			Female sterilisation	01JAN2000	31JAN2000	N
			Knee arthroplasty	08JAN2020	08JAN2020	N
			Large intestinal polypectomy	01FEB2019	28FEB2019	N
	C4591001 1001 10011030^	Injury, poisoning and procedural complications	Ligament rupture	01APR1996	15JUN1996	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2000		Y
		Surgical and medical procedures	Ligament operation	15JUN1996	15JUN1996	N
	C4591001 1001 10011032^	Immune system disorders	Drug hypersensitivity	01JUN2018		Y
		Vascular disorders	Hypertension	01JAN2012	31DEC2013	N
	C4591001 1001 10011034^	Nervous system disorders	Sciatica	01OCT2015		Y
		Surgical and medical procedures	Intervertebral disc operation	18NOV2016	18NOV2016	N
				26FEB2016	26FEB2016	N



16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011066^	Blood and lymphatic system disorders	Iron deficiency anaemia	01OCT2019		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
			Haemorrhoids	01AUG2019	31MAR2020	N
				01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01AUG2008		Y
		Surgical and medical procedures	Spinal fusion surgery	01JUN2009	30JUN2009	N
	C4591001 1001 10011067^	Ear and labyrinth disorders	Excessive cerumen production	30JUN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Papilloma viral infection	01JAN2017	31DEC2018	N
		Investigations	Smear cervix abnormal	01JAN2016	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1981		Y
		Surgical and medical procedures	Hernia repair	01JAN1981	31DEC1981	N
	C4591001 1001 10011068^	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Infections and infestations	Sinusitis	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2001		Y
		Surgical and medical procedures	Lithotripsy	01JAN2001		Y
			Tonsillectomy			N
	C4591001 1001 10011069^	Immune system disorders	Allergy to animal	01JAN1994		Y
		Infections and infestations	Chlamydial infection	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1995	31DEC1995	N
		Investigations	Smear cervix abnormal	16JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Varicose vein operation	01JAN2018	31DEC2018	N
		Vascular disorders	Varicose vein	01JAN2016	31DEC2016	N
	C4591001 1001 10011070^	Injury, poisoning and procedural complications	Cartilage injury	01JAN2016	31DEC2016	N
			Meniscus injury	01JAN2017	31DEC2017	N
			Skeletal injury	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC2007	N
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN2007	31DEC2007	N
			Shoulder operation	01JAN2016	31DEC2016	N
		Vascular disorders	Deep vein thrombosis	14JUN2019	17JUN2019	N
	C4591001 1001 10011071^	Eye disorders	Astigmatism	01JAN2015	31DEC2019	N
		Infections and infestations	Pilonidal cyst	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hair follicle tumour benign	01JAN2002	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN1993		Y
		Surgical and medical procedures	Keratomileusis	01JAN2019	31DEC2019	N
	C4591001 1001 10011076^	Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Fracture treatment	01JAN2002	31DEC2002	N
	C4591001 1001 10011083	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1001 10011085	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Reproductive system and breast disorders	Amenorrhoea	01FEB2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1001 10011086	Gastrointestinal disorders	Large intestine polyp	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01SEP1992	31DEC1992	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1001 10011087	Gastrointestinal disorders	Reflux gastritis	01JAN2020		Y
		General disorders and administration site conditions	Chronic fatigue syndrome	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
	C4591001 1001 10011088	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2006	31DEC2018	N
		Vascular disorders	White coat hypertension	01JAN2015		Y
	C4591001 1001 10011089	Infections and infestations	Fungal skin infection	01JAN2013		Y
		Investigations	Cardiac murmur	01JAN2015		Y
		Nervous system disorders	Syncope	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011091	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tinea pedis	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Intervertebral disc degeneration	26MAY2016		Y
			Spondylolisthesis	29JUL2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1001 10011092	Infections and infestations	Gastroenteritis	01JAN1989	31DEC1989	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1001 10011102	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2012		Y
	C4591001 1001 10011105	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Investigations	Blood bilirubin increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2020		Y
	C4591001 1001 10011106	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Back injury	01JAN1994	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Nervous system disorders	Epilepsy	01JAN1980	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011107	Infections and infestations	Chronic sinusitis	01JAN2015	31JAN2020	N
	C4591001 1001 10011113	Nervous system disorders	Migraine with aura	01JAN2013		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1001 10011126	General disorders and administration site conditions	Oedema peripheral	01APR2020	30APR2020	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01APR2020		Y
		Vascular disorders	Collateral circulation	01JAN2015		Y
			May-Thurner syndrome	01JAN2015		Y
	C4591001 1001 10011129	General disorders and administration site conditions	Chest pain	01JAN2012	31DEC2012	N
		Infections and infestations	Localised infection	04SEP2015	11SEP2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2012		Y
	C4591001 1001 10011130	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2016		Y
	C4591001 1001 10011131	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1001 10011132	Immune system disorders	Allergy to animal	01JUL2020		Y
			Seasonal allergy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1001 10011136	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		General disorders and administration site conditions	Hernia	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Incisional hernia repair	01JAN2013	31DEC2013	N
	C4591001 1001 10011138	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2005		Y
	C4591001 1001 10011143	Eye disorders	Glaucoma	01JAN2014		Y
	C4591001 1001 10011145	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Psychiatric disorders	Aerophobia	01JAN2017		Y
			Panic disorder	01JAN2017		Y
	C4591001 1001 10011146	Immune system disorders	Seasonal allergy	01JAN1987		Y
	C4591001 1001 10011149	Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1002 10021003^	Eye disorders	Myopia	01JAN2003		Y
		Immune system disorders	Food allergy	01JAN2003		Y
				01JAN2007		Y
			Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Headache	01JAN2006		Y
	C4591001 1002 10021004^	Eye disorders	Myopia	01JAN1998		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Dysmenorrhoea	01DEC2003		Y
	C4591001 1002 10021005^	Cardiac disorders	Bradycardia	01APR2000		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	09MAY2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1002 10021006^	Congenital, familial and genetic disorders	Congenital hypothyroidism	01JAN1997		Y
		Eye disorders	Hypermetropia	01JAN1996		Y
			Myopia	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Hepatitis A	01JAN1997	30JUL1997	N
	C4591001 1002 10021007^	Immune system disorders	Seasonal allergy	01JUN2012		Y
		Infections and infestations	Herpes simplex	01SEP2012		Y
		Injury, poisoning and procedural complications	Cartilage injury	01AUG2010	30SEP2010	N
		Skin and subcutaneous tissue disorders	Acne	01APR2019		Y
		Surgical and medical procedures	Chondroplasty	01SEP2010	30SEP2010	N
	C4591001 1002 10021009^	Eye disorders	Dacryostenosis acquired	01JAN1996	31DEC1996	N
			Myopia	01SEP2008		Y
		Immune system disorders	Allergy to animal	01JAN2001		Y
			Seasonal allergy	01JAN1999		Y
		Infections and infestations	Urinary tract infection	01DEC2019	31DEC2019	N
		Surgical and medical procedures	Lacrimal duct procedure	01JAN1996	31DEC1996	N
	C4591001 1002 10021011^	Eye disorders	Myopia	01MAR2010		Y
		Immune system disorders	Food allergy	01JAN2017		Y
			Seasonal allergy	01MAR2019		Y
	C4591001 1002 10021012^	Immune system disorders	Allergy to animal	01JAN1999		Y
			Drug hypersensitivity	01JAN1995		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Perioral dermatitis	01JAN2015		Y
	C4591001 1002 10021013^	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01APR2013		Y
		Psychiatric disorders	Anxiety	08JAN2020		Y
	C4591001 1002 10021014^	Eye disorders	Myopia	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Injury, poisoning and procedural complications	Facial bones fracture	05DEC2009	05DEC2009	N
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
	C4591001 1002 10021015^	Eye disorders	Myopia	01JAN1988		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1002 10021017^	Reproductive system and breast disorders	Polycystic ovaries	01JUN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993		Y
	C4591001 1002 10021018^	Eye disorders	Myopia	01JAN1975		Y
		Hepatobiliary disorders	Hepatic cyst	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01MAR2020		Y
			Hypersensitivity	01JAN1997		Y
			Perfume sensitivity	01MAR2020		Y
			Reaction to colouring	01MAR2020		Y
			Rubber sensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Concussion	01JAN2017	31DEC2017	N
			Muscle strain	20APR2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1999		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1982		Y
	C4591001 1002 10021020^	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1002 10021021^	Eye disorders	Myopia	01JAN1991		Y
		Immune system disorders	Allergy to animal	01JAN2014		Y
			Cockroach allergy	01JAN2014		Y
	C4591001 1002 10021022^	Investigations	Blood cholesterol increased	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1002 10021023^	Immune system disorders	Allergy to animal	01JAN2010		Y
			Drug hypersensitivity	01JAN2017		Y
			Dust allergy	01JAN2010		Y
			Mycotic allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010	30NOV2016	N
		Surgical and medical procedures	Appendectomy	10NOV2009	11NOV2009	N
	C4591001 1002 10021024^	Eye disorders	Myopia	01SEP1984		Y
		Immune system disorders	Seasonal allergy	01SEP1983		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP1983	31MAY1993	N
	C4591001 1002 10021027^	Eye disorders	Myopia	01JAN2005		Y
	C4591001 1002 10021034^	Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1002 10021035^	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1002 10021036^	Endocrine disorders	Hypothyroidism	01DEC2006		Y
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Psychiatric disorders	Depression	01DEC2006		Y
	C4591001 1002 10021038^	Eye disorders	Hypermetropia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01APR2010		Y
		Surgical and medical procedures	Caesarean section	15APR2003	15APR2003	N
				23APR2007	23APR2007	N
	C4591001 1002 10021041^	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Osteomyelitis	01APR2013	31MAY2013	N
		Surgical and medical procedures	Sinuplasty	01OCT2019	31OCT2019	N
	C4591001 1002 10021079^	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1999		Y
			Milk allergy	01JAN1999		Y
			Seasonal allergy	01JAN1994		Y
		Infections and infestations	Genital herpes	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1002 10021080^	Cardiac disorders	Bundle branch block left	01JAN2000		Y
		Immune system disorders	Food allergy	01JAN1987		Y
			Milk allergy	01JAN1987		Y
			Seasonal allergy	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2012	30JUN2012	N
		Reproductive system and breast disorders	Oligospermia	01JAN2010		Y
	C4591001 1002 10021081^	Injury, poisoning and procedural complications	Muscle strain	01JUL2020	18JUL2020	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Rash	01OCT2019		Y
	C4591001 1002 10021082^	Immune system disorders	Rubber sensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN1972		Y
		Surgical and medical procedures	Female sterilisation	01OCT1990	31OCT1990	N
	C4591001 1002 10021083^	Psychiatric disorders	Depression	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2011	31DEC2015	N
		Surgical and medical procedures	Shoulder operation	01JAN2015	31DEC2015	N
	C4591001 1002 10021084^	Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Surgical and medical procedures	Varicose vein operation	01NOV2019	30NOV2019	N
		Vascular disorders	Varicose vein	01JAN2016	30NOV2019	N
	C4591001 1002 10021087^	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	06JUN2006	06JUN2006	N
	C4591001 1003 10031016^	Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2012	31DEC2012	N
	C4591001 1003 10031017^	Immune system disorders	Seasonal allergy	01JAN1981		Y
	C4591001 1003 10031018^	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1003 10031019^	Immune system disorders	Food allergy	01JAN2005		Y
	C4591001 1003 10031020^	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
		Nervous system disorders	Sinus headache	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1003 10031021^	Immune system disorders	Allergy to animal	01JAN2013		Y
	C4591001 1003 10031022^	Surgical and medical procedures	Turbinectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031024^	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1003 10031026^	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1003 10031027^	Injury, poisoning and procedural complications	Arthropod bite	25MAY2020	25MAY2020	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1982		Y
		Social circumstances	Corrective lens user	01JAN1981		Y
	C4591001 1003 10031028^	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01MAY2020		Y
		Skin and subcutaneous tissue disorders	Miliaria	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2020		Y
	C4591001 1003 10031029^	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01OCT2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1003 10031030^	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2009		Y
	C4591001 1003 10031032^	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031034^	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
	C4591001 1003 10031038^	General disorders and administration site conditions	Hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Groin pain	01JAN2018		Y
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
	C4591001 1003 10031050^	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
	C4591001 1003 10031057^	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Helicobacter infection	06JUN2020		Y
	C4591001 1003 10031059^	Immune system disorders	Drug hypersensitivity	24JUN1975		Y
	C4591001 1003 10031061^	Musculoskeletal and connective tissue disorders	Bursitis	01JAN2008		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2015		Y
	C4591001 1003 10031065^	Social circumstances	Corrective lens user	01JAN1982		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1003 10031066^	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN1976		Y
			Seasonal allergy	01JAN1976		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2015	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2020	31DEC2020	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Surgical and medical procedures	Uterine operation	01JAN2013	31DEC2013	N
	C4591001 1003 10031070^	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
	C4591001 1003 10031072^	Nervous system disorders	Nystagmus	01JAN1981		Y
		Surgical and medical procedures	Mastectomy	01JAN2016	31DEC2016	N
	C4591001 1003 10031088	Eye disorders	Myopia	01JAN2003		Y
		Immune system disorders	Allergy to animal	01JAN2005		Y
			Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Social circumstances	Corrective lens user	01JAN2003		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAY2019		Y
	C4591001 1003 10031090	Cardiac disorders	Palpitations	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1003 10031094	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN1989		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1983	31DEC1983	N
			Ear tube removal	01JAN1983	31DEC1983	N
			Sinus operation	01MAR2017	31MAR2017	N
	C4591001 1003 10031096	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Infections and infestations	Tuberculosis	01JAN2006	31DEC2006	N
		Social circumstances	Corrective lens user	01JAN2007		Y
	C4591001 1003 10031100	Cardiac disorders	Arrhythmia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1003 10031101	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2015		Y
		Eye disorders	Astigmatism	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2019		Y
			Dust allergy	01JAN2019		Y
			Mycotic allergy	01JAN2019		Y
			Seasonal allergy	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2007	31DEC2007	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Ear tube removal	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1003 10031104	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1003 10031111	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2005	31DEC2007	N
	C4591001 1003 10031115	Eye disorders	Hypermetropia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	External fixation of fracture	01DEC2019	31DEC2019	N
			Fracture treatment	01DEC2016	31DEC2019	N
	C4591001 1003 10031116	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019	31MAY2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2008	31DEC2009	N
		Nervous system disorders	Migraine	01JAN1988		Y
		Surgical and medical procedures	Hip surgery	01MAY2019	31MAY2019	N
			Hysterectomy	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031122	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN1982		Y
				01JAN2017		Y
	C4591001 1003 10031125	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1003 10031137	Cardiac disorders	Sinus tachycardia	01JAN2020		Y
		Congenital, familial and genetic disorders	Factor V Leiden mutation	(b) (6) 1978		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2015		Y
	C4591001 1003 10031138	Gastrointestinal disorders	Colitis ulcerative	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Colectomy	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1003 10031141	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1003 10031144	Nervous system disorders	Migraine	01JAN2005	31DEC2005	N
	C4591001 1003 10031146	Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031147	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Investigations	Haemoglobin decreased	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Gastrectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1003 10031151	Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1003 10031155	Eye disorders	Hypermetropia	01JAN1997		Y
		Investigations	Blood cholesterol increased	01NOV2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
		Social circumstances	Corrective lens user	01JAN1997		Y
			Tobacco user	01JAN2009		Y
		Surgical and medical procedures	Decompressive craniectomy	01JAN2003	31DEC2003	N
			Ligament operation	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
	C4591001 1003 10031156	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Menopause	01JAN2020		Y
	C4591001 1003 10031158	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1989		Y
			Spondylitis	01JAN2006		Y
		Social circumstances	Corrective lens user	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Brain tumour operation	01JAN2006	31DEC2006	N
			Carpal tunnel decompression	01JAN2009	31DEC2009	N
			Knee operation	01JAN1985	31DEC1985	N
			Shoulder operation	01JAN2017	31DEC2017	N
	C4591001 1003 10031160	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2014		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria thermal	01JAN2018		Y
	C4591001 1003 10031161	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1003 10031162	Ear and labyrinth disorders	Deafness	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Pelvic pain	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1003 10031166	Gastrointestinal disorders	Diverticulum	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Rubber sensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1998		Y
			Plantar fasciitis	01JAN2013	31DEC2013	N
		Nervous system disorders	Cluster headache	01JAN2013	31DEC2013	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1994	31DEC1997	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Knee operation	01JAN1983	31DEC1983	N
				01JAN2000	31DEC2000	N
			Shoulder operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031170	Pregnancy, puerperium and perinatal conditions	Gestational hypertension	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2002		Y
	C4591001 1003 10031174	Eye disorders	Glaucoma	01JAN2016		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Allergy to plants	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1990	31DEC2000	N
		Surgical and medical procedures	Ear tube removal	01JAN1991	31DEC1991	N
			Inguinal hernia repair	01JAN2006	31DEC2006	N
			Trabeculectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031175	Immune system disorders	Food allergy	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Social circumstances	Menopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031177	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
	C4591001 1003 10031179	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1986		Y
		Infections and infestations	Folliculitis	01DEC1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Photodermatitis	01JAN2018		Y
	C4591001 1003 10031180	Cardiac disorders	Tachycardia	01JAN1985	31DEC1997	N
		Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Reproductive system and breast disorders	Infertility	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1986		Y
	C4591001 1003 10031183	Immune system disorders	Seasonal allergy	01JAN1993		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
	C4591001 1003 10031184	Cardiac disorders	Ventricular tachycardia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
	C4591001 1003 10031186	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Nervous system disorders	Narcolepsy	01JAN2010		Y
	C4591001 1003 10031187	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
	C4591001 1003 10031190	Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1003 10031191	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2020		Y
	C4591001 1003 10031194	Surgical and medical procedures	Spinal operation	01JAN2016	31DEC2016	N
	C4591001 1003 10031196	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
	C4591001 1003 10031198	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031199	Endocrine disorders	Autoimmune thyroiditis	01JAN2012		Y
		Eye disorders	Myopia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013	31DEC2019	N
			Latent autoimmune diabetes in adults	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Surgical and medical procedures	Salpingectomy	01JAN2017	31DEC2017	N
	C4591001 1003 10031201	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1003 10031203	Eye disorders	Myopia	01JAN1986		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Granuloma annulare	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Oophorectomy bilateral	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1003 10031205	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1003 10031206	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2003		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1003 10031207	Surgical and medical procedures	Hip arthroplasty	01JAN2018		Y
	C4591001 1005 10051002	Nervous system disorders	Migraine	01JAN2001		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1005 10051003	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1005 10051004	Surgical and medical procedures	Hernia repair	01JAN2001	31DEC2001	N
	C4591001 1005 10051007	Immune system disorders	Hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
	C4591001 1005 10051008	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009	01JAN2011	N
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Investigations	Laparoscopy	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Mammoplasty	01JAN1997	31DEC1997	N
	C4591001 1005 10051015	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2018	31DEC2018	N
	C4591001 1005 10051016	Immune system disorders	Seasonal allergy	01JAN1977		Y
	C4591001 1005 10051017	Immune system disorders	Hypersensitivity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
	C4591001 1005 10051024	Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1005 10051026	Immune system disorders	Hypersensitivity	01JAN1979		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2016	N
		Surgical and medical procedures	Renal stone removal	01JAN2012	31DEC2012	N
	C4591001 1005 10051027	Eye disorders	Glaucoma	01JAN2019		Y
		Nervous system disorders	Tension headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1005 10051028	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2009		Y
			Tension headache	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Spinal laminectomy	01JAN1999	31DEC1999	N
	C4591001 1005 10051029	Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
	C4591001 1005 10051030	Nervous system disorders	Migraine	01JAN1977		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2006	31DEC2006	N
	C4591001 1005 10051031	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN1988		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	12AUG2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1005 10051035	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Suture insertion	01JAN2010	31DEC2010	N
	C4591001 1005 10051036	Immune system disorders	Hypersensitivity	01FEB2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2008		Y
	C4591001 1005 10051041	Surgical and medical procedures	Orchidectomy	01JAN1998	31DEC1998	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Overweight	01JAN1984		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
	C4591001 1005 10051048	Cardiac disorders	Arrhythmia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Salpingectomy	01JAN2019	31DEC2019	N
	C4591001 1005 10051051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
		Immune system disorders	Hypersensitivity	01JAN1975		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1978		Y
			Depression	01JAN1980		Y
			Obsessive-compulsive disorder	01JAN1975		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1005	Vascular disorders	White coat hypertension	01JAN2016		Y
	10051052	Immune system disorders	Hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
	C4591001 1005	Surgical and medical procedures	Appendectomy	01JAN2019	31DEC2019	N
	10051054	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN1985		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1005	Metabolism and nutrition disorders	Overweight	01JAN1998		Y
	10051055					
	C4591001 1005	Investigations	Blood triglycerides increased	01JAN2001		Y
	10051057					
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1005	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
	10051059					
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
			Rosacea	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2016	31DEC2016	N
	C4591001 1005 10051066	Endocrine disorders	Mammoplasty Hypothyroidism	01JAN2000 01JAN2008	31DEC2000	N Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Caesarean section	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1005 10051067	Metabolism and nutrition disorders	Obesity	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2017	31DEC2017	N
	C4591001 1005 10051070	Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2013		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
	C4591001 1005 10051073	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1997		Y
	C4591001 1005 10051075	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1005 10051076	Vascular disorders	Hypertension	01JAN2008	31DEC2010	N
	C4591001 1005 10051077	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2007	31DEC2017	N
		Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051079	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JUN2020	01JUN2020	N
	C4591001 1005 10051081	Cardiac disorders	Mitral valve prolapse	01JAN1986		Y
		Ear and labyrinth disorders	Vertigo	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Hypersensitivity	01JAN2001		Y
		Infections and infestations	Candida infection	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
			Blood triglycerides increased	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1005 10051082	Nervous system disorders	Migraine without aura	01JAN2014		Y
			Tension headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2015		Y
	C4591001 1005 10051084	Immune system disorders	Hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051085	Injury, poisoning and procedural complications	Cartilage injury	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Shoulder operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1005 10051087	Immune system disorders	Allergy to metals	01JAN2010		Y
		Nervous system disorders	Migraine without aura	01JAN2018		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1005 10051093	Congenital, familial and genetic disorders	Congenital hypothyroidism	01JAN1985		Y
		Infections and infestations	Urinary tract infection	01JAN1995		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008		Y
	C4591001 1005 10051094	Psychiatric disorders	Anxiety	01JAN2008		Y
		Surgical and medical procedures	Salpingectomy	30JUN2019	30JUN2019	N
	C4591001 1005 10051100	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Hypersensitivity	01JAN1988		Y
		Infections and infestations	Oral herpes	01JAN1988		Y
		Metabolism and nutrition disorders	Overweight	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051101	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1005 10051105	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2013	31DEC2013	N
		Nervous system disorders	Headache	01JAN1987		Y
			Migraine without aura	01MAR2020		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1005 10051106	Immune system disorders	Hypersensitivity	01JAN1997		Y
		Metabolism and nutrition disorders	Overweight	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Venous thrombosis	01JAN2015		Y
	C4591001 1005 10051108	Ear and labyrinth disorders	Deafness	01JAN2011		Y
			Tinnitus	01JAN2011		Y
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Nervous system disorders	Migraine without aura	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Sexual dysfunction	01JAN2015		Y
	C4591001 1005 10051115	Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Anxiety	01APR2019		Y
	C4591001 1005 10051117	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Appendectomy	01JAN1992	31DEC1992	N
	C4591001 1005 10051118	Immune system disorders	Hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Overweight	01JAN2006		Y
	C4591001 1005 10051119	Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1005 10051123	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2003		Y
		Vascular disorders	White coat hypertension	01JAN2003		Y
	C4591001 1005 10051125	Blood and lymphatic system disorders	Iron deficiency anaemia	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	01JUL2018	30SEP2018	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1005 10051129	Cardiac disorders	Arrhythmia	01JAN1982		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Nervous system disorders	Migraine without aura	01JAN2000		Y
		Renal and urinary disorders	Haematuria	01JAN2015		Y
			Stress urinary incontinence	01JAN2015		Y
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1005 10051134	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Hypersensitivity	01JAN2001		Y
		Infections and infestations	Oral herpes	01JAN2011		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAR2020	31MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01MAR2020		Y
	C4591001 1005 10051142	Infections and infestations	Oral herpes	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1005 10051144	General disorders and administration site conditions	Oedema	01JAN2016		Y
		Metabolism and nutrition disorders	Overweight	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1005 10051145	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1005 10051146	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
	C4591001 1005 10051147	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1005 10051148	Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Overweight	01JAN1986		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1005 10051150	Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN1975		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Tarsal tunnel syndrome	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Surgical and medical procedures	Small intestinal resection	01JAN2017	31DEC2017	N
	C4591001 1005 10051151	Infections and infestations	Oral herpes	01JAN1973		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Nervous system disorders	Migraine without aura	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Caesarean section	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN1996	31DEC1996	N
	C4591001 1005 10051153	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2015		Y
	C4591001 1005 10051164	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Inguinal hernia repair	07AUG2020	07AUG2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051165	Immune system disorders	Hypersensitivity	01JAN1971		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Orchidopexy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051166	Ear and labyrinth disorders	Deafness	01JAN2003		Y
			Tinnitus	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Hypersensitivity	01JAN2001		Y
		Infections and infestations	Oral herpes	01JAN1999		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2004		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2011	31DEC2011	N
	C4591001 1005 10051167	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2017	31DEC2019	N
		Metabolism and nutrition disorders	Overweight	01JAN2017	31DEC2020	N
		Nervous system disorders	Migraine without aura	01JAN1990		Y
			Tension headache	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Bunion operation	01JAN1996	31DEC1996	N
			Laser therapy	01JAN2020	31DEC2020	N
	C4591001 1005 10051168	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1005 10051169	Immune system disorders	Hypersensitivity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1005 10051170	Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1005 10051171	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Nervous system disorders	Migraine without aura	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
	C4591001 1005 10051175	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine without aura	01JAN2000		Y
	C4591001 1005 10051178	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1005 10051179	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Metabolism and nutrition disorders	Overweight	01JAN1993		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1005 10051181	Social circumstances	Menopause	01JAN2013		Y
	C4591001 1005 10051183	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Overweight	01JAN1989		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Surgical and medical procedures	Gastric banding	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1005 10051187	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Thyroidectomy	01JAN2014	31DEC2014	N
	C4591001 1005 10051188	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1005 10051189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Hypersensitivity	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Oral herpes	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Caesarean section	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
			Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN1999	31DEC1999	N
	C4591001 1005 10051192	Immune system disorders	Hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2010		Y
			Lipoma	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1995		Y
			Sleep apnoea syndrome	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Idiopathic urticaria	01JAN1986		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Salpingoplasty	01JAN2018	31DEC2018	N
			Wisdom teeth removal	01JAN2001	31DEC2001	N
	C4591001 1005 10051198	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1005 10051199	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051200	Immune system disorders	Hypersensitivity	01JAN1990		Y
	C4591001 1005 10051203	Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
	C4591001 1005 10051210	Immune system disorders	Hypersensitivity	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1005 10051212	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1005 10051215	Investigations	Blood cholesterol increased	01JAN2015		Y
		Nervous system disorders	Migraine without aura	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1005 10051216	Nervous system disorders	Migraine without aura	01JAN2006		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1005 10051217	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1005 10051220	Immune system disorders	Hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2004	31DEC2010	N
	C4591001 1005 10051222	Infections and infestations	Oral herpes	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint dislocation	14FEB2014		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2014		Y
		Vascular disorders	Hot flush	01JAN2020		Y
	C4591001 1005 10051223	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Hypersensitivity	01JUN2020		Y
	C4591001 1005 10051224	Infections and infestations	Bronchitis	24SEP2020	29SEP2020	N
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2019		Y
	C4591001 1005 10051226	Immune system disorders	Hypersensitivity	01JAN1995		Y
		Nervous system disorders	Migraine without aura	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1005 10051228	Immune system disorders	Allergy to plants	05JAN2012		Y
		Nervous system disorders	Seizure	01SEP2009		Y
	C4591001 1005 10051232	Infections and infestations	Oral herpes	24JAN1985		Y
		Injury, poisoning and procedural complications	Cartilage injury	04OCT2018	04OCT2018	N
		Investigations	Arthroscopy	04OCT2018	04OCT2018	N
		Metabolism and nutrition disorders	Overweight	17APR2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	19OCT2018		Y
	C4591001 1005 10051233	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Mite allergy	01JAN1987		Y
		Infections and infestations	Oral herpes	01FEB2013		Y
		Renal and urinary disorders	Nephrolithiasis	06MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051235	Investigations	Arthroscopy	13MAY2004	13MAY2004	N
		Musculoskeletal and connective tissue disorders	Foot deformity	22FEB2014		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2018		Y
		Social circumstances	Menopause	01OCT2018		Y
		Surgical and medical procedures	Mammoplasty	20MAY1993	20MAY1993	N
	C4591001 1005 10051236	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1005 10051237	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 1005 10051238	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Cartilage injury	01MAR2020	31MAR2020	N
		Investigations	Arthroscopy	01MAR2020	31MAR2020	N
		Nervous system disorders	Migraine without aura	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1005 10051240	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
	C4591001 1005 10051241	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Sacroiliac joint dysfunction	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Bladder spasm	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2013	31DEC2013	N
			Thyroidectomy	01JAN2000	31DEC2000	N
			Hypersensitivity	01JAN1993		Y
	C4591001 1005 10051242	Immune system disorders				
		Surgical and medical procedures	Vasectomy	01JAN2002		Y
	C4591001 1005 10051243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Investigations	Blood cholesterol increased	01JAN1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1005 10051244	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
		Nervous system disorders	Migraine without aura	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1005 10051245	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
		Vascular disorders	White coat hypertension	01JAN2000		Y
	C4591001 1005 10051246	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Nervous system disorders	Migraine with aura	01JAN1980		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Ligament operation	01JAN1996	31DEC1996	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1005 10051248	Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Keratomileusis	01JAN2004	31DEC2004	N
	C4591001 1005 10051251	Endocrine disorders	Goitre	01JAN2009		Y
		Immune system disorders	Hypersensitivity	01JAN1996		Y
		Investigations	Endoscopy	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1997		Y
	C4591001 1005 10051254	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1999	31DEC1999	N
	C4591001 1005 10051257	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Bunion operation	01JAN2002	31DEC2002	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Haemorrhoid operation	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy bilateral	01JAN2018	31DEC2018	N
			Rhinoplasty	01JAN1983	31DEC1983	N
	C4591001 1005 10051259	Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
			Sterilisation reversal	01JAN1992	31DEC1992	N
	C4591001 1005 10051260	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Investigations	Laparoscopy	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1005 10051264	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1005 10051267	Investigations	Arthroscopy	01JAN2003	31DEC2003	N
			Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Migraine without aura	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Bipolar disorder	01JAN2016		Y
			Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	01JUL2020	31JUL2020	N
			Open reduction of fracture	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal decompression	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1005 10051268	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUN2020		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1984	31DEC1984	N
			Muscle operation	01JAN2016	31DEC2016	N
	C4591001 1005 10051270	Immune system disorders	Hypersensitivity	01JAN2000		Y
	C4591001 1005 10051274	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Bipolar disorder	01JAN2008		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1005 10051276	Immune system disorders	Hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN1992		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN1996	31DEC1996	N
			Gastrectomy	01FEB2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1005 10051277	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1996		Y
		Immune system disorders	Hypersensitivity	01JAN1985		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051280	Skin and subcutaneous tissue disorders	Dermatitis atopic	09OCT2020		Y
	C4591001 1005 10051281	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1005 10051283	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1005 10051285	Cardiac disorders	Palpitations	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chondroplasty	24AUG2020	24AUG2020	N
			Renal stone removal	10AUG2020	10AUG2020	N
	C4591001 1005 10051288	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Allergy to plants	01JAN2013		Y
			Contrast media allergy	01JAN2016		Y
			Drug hypersensitivity	01JAN2016		Y
			Hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine without aura	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2014		Y
	C4591001 1005 10051289	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Pain in extremity	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1992		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2000	31DEC2011	N
			Intervertebral disc operation	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051290	Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2016	31DEC2016	N
	C4591001 1005 10051292	Immune system disorders	Hypersensitivity	01JAN1992		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Cataract operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051294	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1005 10051295	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Nervous system disorders	Migraine without aura	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Eczema	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051301	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1987		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
			Blood triglycerides increased	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN2003		Y
			Overweight	01JAN1984		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051302	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1005 10051308	Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2016	30SEP2020	N
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
				24AUG2020	24AUG2020	N
			Female sterilisation	24AUG2020	24AUG2020	N
	C4591001 1005 10051310	Metabolism and nutrition disorders	Hypokalaemia	01JAN2006		Y
			Overweight	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
			Spinal nerve stimulator implantation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051311	Surgical and medical procedures	Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1005 10051314	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2007		Y
		Immune system disorders	Hypersensitivity	01FEB2001		Y
		Investigations	Blood triglycerides increased	01JAN2008		Y
		Metabolism and nutrition disorders	Overweight	01FEB2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2001		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
			Urethral repair	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051315	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Hypersensitivity	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1005 10051316	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Sinus headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Endometrial ablation	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2005	31DEC2005	N
	C4591001 1005 10051318	Immune system disorders	Hypersensitivity	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051323	Cardiac disorders	Coronary artery disease	01JAN2007		Y
			Myocardial infarction	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
			Coronary arterial stent insertion	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1005 10051326	Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01MAR2017	31MAR2017	N
	C4591001 1005 10051331	Psychiatric disorders	Anxiety	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2011		Y
	C4591001 1005 10051332	Psychiatric disorders	Anxiety	01JUN2008		Y
	C4591001 1005 10051335	Immune system disorders	Hypersensitivity	01JAN1988		Y
	C4591001 1005 10051340	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051341	Gastrointestinal disorders	Irritable bowel syndrome	01DEC2019		Y
		Immune system disorders	Hypersensitivity	01OCT2019		Y
		Metabolism and nutrition disorders	Overweight	01DEC2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1005 10051343	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Internal fixation of fracture	01JAN2018	31DEC2018	N
	C4591001 1005 10051345	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051346	Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2013		Y
		Surgical and medical procedures	Pilonidal sinus repair	01MAR2020	31MAR2020	N
	C4591001 1005 10051349	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2007		Y
		Investigations	Mediastinoscopy	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Cystic lung disease	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
	C4591001 1005 10051350	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31JAN2019	N
	C4591001 1005 10051356	Hepatobiliary disorders	Hepatic cirrhosis	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01AUG2020		Y
		Psychiatric disorders	Depression	01APR2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1005 10051358	Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Gastric bypass	01JUN2019	30JUN2019	N
	C4591001 1005 10051361	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1980		Y
	C4591001 1005 10051362	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1005 10051363	Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1005 10051364	Immune system disorders	Hypersensitivity	01JAN1985		Y
		Infections and infestations	Oral herpes	01JAN1996		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Nervous system disorders	Migraine with aura	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2000		Y
	C4591001 1005 10051366	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1005 10051368	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Nervous system disorders	Cognitive disorder	01JAN1995		Y
			Nerve compression	01JAN2008		Y
		Renal and urinary disorders	Urinary retention	01MAY2019		Y
	C4591001 1005 10051369	Metabolism and nutrition disorders	Overweight	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01OCT2019		Y
	C4591001 1005 10051378	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1005 10051380	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01JAN2017		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2018	31DEC2018	N
	C4591001 1005 10051381	Metabolism and nutrition disorders	Overweight	01JAN1975		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Social circumstances	Menopause	01APR2019		Y
	C4591001 1005 10051385	Immune system disorders	Hypersensitivity	01JAN1996		Y
		Nervous system disorders	Headache	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN1997		Y
			Insomnia	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1005 10051386	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1005 10051390	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
	C4591001 1005 10051394	Psychiatric disorders	Anxiety	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01NOV2019		Y
			Insomnia	01OCT2010		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2016		Y
	C4591001 1005 10051396	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1005 10051397	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1005 10051398	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1005 10051407	Immune system disorders	Hypersensitivity	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1985		Y
	C4591001 1005 10051409	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1005 10051411	Congenital, familial and genetic disorders	Anal atresia	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Constipation	01JAN2013		Y
			Short-bowel syndrome	01JAN2003		Y
			Volvulus	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Enterostomy	01JAN2003	31DEC2003	N
			Intestinal resection	01JAN2003	31DEC2003	N
			Stoma closure	01JAN2003	31DEC2003	N
	C4591001 1005 10051416	Immune system disorders	Hypersensitivity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051432	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1005 10051433	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1005 10051435	Blood and lymphatic system disorders	Anaemia	01SEP2019		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1005 10051442	Immune system disorders	Hypersensitivity	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2014		Y
			Migraine without aura	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1005 10051446	Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1006 10061005	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JUL2018		Y
	C4591001 1006 10061007	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2005		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN1990		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2012		Y
	C4591001 1006 10061008	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
			Cough	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Essential hypertension	01JAN2012		Y
	C4591001 1006 10061009	Ear and labyrinth disorders	Cerumen impaction	27FEB2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1006 10061011	Gastrointestinal disorders	Gastroesophageal reflux disease	20JUL2013		Y
		General disorders and administration site conditions	Drug intolerance	04JUN2012		Y
		Immune system disorders	Drug hypersensitivity	04JUN2012		Y
				10JUL2014		Y
				26JUL2011		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN1988		Y
		Psychiatric disorders	Depression	27JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	27JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061012	Ear and labyrinth disorders	Deafness bilateral	01MAY2010		Y
			Tinnitus	01JAN2005		Y
		Endocrine disorders	Basedow's disease	01JAN2015		Y
			Hypogonadism	01JAN2010		Y
			Hypothyroidism	01MAR2011		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	20FEB2009		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
				13MAR2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	19DEC2013		Y
	C4591001 1006 10061013	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Urinary tract infection	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	19OCT2019	19OCT2019	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
	C4591001 1006 10061014	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2015		Y
		Immune system disorders	Amyloidosis	05FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1987		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
	C4591001 1006 10061018	Gastrointestinal disorders	Inguinal hernia	17MAY2019	24MAY2019	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1994		Y
	C4591001 1006 10061019	Infections and infestations	Genital herpes	26DEC2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26DEC2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Vascular disorders	Hypertension	26DEC2019		Y
	C4591001 1006 10061021	General disorders and administration site conditions	Drug intolerance	03JUL2019		Y
	C4591001 1006 10061022	Gastrointestinal disorders	Diverticulum intestinal	27DEC2016		Y
			Haemorrhoids	27DEC2016		Y
		Immune system disorders	Seasonal allergy	10APR2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10APR2008		Y
			Intervertebral disc protrusion	10AUG2008		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	30APR2009		Y
		Vascular disorders	Hypertension	29SEP2017		Y
	C4591001 1006 10061023	Endocrine disorders	Hypothyroidism	22JUL2019		Y
			Thyroid stimulating hormone deficiency	11JUL2019		Y
	C4591001 1006 10061024	Immune system disorders	Drug hypersensitivity	01JUN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Urinary tract infection	01MAR2020		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019		Y
				01FEB2020		Y
	C4591001 1006 10061028	Infections and infestations	Papilloma viral infection	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2020		Y
	C4591001 1006 10061031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	(b) (6) 2000		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Autism spectrum disorder	(b) (6) 2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1006 10061032	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		General disorders and administration site conditions	Drug intolerance	13FEB2019		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Investigations	Blood glucose increased	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
			Insomnia	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1006 10061033	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Autism spectrum disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1006 10061036	Skin and subcutaneous tissue disorders	Drug eruption	01JAN1999		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	07NOV2019		Y
			Rubber sensitivity	02AUG2013		Y
		Infections and infestations	Oral herpes	12JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	07NOV2019		Y
			Intervertebral disc protrusion	01JAN2002	31DEC2018	N
		Psychiatric disorders	Anxiety	09NOV2012		Y
			Major depression	01JAN2009		Y
		Reproductive system and breast disorders	Anisomastia	01JUL2020		Y
			Polycystic ovaries	05JUL2013		Y
	C4591001 1006 10061037	Surgical and medical procedures	Intervertebral disc operation	01JAN2018	31DEC2018	N
		Cardiac disorders	Atrioventricular block first degree	08APR2018		Y
		Ear and labyrinth disorders	Deafness bilateral	10MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypogonadism	18MAR2020		Y
		Gastrointestinal disorders	Diverticulum	09JUN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	28MAY2010		Y
			Type 2 diabetes mellitus	07SEP2018		Y
		Nervous system disorders	Neuropathy peripheral	21SEP2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	28DEC2009		Y
		Reproductive system and breast disorders	Erectile dysfunction	10JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	09JUN2017		Y
	C4591001 1006 10061040	Congenital, familial and genetic disorders	Cancer gene carrier	01NOV2018		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN2018	28DEC2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back disorder	16AUG2019		Y
			Muscle spasms	23AUG2019		Y
		Nervous system disorders	Migraine	30AUG2016		Y
			Trigeminal nerve disorder	16AUG2019		Y
		Psychiatric disorders	Major depression	13JUL2018		Y
	C4591001 1006 10061041	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1006 10061050	Metabolism and nutrition disorders	Obesity	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Insomnia	01JAN2000		Y
			Major depression	14APR2020		Y
			Drug intolerance	01JAN2002		Y
	C4591001 1006 10061052	General disorders and administration site conditions				
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	03NOV2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01JAN2018		Y
	C4591001 1006 10061053	Psychiatric disorders	Anxiety	01JAN1994		Y
			Insomnia	01JAN2015		Y
	C4591001 1006 10061054	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1986	31DEC2006	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1006 10061055	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
			Depression	01APR2020		Y
	C4591001 1006 10061056	Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1006 10061057	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1006 10061061	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1996		Y
			Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Back pain	01JAN2000		Y
			Muscle spasms	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1006 10061066	Endocrine disorders	Hypothyroidism	01JAN2003		Y
			Thyroid mass	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Procedural pain	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Shoulder operation	01JAN2009	31DEC2009	N
	C4591001 1006 10061067	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN2018		Y
	C4591001 1006 10061068	Investigations	Weight increased	15JUN2020		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	19JUL2019		Y
	C4591001 1006 10061070	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2010		Y
		Gastrointestinal disorders	Gastric ulcer	13APR1998	14JUL1998	N
			Gastroesophageal reflux disease	13APR1998	14JUL1998	N
			Oesophagitis	13APR1998	14JUL1998	N
		Immune system disorders	Allergy to animal	01JAN1988		Y
			Seasonal allergy	01JAN1988		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01MAY2002	12JUN2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	06SEP2014		Y
		Psychiatric disorders	Depression	25SEP2019		Y
			Insomnia	25SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Drug eruption	14JUL1998		Y
		Surgical and medical procedures	Fracture reduction	12JUN2002	12JUN2002	N
			Oesophagogastric fundoplasty	14JUL1998	14JUL1998	N
	C4591001 1006 10061071	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1006 10061073	Musculoskeletal and connective tissue disorders	Arthritis	01FEB2020		Y
	C4591001 1006 10061074	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Bipolar II disorder	01JAN2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
	C4591001 1006 10061075	Cardiac disorders	Palpitations	01JAN2015		Y
		Endocrine disorders	Thyroid mass	01JAN2015		Y
		Eye disorders	Dry eye	01JAN2017		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Pain in extremity	01MAR2020		Y
	C4591001 1006 10061078	Immune system disorders	Allergy to animal	01JAN1990		Y
		Investigations	Blood pressure diastolic increased	01JAN1995		Y
			Mean cell volume increased	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
	C4591001 1006 10061079	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Large intestine perforation	30AUG2015	30AUG2015	N
		General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
		Infections and infestations	Appendicitis	30SEP2015	30SEP2015	N
			Oral herpes	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1988		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Infertility	30AUG2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	30SEP2015	30SEP2015	N
			Colon operation	30AUG2015	30AUG2015	N
			Female sterilisation	30SEP2015	30SEP2015	N
	C4591001 1006 10061081	Immune system disorders	Allergy to animal	01JAN2007		Y
			Hypersensitivity	01JAN2007		Y
		Infections and infestations	Staphylococcal infection	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1006 10061084	Psychiatric disorders	Anxiety	01MAR2018		Y
			Depression	01MAR2018		Y
	C4591001 1006 10061088	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
			Generalised anxiety disorder	11SEP2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1006 10061089	Investigations	Mammogram abnormal	03APR2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	05NOV2014		Y
				06DEC2014		Y
			Back pain	01JAN1993		Y
			Intervertebral disc degeneration	27NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1990		Y
			Pain in extremity	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1995		Y
		Social circumstances	Organ donor	30APR2019	30APR2019	N
			Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Nephrectomy	30APR2019	30APR2019	N
	C4591001 1006 10061090	Immune system disorders	Seasonal allergy	16AUG2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
		Nervous system disorders	Migraine	19JUL2016		Y
		Reproductive system and breast disorders	Polycystic ovaries	30MAR2017		Y
	C4591001 1006 10061091	Metabolism and nutrition disorders	Obesity	25JUL2014		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1006 10061092	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1006 10061094	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN1986		Y
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN1986		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
			Oesophageal spasm	01JAN2015		Y
		Immune system disorders	Contrast media allergy	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1988		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
			Sinusitis	01JAN2010		Y
		Investigations	Cardiac murmur	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2003		Y
			Temporomandibular joint syndrome	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
			Post-traumatic stress disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Nasal septum deviation	01JAN1987	31DEC2004	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2004	31DEC2004	N
			Oesophagogastric fundoplasty	01JAN2009		Y
	C4591001 1006 10061095	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Insomnia	01JAN2004		Y
			Perinatal depression	01APR2019		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2020		Y
	C4591001 1006 10061096	Infections and infestations	Cystitis	18JUN2019	31JUL2019	N
			Urinary tract infection	01JAN2015		Y
		Nervous system disorders	Migraine	22APR2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	14MAY2015	31DEC2016	N
		Psychiatric disorders	Anxiety	08JUN2015		Y
			Depression	01JAN2018		Y
			Generalised anxiety disorder	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	10JAN2013		Y
			Menorrhagia	22JUN2016		Y
	C4591001 1006 10061099	Cardiac disorders	Tachycardia	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
	C4591001 1006 10061100	Infections and infestations	Oral herpes	01JAN1983		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	02MAY2017		Y
	C4591001 1006 10061102	Immune system disorders	Food allergy	01JAN1986		Y
			Seasonal allergy	29JUN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	13MAY2013		Y
			Intervertebral disc protrusion	14MAY2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	27AUG2012		Y
		Psychiatric disorders	Generalised anxiety disorder	19MAY2014		Y
			Major depression	06APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	30MAY2007		Y
		Skin and subcutaneous tissue disorders	Chloasma	17AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061103	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	03AUG2016		Y
		Psychiatric disorders	Depression	17DEC2015		Y
		Surgical and medical procedures	Vasectomy	07AUG2020		Y
	C4591001 1006 10061104	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1006 10061106	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
	C4591001 1006 10061107	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19APR2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Anisomastia	10APR2019		Y
			Menorrhagia	01JAN2015		Y
	C4591001 1006 10061108	Gastrointestinal disorders	Haemorrhoids	17OCT2017		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	18APR2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1006 10061109	Immune system disorders	Seasonal allergy	01JAN1996		Y
	C4591001 1006 10061110	Ear and labyrinth disorders	Deafness unilateral	01JAN2006		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2010		Y
			Gastrointestinal disorder	01JAN2009		Y
			Gastroesophageal reflux disease	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010		Y
			Hiatus hernia	(b) (6) 1989		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN1998		Y
			Neck pain	01JAN1993	30APR2020	N
			Vertebral osteophyte	01JAN1993	30APR2020	N
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Spinal fusion surgery	01APR2020	30APR2020	N
	C4591001 1006 10061112	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Genital herpes simplex	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016		Y
	C4591001 1006 10061113	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 1989		Y
		Infections and infestations	Tinea versicolour	01JAN2010		Y
		Nervous system disorders	Syncope	06OCT2015	06OCT2015	N
	C4591001 1006 10061114	Gastrointestinal disorders	Enlarged uvula	01JUN2016		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2016		Y
			Nasal septum deviation	01JUN2016	15DEC2016	N
			Nasal turbinate hypertrophy	01JUN2016		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Nasal septal operation	15DEC2016	15DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1006 10061116	General disorders and administration site conditions	Drug intolerance	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
			Major depression	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01DEC2001	31DEC2001	N
	C4591001 1006 10061117	Psychiatric disorders	Bipolar disorder	01JAN2005		Y
	C4591001 1006 10061118	Congenital, familial and genetic disorders	Tuberous sclerosis complex	01JAN2018		Y
		Immune system disorders	Allergy to animal	01JAN1995		Y
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1006 10061122	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1996		Y
		Nervous system disorders	Headache	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1006 10061124	Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
	C4591001 1006 10061128	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01DEC2019		Y
			Rubber sensitivity	01JAN1977		Y
		Pregnancy, puerperium and perinatal conditions	Placenta accreta	30NOV1997	30NOV1997	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	30NOV1997	30NOV1997	N
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1006 10061129	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Skin and subcutaneous tissue disorders	Acne	28MAY2013		Y
	C4591001 1006 10061130	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2017		Y
	C4591001 1006 10061131	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061133	General disorders and administration site conditions	Fatigue	06JUN2020	01JUL2020	N
		Renal and urinary disorders	Pollakiuria	19SEP2017	31MAR2018	N
	C4591001 1006 10061134	Gastrointestinal disorders	Abdominal pain	01JAN2006		Y
			Gastrointestinal pain	01JAN2006		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01OCT2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Radiotherapy	01JAN2006	31DEC2006	N
	C4591001 1006 10061136	Gastrointestinal disorders	Volvulus	27JUL2015		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1006 10061138	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Major depression	01JAN2000		Y
			Tic	01JAN2007		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061140	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1006 10061141	Immune system disorders	Perennial allergy	01OCT2019		Y
		Metabolism and nutrition disorders	Underweight	01JAN2015		Y
		Vascular disorders	Hypotension	01JAN2012		Y
	C4591001 1006 10061142	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Nervous system disorders	Complex regional pain syndrome	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1006 10061144	General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
				01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Epicondylitis	01APR2020		Y
				01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN1986		Y
	C4591001 1006 10061148	General disorders and administration site conditions	Fatigue	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Concussion	01FEB2020		Y
			Head injury	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
				01JAN2018		Y
		Nervous system disorders	Memory impairment	01FEB2020		Y
			Mental impairment	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	07JAN2020		Y
			Depression	07JAN2020		Y
			Insomnia	01MAR2020		Y
		Surgical and medical procedures	Endometrial ablation	01MAR2019		Y
			Female sterilisation	01MAR2018	31MAR2018	N
	C4591001 1006 10061151	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01FEB2018		Y
			Obesity	01FEB2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
				01MAY2020	31MAY2020	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1999		Y
	C4591001 1006 10061152	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	12MAR2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
			Rhinitis allergic	01JAN1972		Y
		Skin and subcutaneous tissue disorders	Granuloma annulare	01JAN2011		Y
		Vascular disorders	Hypertension	21JAN2019		Y
	C4591001 1006 10061153	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Fructose intolerance	09AUG2010		Y
		Psychiatric disorders	Anxiety	26JUL2019		Y
			Depression	12SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061154	Ear and labyrinth disorders	Deafness unilateral	01JAN2006		Y
		Psychiatric disorders	Autism spectrum disorder	01MAR2010		Y
	C4591001 1006 10061155	Skin and subcutaneous tissue disorders	Acne cystic	02DEC2019		Y
	C4591001 1006 10061156	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
			Back pain	01JUL2019		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1006 10061159	General disorders and administration site conditions	Drug intolerance	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Connective tissue disorder	01MAY2018	01JUN2018	N
			Femoroacetabular impingement	01APR2019	31MAR2020	N
		Surgical and medical procedures	Bone operation	01JAN2020	31MAR2020	N
			Chondroplasty	01JAN2020	31MAR2020	N
			Fascial operation	01JUN2018	01JUN2018	N
	C4591001 1006 10061160	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	18SEP2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	18SEP2017	18SEP2017	N
	C4591001 1006 10061161	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Rubber sensitivity	01JAN2003		Y
		Infections and infestations	Kidney infection	01JAN2015		Y
			Urinary tract infection	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
		Surgical and medical procedures	Ureteral stent insertion	01JAN2016		Y
	C4591001 1006 10061162	Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2005		Y
	C4591001 1006 10061163	General disorders and administration site conditions	Fatigue	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Abnormal weight gain	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1006 10061164	Immune system disorders	Allergy to animal	01JAN2017		Y
			Hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
	C4591001 1006 10061166	Endocrine disorders	Hypogonadism	01JAN2005		Y
			Hypothyroidism	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Bilateral orchidectomy	01JAN2005	31DEC2005	N
	C4591001 1006 10061167	Blood and lymphatic system disorders	Iron deficiency anaemia	26FEB2016		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061169	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1006 10061170	Immune system disorders	Perennial allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
			Autism spectrum disorder	01JAN2007		Y
	C4591001 1006 10061171	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	03APR2013		Y
	C4591001 1006 10061173	Reproductive system and breast disorders	Menstruation irregular	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1006 10061176	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1006 10061179	Gastrointestinal disorders	Constipation	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Sinusitis	01JAN1988		Y
		Injury, poisoning and procedural complications	Spinal cord injury thoracic	19FEB2020		Y
			Spinal fracture	19FEB2020	20FEB2020	N
		Musculoskeletal and connective tissue disorders	Back pain	19FEB2020		Y
		Nervous system disorders	Neuropathy peripheral	19FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Spinal fusion surgery	20FEB2020	20FEB2020	N
	C4591001 1006 10061180	Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1006 10061181	Eye disorders	Myopia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1006 10061182	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1006 10061185	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061186	Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
		Immune system disorders	Food allergy	01OCT2020		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2009		Y
	C4591001 1006 10061187	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	16JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	08SEP2020	N
		Surgical and medical procedures	Nasal septal operation	08SEP2020	08SEP2020	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1006 10061192	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
	C4591001 1006 10061193	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061194	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1006 10061195	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1006 10061197	Psychiatric disorders	Anxiety	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1006 10061199	Gastrointestinal disorders	Abdominal pain lower	01JAN2017		Y
	C4591001 1006 10061202	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01AUG2020		Y
	C4591001 1006 10061204	Infections and infestations	Pharyngitis	01MAY2007	31DEC2008	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2011		Y
		Surgical and medical procedures	Adenoidectomy	01MAY2008	31MAY2008	N
			Tonsillectomy	01MAY2008	31MAY2008	N
	C4591001 1006 10061205	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1006 10061208	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1006 10061210	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061215	Congenital, familial and genetic disorders	Hypospadias	(b) (6) 2004	31DEC2005	N
		Gastrointestinal disorders	Inguinal hernia	(b) (6) 2004	31DEC2005	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
			Urethral repair	01JAN2005	31DEC2005	N
	C4591001 1006 10061216	Infections and infestations	Oral herpes	01JAN2011		Y
		Nervous system disorders	Facial paralysis	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Granuloma annulare	22NOV2020	23DEC2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061217	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1006 10061222	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Injury, poisoning and procedural complications	Concussion	01OCT2017	31OCT2017	N
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1006 10061225	Blood and lymphatic system disorders	Iron deficiency anaemia	05AUG2020		Y
	C4591001 1006 10061238	Injury, poisoning and procedural complications	Back injury	06JUN2018		Y
	C4591001 1006 10061240	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1006 10061246	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Suicidal ideation	01JUN2020	01NOV2020	N
	C4591001 1006 10061255	Cardiac disorders	Palpitations	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Pneumonia viral	10NOV2012	20NOV2012	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Menorrhagia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1007 10071014^	Hepatobiliary disorders	Cholelithiasis	25NOV2019	25NOV2019	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01OCT2013		Y
			Depression	01OCT2013		Y
		Surgical and medical procedures	Cholecystectomy	25NOV2019	25NOV2019	N
	C4591001 1007 10071015^	Immune system disorders	Allergy to animal	01JAN1985		Y
			Seasonal allergy	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01NOV2008	31MAY2009	N
			Tendonitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Rotator cuff repair	01MAY2009	31MAY2009	N
	C4591001 1007 10071016^	Psychiatric disorders	Anxiety	01OCT2018		Y
	C4591001 1007 10071017^	Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1007 10071019^	Skin and subcutaneous tissue disorders	Dermatitis contact	29APR2020	15MAY2020	N
	C4591001 1007 10071020^	Musculoskeletal and connective tissue disorders	Musculoskeletal pain	02JUN2020	03JUN2020	N
	C4591001 1007 10071021^	Ear and labyrinth disorders	Otosclerosis	01JAN2017		Y
		Social circumstances	Hearing aid user	01JAN2017		Y
		Surgical and medical procedures	Stapedectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071023^	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1007 10071025^	Infections and infestations	Paronychia	01AUG2019		Y
	C4591001 1007 10071026^	Immune system disorders	Hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1007 10071027^	General disorders and administration site conditions	Pain	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Investigations	False positive tuberculosis test	01JAN2012		Y
		Nervous system disorders	Syncope	05MAY2020		Y
	C4591001 1007 10071029^	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1007 10071040^	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Seizure	21JUN2016	21JUN2016	N
		Surgical and medical procedures	Ligament operation	01JAN1997	31DEC1997	N
				01JAN2000	31DEC2015	N
	C4591001 1007 10071046^	General disorders and administration site conditions	Hernia	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Surgical and medical procedures	Hernia repair	01JAN2011	31DEC2011	N
	C4591001 1007 10071050^	Blood and lymphatic system disorders	Anaemia	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP2019		Y
	C4591001 1007 10071063^	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2004		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
	C4591001 1007 10071064^	Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2012	31DEC2012	N
	C4591001 1007 10071065^	Injury, poisoning and procedural complications	Concussion	01SEP2017	30SEP2017	N
			Contusion	22JUN2020		Y
		Nervous system disorders	Seizure	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	06JUN2020		Y
	C4591001 1007 10071082	Immune system disorders	Hypersensitivity	03JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1007 10071083	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1007 10071087	Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01FEB2020		Y
	C4591001 1007 10071089	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Injury, poisoning and procedural complications	Meniscus injury	01FEB2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	05DEC2011	05DEC2011	N
	C4591001 1007 10071092	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Gastric banding	01JAN2009	31JAN2009	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1007 10071093	Congenital, familial and genetic disorders	Sickle cell trait	(b) (6) 1983		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Bacterial tracheitis	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Femoroacetabular impingement	01JUN2014	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019	11NOV2020	N
	C4591001 1007 10071095	Psychiatric disorders	Anxiety	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071096	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1994	31DEC1996	N
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1007 10071097	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01FEB2020		Y
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
	C4591001 1007 10071100	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Insomnia	04APR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1981	31DEC1988	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2003	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
			Spondylitis	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1007 10071106	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1999	31DEC1999	N
			Meniscus injury	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Ligament operation	01JAN1999	31DEC1999	N
			Meniscus operation	01JAN2001	31DEC2001	N
	C4591001 1007 10071107	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
	C4591001 1007 10071108	Cardiac disorders	Myocardial infarction	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Type 2 diabetes mellitus	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendonitis	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1007 10071109	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986	31DEC1993	N
		Surgical and medical procedures	Keratomileusis	01JAN2015	31DEC2015	N
	C4591001 1007 10071110	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
	C4591001 1007 10071111	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018	31JAN2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2020	31JAN2020	N
	C4591001 1007 10071112	Immune system disorders	Seasonal allergy	01JUN2020		Y
	C4591001 1007 10071117	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
				01JAN2001		Y
			Rubber sensitivity	01JAN1974		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Hysterectomy	01DEC2019	31DEC2019	N
			Uterine dilation and curettage	01MAY2019	31MAY2019	N
	C4591001 1007 10071118	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1007 10071119	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017	03OCT2019	N
		Surgical and medical procedures	Nasal septal operation	03OCT2019	03OCT2019	N
	C4591001 1007 10071123	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1007 10071125	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071129	Eye disorders	Glaucoma	01AUG2019	05NOV2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
			Irritable bowel syndrome	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1996	31DEC1996	N
			Non-alcoholic steatohepatitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Iridotomy	05NOV2019	05NOV2019	N
		Vascular disorders	Hypertension	05NOV2019		Y
	C4591001 1007 10071130	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1007 10071132	Cardiac disorders	Bundle branch block right	01JAN1990		Y
		Immune system disorders	Food allergy	01JAN1985		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071137	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
	C4591001 1007 10071138	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN2015		Y
			Seasonal allergy	01JAN2009		Y
	C4591001 1007 10071143	Blood and lymphatic system disorders	Immune thrombocytopenia	01FEB2013	30APR2013	N
		Metabolism and nutrition disorders	Diabetes mellitus	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2008	N
		Nervous system disorders	Occipital neuralgia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2018	31MAR2019	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2008	31DEC2008	N
	C4591001 1007 10071145	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	20APR2012	20APR2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1007 10071148	Immune system disorders	Allergy to metals	01JAN2001		Y
			Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1998		Y
	C4591001 1007 10071151	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071152	Immune system disorders	Contrast media allergy	01JAN2005		Y
			Seasonal allergy	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1007 10071153	Surgical and medical procedures	Hysterectomy	19FEB2010	19FEB2010	N
	C4591001 1007 10071154	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2018		Y
	C4591001 1007 10071155	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1992		Y
	C4591001 1007 10071157	Gastrointestinal disorders	Colitis ulcerative	01JAN2012		Y
		Immune system disorders	Food allergy	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Surgical and medical procedures	Breast conserving surgery	15JUN2020	15JUN2020	N
	C4591001 1007 10071159	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Nervous system disorders	Headache	01JAN1985		Y
	C4591001 1007 10071162	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01MAY2019	31MAY2019	N
	C4591001 1007 10071171	Immune system disorders	Seasonal allergy	01JAN1984		Y
	C4591001 1007 10071172	Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071175	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1007 10071178	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Langerhans' cell histiocytosis	01JAN1993	31DEC1994	N
	C4591001 1007 10071179	Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	04MAY2017	04MAY2017	N
	C4591001 1007 10071181	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
	C4591001 1007 10071184	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	14JUN2020	N
		Surgical and medical procedures	Prostatectomy	01JAN2015	31DEC2015	N
	C4591001 1007 10071185	Gastrointestinal disorders	Pancreatitis	01MAY2019	31MAY2019	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
		Renal and urinary disorders	Chronic kidney disease	01APR2015		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2019	31MAY2019	N
	C4591001 1007 10071186	General disorders and administration site conditions	Oedema peripheral	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes zoster	17MAY2020	30JUN2020	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y
	C4591001 1007 10071193	Endocrine disorders	Thyroid mass	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
			Thyroidectomy	01JAN2014	31DEC2014	N
	C4591001 1007 10071194	Cardiac disorders	Cardiac failure congestive	01JAN2008		Y
			Cardiomyopathy	01JAN2015		Y
		Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
				01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	04OCT2004		Y
			Pleural neoplasm	01JAN2008		Y
		Nervous system disorders	Intracranial mass	01JAN2010		Y
			Migraine	01JAN2009		Y
			Transient ischaemic attack	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
		Surgical and medical procedures	Abdominoplasty	03JAN2005	03JAN2005	N
			Breast reconstruction	03JAN2005	03JAN2005	N
			Hysterectomy	03JAN2005	03JAN2005	N
			Mastectomy	03JAN2005	03JAN2005	N
	C4591001 1007 10071195	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1007 10071196	Eye disorders	Retinal detachment	01JAN2017	31DEC2017	N
		Immune system disorders	Allergy to animal	01JAN2016		Y
			Drug hypersensitivity	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1007 10071197	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Hypersensitivity	01JAN2016		Y
		Injury, poisoning and procedural complications	Limb injury	01MAR2020		Y
	C4591001 1007 10071204	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1007 10071206	Surgical and medical procedures	Female sterilisation	01DEC2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Social circumstances	Menopause	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Gastric bypass	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1007 10071207	Endocrine disorders	Hyperparathyroidism	01JAN2014		Y
		Injury, poisoning and procedural complications	Pancreatic injury	01NOV2002	30NOV2002	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
			Vasectomy reversal	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071211	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1007 10071212	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Nasal polypectomy	01JAN1998	31DEC1998	N
	C4591001 1007 10071214	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2007	31DEC2009	N
	C4591001 1007 10071217	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1007 10071218	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1007 10071221	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
	C4591001 1007 10071225	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071228	Immune system disorders	Allergy to animal	01JAN1984		Y
			Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071229	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hypolipidaemia	01FEB2019		Y
	C4591001 1007 10071230	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071231	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1007 10071232	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1007 10071233	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1007 10071235	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety disorder	01JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2018		Y
	C4591001 1007 10071236	Endocrine disorders	Autoimmune thyroiditis	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Thyroidectomy	12JUN2020	12JUN2020	N
	C4591001 1007 10071238	Surgical and medical procedures	Caesarean section	28AUG2013	28AUG2013	N
	C4591001 1007 10071240	Immune system disorders	Allergy to animal	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN1997		Y
			Hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Nervous system disorders	Headache	01JAN1980		Y
			Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
	C4591001 1007 10071243	Immune system disorders	Hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JUN2020		Y
		Surgical and medical procedures	Caesarean section	13APR2013	13APR2013	N
			Intrauterine contraception	18SEP2019		Y
	C4591001 1007 10071246	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1007 10071250	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	20AUG2020		Y
	C4591001 1007 10071252	Gastrointestinal disorders	Coeliac disease	01JAN2012		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2012		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	08MAY2020	08MAY2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	26JAN2012	26JAN2012	N
	C4591001 1007 10071253	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Metabolism and nutrition disorders	Overweight	01MAR2020		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	02NOV2015	02NOV2015	N
			Intrauterine contraception	01FEB2016		Y
	C4591001 1007 10071256	Immune system disorders	Seasonal allergy	01JAN1984		Y
	C4591001 1007 10071258	Immune system disorders	Food allergy	01JAN1980		Y
		Surgical and medical procedures	Gastric banding	01JAN1990		Y
			Tenoplasty	01JAN2008	31DEC2008	N
			Drug hypersensitivity	29JUN2020	29JUN2020	N
	C4591001 1007 10071264	Immune system disorders		01JAN2004		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1007 10071266	Nervous system disorders	Migraine	01JAN1986		Y
	C4591001 1007 10071269	Injury, poisoning and procedural complications	Foot fracture	09AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN1993	31DEC2001	N
		Surgical and medical procedures	Haemangioma removal	01JAN2001	31DEC2001	N
	C4591001 1007 10071270	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1007 10071272	Gastrointestinal disorders	Rectal polyp	24JAN2020	24JAN2020	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Investigations	Colonoscopy	07AUG2020	07AUG2020	N
		Surgical and medical procedures	Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1007 10071275	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1007 10071276	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1007 10071278	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Tenoplasty	01JAN1995	31DEC1995	N
			Thyroidectomy	01JAN2006	31DEC2006	N
	C4591001 1007 10071280	Immune system disorders	Allergy to animal	01JAN1990		Y
			Dust allergy	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Overweight	01JAN1996	30JUN2020	N
		Renal and urinary disorders	Nephrolithiasis	01NOV2019	04AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Gastrectomy	01MAY2019	31MAY2019	N
			Lithotripsy	01NOV2019	30NOV2019	N
			Pyeloplasty	04AUG2020	04AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071286	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1007 10071289	Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2007		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
			Nasal turbinate hypertrophy	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Nasal septal operation	01JAN2012	31DEC2012	N
			Turbinectomy	01JAN2012	31DEC2012	N
	C4591001 1007 10071295	Cardiac disorders	Atrial fibrillation	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN1981		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1007 10071296	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
		Social circumstances	Postmenopause	01APR2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Essential hypertension	01JAN2019		Y
	C4591001 1007 10071307	Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01JAN2000		Y
	C4591001 1007 10071309	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012	31AUG2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Chondrectomy	01AUG2015	31AUG2015	N
			Renal stone removal	01JAN2020	31JAN2020	N
				08SEP2016	08SEP2016	N
	C4591001 1007 10071334	Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1973		Y
	C4591001 1007 10071337	Social circumstances	Menopause	01JAN2017		Y
	C4591001 1007 10071339	Immune system disorders	Food allergy	01JAN1978		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1007 10071341	Immune system disorders	Allergy to metals	01JAN2016		Y
			Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1007 10071342	Gastrointestinal disorders	Anal fistula	01JAN2007	31DEC2010	N
			Gastrooesophageal reflux disease	01JAN2010		Y
		Surgical and medical procedures	Anal fistula repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071350	Gastrointestinal disorders	Diverticulum	01JAN2015		Y
		General disorders and administration site conditions	Hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01APR2020	30APR2020	N
				01JUL2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2015	31DEC2015	N
			Shoulder arthroplasty	01APR2020	31DEC2020	N
				01JAN2013	31DEC2013	N
	C4591001 1007 10071352	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Allergy to vaccine	01JAN1969		Y
		Infections and infestations	Histoplasmosis	01OCT2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01FEB2016	30APR2016	N
		Surgical and medical procedures	Endometrial ablation	01JAN2016	30APR2016	N
			Female sterilisation	01JUL2015	31JUL2015	N
	C4591001 1007 10071353	Immune system disorders	Food allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2015		Y
			Obsessive-compulsive symptom	01JAN2015		Y
	C4591001 1007 10071358	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Torticollis	01JAN2015		Y
	C4591001 1007 10071362	Nervous system disorders	Migraine	01JAN2008		Y
	C4591001 1007 10071363	Gastrointestinal disorders	Dyspepsia	01JAN2018	31AUG2020	N
		Psychiatric disorders	Anxiety	01SEP2020		Y
	C4591001 1007 10071365	Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992	31DEC1994	N
			Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
	C4591001 1007 10071366	Gastrointestinal disorders	Gastroenteritis eosinophilic	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Shoulder operation	01JAN2001	31DEC2001	N
	C4591001 1007 10071367	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Oral herpes	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1007 10071368	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
			Obesity	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1982		Y
			Obsessive-compulsive disorder	01JAN1982		Y
	C4591001 1007 10071369	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
	C4591001 1007 10071373	Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1007 10071374	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
				01JAN2012		Y
	C4591001 1007 10071376	Immune system disorders	Seasonal allergy	01APR2020		Y
	C4591001 1007 10071377	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1007 10071378	Immune system disorders	Rubber sensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1007 10071380	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1007 10071381	Immune system disorders	Allergy to animal	01JAN1990		Y
			Seasonal allergy	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1985		Y
	C4591001 1007 10071382	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
	C4591001 1007 10071385	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1007 10071386	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1007 10071387	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1007 10071388	Gastrointestinal disorders	Oesophageal stenosis	01AUG2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01DEC2019	31DEC2019	N
	C4591001 1007 10071390	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Rhinitis	01JAN2019		Y
	C4591001 1007 10071392	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Gastrointestinal disorders	Noninfective sialoadenitis	01JAN2000	31DEC2003	N
		Infections and infestations	Latent tuberculosis	01JAN1997	31DEC1998	N
		Injury, poisoning and procedural complications	Foot fracture	16JUN2020	30JUN2020	N
		Investigations	Arthroscopy	01MAY2019	31MAY2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2002		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Plantar fasciitis	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
		Surgical and medical procedures	Fracture treatment	01JUN2020	30JUN2020	N
			Parotidectomy	01JAN2003	31DEC2003	N
	C4591001 1007 10071397	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Allergy to animal	01JAN2013		Y
	C4591001 1007 10071399	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2004		Y
	C4591001 1007 10071401	Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2016		Y
		Psychiatric disorders	Anxiety	01OCT2014		Y
			Depression	01OCT2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1007 10071402	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071403	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1007 10071404	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1007 10071405	Investigations	Blood cholesterol increased	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Post-traumatic stress disorder	01JAN2007		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1007 10071406	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Social circumstances	Menopause	01FEB2020		Y
	C4591001 1007 10071407	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006	31DEC2015	N
	C4591001 1007 10071408	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1007 10071410	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1007 10071416	Immune system disorders	Allergy to animal	01JAN2003		Y
			Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	19OCT2020		Y
	C4591001 1007 10071418	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN2011		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
			Exostosis	01JAN2017	05NOV2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2011		Y
	C4591001 1007 10071419	Endocrine disorders	Hyperandrogenism	01JAN1990		Y
	C4591001 1007 10071421	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1007 10071422	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071423	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1007 10071425	Nervous system disorders	Epilepsy	01JAN2008		Y
	C4591001 1007 10071426	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1007 10071433	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Depression	01MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01FEB2019	28FEB2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071434	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2006		Y
		Infections and infestations	Ear infection	01JAN2004	31DEC2007	N
		Nervous system disorders	Migraine	01JAN2017		Y
		Renal and urinary disorders	Hypercalciuria	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1007 10071435	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1007 10071436	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2012		Y
	C4591001 1007 10071437	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1007 10071438	Immune system disorders	Food allergy	01JAN2018		Y
			Seasonal allergy	01JAN1987		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1007 10071440	Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1007 10071443	Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2017		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1007 10071444	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Decreased appetite	01JAN2019		Y
		Psychiatric disorders	Depression suicidal	01JAN2019	30JUL2019	N
	C4591001 1007 10071446	Cardiac disorders	Sinus tachycardia	01AUG2020		Y
	C4591001 1007 10071448	Immune system disorders	Allergy to animal	01JAN2011		Y
			Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
	C4591001 1007 10071449	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2010		Y
	C4591001 1007 10071450	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071451	Immune system disorders	Allergy to animal	01JAN2007		Y
			Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2004		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Autism spectrum disorder	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2013		Y
	C4591001 1007 10071452	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2018		Y
	C4591001 1007 10071455	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1007 10071456	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Investigations	Blood iron decreased	01JAN2015	31DEC2018	N
	C4591001 1007 10071457	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1007 10071458	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1007 10071461	Psychiatric disorders	Anxiety	01OCT2019		Y
			Attention deficit hyperactivity disorder	01MAR2016		Y
	C4591001 1007 10071462	Psychiatric disorders	Depression	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1007 10071464	Immune system disorders	Seasonal allergy	01JAN2007		Y
	C4591001 1007 10071465	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1007 10071468	Metabolism and nutrition disorders	Gluten sensitivity	01AUG2020		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1007 10071473	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Spondylolysis	01DEC2020		Y
	C4591001 1007 10071474	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Cardiac murmur	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	16MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1007 10071477	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1007 10071479	Surgical and medical procedures	Ankle operation	15JAN2019	15JAN2019	N
	C4591001 1007 10071487	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1007 10071489	Immune system disorders	Hypersensitivity	01JAN2003		Y
	C4591001 1007 10071491	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2017		Y
	C4591001 1007 10071498	Immune system disorders	Food allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1007 10071501	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071502	Congenital, familial and genetic disorders	Falot's tetralogy	(b) (6) 2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Heart valve replacement	05AUG2020	05AUG2020	N
			Lung assist device therapy	(b) (6)2004	(b) (6)2004	N
			Tetralogy of Fallot repair	(b) (6)2004	(b) (6)2004	N
	C4591001 1007 10071503	Congenital, familial and genetic disorders	Cataract congenital	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Scapular dyskinesia	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Erythema annulare	01JAN2019		Y
	C4591001 1007 10071510	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01SEP2020	30SEP2020	N
	C4591001 1007 10071513	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN2004		Y
	C4591001 1007 10071532	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Surgical and medical procedures	Adenotonsillectomy	30JAN2018	30JAN2018	N
	C4591001 1007 10071534	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1007 10071548	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1007 10071553	Immune system disorders	Drug hypersensitivity	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081007	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081011	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1008 10081015	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1008 10081019	Psychiatric disorders	Anxiety	01JAN1996		Y
			Attention deficit hyperactivity disorder	01JAN1994		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2010		Y
		Surgical and medical procedures	Transgender hormonal therapy	01JAN2010		Y
	C4591001 1008 10081022	Gastrointestinal disorders	Diverticulum	01JAN2012		Y
	C4591001 1008 10081024	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Nervous system disorders	Arachnoiditis	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1984		Y
			Eczema	01JAN1984		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1008 10081025	Metabolism and nutrition disorders	Gout	01JAN2005		Y
		Vascular disorders	Hypertension	15JUN2020		Y
	C4591001 1008 10081028	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1008 10081029	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1008 10081030	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01APR2018		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
			Attention deficit hyperactivity disorder	01JAN1975		Y
			Autism spectrum disorder	01JAN2002		Y
		Renal and urinary disorders	Cystitis interstitial	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma			Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01AUG2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081031	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
	C4591001 1008 10081032	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JUN2020		Y
	C4591001 1008 10081033	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1008 10081036	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1008 10081040	Cardiac disorders	Myocardial infarction	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Coronary artery surgery	01JAN2016	31DEC2016	N
	C4591001 1008 10081042	Infections and infestations	Herpes simplex	01JUN2020		Y
	C4591001 1008 10081043	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1008 10081046	Immune system disorders	Seasonal allergy	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
	C4591001 1008 10081047	General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAR2020		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Scoliosis	01JAN2019		Y
	C4591001 1008 10081048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2011		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Sciatica	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
			Hypertension	01JAN2018		Y
	C4591001 1008 10081049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
				01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1989		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Nervous system disorders	Neuropathy peripheral	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
			Chronic obstructive pulmonary disease	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2000		Y
			Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1008 10081051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Seasonal allergy	01JAN1981		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1008 10081052	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
			Human papilloma virus test positive	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081054	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1008 10081059	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
				01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1008 10081064	Gastrointestinal disorders	Large intestine polyp	01MAR2020	31MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Large intestinal polypectomy	01MAR2020	31MAR2020	N
	C4591001 1008 10081065	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1008 10081066	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
	C4591001 1008 10081067	Gastrointestinal disorders	Coeliac disease	01JAN2009		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1994		Y
		Nervous system disorders	Epilepsy	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
	C4591001 1008 10081068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081071	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
	C4591001 1008 10081077	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
	C4591001 1008 10081078	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01APR2019	30APR2019	N
		Surgical and medical procedures	Hysterectomy	01APR2019	30APR2019	N
	C4591001 1008 10081079	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
	C4591001 1008 10081086	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081087	Investigations	Blood cholesterol increased	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1008 10081088	Gastrointestinal disorders	Constipation	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1008 10081091	Surgical and medical procedures	Intrauterine contraception	05MAY2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
	C4591001 1008 10081095	Surgical and medical procedures	Vasectomy	01DEC2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1008 10081099	Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN1966		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988		Y
			Impaired gastric emptying	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN1989		Y
			Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1969		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01SEP2017		Y
		Surgical and medical procedures	Gastric banding	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081101	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN2004	31DEC2004	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1008 10081102	Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1008 10081103	Psychiatric disorders	Depression	01JAN2001		Y
	C4591001 1008 10081113	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1008 10081116	Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1008 10081121	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081130	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN1989		Y
				01JAN2016		Y
		Investigations	Blood cholesterol increased	01MAY2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2016		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Lumbar spinal stenosis	01JAN2018		Y
			Spinal osteoarthritis	01AUG2018		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Major depression	01OCT2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2009	31DEC2009	N
			Female sterilisation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1008 10081136	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081138	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
				01JUN2020		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1008 10081140	Cardiac disorders	Palpitations	01OCT2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2001		Y
				01JAN2003		Y
			Seasonal allergy	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081143	Gastrointestinal disorders	Coeliac disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1008 10081147	Nervous system disorders	Occipital neuralgia	01JAN2016		Y
	C4591001 1008 10081148	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
	C4591001 1008 10081149	Investigations	Blood cholesterol increased	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081150	Gastrointestinal disorders	Umbilical hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2016	31DEC2016	N
	C4591001 1008 10081151	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Herpes simplex	01JAN1985		Y
		Nervous system disorders	Sciatica	01AUG2019		Y
	C4591001 1008 10081152	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tinea versicolour	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081153	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01DEC2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Gastrectomy	01JAN2020	31JAN2020	N
	C4591001 1008 10081156	Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2018		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2016	31DEC2016	N
	C4591001 1008 10081159	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
	C4591001 1008 10081160	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1008 10081166	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Insomnia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081183	Cardiac disorders	Supraventricular tachycardia	01JAN2001	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2001	31DEC2001	N
	C4591001 1008 10081187	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Cardiac murmur	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081191	Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1008 10081193	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1008 10081194	General disorders and administration site conditions	Oedema	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1008 10081197	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1008 10081198	Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081199	Ear and labyrinth disorders	Hypoacusis	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01DEC2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Cancer surgery	01JAN2017	31DEC2017	N
	C4591001 1008 10081200	Investigations	Precancerous cells present	01JAN2007	31DEC2007	N
		Nervous system disorders	Cerebrovascular accident	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01DEC2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1989		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1008 10081202	Cardiac disorders	Supraventricular tachycardia	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Viral infection	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Cardiac ablation	01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN1981	31DEC1981	N
	C4591001 1008 10081212	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN1988		Y
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1008 10081217	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081218	Congenital, familial and genetic disorders	Hereditary non-polyposis colorectal cancer syndrome	01JAN2018		Y
			Methylenetetrahydrofolate reductase gene mutation	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01AUG2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010	31DEC2018	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1008 10081220	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2008	31DEC2008	N
			Female sterilisation	09JUL2004	09JUL2004	N
	C4591001 1008 10081221	Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1008 10081224	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Idiopathic urticaria	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1008 10081225	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1008 10081232	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2008	N
			Vulvovaginal dryness	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2008	31DEC2008	N
	C4591001 1008 10081233	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1008 10081234	Ear and labyrinth disorders	Vertigo	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1994		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1008 10081235	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN1975		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2019		Y
	C4591001 1008 10081238	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN1998		Y
		Investigations	Smear cervix abnormal	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2017	31DEC2017	N
	C4591001 1008 10081239	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1008 10081240	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Renal and urinary disorders	Urinary retention	01APR2020		Y
	C4591001 1008 10081244	Gastrointestinal disorders	Colitis microscopic	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2005		Y
	C4591001 1008 10081251	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081253	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hypercholesterolaemia	01JAN2017		Y
	C4591001 1008 10081256	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1008 10081257	Injury, poisoning and procedural complications	Meniscus injury	01JAN2020	12MAY2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Surgical and medical procedures	Meniscus operation	12MAY2020	12MAY2020	N
	C4591001 1008 10081258	Psychiatric disorders	Anxiety	01JAN2007		Y
	C4591001 1008 10081260	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Surgical and medical procedures	Gastric bypass	09SEP2015	09SEP2015	N
	C4591001 1008 10081261	Endocrine disorders	Hypothyroidism	01JAN2012		Y
	C4591001 1008 10081263	Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1008 10081271	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081274	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1008 10081281	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081286	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Schizophrenia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1008 10081289	Investigations	Blood cholesterol increased	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1008 10081290	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1008 10081292	Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Obesity	01JAN2010		Y
	C4591001 1008 10081293	Injury, poisoning and procedural complications	Back injury	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1008 10081295	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1008 10081297	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2020	31AUG2020	N
		Surgical and medical procedures	Skin neoplasm excision	01AUG2020	31AUG2020	N
	C4591001 1008 10081300	Ear and labyrinth disorders	Meniere's disease	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2011		Y
	C4591001 1008 10081304	Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01JAN2005		Y
	C4591001 1008 10081306	Gastrointestinal disorders	Abdominal pain	01JAN2016	31DEC2016	N
		Immune system disorders	Allergy to metals	01JAN1981		Y
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2019		Y
			Benign uterine neoplasm	01JAN2019		Y
			Uterine leiomyoma	01JAN1998	31DEC2006	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2012		Y
			Rosacea	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Endometrial ablation	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1996	31DEC1996	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1008 10081310	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2019		Y
	C4591001 1008 10081312	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Umbilical hernia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Psychiatric disorders	Alcoholism	01JAN2008		Y
			Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1008 10081313	Eye disorders	Astigmatism	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2004		Y
			Nystagmus	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1008 10081314	Cardiac disorders	Supraventricular extrasystoles	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1008 10081315	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081316	Cardiac disorders	Mitral valve prolapse	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1008 10081320	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1008 10081321	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2003		Y
				01JAN2014		Y
				01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2019		Y
		Nervous system disorders	Epilepsy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Gastric bypass	01JAN2017	31DEC2017	N
	C4591001 1008 10081326	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Umbilical hernia	01JAN1965		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081327	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Depression	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081333	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1008 10081336	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1008 10081337	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081338	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1008 10081341	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1008 10081344	Investigations	Coagulation factor V level	01JAN2004		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
	C4591001 1008 10081346	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Contrast media allergy	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
	C4591001 1008 10081347	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081348	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1008 10081349	Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1008 10081350	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
		Reproductive system and breast disorders	Fallopian tube adhesion	01JAN2016		Y
			Infertility	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1986		Y
		Surgical and medical procedures	Gastric bypass	01JAN2016	31DEC2016	N
	C4591001 1008 10081351	Nervous system disorders	Headache	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081354	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1996		Y
	C4591001 1008 10081357	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081358	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1008 10081359	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
	C4591001 1008 10081360	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1008 10081364	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1008 10081365	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2014		Y
	C4591001 1008 10081366	Ear and labyrinth disorders	Hypoacusis	01JAN1988		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1008 10081367	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01MAR2019	31MAR2019	N
	C4591001 1008 10081368	Psychiatric disorders	Anxiety	01SEP2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2004		Y
	C4591001 1008 10081370	Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1008 10081372	Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
			Depression	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1008 10081374	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1981		Y
		Ear and labyrinth disorders	Vertigo	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
				01JAN1985		Y
				01JAN1998		Y
				01JAN2003		Y
		Nervous system disorders	Migraine	01JAN1986		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1008 10081379	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
	C4591001 1008 10081382	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Tinea versicolour	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obsessive-compulsive disorder	01JAN2013		Y
	C4591001 1008 10081383	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1008 10081384	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2018		Y
			Seborrhoeic dermatitis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1008 10081391	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1008 10081392	Gastrointestinal disorders	Diarrhoea	01JAN1997		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1008 10081393	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
	C4591001 1008 10081394	Skin and subcutaneous tissue disorders	Acne	01JAN2001		Y
	C4591001 1008 10081395	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1982		Y
	C4591001 1008 10081396	Endocrine disorders	Hypothyroidism	01JAN2009		Y
	C4591001 1008 10081397	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1991		Y
	C4591001 1008 10081398	Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN1980		Y
				01JAN1991		Y
			Seasonal allergy	01JAN1975		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Cough	01SEP2019		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1008 10081401	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1008 10081404	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1008 10081407	Immune system disorders	Drug hypersensitivity	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1008 10081408	Cardiac disorders	Type 2 diabetes mellitus Mitral valve prolapse	01JAN2017 01JAN2010		Y Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1008 10081410	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2017		Y
		Reproductive system and breast disorders	Menstrual discomfort	01JAN2003		Y
	C4591001 1008 10081411	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081413	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Intervertebral disc operation	01MAR2020	31MAR2020	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1008 10081418	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Tinea versicolour	01JAN2013		Y
		Injury, poisoning and procedural complications	Arthropod bite	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Spinal pain	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081419	Blood and lymphatic system disorders	Anaemia	26AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081420	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar II disorder	01JAN2012		Y
			Gender dysphoria	01JAN2014		Y
	C4591001 1008 10081421	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
	C4591001 1008 10081422	Reproductive system and breast disorders	Menstruation irregular	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1008 10081423	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081425	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
			Hiatus hernia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2016	31DEC2016	N
	C4591001 1008 10081426	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1008 10081427	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1008 10081430	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1994		Y
	C4591001 1008 10081432	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN1992		Y
			Depression	01AUG2019		Y
		Surgical and medical procedures	Vasectomy	01DEC2019	31DEC2019	N
	C4591001 1008 10081433	Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1008 10081435	Gastrointestinal disorders	Toothache	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JUN2020		Y
	C4591001 1008 10081436	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN2001		Y
			Seasonal allergy	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081437	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1986		Y
	C4591001 1008 10081438	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Investigations	Blood cholesterol increased	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1008 10081439	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Lumbar spinal stenosis	01JUL2020		Y
	C4591001 1008 10081440	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Hepatic enzyme increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081441	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Perinatal depression	01APR2020		Y
	C4591001 1008 10081442	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1008 10081444	Psychiatric disorders	Depression	01DEC2019		Y
	C4591001 1008 10081447	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Helicobacter test positive	01JAN2017	31DEC2017	N
	C4591001 1008 10081449	Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1008 10081450	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1008 10081453	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1008 10081456	Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2005	31DEC2005	N
	C4591001 1008 10081457	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
	C4591001 1008 10081463	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
	C4591001 1008 10081467	Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC2017	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1008 10081468	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1008 10081469	Immune system disorders	Contrast media allergy	01JAN1982		Y
	C4591001 1008 10081470	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
	C4591001 1008 10081471	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1979		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01MAY2019		Y
	C4591001 1008 10081472	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1008 10081473	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1993	31DEC1993	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1008 10081474	Immune system disorders	Seasonal allergy	01JAN1991		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1008 10081475	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2017		Y
	C4591001 1008 10081476	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN1980		Y
	C4591001 1008 10081477	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081479	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
	C4591001 1008 10081481	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1008 10081485	Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1008 10081487	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081492	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Psychiatric disorders	Perinatal depression	01SEP2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1008 10081496	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1008 10081497	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1008 10081499	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1008 10081500	Ear and labyrinth disorders	Hypoacusis	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2002		Y
			Rubber sensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001		Y
	C4591001 1008 10081504	Endocrine disorders	Hypothyroidism	01AUG2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Iodine allergy	01JAN1985		Y
			Seasonal allergy	01JAN1992		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
	C4591001 1008 10081505	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1996		Y
				01JAN2001		Y
			Seasonal allergy	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2010		Y
	C4591001 1008 10081507	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081509	Investigations	Blood cholesterol increased	01JAN2018		Y
	C4591001 1008 10081512	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2018		Y
	C4591001 1008 10081513	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1008 10081514	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1008 10081520	Ear and labyrinth disorders	Hypoacusis	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1008 10081521	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2011		Y
			Rubber sensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2017		Y
	C4591001 1008 10081524	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1996		Y
	C4591001 1008 10081525	Psychiatric disorders	Anxiety	01JAN2004		Y
	C4591001 1008 10081528	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
	C4591001 1008 10081529	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1008 10081532	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1008 10081533	Psychiatric disorders	Anxiety	01FEB2020		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2007	31DEC2007	N
			Ovarian cyst	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN2007	31DEC2007	N
	C4591001 1008 10081534	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1008 10081541	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1008 10081542	Immune system disorders	Seasonal allergy	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1008 10081543	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1008 10081544	Reproductive system and breast disorders	Polycystic ovaries	01JAN2011		Y
	C4591001 1008 10081547	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
	C4591001 1008 10081548	Immune system disorders	Rubber sensitivity	01JAN1987		Y
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017	31DEC2017	N
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
				01JAN2018		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2017	31DEC2017	N
	C4591001 1008 10081549	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2015		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1008 10081551	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1008 10081552	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081553	Skin and subcutaneous tissue disorders	Acne	01DEC2019		Y
	C4591001 1008 10081554	Eye disorders	Strabismus	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2006		Y
			Insomnia	01JAN2009		Y
	C4591001 1008 10081555	Endocrine disorders	Autoimmune thyroiditis	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2019		Y
			Rubber sensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Herpes simplex	01JAN2009		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1978		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1008 10081556	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1008 10081557	Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1008 10081558	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081559	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081567	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081568	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Irritable bowel syndrome	01JAN2018		Y
	C4591001 1008 10081572	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1993		Y
	C4591001 1008 10081574	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1008 10081576	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2010		Y
			Oesophagitis	01JAN2008		Y
		Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1008 10081577	Investigations	Blood cholesterol increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081579	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081580	Ear and labyrinth disorders	Tinnitus	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081581	Gastrointestinal disorders	Constipation	01JAN2019		Y
			Eosinophilic oesophagitis	01JAN2016		Y
			Gastrooesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN2019		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1008 10081583	Immune system disorders	Rubber sensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
	C4591001 1008 10081584	Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1008 10081590	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1008 10081595	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1008 10081596	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
	C4591001 1008 10081598	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081600	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Bipolar I disorder	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1008 10081604	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
	C4591001 1008 10081605	Cardiac disorders	Palpitations	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1008 10081606	Metabolism and nutrition disorders	Gout	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1008 10081607	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 1999		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1008 10081608	Infections and infestations	Tinea versicolour	01JAN2012		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1008 10081612	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Salpingectomy	01MAR2015	31MAR2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081617	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081618	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JUN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1008 10081620	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1008 10081628	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Nervous system disorders	Migraine	01OCT2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1008 10081629	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1008 10081630	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1008 10081631	Surgical and medical procedures	Vasectomy	01APR2019	30APR2019	N
	C4591001 1008 10081632	Immune system disorders	Seasonal allergy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
			Hand dermatitis	01JAN2009		Y
	C4591001 1008 10081633	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081637	Immune system disorders	Seasonal allergy	01JAN1981		Y
	C4591001 1008 10081638	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
		Surgical and medical procedures	Vascular stent insertion	01JAN1997	31DEC1997	N
		Vascular disorders	Aortic stenosis	01JAN1997	31DEC1997	N
	C4591001 1008 10081643	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1008 10081647	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Food allergy	01JAN2020		Y
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Genital herpes	01JAN2015		Y
			Herpes simplex	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1008 10081648	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081653	Ear and labyrinth disorders	Hypoacusis	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2001		Y
	C4591001 1008 10081655	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1008 10081657	Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1008 10081663	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081664	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Hormone level abnormal	01JAN2015		Y
	C4591001 1008 10081665	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2010		Y
	C4591001 1008 10081668	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN1977		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Meningitis aseptic	01JAN2007	31DEC2007	N
		Nervous system disorders	Seizure	01JAN2007	31DEC2007	N
	C4591001 1008 10081669	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081670	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Immune system disorders	Contrast media allergy	01JAN2018		Y
			Seasonal allergy	01JAN1996		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081672	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
	C4591001 1008 10081673	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
	C4591001 1008 10081674	Cardiac disorders	Coronary artery disease	21APR2020		Y
			Myocardial infarction	21APR2020	21APR2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	21APR2020		Y
		Surgical and medical procedures	Coronary arterial stent insertion	21APR2020	21APR2020	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1008 10081676	Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081677	Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2015		Y
	C4591001 1008 10081678	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081680	Immune system disorders	Seasonal allergy	01JAN1998		Y
	C4591001 1008 10081682	Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1008 10081683	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1008 10081692	Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1008 10081695	Investigations	Seasonal allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Blood cholesterol increased	01JAN2018		Y
		Obesity	01JAN2012		Y	
		Vitamin D deficiency	01JAN2018		Y	
		Psychiatric disorders	Anxiety	01APR2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1008 10081696	Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1008 10081696	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1008 10081698	Immune system disorders	Contrast media allergy	01JUL2020		Y
	C4591001 1008 10081700	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	Seasonal allergy		01JAN2000		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1008 10081703	Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081704	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1984		Y
	C4591001 1008 10081706	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1008 10081710	Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Blood and lymphatic system disorders	Anaemia	01SEP2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
			Thyroid mass	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Diffuse idiopathic skeletal hyperostosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN1987		Y
			Insomnia	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Thyroidectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081712	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081713	Investigations	Blood cholesterol increased	01JAN2010		Y
			Blood testosterone decreased	01JAN2015		Y
	C4591001 1008 10081715	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1998		Y
		Surgical and medical procedures	Salpingectomy	01JAN2017	31JAN2017	N
	C4591001 1008 10081717	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1008 10081719	Congenital, familial and genetic disorders	Thalassaemia alpha	01JAN1989		Y
	C4591001 1008 10081720	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1967		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1008 10081721	Congenital, familial and genetic disorders	Phenylketonuria	01JAN1983		Y
	C4591001 1008 10081727	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Herpes simplex	01JAN1983		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081728	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1008 10081733	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1008 10081736	Gastrointestinal disorders	Gastritis	01MAR2020		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1008 10081737	Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1008 10081738	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1008 10081741	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081742	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081743	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081744	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1008 10081746	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081747	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1008 10081748	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1008 10081749	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2017		Y
	C4591001 1008 10081750	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01SEP2020		Y
	C4591001 1008 10081762	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1008 10081765	Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081766	Nervous system disorders	Migraine	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081776	Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
	C4591001 1008 10081778	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1008 10081779	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Eczema	01JAN2009		Y
	C4591001 1008 10081782	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1008 10081783	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1008 10081784	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1008 10081786	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1009 10091002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1009 10091005	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1009 10091012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Headache	01JAN1980		Y
	C4591001 1009 10091021	Eye disorders	Dry eye	01JAN2012		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2005		Y
		Infections and infestations	Diverticulitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Nervous system disorders	Disturbance in attention	01JAN1970		Y
			Spasmodic dysphonia	01JAN2007		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2000		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Social circumstances	Postmenopause	01MAY2018		Y
	C4591001 1009 10091023	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Back pain	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1009 10091028	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008		Y
	C4591001 1009 10091030	General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2014		Y
	C4591001 1009 10091032	Metabolism and nutrition disorders	Hyperlipidaemia	12APR2012		Y
	C4591001 1009 10091042	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01APR2019		Y
	C4591001 1009 10091045	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Food allergy	01JAN1989		Y
			Seasonal allergy	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anogenital warts	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Vascular disorders	Hypertension	05DEC2019		Y
	C4591001 1009 10091046	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUL2015		Y
			Nausea	01JAN2009		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
				01JAN2000		Y
				01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Liver disorder	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Metabolic syndrome	01JAN2012		Y
			Overweight	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1009 10091049	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2011		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood pressure increased	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1009 10091050	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Perioral dermatitis	01JAN2019		Y
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Bunion operation	01JUL2016	31JUL2016	N
	C4591001 1009 10091053	Blood and lymphatic system disorders	Anaemia	01AUG2017		Y
		Ear and labyrinth disorders	Meniere's disease	01OCT2019		Y
		Endocrine disorders	Hyperthyroidism	11AUG2020		Y
		Infections and infestations	Pharyngitis	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015		Y
	C4591001 1009 10091056	Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2009		Y
	C4591001 1009 10091058	Immune system disorders	Allergy to arthropod sting	01JAN2017		Y
			Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
	C4591001 1009 10091059	Investigations	Blood cholesterol increased	04NOV2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	06NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
		Vascular disorders	Hypertension	05JUL2017		Y
	C4591001 1009 10091061	Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091063	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Surgical and medical procedures	Gastric banding	01OCT2018		Y
		Vascular disorders	Hypertension	25JAN2011		Y
			Lymphoedema	23MAY2014		Y
	C4591001 1009 10091066	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1009 10091070	Psychiatric disorders	Anxiety	01DEC2019		Y
	C4591001 1009 10091073	Immune system disorders	Allergy to arthropod sting	01JAN1990		Y
			Food allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01DEC2011		Y
	C4591001 1009 10091075	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Investigations	Blood triglycerides increased	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091079	Cardiac disorders	Arrhythmia	07APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	28JUL2011	28JUL2011	N
	C4591001 1009 10091080	Investigations	Blood pressure increased	20AUG2020		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	15DEC2011		Y
	C4591001 1009 10091081	Ear and labyrinth disorders	Deafness unilateral	01JAN1970		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Pain in extremity	20JUL2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Social circumstances	Hearing aid user	01JAN2017		Y
	C4591001 1009 10091082	Eye disorders	Myopia	01JAN1976		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1009 10091084	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Investigations	Blood pressure increased	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01DEC2019	31DEC2019	N
			Mastectomy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091085	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1009 10091086	General disorders and administration site conditions	Drug intolerance	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
			Food allergy	01JAN2008		Y
		Investigations	Blood pressure increased	20AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
	C4591001 1009 10091092	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2004		Y
			Insomnia	01JAN2020		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01JUL2018		Y
		Social circumstances	Postmenopause	01JUL2018		Y
		Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1009 10091095	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1009 10091097	General disorders and administration site conditions	Drug intolerance	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
	C4591001 1009 10091098	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Scoliosis	01JAN2010		Y
	C4591001 1009 10091103	General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1979		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1009 10091105	General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
	C4591001 1009 10091106	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1009 10091108	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y
		Surgical and medical procedures	Vasectomy	01FEB2019	28FEB2019	N
	C4591001 1009 10091109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	08OCT2019		Y
			Testicular cyst	01JUN2019		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Vasectomy	01JUL2009	31JUL2009	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1009 10091110	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010		Y
			Pain in extremity	07JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Insomnia	01JAN2016		Y
	C4591001 1009 10091112	Skin and subcutaneous tissue disorders	Urticaria	01JAN1991		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Epicondylitis	06AUG2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1973		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y
	C4591001 1009 10091113	Skin and subcutaneous tissue disorders	Acne	01MAY2012		Y
			Dermatitis	01JAN2018		Y
			Urticaria	01JAN2011		Y
	C4591001 1009 10091116	Metabolism and nutrition disorders	Obesity	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Osteoarthritis	01JAN2017		Y
			Pain in extremity	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1009 10091117	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2005		Y
			Tension headache	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1009 10091118	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1009 10091124	Endocrine disorders	Hypothyroidism	03FEB2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12MAY2020		Y
		Nervous system disorders	Tension headache	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
	C4591001 1009 10091128	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	30AUG2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
			Urticaria	01JAN2019		Y
		Surgical and medical procedures	Gastric bypass	01JUN2019	30JUN2019	N
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
			Vomiting	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1990		Y
			Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Ingrowing nail	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Nail operation	01FEB2020	29FEB2020	N
			Sinus operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1009 10091131	Injury, poisoning and procedural complications	Fractured coccyx	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1009 10091133	Nervous system disorders	Headache	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Vascular disorders	Varicose vein	01JAN2013		Y
	C4591001 1009 10091134	Immune system disorders	Allergy to animal	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Tenosynovitis	29JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1009 10091138	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Genital herpes	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1009 10091142	Congenital, familial and genetic disorders	Type V hyperlipidaemia	29OCT2013		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2013		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Sinus operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091147	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Hepatobiliary disorders	Bile duct stone	01JAN2002	31DEC2011	N
		Immune system disorders	Allergic oedema	01JAN2000		Y
		Infections and infestations	Herpes simplex	01APR2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01MAY2015		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1009 10091158	Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Pain in extremity	01DEC2019		Y
			Plantar fasciitis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1009 10091159	Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
		Cardiac disorders	Atrial fibrillation	01JAN2017		Y
			Cardiomyopathy	01JAN2002		Y
		Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1009 10091163	Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	13MAY2013		Y
		Gastrointestinal disorders	Diverticulum	31AUG2017		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Oral herpes	01JAN2017		Y
	C4591001 1009 10091164	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01MAR2020		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Shift work disorder	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2012		Y
			Insomnia	01JAN2018		Y
	C4591001 1009 10091166	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01APR2007		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01FEB2020		Y
	C4591001 1009 10091171	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Generalised anxiety disorder	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000	31DEC2016	N
		Surgical and medical procedures	Endometrial ablation	01JAN2016	31DEC2016	N
	C4591001 1009 10091172	Eye disorders	Dry eye	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
	C4591001 1009 10091174	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2014		Y
		Nervous system disorders	Tension headache	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1009 10091175	Immune system disorders	Drug hypersensitivity	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1985		Y
		Infections and infestations	Chronic sinusitis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1009 10091177	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2012		Y
	C4591001 1009 10091178	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
			Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1009 10091183	General disorders and administration site conditions	Drug intolerance	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Nervous system disorders	Transient ischaemic attack	01JAN1995	31DEC1995	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1979		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	23NOV2018		Y
	C4591001 1009 10091184	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1009 10091186	Investigations	Blood pressure increased	21SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	06SEP2020		Y
	C4591001 1009 10091187	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Renal and urinary disorders	Nephrolithiasis	06SEP2020	10SEP2020	N
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1009 10091188	General disorders and administration site conditions	Fatigue	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1009 10091192	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Oral herpes	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091194	Congenital, familial and genetic disorders	Alpha-1 antitrypsin deficiency	01JAN2013		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1978		Y
		Surgical and medical procedures	Ovarian lesion excision	01JAN2008	31DEC2008	N
	C4591001 1009 10091197	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Vitamin B12 deficiency	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Trigeminal neuralgia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01MAR2020		Y
	C4591001 1009 10091198	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Urticaria	27JUL2020		Y
	C4591001 1009 10091200	Psychiatric disorders	Depression	01JAN2020		Y
			Insomnia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1009 10091201	Metabolism and nutrition disorders	Underweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2020		Y
			Limb asymmetry	01JAN2018		Y
		Surgical and medical procedures	Bone operation	01JUL2020	31JUL2020	N
				01SEP2019	30SEP2019	N
	C4591001 1009 10091202	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1009 10091206	Endocrine disorders	Hypopituitarism	01JAN2005		Y
			Testicular failure	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01SEP2020		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1009 10091207	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1009 10091210	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
	C4591001 1009 10091211	Eye disorders	Astigmatism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18NOV2014		Y
			Insulin resistance	18NOV2014		Y
			Obesity	01JAN2010		Y
			Vitamin D deficiency	09MAY2017		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015		Y
	C4591001 1009 10091214	General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
			Urinary bladder suspension	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091219	Reproductive system and breast disorders	Ovarian cyst ruptured	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Female sterilisation	01JAN2008		Y
			Oophorectomy	01MAR2020	31MAR2020	N
	C4591001 1009 10091222	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Neck pain	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01JAN2014		Y
	C4591001 1009 10091224	Psychiatric disorders	Attention deficit hyperactivity disorder	13SEP2016		Y
	C4591001 1009 10091225	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091228	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Abdominal wall operation	01JUN2019	30JUN2019	N
			Abdominoplasty	01JAN2020	31JAN2020	N
			Keratomileusis	01JUL2013	31JUL2013	N
	C4591001 1009 10091230	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Disaccharide metabolism disorder	08MAY2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	22SEP2020		Y
		Nervous system disorders	Migraine	01NOV2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010		Y
			Menstruation irregular	01JAN2010		Y
	C4591001 1009 10091232	Immune system disorders	Contrast media allergy	01JAN2015		Y
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1999		Y
		Investigations	Liver function test increased	27SEP2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2013		Y
	C4591001 1009 10091235	Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091236	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1009 10091239	Surgical and medical procedures	Knee arthroplasty	01JUN2019	30JUN2019	N
	C4591001 1009 10091241	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1009 10091242	Psychiatric disorders	Attention deficit hyperactivity disorder	26JUL2011		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1009 10091243	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1009 10091244	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1995	31AUG2017	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01AUG2017	31AUG2017	N
		Vascular disorders	Hypertension	21APR2020		Y
	C4591001 1009 10091252	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1009 10091253	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Vitamin D deficiency	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1009 10091256	Ear and labyrinth disorders	Deafness neurosensory	01JAN2005		Y
		Surgical and medical procedures	Cochlea implant	01JUN2020	30JUN2020	N
	C4591001 1009 10091257	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1009 10091260	Skin and subcutaneous tissue disorders	Acne	01NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091261	Infections and infestations	Ear infection	01JAN2015	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2017		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2018	31DEC2018	N
	C4591001 1009 10091262	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2007		Y
	C4591001 1009 10091263	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2016		Y
			Seasonal allergy	01JAN2012		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1009 10091264	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1009 10091271	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1009 10091276	Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1009 10091278	Immune system disorders	Hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Obsessive-compulsive disorder	01JAN2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2019		Y
	C4591001 1009 10091279	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1009 10091285	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1009 10091286	Metabolism and nutrition disorders	Eczema Obesity	01JAN2017 01JAN2015		Y Y
	C4591001 1009 10091290	Respiratory, thoracic and mediastinal disorders Immune system disorders	Asthma Seasonal allergy	01JAN2006 01JAN2004		Y Y
	C4591001 1009 10091291	Skin and subcutaneous tissue disorders Psychiatric disorders	Acne Attention deficit hyperactivity disorder	01NOV2017 01JAN2012		Y Y
	C4591001 1009 10091299	Respiratory, thoracic and mediastinal disorders Skin and subcutaneous tissue disorders Immune system disorders	Asthma exercise induced Acne Allergy to animal	01JAN2016 01JAN2017 01JAN2010		Y Y Y
	C4591001 1011 10111001	Respiratory, thoracic and mediastinal disorders Immune system disorders	Asthma Seasonal allergy	01JAN2010 01JAN2018		Y Y
	C4591001 1011 10111004	Psychiatric disorders Cardiac disorders	Anxiety Bradycardia	01JAN2017 01JAN2017		Y Y
	C4591001 1011 10111005	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1011 10111008	Immune system disorders	Drug hypersensitivity	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Social circumstances	Postmenopause	01FEB2017		Y
		Surgical and medical procedures	Caesarean section	06JUN1992	06JUN1992	N
	C4591001 1011 10111009	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1011 10111013	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Infections and infestations	Lyme disease	01JAN1999	31DEC1999	N
			Upper respiratory tract infection	05AUG2019	10AUG2019	N
		Renal and urinary disorders	Urge incontinence	01JAN2019		Y
	C4591001 1011 10111016	Nervous system disorders	Migraine	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1011 10111021	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1011 10111024	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2003	31DEC2003	N
			Ovarian cyst	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Meniscus removal	01JAN2019	31DEC2019	N
			Oophorectomy	01JAN2003	31DEC2003	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1011 10111031	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1011 10111034	Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1011 10111038	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1011 10111039	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Lyme disease	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1996	31DEC1996	N
			Meniscus injury	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	10JUL2018	10JUL2018	N
			Ligament operation	01JAN1996	31DEC1996	N
			Meniscus operation	01JAN1996	31DEC1996	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
			Myomectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1011 10111042	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1011 10111043	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1011 10111044	Infections and infestations	Skin bacterial infection	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	06FEB2020	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	02MAY1998	02MAY1998	N
			Carpal tunnel decompression	06FEB2020	06FEB2020	N
			Debridement	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1011 10111046	Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Limb asymmetry	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Metatarsal excision	01JAN2010	31DEC2010	N
	C4591001 1011 10111052	Infections and infestations	Tonsillitis	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2014		Y
					31DEC2014	N
		Nervous system disorders	Headache	28SEP2019	28SEP2019	N
		Psychiatric disorders	Anxiety	01MAR2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN2012	31DEC2012	N
			Fracture treatment	01JAN2014	31JAN2014	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1011 10111053	Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2019		Y
	C4591001 1011 10111070	Psychiatric disorders	Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1011 10111074	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1011 10111077	Infections and infestations	Diverticulitis	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1011 10111078	Cardiac disorders	Bradycardia	01JAN2013		Y
		Infections and infestations	Lyme disease	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01DEC2000		Y
	C4591001 1011 10111079	Nervous system disorders	Epilepsy	01JAN2010		Y
	C4591001 1011 10111082	Investigations	Laparoscopy	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2009	31DEC2009	N
			Ovarian germ cell teratoma benign	01JAN1990	31DEC1990	N
		Psychiatric disorders	Anxiety	01FEB2019		Y
			Depression	01FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
			Mammoplasty	04OCT2019	04OCT2019	N
	C4591001 1011 10111087	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1011 10111088	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1011 10111089	Nervous system disorders	Migraine	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
	C4591001 1011 10111090	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1011 10111091	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
	C4591001 1011 10111092	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1011 10111093	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Infections and infestations	Herpes virus infection	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2013	N
		Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1011 10111095	Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1011 10111097	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	02DEC2016	02DEC2016	N
	C4591001 1011 10111098	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1011 10111102	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Reproductive system and breast disorders	Uterine enlargement	01JAN2009	30NOV2015	N
		Surgical and medical procedures	Hysterectomy	01NOV2015	30NOV2015	N
	C4591001 1011 10111106	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1011 10111107	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2000	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1011 10111111	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2020	31JAN2020	N
	C4591001 1011 10111115	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
	C4591001 1011 10111116	Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1011 10111117	Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
	C4591001 1011 10111118	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1011 10111119	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1011 10111122	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1011 10111123	Cardiac disorders	Supraventricular tachycardia	01JAN1985	30NOV2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	28MAR2005	28MAR2005	N
			Cardiac ablation	01NOV2019	30NOV2019	N
	C4591001 1011 10111124	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1011 10111125	Endocrine disorders	Autoimmune thyroiditis	01JAN2012		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1011 10111130	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111134	Infections and infestations	Fungal infection	01JAN2015		Y
	C4591001 1011 10111135	Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1011 10111141	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1011 10111142	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1011 10111143	Infections and infestations	Lymph gland infection	01NOV2000	30NOV2000	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Obesity	01JAN1996	31DEC2019	N
		Surgical and medical procedures	Gastric bypass	01JUN2017	30JUN2017	N
			Lymphadenectomy	01NOV2000	30NOV2000	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1011 10111148	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2020	31JAN2020	N
			Thyroid cancer	01JAN2001	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Myomectomy	01JAN2020	31JAN2020	N
			Thyroidectomy	01JAN2001	31DEC2001	N
	C4591001 1011 10111154	Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendectomy	01JAN2013	31DEC2013	N
	C4591001 1011 10111159	Infections and infestations	Lyme disease	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
	C4591001 1011 10111164	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2019		Y
	C4591001 1011 10111166	Gastrointestinal disorders	Colitis ulcerative	01JAN2007		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1998	31DEC1998	N
			Mammoplasty	01JAN1986	31DEC1986	N
			Metabolic surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hot flush	01JAN2008	31DEC2016	N
	C4591001 1011 10111169	Infections and infestations	Lyme disease	01JAN2004	31DEC2004	N
	C4591001 1011 10111170	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1011 10111173	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111174	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1011 10111175	Endocrine disorders	Hyperthyroidism	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1011 10111176	Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1011 10111179	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1011 10111182	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2010		Y
	C4591001 1011 10111183	Nervous system disorders	Migraine	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1011 10111186	Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
	C4591001 1011 10111190	Psychiatric disorders	Anxiety	01JAN2007		Y
	C4591001 1011 10111193	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1011 10111197	Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1011 10111199	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1011 10111214	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1011 10111215	Endocrine disorders	Hyperthyroidism	01JAN2009		Y
	C4591001 1011 10111216	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 1 diabetes mellitus	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1011 10111219	Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1011 10111222	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1011 10111232	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1011 10111233	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2019		Y
	C4591001 1011 10111234	Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2020		Y
	C4591001 1011 10111235	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1011 10111236	Surgical and medical procedures	Vasectomy	01FEB2020	29FEB2020	N
	C4591001 1011 10111237	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasm	01JAN2015	31JAN2015	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01OCT2017	31OCT2017	N
		Surgical and medical procedures	Lymphadenectomy	01FEB2015	28FEB2015	N
	C4591001 1012 10121001	Ear and labyrinth disorders	Hypoacusis	10AUG2017	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Dizziness	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Epistaxis	10AUG2017		Y
	C4591001 1012 10121003	Vascular disorders	Hypertension	01JAN2007		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Haemorrhoids	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2018		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1012 10121005	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1012 10121006	Cardiac disorders	Palpitations	01OCT2015		Y
			Ventricular tachycardia	01OCT2015	07OCT2015	N
		Gastrointestinal disorders	Abdominal distension	01JAN2015		Y
			Abdominal pain	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Infections and infestations	Babesiosis	01MAR2016	31MAR2016	N
			Bartonellosis	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Human ehrlichiosis	01MAR2016	31MAR2016	N
			Lyme disease	01MAR2016		Y
			Oral candidiasis	01JAN2018		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2015		Y
		Nervous system disorders	Encephalopathy	01MAR2016	31MAR2016	N
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01OCT2015	31OCT2015	N
				07OCT2015		Y
	C4591001 1012 10121013	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2017	31DEC2017	N
	C4591001 1012 10121016	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1012 10121020	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1012 10121021	Gastrointestinal disorders	Colitis ulcerative	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1993		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1012 10121022	Psychiatric disorders	Anxiety	01APR2020		Y
			Depression	01APR2020		Y
	C4591001 1012 10121024	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1012 10121025	Endocrine disorders	Goitre	01JAN2017	31DEC2017	N
			Hypothyroidism	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Arthritis	01JAN1990		Y
			Pain in extremity	01JAN2017		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1012 10121027	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
	C4591001 1012 10121030	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2015		Y
	C4591001 1012 10121032	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1012 10121036	Infections and infestations	Herpes zoster	01MAR2020	31MAR2020	N
	C4591001 1012 10121037	Ear and labyrinth disorders	Ear disorder	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
			Trigger finger	01JAN2019		Y
	C4591001 1012 10121043	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1987		Y
	C4591001 1012 10121046	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1998		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
	C4591001 1012 10121051	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2004		Y
	C4591001 1012 10121053	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1012 10121055	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y
	C4591001 1012 10121058	Cardiac disorders	Mitral valve prolapse	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
	C4591001 1012 10121059	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1012 10121061	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1012 10121065	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Hiatus hernia	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
			Back pain	01JAN2006		Y
		Nervous system disorders	Headache	01JAN1994		Y
	C4591001 1012 10121072	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
	C4591001 1012 10121073	Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
	C4591001 1012 10121076	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2000		Y
			Vertebral foraminal stenosis	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1964		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1012 10121079	Gastrointestinal disorders	Umbilical hernia	01JAN2019		Y
		General disorders and administration site conditions	Fatigue	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2010		Y
			Polyarthritits	01JAN2005		Y
		Nervous system disorders	Seizure	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Major depression	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1012 10121083	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01MAR2020		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1012 10121085	Infections and infestations	Bacterial infection	01JAN2009	31DEC2009	N
			Coccidioidomycosis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1012 10121087	Ear and labyrinth disorders	Otosclerosis	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1983		Y
		Infections and infestations	Herpes simplex	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
	C4591001 1012 10121089	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
	C4591001 1012 10121090	Musculoskeletal and connective tissue disorders	Torticollis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1012 10121091	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Shoulder operation	01JAN2000	31DEC2000	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1012 10121092	Immune system disorders	Seasonal allergy	01JAN1983		Y
	C4591001 1012 10121096	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2006		Y
		Nervous system disorders	Sciatica	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1994		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121101	Surgical and medical procedures	Bunion operation	07AUG2019	07AUG2019	N
	C4591001 1012 10121102	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1012 10121103	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1012 10121104	Congenital, familial and genetic disorders	Myotonia congenita	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1012 10121105	Endocrine disorders	Hyperparathyroidism	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2006	31DEC2017	N
		Surgical and medical procedures	Chondroplasty	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1012 10121110	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2005		Y
	C4591001 1012 10121111	Cardiac disorders	Adams-Stokes syndrome	01JAN1980		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2007	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN1988		Y
			Schizophrenia	01JAN1980		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121116	Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1012 10121117	Reproductive system and breast disorders	Endometriosis	01JAN2016	31DEC2016	N
			Uterine haemorrhage	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1012 10121118	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2003		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1012 10121119	Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1012 10121121	Endocrine disorders	Basedow's disease	03AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1012 10121124	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1012 10121130	Gastrointestinal disorders	Colitis ulcerative	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1012 10121131	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1989		Y
	C4591001 1012 10121132	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatomyositis	01JAN2007		Y
	C4591001 1012 10121133	Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1012 10121134	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1012 10121136	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1012 10121137	Immune system disorders	Mite allergy	01JAN1992		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1012 10121138	Psychiatric disorders	Anxiety	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01OCT2019		Y
	C4591001 1012 10121141	Ear and labyrinth disorders	Tinnitus	01JAN2001		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Psychiatric disorders	Generalised anxiety disorder	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1012 10121144	Cardiac disorders	Arrhythmia	01JAN2009		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1012 10121145	Immune system disorders	Seasonal allergy	01DEC2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1012 10121146	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1997		Y
	C4591001 1012 10121151	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1989		Y
	C4591001 1012 10121154	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
	C4591001 1012 10121155	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1984		Y
	C4591001 1012 10121157	Investigations	Blood testosterone decreased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1996		Y
	C4591001 1012 10121158	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1012 10121162	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2020		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	13DEC2019	13DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1012 10121163	Immune system disorders	Anaphylactic shock	01JAN1984		Y
			Drug hypersensitivity	01JAN1984		Y
			Iodine allergy	01JAN2017		Y
		Infections and infestations	Cat scratch disease	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2016		Y
	C4591001 1012 10121164	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
	C4591001 1012 10121166	Skin and subcutaneous tissue disorders	Urticaria	01JAN2015		Y
	C4591001 1012 10121172	Hepatobiliary disorders	Cholelithiasis	01MAY1997	31MAY1997	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Nervous system disorders	Migraine	01JAN1985	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976	31DEC2002	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01FEB2019	28FEB2019	N
		Surgical and medical procedures	Cholecystectomy	01MAY1997	31MAY1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121173	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN2018		Y
	C4591001 1012 10121174	Psychiatric disorders	Anxiety	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
	C4591001 1012 10121178	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1993		Y
	C4591001 1012 10121180	Endocrine disorders	Thyroiditis subacute	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JUN2019		Y
	C4591001 1012 10121181	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2007		Y
	C4591001 1012 10121182	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1012 10121183	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN1998		Y
	C4591001 1012 10121187	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN1982		Y
		Renal and urinary disorders	Hydronephrosis	01JAN2019		Y
			Nephrolithiasis	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1013 10131002	General disorders and administration site conditions	Peripheral swelling	01DEC2013		Y
	C4591001 1013 10131003	Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
			Tonsillitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
	C4591001 1013 10131005	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1013 10131006	Eye disorders	Myopia	01JAN1999	28JUL2014	N
		Surgical and medical procedures	Myopia correction	28JUL2014	28JUL2014	N
	C4591001 1013 10131007	Surgical and medical procedures	Female sterilisation	14JUN2006	14JUN2006	N
	C4591001 1013 10131008	Surgical and medical procedures	Nasal septal operation	01JUL2005		Y
				01MAR2016	31MAR2016	N
			Orthognathic surgery	01JAN2015		Y
			Tonsillectomy	01MAY2008	31MAY2008	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1013 10131009	Injury, poisoning and procedural complications	Epicondylitis	01JAN1994	31DEC2012	N
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2000	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Elbow operation	01JAN2012	31DEC2012	N
			Gastric bypass	01JAN2013	31DEC2013	N
	C4591001 1013 10131010	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131011	Musculoskeletal and connective tissue disorders	Back pain	01JAN1988	31DEC1997	N
			Pain in extremity	01JAN1988	31DEC2018	N
		Surgical and medical procedures	Intervertebral disc operation	01APR1997	30APR1997	N
				01DEC1997	31DEC1997	N
			Neurectomy	01APR1998	30APR1998	N
				01JAN2018	31JAN2018	N
				01MAR1997	31MAR1997	N
	C4591001 1013 10131012	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1990		Y
	C4591001 1013 10131013	Eye disorders	Glaucoma	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Iodine allergy	01JAN2004		Y
			Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Palmoplantar keratoderma	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131014	Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1013 10131015	Immune system disorders	Seasonal allergy	01MAR2016		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
			Major depression	01JAN2005		Y
	C4591001 1013 10131018	Eye disorders	Myopia	01JAN2006	27JUN2020	N
		Surgical and medical procedures	Myopia correction	27JUN2020	27JUN2020	N
	C4591001 1013 10131020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2016		Y
		Immune system disorders	Food allergy	01JUN2004		Y
			Hypersensitivity	01JUN2016		Y
	C4591001 1013 10131022	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131023	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131024	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1013 10131025	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Prophylaxis against HIV infection	01MAR2018		Y
	C4591001 1013 10131027	Immune system disorders	Drug hypersensitivity	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Arthropod bite	24JUL2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01SEP2013	30SEP2013	N
	C4591001 1013 10131030	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Attention deficit hyperactivity disorder	01JAN2003		Y
			Insomnia	01JAN2017		Y
			Major depression	01JAN2003	31DEC2010	N
	C4591001 1013 10131031	Immune system disorders	Seasonal allergy	01JUN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1013 10131032	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1013 10131033	Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016		Y
	C4591001 1013 10131034	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1013 10131035	Surgical and medical procedures	Caesarean section	23JAN2006	23JAN2006	N
	C4591001 1013 10131036	Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1013 10131038	Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1013 10131039	Immune system disorders	Allergy to animal	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypersensitivity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31JUL2008	N
		Surgical and medical procedures	Nasal septal operation	01JUL2008	31JUL2008	N
	C4591001 1013 10131040	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Generalised anxiety disorder	01JAN2012		Y
	C4591001 1013 10131044	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01OCT1990		Y
			Foot deformity	01JAN2017	31MAR2017	N
			Intervertebral disc protrusion	01OCT1990		Y
		Nervous system disorders	Neuropathy peripheral	01OCT1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Social circumstances	Substance use	01JAN1990		Y
		Surgical and medical procedures	Bunion operation	01MAR2017	31MAR2017	N
	C4591001 1013 10131045	Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1013 10131047	Surgical and medical procedures	Mammoplasty	01JAN2017	31JAN2017	N
	C4591001 1013 10131048	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1013 10131049	Injury, poisoning and procedural complications	Gun shot wound	21JAN1985	21JAN1985	N
		Nervous system disorders	Hemiplegia	21JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131050	Gastrointestinal disorders	Constipation	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Serum ferritin increased	01SEP2017		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Knee arthroplasty	28JAN2020	28JAN2020	N
	C4591001 1013 10131051	Eye disorders	Myopia	01SEP1996	05JAN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Surgical and medical procedures	Keratomileusis	05JAN2020	05JAN2020	N
	C4591001 1013 10131052	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Food allergy	01JAN1991		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1991		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
	C4591001 1013 10131054	Injury, poisoning and procedural complications	Joint injury	01JAN2007		Y
	C4591001 1013 10131056	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2011		Y
		Surgical and medical procedures	Chondroplasty	01OCT2013	31OCT2013	N
			Ligament operation	01NOV2000	30NOV2000	N
	C4591001 1013 10131058	Immune system disorders	Allergy to arthropod sting	01JAN1980		Y
		Psychiatric disorders	Post-traumatic amnesic disorder	01APR2004	31DEC2012	N
		Surgical and medical procedures	Vasectomy	01JUN2008	30JUN2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131059	Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
	C4591001 1013 10131060	Infections and infestations	Gingivitis	30JUL2020		Y
	C4591001 1013 10131062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131064	Immune system disorders	Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
			Depression	01DEC2019		Y
	C4591001 1013 10131066	Immune system disorders	Sunscreen sensitivity	01JAN2000		Y
		Surgical and medical procedures	Lipoma excision	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2009	31DEC2009	N
	C4591001 1013 10131067	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Hypersensitivity	01JAN2013		Y
		Infections and infestations	Pharyngitis streptococcal	01FEB2014	30APR2014	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JUL2019		Y
			Intervertebral disc protrusion	01JUL2019	16SEP2019	N
		Surgical and medical procedures	Adenoidectomy	01APR2014	30APR2014	N
			Intervertebral disc operation	16SEP2019	16SEP2019	N
			Tonsillectomy	01APR2014	30APR2014	N
	C4591001 1013 10131068	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1013 10131071	Injury, poisoning and procedural complications	Muscle rupture	01JUL2008	31JUL2008	N
				01JUL2009	31JUL2009	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUL2008	31JUL2008	N
				01JUL2009	31JUL2009	N
		Surgical and medical procedures	Muscle operation	01JUL2008	31JUL2008	N
				01JUL2009	31JUL2009	N
			Rotator cuff repair	01JUL2008	31JUL2008	N
				01JUL2009	31JUL2009	N
	C4591001 1013 10131074	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN1990		Y
	C4591001 1013 10131076	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	04JUN2019	20JUN2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
		Reproductive system and breast disorders	Endometriosis	04JUN2019	20JUN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	20JUN2019	20JUN2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131077	Eye disorders	Myopia	01SEP2007		Y
		Infections and infestations	Chronic tonsillitis	01JAN2003	30JUN2003	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2003	30JUN2003	N
	C4591001 1013 10131079	Injury, poisoning and procedural complications	Joint dislocation	01NOV1999	29FEB2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01FEB2000	29FEB2000	N
	C4591001 1013 10131081	Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
			Peripheral nerve operation	01JAN1993	31DEC1993	N
			Tenoplasty	01JAN1993	31DEC1993	N
	C4591001 1013 10131082	Injury, poisoning and procedural complications	Post procedural complication	01JUL2017	31AUG2018	N
		Surgical and medical procedures	Gastric bypass	01NOV2018	30NOV2018	N
			Hysterectomy	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN2011		Y
			Thrombosis	01JUL2017	31AUG2018	N
	C4591001 1013 10131083	Infections and infestations	Meningitis	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1976	31DEC1976	N
	C4591001 1013 10131084	Surgical and medical procedures	Renal surgery	01FEB2020	29FEB2020	N
	C4591001 1013 10131087	Hepatobiliary disorders	Cholecystitis	01MAR2012	31MAR2012	N
		Injury, poisoning and procedural complications	Fibula fracture	01APR1997	30APR1997	N
			Tibia fracture	01APR1997	30APR1997	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Bone operation	01APR1997	30APR1997	N
			Cholecystectomy	01MAR2012	31MAR2012	N
	C4591001 1013 10131089	Immune system disorders	Hypersensitivity	01FEB2020		Y
		Injury, poisoning and procedural complications	Cartilage injury	01SEP2009	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Seizure	01JAN2004	31DEC2008	N
		Surgical and medical procedures	Chondroplasty	01JAN2011	31DEC2011	N
	C4591001 1013 10131090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01FEB2019	28FEB2019	N
		Nervous system disorders	Migraine without aura	01JAN1990		Y
		Surgical and medical procedures	Bunion operation	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1013 10131093	Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC2012	N
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Nervous system disorders	Migraine with aura	01JAN1976		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1013 10131094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2005		Y
		Immune system disorders	Seasonal allergy	01JUN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31OCT2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01OCT2014	31OCT2014	N
	C4591001 1013 10131098	Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Spinal fracture treatment	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131102	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1013 10131103	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Rotator cuff repair	16JUN2020	16JUN2020	N
		Vascular disorders	Phleboscclerosis	01JAN1992	31DEC1992	N
	C4591001 1013 10131105	Endocrine disorders	Hypothyroidism	01OCT2015		Y
		Immune system disorders	Seasonal allergy	01OCT2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2005		Y
		Vascular disorders	Hypertension	01APR2005		Y
	C4591001 1013 10131106	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131107	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1013 10131108	Psychiatric disorders	Anxiety	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Surgical and medical procedures	Keratomileusis	01APR2019	30APR2019	N
	C4591001 1013 10131109	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Investigations	Pelvic laparoscopy	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2011		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2007		Y
		Surgical and medical procedures	Mammoplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1013 10131111	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1013 10131112	Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1013 10131113	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Major depression	01JAN2016	30APR2020	N
	C4591001 1013 10131115	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1985		Y
		Surgical and medical procedures	Facial operation	01JAN2020	31JAN2020	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1013 10131116	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1013 10131117	Nervous system disorders	Carpal tunnel syndrome	01JAN2010	30JUN2010	N
		Surgical and medical procedures	Carpal tunnel decompression	01JUN2010	30JUN2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131118	Injury, poisoning and procedural complications	Ulna fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131119	Infections and infestations	Lyme disease	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
	C4591001 1013 10131120	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
	C4591001 1013 10131121	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1013 10131122	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
	C4591001 1013 10131124	Infections and infestations	Diverticulitis	01MAR2014	31MAR2014	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Colectomy	01MAR2015	31MAR2015	N
			Inguinal hernia repair	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
	C4591001 1013 10131125	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
	C4591001 1013 10131126	Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Arthroscopy	01JUL2020	31JUL2020	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Ligament operation	01APR2014	30APR2014	N
				01OCT2017	31OCT2017	N
			Meniscus operation	01APR2014	30APR2014	N
				01OCT2017	31OCT2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131127	Blood and lymphatic system disorders	Anaemia	01JAN1995		Y
		Eye disorders	Strabismus	01JAN1979	31DEC1983	N
		Nervous system disorders	Epilepsy	01JAN2002		Y
		Surgical and medical procedures	Eye muscle operation	01JAN1983	31DEC1983	N
			Scar excision	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1013 10131128	Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Major depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1013 10131131	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Ear infection	01JAN1981	31DEC1985	N
		Surgical and medical procedures	Myringotomy	01JAN1985	31DEC1985	N
	C4591001 1013 10131132	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
	C4591001 1013 10131134	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2018		Y
	C4591001 1013 10131135	Congenital, familial and genetic disorders	Wolff-Parkinson-White syndrome congenital	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	31OCT2017	31OCT2017	N
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
	C4591001 1013 10131136	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2005		Y
		Infections and infestations	Cat scratch disease	01JAN1996	31DEC1996	N
			Lymph node abscess	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982	31DEC1986	N
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1998		Y
		Surgical and medical procedures	Abscess drainage	01JAN2000	31DEC2000	N
			Meniscus operation	01JAN2001	31DEC2001	N
	C4591001 1013 10131137	Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1013 10131139	Infections and infestations	Appendicitis	01JUN2018	30JUN2018	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JUN2018	30JUN2018	N
	C4591001 1013 10131143	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1013 10131145	Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1013 10131146	Musculoskeletal and connective tissue disorders	Bursitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Joint fluid drainage	01JAN2018	31DEC2018	N
	C4591001 1013 10131148	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01NOV2016	30NOV2016	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2012	31MAY2012	N
		Surgical and medical procedures	Lung lobectomy	01NOV2016	30NOV2016	N
			Oophorectomy	01MAY2012	31MAY2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1013 10131149	Gastrointestinal disorders	Inguinal hernia	01JAN1984	31DEC1984	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1997		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1984	31DEC1984	N
	C4591001 1013 10131155	Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	14DEC1987	14DEC1987	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131156	Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1013 10131158	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1013 10131159	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1013 10131163	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1995	31DEC1995	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1985		Y
		Surgical and medical procedures	Fracture treatment	01JAN1995	31DEC1995	N
			Keratomileusis	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1013 10131165	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Infections and infestations	Genital herpes	10AUG2019		Y
		Investigations	Blood triglycerides increased	01JAN2018		Y
		Social circumstances	Electronic cigarette user	01JAN2016		Y
	C4591001 1013 10131166	Gastrointestinal disorders	Crohn's disease	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2017		Y
	C4591001 1013 10131167	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 1 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1013 10131169	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAR2020		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2014	31DEC2014	N
	C4591001 1013 10131172	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Bipolar disorder	01JAN2018		Y
			Insomnia	01FEB2020		Y
			Major depression	01JAN2018		Y
		Surgical and medical procedures	Duodenal switch	01JAN2016	31DEC2016	N
			Gastrectomy	01JAN2016	31DEC2016	N
	C4591001 1013 10131173	Gastrointestinal disorders	Nausea	01JUN2020		Y
		Immune system disorders	Dust allergy	01JAN1985	31DEC1992	N
			Hypersensitivity	01JAN2016		Y
		Infections and infestations	Chronic sinusitis	01JAN2004	31DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Nervous system disorders	Tension headache	01JUN2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Nasal septal operation	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1013 10131174	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1013 10131177	Immune system disorders	Contrast media allergy	01JAN1992		Y
		Investigations	Arthroscopy	01JUL2009	31JUL2009	N
		Nervous system disorders	Tension headache	01JAN1990		Y
		Surgical and medical procedures	Ligament operation	01JAN2014	31DEC2014	N
			Shoulder operation	01FEB2012	29FEB2012	N
	C4591001 1013 10131179	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	24APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Pleurisy	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2008	31DEC2008	N
	C4591001 1013 10131180	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01FEB2019	31AUG2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Meniscus operation	01AUG2019	31AUG2019	N
				01JAN2020	31JAN2020	N
			Nasal septal operation	01JAN2015	31DEC2015	N
			Sinuplasty	01JAN2014	31DEC2014	N
	C4591001 1013 10131182	Endocrine disorders	Hypothyroidism	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131185	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2007	31DEC2007	N
	C4591001 1013 10131187	Immune system disorders	Hypersensitivity	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1986		Y
	C4591001 1013 10131188	Infections and infestations	Ear infection	01JAN1973	31DEC1977	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
		Surgical and medical procedures	Myringotomy	01JAN1976	31DEC1977	N
	C4591001 1013 10131190	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2000		Y
			Perineurial cyst	01DEC2019		Y
	C4591001 1013 10131195	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1988		Y
	C4591001 1013 10131197	Skin and subcutaneous tissue disorders	Acne	01AUG2019		Y
	C4591001 1013 10131199	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	05SEP2003	11SEP2003	N
		Surgical and medical procedures	Caesarean section	10SEP2003	10SEP2003	N
		Vascular disorders	Hypertension	11SEP2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131200	Hepatobiliary disorders	Hepatic steatosis	01JUL2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Hypersensitivity	01JAN2004		Y
		Investigations	Biopsy liver	01JUL2019	31JUL2019	N
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01MAR2020		Y
	C4591001 1013 10131204	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1991		Y
			Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	06JUN2019		Y
			Type 2 diabetes mellitus	06JUN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	06JUN2019		Y
	C4591001 1013 10131205	Musculoskeletal and connective tissue disorders	Pain in jaw	01JAN2011	31DEC2017	N
		Surgical and medical procedures	Orthognathic surgery	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131207	Investigations	Arthroscopy	08JUN1986	08JUN1986	N
				14SEP1994	14SEP1994	N
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Spinal fusion surgery	03DEC1998	30DEC1998	N
	C4591001 1013 10131209	Endocrine disorders	Goitre	01JAN2013	31DEC2013	N
			Hypothyroidism	01JAN2013		Y
		Infections and infestations	Eyelid infection	01JUL2020	31AUG2020	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thyroidectomy	01JAN2013	31DEC2013	N
			Uterine dilation and curettage	01JAN1992	31DEC1992	N
	C4591001 1013 10131210	Gastrointestinal disorders	Colitis ulcerative	01JAN2002		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131211	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1013 10131214	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131216	Surgical and medical procedures	Caesarean section	09OCT2005	09OCT2005	N
				19DEC2008	19DEC2008	N
			Female sterilisation	19DEC2008	19DEC2008	N
			Thyroidectomy	01JAN2018	31JAN2018	N
	C4591001 1013 10131218	Eye disorders	Hypermetropia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2019		Y
	C4591001 1013 10131219	Nervous system disorders	Tension headache	01JAN2017		Y
	C4591001 1013 10131220	Injury, poisoning and procedural complications	Ligament rupture	01JAN1996	31DEC1996	N
				01JAN2001	31DEC2001	N
				01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N
				01JAN2016	31DEC2016	N
	C4591001 1013 10131221	Immune system disorders	Food allergy	01JAN1984		Y
			Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1984		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1985	31DEC1985	N
	C4591001 1013 10131223	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Seasonal allergy	01JAN2009		Y
	C4591001 1013 10131224	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Investigations	Biopsy cervix	01JAN1993	31DEC1993	N
				01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2009	31DEC2009	N
		Nervous system disorders	Sciatica	01JAN2009		Y
		Psychiatric disorders	Major depression	01JAN1996		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1993	31DEC1995	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2009	31DEC2009	N
	C4591001 1013 10131225	Injury, poisoning and procedural complications	Joint dislocation	01APR2000	30APR2000	N
			Tendon rupture	01APR2002	30APR2002	N
		Surgical and medical procedures	Rectal lesion excision	01FEB2018	28FEB2018	N
	C4591001 1013 10131228	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1990	31JUL2000	N
				01JAN2002		Y
		Surgical and medical procedures	Cardiac ablation	01JAN1999	31DEC1999	N
			Gastric bypass	01JUL2000	31JUL2000	N
	C4591001 1013 10131229	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JUN2020	30JUN2020	N
	C4591001 1013 10131231	Immune system disorders	Milk allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131237	Injury, poisoning and procedural complications	Tendon injury	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
		Surgical and medical procedures	Tenoplasty	01JUN2019	30JUN2019	N
	C4591001 1013 10131241	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1013 10131245	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Hyperglycaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	08FEB2001	08FEB2001	N
				14NOV1996	14NOV1996	N
			Female sterilisation	08FEB2001	08FEB2001	N
	C4591001 1013 10131250	Metabolism and nutrition disorders	Obesity	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131251	Infections and infestations	Appendicitis	01APR2008	30APR2008	N
		Surgical and medical procedures	Appendicectomy	01APR2008	30APR2008	N
	C4591001 1013 10131252	Gastrointestinal disorders	Hiatus hernia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hernia hiatus repair	01JAN2010	31DEC2010	N
	C4591001 1013 10131254	Immune system disorders	Hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2001		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1013 10131255	Surgical and medical procedures	Wisdom teeth removal	01MAY2016	31MAY2016	N
	C4591001 1013 10131256	Surgical and medical procedures	Ligament operation	01MAY2010	31MAY2010	N
			Wisdom teeth removal	01OCT2017	31OCT2017	N
	C4591001 1013 10131258	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Streptococcal infection	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2006		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131259	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal affective disorder	01JAN2014		Y
	C4591001 1013 10131263	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1013 10131264	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1013 10131266	Psychiatric disorders	Anxiety	01MAY2006		Y
			Depression	01MAY2006		Y
			Psychotic disorder	01JAN2018		Y
	C4591001 1013 10131267	Surgical and medical procedures	Caesarean section	15AUG2008	15AUG2008	N
				23NOV2006	23NOV2006	N
			Female sterilisation	15AUG2008	15AUG2008	N
	C4591001 1013 10131268	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1013 10131269	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1013 10131271	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Migraine without aura	01JAN1994		Y
			Tension headache	01JAN1994		Y
	C4591001 1013 10131275	Infections and infestations	Joint abscess	01JAN2004	31MAR2004	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAY2010		Y
			Major depression	03AUG2020		Y
		Surgical and medical procedures	Abscess drainage	01MAR2005	31MAR2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	21MAR2009	21MAR2009	N
	C4591001 1013 10131276	Nervous system disorders	Migraine without aura	01JAN2007		Y
		Psychiatric disorders	Major depression	01JAN2012		Y
	C4591001 1013 10131280	Gastrointestinal disorders	Umbilical hernia	01JAN2017	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01NOV2019	30NOV2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2019	30NOV2019	N
			Fasciotomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1977	31DEC1977	N
			Umbilical hernia repair	01MAY2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131281	Eye disorders	Strabismus	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
			Strabismus correction	01JAN1981	31DEC1981	N
	C4591001 1013 10131283	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
	C4591001 1013 10131285	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131287	Injury, poisoning and procedural complications	Ligament rupture	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Ligament operation	01JAN1992	31DEC1992	N
	C4591001 1013 10131288	Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Infections and infestations	Cat scratch disease	01JAN1977	31DEC1977	N
			Herpes zoster	01APR2007	30APR2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Coronary arterial stent insertion	01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131290	Infections and infestations	Tonsillitis	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Tonsillectomy	01MAR1984	31MAR1984	N
	C4591001 1013 10131291	Immune system disorders	Food allergy	01JAN1986		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
	C4591001 1013 10131292	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005	31DEC2006	N
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1013 10131296	Infections and infestations	Herpes simplex	01AUG2018		Y
		Psychiatric disorders	Anxiety	01AUG2014		Y
			Attention deficit hyperactivity disorder	01FEB2019		Y
	C4591001 1013 10131299	Endocrine disorders	Goitre	01JAN1997	31DEC1997	N
			Hypothyroidism	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2018	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
			Breast reconstruction	01MAY2020	31MAY2020	N
			Mastectomy	01JAN2018	31DEC2018	N
			Oophorectomy bilateral	01JAN2007	31DEC2007	N
			Thyroidectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131302	Gastrointestinal disorders	Inguinal hernia	01JAN1985	31DEC1985	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hernia repair	01JAN1985	31DEC1985	N
			Tenoplasty	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131303	Gastrointestinal disorders	Rectal fissure	01APR2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Herpes simplex	01OCT2014		Y
	C4591001 1013 10131304	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN1980	31DEC1980	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2019	31DEC2019	N
		Nervous system disorders	Tension headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Caesarean section	16MAY2003	16MAY2003	N
				30DEC2004	30DEC2004	N
	C4591001 1013 10131307	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1013 10131308	Surgical and medical procedures	Caesarean section	31DEC2013	31DEC2013	N
	C4591001 1013 10131309	Psychiatric disorders	Major depression	01JAN2012		Y
	C4591001 1013 10131311	Gastrointestinal disorders	Intestinal obstruction	01DEC1980	31DEC1980	N
		Injury, poisoning and procedural complications	Foreign body in gastrointestinal tract	01DEC1980	31DEC1980	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Removal of foreign body from gastrointestinal tract	01DEC1980	31DEC1980	N
	C4591001 1013 10131312	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1013 10131313	Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2012		Y
			Myalgia intercostal	01JAN2011		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1013 10131315	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
			Major depression	01JAN2018		Y
	C4591001 1013 10131316	Metabolism and nutrition disorders	Obesity	01MAR2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2020		Y
	C4591001 1013 10131317	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1990	31DEC1990	N
			Meniscus injury	01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Hernia repair	01JAN2015	31DEC2015	N
			Ligament operation	01JAN1990	31DEC1990	N
			Meniscus operation	01JAN1990	31DEC1990	N
			Prostatectomy	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1013 10131318	Nervous system disorders	Tension headache	01JAN2010		Y
	C4591001 1013 10131321	Eye disorders	Blindness unilateral	01JAN2014		Y
			Cataract	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Retinal detachment	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Renal and urinary disorders	Renal failure	01JAN2017		Y
		Surgical and medical procedures	Retinal operation	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1013 10131322	Metabolism and nutrition disorders	Obesity	01JUL2020		Y
	C4591001 1013 10131325	Gastrointestinal disorders	Barrett's oesophagus	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
			Inguinal hernia	01AUG2006	31AUG2006	N
				01FEB2006	28FEB2006	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1997	30JUN2018	N
		Surgical and medical procedures	Hair transplant	01JUN2018	30JUN2018	N
			Inguinal hernia repair	01AUG2006	31AUG2006	N
				01FEB2006	28FEB2006	N
	C4591001 1013 10131332	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Spinal osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Generalised anxiety disorder	01JAN2013		Y
	C4591001 1013 10131339	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2018	N
	C4591001 1013 10131340	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2018		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2018		Y
			Cerebrovascular accident	01JAN2018	31DEC2018	N
			Myasthenia gravis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1013 10131343	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 1 diabetes mellitus	01JAN1973		Y
	C4591001 1013 10131348	Blood and lymphatic system disorders	Anaemia	01OCT2016		Y
		Vascular disorders	Deep vein thrombosis	01OCT2016	31OCT2016	N
	C4591001 1013 10131349	Eye disorders	Presbyopia	01JAN1985	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1990	31DEC1995	N
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
			Keratomileusis	01JAN2012	31DEC2012	N
	C4591001 1013 10131351	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131352	Eye disorders	Astigmatism	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Chronic tonsillitis	01JAN2000		Y
	C4591001 1013 10131353	Endocrine disorders	Hypothyroidism	01MAY2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015		Y
			Irritable bowel syndrome	01JAN2016		Y
		Psychiatric disorders	Anxiety	01SEP2018		Y
			Depression	01OCT2018		Y
	C4591001 1013 10131355	Immune system disorders	Food allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1013 10131357	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Glaucoma	01JAN2015		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31DEC2015	N
			Retinal detachment	01DEC2019	31DEC2019	N
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Fracture infection	01JAN1977	31DEC1977	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Arm amputation	01AUG1977	31AUG1977	N
			Intraocular lens implant	01JAN2015	31DEC2015	N
			Retinopexy	01DEC2019	31DEC2019	N
	C4591001 1013 10131361	Injury, poisoning and procedural complications	Fibula fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1984		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2008	31DEC2008	N
	C4591001 1013 10131364	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Injury, poisoning and procedural complications	Tendon rupture	01DEC2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian mass	01JAN2003	05JUN2003	N
		Surgical and medical procedures	Caesarean section	05JUN2003	05JUN2003	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Oophorectomy	05JUN2003	05JUN2003	N
			Tenoplasty	01DEC2018	31DEC2018	N
	C4591001 1013 10131365	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JUN2015	30JUN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Meniscus operation	01JUN2015	30JUN2015	N
	C4591001 1013 10131366	Psychiatric disorders	Autism spectrum disorder	01JAN2004		Y
	C4591001 1013 10131370	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2002		Y
		Psychiatric disorders	Gender dysphoria	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1990	31DEC1990	N
	C4591001 1013 10131371	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1013 10131375	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Bunion operation	01JAN1999	31DEC1999	N
		Vascular disorders	Deep vein thrombosis	01JAN2013	31DEC2013	N
	C4591001 1013 10131376	Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1987	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
			Endometrial ablation	01JAN1988	31DEC1988	N
				01JAN1991	31DEC1991	N
				01JAN1996	31DEC1996	N
				01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
			Oophorectomy bilateral	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131377	Eye disorders	Myopia	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Chronic sinusitis	01JAN1982		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Periarthritis	01APR2020	31JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Chondroplasty	01JAN2011	31DEC2011	N
			Shoulder operation	01JUL2020	31JUL2020	N
			Sinus operation	01JAN2008	31DEC2008	N
	C4591001 1013 10131379	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2019	N
		Reproductive system and breast disorders	Endometriosis	01JAN1996	31DEC2019	N
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
			Oophorectomy	01JAN2019	31DEC2019	N
			Salpingectomy	01JAN2019	31DEC2019	N
	C4591001 1013 10131383	Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1992	31DEC1992	N
		Investigations	Arthroscopy	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Nervous system disorders	Morton's neuralgia	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Endometriosis	01JAN2006	31DEC2010	N
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	10MAR1999	10MAR1999	N
				25MAY2001	25MAY2001	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Neurectomy	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1013 10131385	Cardiac disorders	Mitral valve prolapse	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Investigations	Cardiac murmur	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Artificial insemination	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Myomectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1013 10131388	Injury, poisoning and procedural complications	Intentional product misuse	01JAN1999	31DEC2011	N
		Nervous system disorders	Tension headache	01JAN2012		Y
	C4591001 1013 10131389	Congenital, familial and genetic disorders	Deafness congenital	01JAN1978		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus injury	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
		Surgical and medical procedures	Ligament operation	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1013 10131391	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1013 10131394	General disorders and administration site conditions	Cyst	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Surgical and medical procedures	Thoracic operation	01JAN2017	31DEC2017	N
	C4591001 1013 10131395	Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2019	03AUG2020	N
		Surgical and medical procedures	Tonsillectomy	03AUG2020	03AUG2020	N
	C4591001 1013 10131396	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1013 10131397	Gastrointestinal disorders	Umbilical hernia	01AUG1983	31AUG1983	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JUN1993	30JUN1993	N
			Hernia repair	01AUG1983	31AUG1983	N
	C4591001 1013 10131400	Eye disorders	Myopia	01JAN1990	29FEB2012	N
		Injury, poisoning and procedural complications	Cartilage injury	01SEP1996	30SEP1996	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	29JUL2013	29JUL2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratomileusis	01FEB2012	29FEB2012	N
			Knee operation	01SEP1996	30SEP1996	N
	C4591001 1013 10131401	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN1987		Y
			Post-traumatic stress disorder	01JAN1987		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Caesarean section	04FEB2005	04FEB2005	N
				27NOV2007	27NOV2007	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN2007	31DEC2007	N
			Gastric bypass	01JAN2000	31DEC2000	N
	C4591001 1013 10131403	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Meniscus removal	01JAN2006	31DEC2006	N
	C4591001 1013 10131405	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN1999	31DEC1999	N
			Rhinoplasty	01JAN1994	31DEC1994	N
	C4591001 1013 10131406	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1013 10131407	Immune system disorders	Allergy to animal	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2003		Y
	C4591001 1013 10131408	Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
			Synovial cyst	01JAN1998	31DEC1998	N
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
	C4591001 1013 10131409	Surgical and medical procedures	Synovial cyst removal	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2008	30NOV2018	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Gastrectomy	01AUG2019	31AUG2019	N
			Intervertebral disc operation	01NOV2018	30NOV2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131411	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2020		Y
			Obesity	01JAN2009		Y
		Nervous system disorders	Tension headache	01JAN2012		Y
	C4591001 1013 10131412	Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2002	N
				01JAN2009	31DEC2009	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
			Rotator cuff repair	01JAN2002	31DEC2002	N
				01JAN2009	31DEC2009	N
	C4591001 1013 10131413	Metabolism and nutrition disorders	Obesity	01AUG2010		Y
	C4591001 1013 10131416	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Bursitis	20JUL2020		Y
			Osteoporosis	01JUN2020		Y
	C4591001 1013 10131417	Surgical and medical procedures	Caesarean section	15SEP1995	15SEP1995	N
				20OCT1997	20OCT1997	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1013 10131418	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Headache	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131419	Gastrointestinal disorders	Inguinal hernia	01JUL2016	31JUL2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JUL2015	31JUL2015	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1013 10131420	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2019	31AUG2019	N
		Social circumstances	Postmenopause	01MAR2018		Y
		Surgical and medical procedures	Skin neoplasm excision	01AUG2019	31AUG2019	N
	C4591001 1013 10131421	Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
			Meniscus injury	01JAN2018	31DEC2018	N
				01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Generalised anxiety disorder	01JAN2016		Y
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
	C4591001 1013 10131423	Gastrointestinal disorders	Irritable bowel syndrome	01DEC2018		Y
		Hepatobiliary disorders	Cholelithiasis	01APR2013	30APR2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Chronic sinusitis	01MAR2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
				01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01OCT2019		Y
		Nervous system disorders	Migraine	01DEC1999		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01APR2013	30APR2013	N
			Spinal laminectomy	01DEC2019		Y
		Vascular disorders	Hypertension	01DEC2016		Y
	C4591001 1013 10131424	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Tonsillitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1013 10131425	Immune system disorders	Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1013 10131426	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1013 10131427	Psychiatric disorders	Anxiety	01NOV2017		Y
			Depression	01NOV2017		Y
	C4591001 1013 10131430	Gastrointestinal disorders	Gastrointestinal haemorrhage	01MAY2017	31MAY2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Gastric operation	01MAY2017	31MAY2017	N
	C4591001 1013 10131432	Immune system disorders	Drug hypersensitivity	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2002		Y
			Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Major depression	01JAN2013		Y
	C4591001 1013 10131436	Injury, poisoning and procedural complications	Ligament rupture	01MAY1985	31MAY1985	N
		Surgical and medical procedures	Ligament operation	01MAY1985	31MAY1985	N
	C4591001 1013 10131437	Gastrointestinal disorders	Tooth impacted	01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1013 10131438	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	10JAN2019	10JAN2019	N
				13NOV2013	13NOV2013	N
				20SEP2016	20SEP2016	N
			Female sterilisation	10JAN2019	10JAN2019	N
			Meniscus operation	01JAN2008	31DEC2008	N
	C4591001 1013 10131440	Gastrointestinal disorders	Constipation	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Tension headache	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Major depression	01JAN2013		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1013 10131441	Metabolism and nutrition disorders	Obesity	01AUG2010		Y
	C4591001 1013 10131442	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Generalised anxiety disorder	01JAN2019		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN2013	31DEC2013	N
	C4591001 1013 10131444	Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1013 10131445	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985		Y
			Mammoplasty	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131446	Injury, poisoning and procedural complications	Splenic rupture	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Splenectomy	01JAN1983	31DEC1983	N
	C4591001 1013 10131449	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
	C4591001 1013 10131452	Infections and infestations	Arthritis infective	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Hip arthroplasty	01JAN1999	31DEC1999	N
	C4591001 1013 10131454	Eye disorders	Strabismus	01JAN1989	31DEC1989	N
		Injury, poisoning and procedural complications	Gun shot wound	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Removal of foreign body from gastrointestinal tract	01JAN2008	31DEC2008	N
	C4591001 1013 10131458	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Inguinal hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Iodine allergy	01JAN2017		Y
			Seasonal allergy	01JAN1972		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2019	31DEC2019	N
		Investigations	Arthroscopy	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1013 10131463	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131464	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN2013		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2014	31DEC2014	N
		Psychiatric disorders	Bruxism	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN1998	31DEC1998	N
	C4591001 1013 10131467	Psychiatric disorders	Autism spectrum disorder	01JAN1986		Y
	C4591001 1013 10131468	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1013 10131470	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1013 10131471	Injury, poisoning and procedural complications	Cartilage injury	01JAN2019	31JUL2020	N
		Investigations	Arthroscopy	01JUL2020	31JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1013 10131472	Immune system disorders	Mite allergy	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament sprain	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
			Myalgia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1013 10131473	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN2011	31DEC2011	N
	C4591001 1013 10131475	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1013 10131476	Infections and infestations	Herpes simplex	01JAN2014		Y
			Latent tuberculosis	01APR2020	31JUL2020	N
			Sinusitis	01JAN2001	31DEC2002	N
	C4591001 1013 10131477	Surgical and medical procedures	Sinus operation	01JAN2002	31DEC2002	N
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Obesity	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Nasal septal operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1013 10131478	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	26JAN1999	26JAN1999	N
	C4591001 1013 10131484	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131486	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JUN2019		Y
	C4591001 1013 10131487	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
	C4591001 1013 10131492	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1013 10131493	Surgical and medical procedures	Gastrectomy	01JAN2015	31JAN2015	N
		Immune system disorders	Food allergy	01JAN2012		Y
		Infections and infestations	Chronic tonsillitis	01JAN2000	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2016		Y
	C4591001 1013 10131498	Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Infections and infestations	Tinea versicolour	01MAY2020		Y
	C4591001 1013 10131499	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2011	31DEC2012	N
	C4591001 1013 10131499	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Infections and infestations	Ear infection	01JAN2011	31AUG2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2017		Y
		Surgical and medical procedures	Ear tube insertion	01AUG2013		Y
			Ear tube removal	01AUG2013	31AUG2013	N
			Myringotomy	01JAN2012	31AUG2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131500	Investigations	Arthroscopy	01NOV2016	30NOV2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2016		Y
				01NOV2016		Y
		Surgical and medical procedures	Knee operation	01JUN2016	30JUN2016	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131501	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1013 10131502	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
	C4591001 1013 10131503	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1013 10131504	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2005	31DEC2005	N
	C4591001 1013 10131513	Cardiac disorders	Mitral valve prolapse	01JAN1986		Y
		Eye disorders	Amblyopia	01JAN1966		Y
			Presbyopia	01JAN1968		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Oesophageal stenosis	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Mastoiditis	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Mastoidectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131514	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1013 10131515	Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	16SEP2004	16SEP2004	N
	C4591001 1013 10131518	General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
			Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Chronic tonsillitis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1013 10131522	Gastrointestinal disorders	Haemorrhoids	01JUN2020	30JUN2020	N
		Immune system disorders	Food allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01NOV2010	20NOV2010	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Haemorrhoid operation	01JUN2020	30JUN2020	N
			Intervertebral disc operation	20NOV2010	20NOV2010	N
			Spinal laminectomy	20NOV2010	20NOV2010	N
	C4591001 1013 10131526	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
	C4591001 1013 10131529	Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
	C4591001 1013 10131530	Surgical and medical procedures	Bone cyst excision	01JAN1992	31DEC1992	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1013 10131531	Surgical and medical procedures	Vasectomy	01JUL2020	31JUL2020	N
		Gastrointestinal disorders	Anal fistula	01AUG2019	30SEP2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2020		Y
	C4591001 1013 10131532	Surgical and medical procedures	Anal fistula repair	01SEP2019	30SEP2019	N
		Gastrointestinal disorders	Inguinal hernia	01FEB2020	29FEB2020	N
		Infections and infestations	Genital herpes simplex	01JAN2018		Y
			Tonsillitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of eye	01JAN1971	31DEC1971	N
		Social circumstances	Eye prosthesis user	01JAN1971		Y
		Surgical and medical procedures	Eye excision	01JAN1971	31DEC1971	N
			Inguinal hernia repair	01FEB2020	29FEB2020	N
			Surgery	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1013 10131533	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2012		Y
	C4591001 1013 10131534	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
	C4591001 1013 10131535	Cardiac disorders	Arteriospasm coronary	01JAN2019		Y
		Eye disorders	Myopia	01JAN1985	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Catheterisation cardiac	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Keratomileusis	01JAN2008	31DEC2008	N
			Vasectomy	01JUL2019	31JUL2019	N
	C4591001 1013 10131538	Psychiatric disorders	Depression	01AUG2018		Y
	C4591001 1013 10131541	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Autism spectrum disorder	01JAN2008		Y
	C4591001 1013 10131542	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Salivary gland resection	01DEC2019	31DEC2019	N
	C4591001 1013 10131545	Congenital, familial and genetic disorders	Pulmonary malformation	(b) (6) 1993		Y
			Tracheo-oesophageal fistula	(b) (6) 1993	(b) (6) 1993	N
		Ear and labyrinth disorders	Hypoacusis	01JAN1996		Y
		Gastrointestinal disorders	Diaphragmatic hernia	(b) (6) 1993	(b) (6) 1993	N
		Nervous system disorders	Cerebral atrophy	(b) (6) 1993	31DEC1999	N
		Surgical and medical procedures	Hernia diaphragmatic repair	(b) (6) 1993	(b) (6) 1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tracheal fistula repair	(b) (6) 1993	(b) (6) 1993	N
	C4591001 1013 10131552	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1013 10131553	Hepatobiliary disorders	Cholecystitis	01JAN1993	31DEC1993	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Generalised anxiety disorder	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Female sterilisation	01JAN2009	31DEC2009	N
			Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1013 10131556	Injury, poisoning and procedural complications	Joint injury	01JAN2018	31DEC2018	N
			Ligament rupture	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Ligament operation	01JAN2014	31DEC2014	N
	C4591001 1013 10131557	Cardiac disorders	Tachycardia	01JAN1996		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN2020		Y
			Food allergy	01JAN2020		Y
			Seasonal allergy	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN1993		Y
			Insomnia	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131559	Nervous system disorders	Essential tremor	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Bipolar II disorder	01JAN2020		Y
	C4591001 1013 10131562	Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1013 10131563	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1013 10131564	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Plica syndrome	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1013 10131565	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1013 10131567	Cardiac disorders	Ventricular extrasystoles	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	06OCT2001	06OCT2001	N
				28JUL2004	28JUL2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131568	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1013 10131569	Infections and infestations	Scarlet fever	01AUG2017	01AUG2017	N
	C4591001 1013 10131570	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Renal and urinary disorders	Bladder obstruction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131571†	Investigations	HIV test positive	01JAN2010		Y
	C4591001 1013 10131572†	Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
			Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Genital herpes	01JAN2002		Y
			HIV infection	01JAN2002		Y
			Staphylococcal infection	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Surgical and medical procedures	Incisional drainage	01JAN2009	31DEC2009	N
	C4591001 1013 10131573	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2020		Y
	C4591001 1013 10131581	Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
	C4591001 1013 10131582	Immune system disorders	Seasonal allergy	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	19NOV2009	19NOV2009	N
			Gastrectomy	01JAN2011	31DEC2011	N
	C4591001 1013 10131585	Immune system disorders	Seasonal allergy	01JAN1981		Y
	C4591001 1013 10131586	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
			Myalgia	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
			Generalised anxiety disorder	01JAN2016		Y
			Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1013 10131587	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1013 10131591	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1013 10131592	Congenital, familial and genetic disorders	Congenital hand malformation	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Surgical and medical procedures	Hand repair operation	01JAN1997	31DEC1997	N
	C4591001 1013 10131593	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
			Irritable bowel syndrome	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
			Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1013 10131594	Immune system disorders	Dust allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131595	Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1999		Y
		Surgical and medical procedures	Nasal polypectomy	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
				01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
	C4591001 1013 10131597	Injury, poisoning and procedural complications	Cartilage injury	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Gout	01JAN2003		Y
			Obesity	01JAN2006		Y
		Surgical and medical procedures	Ankle operation	01JAN2008	31DEC2008	N
			Knee operation	01JAN2007	31DEC2007	N
			Vasectomy	01FEB1998	28FEB1998	N
	C4591001 1013 10131598	Injury, poisoning and procedural complications	Hand fracture	01JAN2001	31DEC2001	N
	C4591001 1013 10131599	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1013 10131600	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018		Y
		Immune system disorders	Allergy to animal	01JAN2018		Y
			Seasonal allergy	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1013 10131601	Infections and infestations	Pneumonia bacterial	01JAN2020	15JAN2020	N
	C4591001 1013 10131603	Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
			Nasal septum deviation	01JAN1999	30APR2018	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1990		Y
		Surgical and medical procedures	Meniscus operation	01JAN1999	31DEC1999	N
			Nasal septal operation	01APR2018	30APR2018	N
	C4591001 1013 10131605	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1013 10131606	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	High density lipoprotein decreased	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Nystagmus	01JAN1965		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018	31DEC2018	N
			Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Therapeutic embolisation	01JUL2019	31JUL2019	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1013 10131607	Eye disorders	Amblyopia	01JAN1994	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2004	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2004		Y
			Autism spectrum disorder	01JAN2004		Y
			Major depression	01JAN2004	31DEC2015	N
		Surgical and medical procedures	Vision correction operation	01JAN2001	31DEC2001	N
	C4591001 1013 10131608	Immune system disorders	Hypersensitivity	01JAN2007		Y
	C4591001 1013 10131611	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
			Insomnia	01APR2020		Y
			Major depression	01APR2020		Y
	C4591001 1013 10131613	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
	C4591001 1013 10131614†	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	HIV test positive	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Obesity	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Gastrectomy	01JAN2016	31DEC2016	N
			Intervertebral disc operation	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1013 10131616	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1013 10131619	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Infections and infestations	Appendicitis	01MAR2019	31MAR2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pilonidal cyst	01MAR2014	31MAR2014	N
				01NOV2011	30NOV2011	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01MAR2019	31MAR2019	N
			Caesarean section	05APR2014	05APR2014	N
				24SEP2012	24SEP2012	N
			Cataract operation	01JAN2016	31DEC2016	N
			Pilonidal sinus repair	01MAR2014	31MAR2014	N
				01NOV2011	30NOV2011	N
	C4591001 1013 10131621	Infections and infestations	Escherichia sepsis	01JUL2019	31JUL2019	N
		Reproductive system and breast disorders	Bartholin's cyst	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Uterine polyp	01JUL2019	31JUL2019	N
		Surgical and medical procedures	Bartholin's cyst removal	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2009	31DEC2009	N
			Uterine polypectomy	01JUL2019	31JUL2019	N
	C4591001 1013 10131624	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1013 10131625	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	05FEB2001	05FEB2001	N
				20AUG2006	20AUG2006	N
			Female sterilisation	01AUG2006	31AUG2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131628	Endocrine disorders	Hypothyroidism	01JAN1978	31DEC1978	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy bilateral	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2009	31DEC2009	N
			Thyroidectomy	01JAN1978	31DEC1978	N
	C4591001 1013 10131629	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131630	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2003		Y
			Major depression	01JAN2003		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1013 10131632	Injury, poisoning and procedural complications	Testicular injury	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Orchidectomy	01JAN1998	31DEC1998	N
	C4591001 1013 10131633	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001	31DEC2016	N
	C4591001 1013 10131634	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131635	Immune system disorders	Hypersensitivity	01JAN1976		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
	C4591001 1013 10131636	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1013 10131637	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1989		Y
				01JAN2003		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Vitamin B complex deficiency	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Retinoblastoma	01JAN1980	31DEC1982	N
		Nervous system disorders	Migraine without aura	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Eye excision	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131638	Reproductive system and breast disorders	Gynaecomastia	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Dermatitis	01MAY2020		Y
	C4591001 1013 10131639	Injury, poisoning and procedural complications	Wrist fracture	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Varicocele	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Fracture reduction	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Wrist surgery	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131642	Congenital, familial and genetic disorders	Sickle cell trait	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1013 10131644	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2003	31DEC2003	N
			Vocal cord thickening	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Metabolic surgery	01JAN2000	31DEC2000	N
				01JAN2016	31DEC2016	N
			Nasal septal operation	01JAN2003	31DEC2003	N
			Vocal cord nodule removal	01JAN2003	31DEC2003	N
	C4591001 1013 10131645	Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Psychiatric disorders	Major depression	01SEP2017		Y
		Surgical and medical procedures	Gastric bypass	01JAN2017	31DEC2017	N
	C4591001 1013 10131651	Nervous system disorders	Syncope	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1013 10131652	Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2004		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Cranial operation	01JAN2004	31DEC2004	N
	C4591001 1013 10131653	Congenital, familial and genetic disorders	Hereditary motor and sensory neuropathy	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	11SEP2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Tenoplasty	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
	C4591001 1013 10131654	Immune system disorders	Food allergy	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	15DEC2003	15DEC2003	N
				21FEB2011	21FEB2011	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1013 10131656	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
	C4591001 1013 10131657	Injury, poisoning and procedural complications	Muscle strain	17SEP2020		Y
			Ulna fracture	17SEP2020		Y
	C4591001 1013 10131660	Surgical and medical procedures	Caesarean section	22JAN1996	22JAN1996	N



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1013 10131663	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131665	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
	C4591001 1013 10131666	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Nervous system disorders	Migraine with aura	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1013 10131667	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1013 10131668	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008		Y
	C4591001 1013 10131670†	Investigations	HIV test positive	01JAN2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1013 10131671	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01SEP2019		Y
	C4591001 1013 10131673†	Vascular disorders	Hypertension	01JAN2000		Y
		Investigations	HIV test positive	01JAN2012		Y
	C4591001 1013 10131675	Immune system disorders	Allergy to animal	01JAN2010		Y
			Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2013		Y
			Major depression	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Oophorectomy	01JAN1997	31DEC1997	N
	C4591001 1013 10131676	Immune system disorders	Seasonal allergy	01JAN1982		Y
	C4591001 1013 10131677	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2020		Y
		Surgical and medical procedures	Caesarean section	11NOV2018	11NOV2018	N
	C4591001 1013 10131680	Metabolism and nutrition disorders	Obesity	01APR2020		Y
		Nervous system disorders	Tension headache	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2002	31JUL2019	N
	C4591001 1013 10131681	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Intervertebral disc protrusion	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine without aura	01JAN1997		Y
	C4591001 1013 10131682	Surgical and medical procedures	Laryngoplasty	01JUL2018	31JUL2018	N
			Mammoplasty	12DEC2016	12DEC2016	N
	C4591001 1013 10131685	Congenital, familial and genetic disorders	Dermoid cyst	01JAN1993	31DEC1993	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Serotonin syndrome	01JAN1995	31DEC1995	N
		Psychiatric disorders	Depression	01JAN1987	31DEC1995	N
		Surgical and medical procedures	Epidermoid cyst excision	01JAN1993	31DEC1993	N
	C4591001 1013 10131689	Eye disorders	Retinal detachment	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Retinal operation	01JAN2006	31DEC2006	N
	C4591001 1013 10131691	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1013 10131693	Eye disorders	Mydriasis	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y
		Nervous system disorders	Intracranial aneurysm	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2011		Y
			Generalised anxiety disorder	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
			Intra-cerebral aneurysm operation	01JAN2000	31DEC2000	N
	C4591001 1013 10131696	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2001	31DEC2001	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1013 10131697	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Food allergy	01JAN2010		Y
	C4591001 1013 10131700	Injury, poisoning and procedural complications	Arterial injury	01JAN2008	31DEC2008	N
		Nervous system disorders	Carotid artery dissection	01JAN2008	31DEC2008	N
	C4591001 1013 10131703	Vascular disorders	Hypertension	13OCT2000		Y
	C4591001 1013 10131709	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1013 10131710	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2020		Y
			Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1013 10131713	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteosarcoma	01JUN1998	30JUN1998	N
		Psychiatric disorders	Major depression	01JAN2016		Y
		Surgical and medical procedures	Knee arthroplasty	01JUN1998	30JUN1998	N
			Leg amputation	01JUN1998	30JUN1998	N
	C4591001 1013 10131716	Gastrointestinal disorders	Abdominal hernia	01SEP2019	10SEP2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	23AUG2019		Y
	C4591001 1013 10131717	Surgical and medical procedures	Abdominal hernia repair	10SEP2019	10SEP2019	N
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Gastrointestinal disorders	Pancreatic failure	01JAN2018		Y
		Psychiatric disorders	Major depression	01JAN1994		Y
		Reproductive system and breast disorders	Menorrhagia	01MAY2020		Y
	C4591001 1013 10131718		Uterine polyp	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
	C4591001 1013 10131720	Surgical and medical procedures	Hysterectomy	01FEB2017	28FEB2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1013 10131722	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01MAY2014	31DEC2014	N
		Surgical and medical procedures	Colectomy	01OCT2014	14OCT2014	N
	C4591001 1013 10131723	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1013 10131724	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	06OCT2005	06OCT2005	N
				12OCT2007	12OCT2007	N
				16DEC1983	16DEC1983	N
			Coronary arterial stent insertion	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131729	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1013 10131733	Immune system disorders	Allergy to animal	01JAN1995		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2007		Y
	C4591001 1013 10131734	General disorders and administration site conditions	Inflammation	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
			Generalised anxiety disorder	01JAN2014		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01OCT2019	31AUG2020	N
		Surgical and medical procedures	Hysterectomy	01AUG2020	31AUG2020	N
	C4591001 1013 10131736	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131738	Gastrointestinal disorders	Diverticulum	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1984		Y
		Infections and infestations	Chronic sinusitis	01JAN1990	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2020		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc degeneration	01JAN2018		Y
		Nervous system disorders	Migraine with aura	01JAN1995		Y
			Migraine without aura	01JAN1995		Y
		Psychiatric disorders	Major depression	01JAN2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Surgical and medical procedures	Colectomy	01JAN2016	31DEC2016	N
			Frontal sinus operation	01JAN1996	31DEC1996	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Sinus antrotomy	01JAN1995	31DEC1995	N
	C4591001 1013 10131739	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	05MAY2014	05MAY2014	N
	C4591001 1013 10131740	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1013 10131744	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1013 10131745	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Contrast media allergy	01JAN2016		Y
			Iodine allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1013 10131746	Gastrointestinal disorders	Crohn's disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1013 10131748	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1013 10131749	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01APR2020		Y
	C4591001 1013 10131752	Reproductive system and breast disorders	Menorrhagia	01JAN2015	30NOV2019	N
		Surgical and medical procedures	Hysterectomy	01NOV2019	30NOV2019	N
	C4591001 1013 10131756	Cardiac disorders	Cardiovascular disorder	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2001		Y
	C4591001 1013 10131757	Psychiatric disorders	Major depression	01JAN2005		Y
	C4591001 1013 10131759	Injury, poisoning and procedural complications	Ankle fracture	01APR2020	30APR2020	N
			Tibia fracture	01APR2020	30APR2020	N
		Nervous system disorders	Migraine with aura	01JAN2020		Y
		Surgical and medical procedures	Limb operation	01APR2020	30APR2020	N
			Open reduction of fracture	01APR2020	30APR2020	N
	C4591001 1013 10131760	Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2005	31DEC2007	N
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Oophorectomy	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131761	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1013 10131763	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Otitis media	09OCT2020	18OCT2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1013 10131770	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1013 10131771	Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1991	31DEC1991	N
	C4591001 1013 10131772	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1995		Y
	C4591001 1013 10131774	Gastrointestinal disorders	Irritable bowel syndrome	12FEB2020		Y
			Peptic ulcer	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131777	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01MAR2020	31MAR2020	N
		Psychiatric disorders	Depression	01JAN2017		Y
			Generalised anxiety disorder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Surgical and medical procedures	Benign breast lump removal	01MAR2020	31MAR2020	N
	C4591001 1013 10131778	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1013 10131780	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1013 10131783	Immune system disorders	Allergy to arthropod sting	01JAN1978		Y
	C4591001 1013 10131785	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131790	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1013 10131792	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1013 10131793	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1013 10131794	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01NOV2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01FEB2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2015	N
			Ovarian cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN2018	31DEC2018	N
			Removal of foreign body	01JAN2016	31DEC2016	N
	C4591001 1013 10131796	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
			Major depression	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	23SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1013 10131801	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JUN2011	30JUN2011	N
	C4591001 1013 10131802	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN2019		Y
	C4591001 1013 10131804	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1013 10131806	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Psychiatric disorders	Major depression	01AUG2020		Y
	C4591001 1013 10131807	Immune system disorders	Drug hypersensitivity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1013 10131808	Psychiatric disorders	Anxiety	01JAN2009		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y	
				Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y	
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2011	31DEC2011	N	
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y	
		Psychiatric disorders	Insomnia	01JAN2000		Y	
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N	
				01JAN2011	31DEC2011	N	
				01JAN2015	31DEC2015	N	
	C4591001 1013 10131809			01MAY2016	31DEC2016	N	
		Cardiac disorders	Myocardial infarction	01JAN2013	31DEC2013	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y	
				01JAN1999		Y	
				Hypersensitivity	01JAN2012		Y
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2017	31DEC2017	N	
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y	
			Type 1 diabetes mellitus	01JAN1979		Y	
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2003	N		
	Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N		
		Oophorectomy bilateral	01JAN2003	31DEC2003	N		
		Salpingostomy	01JAN2003	31DEC2003	N		

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1013 10131810		Spinal fusion surgery	01JAN2017	31DEC2017	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2010		Y	
			Rectal prolapse		27DEC2016	27DEC2016	N
		Immune system disorders	Drug hypersensitivity		01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion		01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma		01JAN2004	31DEC2004	N
		Nervous system disorders	Carpal tunnel syndrome		01JAN2000	31DEC2000	N
		Psychiatric disorders	Insomnia		01JAN1989		Y
		Renal and urinary disorders	Bladder prolapse		27DEC2016	27DEC2016	N
			Urinary incontinence		01JUN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea		01JAN2004	31DEC2004	N
			Endometriosis		01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease		01JAN2017		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis		01JAN2015		Y
		Surgical and medical procedures	Bladder operation		27DEC2016	27DEC2016	N
			Breast conserving surgery		01JAN2017	31DEC2017	N
			Hysterectomy		01JAN2004	31DEC2004	N
			Surgery		27DEC2016	27DEC2016	N
		C4591001 1013 10131811	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		C4591001 1013 10131813	Infections and infestations	Appendicitis	01SEP2016	30SEP2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y	
		Surgical and medical procedures	Appendicectomy	01SEP2016	30SEP2016	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131815	Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1013 10131817	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01MAY2019		Y
	C4591001 1013 10131818	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Surgical and medical procedures	Scleral buckling surgery	01MAR2019	31MAR2019	N
	C4591001 1013 10131819	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
	C4591001 1013 10131820	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
	C4591001 1013 10131825	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1013 10131829	Immune system disorders	Food allergy	01JAN2003		Y
	C4591001 1013 10131831	Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1013 10131832	Immune system disorders	Hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1013 10131833	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Autism spectrum disorder	01NOV2020		Y
			Encopresis	01JAN2008		Y
			Generalised anxiety disorder	01JAN2016		Y
			Major depression	01JAN2016		Y
	C4591001 1013 10131837	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2012		Y
	C4591001 1013 10131838	Psychiatric disorders	Depression	01JUL2020		Y
			Generalised anxiety disorder	01JUL2020		Y
	C4591001 1013 10131840	Immune system disorders	Food allergy	01JAN2004		Y
	C4591001 1013 10131847	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
	C4591001 1013 10131854	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1013 10131857	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1015 10151010	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1015 10151015	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1015 10151017	Nervous system disorders	Epilepsy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1015 10151020	Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1015 10151021	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1015 10151023	Gastrointestinal disorders	Gastroesophageal reflux disease	23NOV2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	03FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	03FEB2019		Y
	C4591001 1015 10151028	Gastrointestinal disorders	Crohn's disease	01JAN2000		Y
	C4591001 1015 10151029	Nervous system disorders	Migraine	01JAN2008		Y
			Narcolepsy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
	C4591001 1015 10151030	Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Trans-sexualism	01JAN2019		Y
	C4591001 1015 10151034	Gastrointestinal disorders	Irritable bowel syndrome	01MAY2020		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
	C4591001 1015 10151038	Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1015 10151039	Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1015 10151041	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1015 10151044	Gastrointestinal disorders	Coeliac disease	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151046	Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Intestinal operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1015 10151047	Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1015 10151048	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1015 10151049	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Food allergy	30JUN2020		Y
			Seasonal allergy	30JUN2020		Y
	C4591001 1015 10151050	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1015 10151052	Immune system disorders	Seasonal allergy	01JAN2020		Y
	C4591001 1015 10151055	Nervous system disorders	Neuralgia	01JAN2016		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1015 10151056	Psychiatric disorders	Anxiety	01JUL2020		Y
	C4591001 1015 10151058	Gastrointestinal disorders	Barrett's oesophagus	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Seasonal affective disorder	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151061	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Sjogren's syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
		Surgical and medical procedures	Female sterilisation	20FEB2017	20FEB2017	N
			Intrauterine contraception	01MAR2020		Y
	C4591001 1015 10151062	Psychiatric disorders	Depression	01JAN2003		Y
			Insomnia	01JAN2003		Y
	C4591001 1015 10151064	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1015 10151066	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1015 10151068	Reproductive system and breast disorders	Polycystic ovaries	22OCT2019		Y
	C4591001 1015 10151070	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1015 10151073	Investigations	Heart rate irregular	01JUN2020		Y
	C4591001 1015 10151074	Infections and infestations	Pneumonia bacterial	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1015 10151075	Immune system disorders	Food allergy	01JAN2018		Y
			Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1015 10151076	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1015 10151080	Immune system disorders	Seasonal allergy	01JAN2020		Y
	C4591001 1015 10151081	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Obsessive-compulsive disorder	01JAN2014		Y
	C4591001 1015 10151082	Nervous system disorders	Migraine	01JAN2008		Y
	C4591001 1015 10151083	Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1015 10151084	Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
	C4591001 1015 10151086	Immune system disorders	Food allergy	01JAN2002		Y
	C4591001 1015 10151088	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1015 10151089	Immune system disorders	Multiple allergies	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1991		Y
	C4591001 1015 10151092	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1991		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151094	Cardiac disorders	Arrhythmia	01JAN1992		Y
	C4591001 1015 10151097	Investigations	Biopsy prostate	01FEB2020	29FEB2020	N
	C4591001 1015 10151098	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1015 10151099	Congenital, familial and genetic disorders	Congenital hypothyroidism	(b) (6) 1997		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1015 10151101	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1015 10151102	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1015 10151103	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1970	31DEC1970	N
			Appendectomy	01JAN1983	31DEC1983	N
	C4591001 1015 10151105	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1015 10151107	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1015 10151108	Immune system disorders	Allergy to animal	01JAN1976		Y
			Seasonal allergy	01JAN1976		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN1994	31DEC1994	N
	C4591001 1015 10151112	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Multiple allergies	01JAN1992		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999		Y
	C4591001 1015 10151113	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1015 10151115	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2018	31DEC2018	N
	C4591001 1015 10151116	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2018	31DEC2018	N
	C4591001 1015 10151117	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2018		Y
	C4591001 1015 10151118	Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1015 10151119	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
	C4591001 1015 10151120	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1015 10151121	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151126	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1015 10151128	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1015 10151130	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1015 10151133	Ear and labyrinth disorders	Eustachian tube patulous	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1015 10151134	Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1975		Y
	C4591001 1015 10151135	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JUN2017		Y
			Obsessive-compulsive disorder	01JUN2017		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1015 10151136	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1015 10151137	Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Depression	01JUL2019		Y
		Surgical and medical procedures	Ligament operation	01JAN2003	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151139	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1015 10151143	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1015 10151146	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1015 10151147	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1015 10151148	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Herpes zoster	03AUG2020	15AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1015 10151149	Psychiatric disorders	Depression	01JAN2008		Y
	C4591001 1015 10151151	Immune system disorders	Seasonal allergy	01FEB2020		Y
	C4591001 1015 10151159	Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1015 10151161	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1015 10151162	Immune system disorders	Drug hypersensitivity	01NOV2008		Y
			Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Migraine	19SEP2019		Y
	C4591001 1015 10151163	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Intracranial pressure increased	01JAN2009	31DEC2009	N
	C4591001 1015 10151164	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1015 10151165	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Gastric bypass	01JAN2013	31DEC2013	N
	C4591001 1015 10151166	Infections and infestations	Herpes simplex	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1015 10151167	Nervous system disorders	Migraine	01JAN1977		Y
	C4591001 1015 10151170	Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1015 10151172	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01OCT2018		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	25APR2019	25APR2019	N
			Mastectomy	23OCT2019	23OCT2019	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1015 10151174	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2015		Y
	C4591001 1015 10151175	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1015 10151177	Nervous system disorders	IVth nerve paralysis	(b) (6) 1992		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	01JAN2008	31DEC2008	N
	C4591001 1015 10151182	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1015 10151183	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2016	31DEC2018	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1015 10151185	Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1015 10151187	Nervous system disorders	Epilepsy	01JAN1983	31DEC1998	N
	C4591001 1015 10151189	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1015 10151191	Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1015 10151192	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1015 10151193	Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
	C4591001 1015 10151198	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151199	Nervous system disorders	Disturbance in attention	01JAN2015		Y
	C4591001 1015 10151200	Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1015 10151201	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1015 10151202	Nervous system disorders	Migraine	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2013		Y
	C4591001 1015 10151204	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1015 10151205	Immune system disorders	Seasonal allergy	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1015 10151206	Immune system disorders	Seasonal allergy	01DEC2019		Y
	C4591001 1015 10151207	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1015 10151208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
			Depression	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151209	Eye disorders	Glaucoma	01MAY2018		Y
	C4591001 1015 10151210	Surgical and medical procedures	Cardiac ablation	01JAN2009	31DEC2009	N
	C4591001 1015 10151211	Congenital, familial and genetic disorders	Sickle cell anaemia	01JAN1996		Y
	C4591001 1015 10151214	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Psychiatric disorders	Major depression	01JAN2017		Y
			Post-traumatic stress disorder	01JAN2017		Y
	C4591001 1015 10151217	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1015 10151222	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
	C4591001 1015 10151223	Immune system disorders	Sarcoidosis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Surgical and medical procedures	Vascular stent insertion	01JUN2020		Y
		Vascular disorders	May-Thurner syndrome	01JUN2020		Y
	C4591001 1015 10151224	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
	C4591001 1015 10151225	Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1015 10151229	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Major depression	01JAN1993		Y
	C4591001 1015 10151230	Nervous system disorders	Headache	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151234	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2006		Y
	C4591001 1015 10151235	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Irritable bowel syndrome	01JAN2018		Y
		Psychiatric disorders	Panic attack	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2013		Y
	C4591001 1015 10151236	Psychiatric disorders	Depression	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
	C4591001 1015 10151239	Investigations	Blood cholesterol increased	01AUG2019		Y
	C4591001 1015 10151240	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1015 10151241	Reproductive system and breast disorders	Polycystic ovaries	01JAN2006		Y
	C4591001 1015 10151242	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1015 10151243	Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1015 10151245	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1015 10151246	Psychiatric disorders	Anxiety	01JAN2009		Y
	C4591001 1015 10151248	Nervous system disorders	Headache	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1998		Y
		Social circumstances	Menopause	01JAN2004		Y
	C4591001 1015 10151254	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1015 10151255	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1015 10151256	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2018		Y
	C4591001 1015 10151259	Psychiatric disorders	Anxiety	01JAN2007		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1015 10151260	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2013		Y
	C4591001 1015 10151262	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1015 10151265	Immune system disorders	Seasonal allergy	01JAN2002		Y
	C4591001 1015 10151266	Endocrine disorders	Hypothyroidism	01JAN2012		Y
	C4591001 1015 10151267	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
	C4591001 1016 10161003	Immune system disorders	Seasonal allergy	01MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian neoplasm	01JUN2016	30JUN2016	N
		Skin and subcutaneous tissue disorders	Acne	01JUN2010		Y
	C4591001 1016 10161004	Renal and urinary disorders	Hypertonic bladder	01JUN2014	31OCT2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Bladder repair	01OCT2018	31OCT2018	N
	C4591001 1016 10161005	Renal and urinary disorders	Bladder perforation	10MAR2017	10MAR2017	N
		Surgical and medical procedures	Bladder repair	10MAR2017	10MAR2017	N
			Hysterectomy	10MAR2017	10MAR2017	N
	C4591001 1016 10161006	General disorders and administration site conditions	Hernia	01JUN1997	30SEP2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2000		Y
			Intervertebral disc protrusion	01AUG2000		Y
		Psychiatric disorders	Anxiety	11SEP2001		Y
			Depression	11SEP2001		Y
			Insomnia	03AUG2013		Y
		Reproductive system and breast disorders	Endometriosis	01AUG1981	01OCT2009	N
		Surgical and medical procedures	Hernia repair	01JUL1997	31JUL1997	N
				01SEP2000	30SEP2000	N
			Hysterectomy	01OCT2009	01OCT2009	N
	C4591001 1016 10161009	Nervous system disorders	Headache	01JUN2015		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
	C4591001 1016 10161010	Psychiatric disorders	Bipolar disorder	01DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01APR2017		Y
	C4591001 1016 10161018	Immune system disorders	Seasonal allergy	01JUL1990		Y
	C4591001 1016 10161019	Cardiac disorders	Atrial fibrillation	01JUN2017	30JUN2017	N
		Immune system disorders	Seasonal allergy	01FEB1986		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Psychiatric disorders	Anxiety	15FEB2004		Y
		Renal and urinary disorders	Bladder spasm	01MAY2020		Y
		Surgical and medical procedures	Hysterectomy	11MAY2020	11MAY2020	N
			Sinus operation	01JUN2000	30JUN2000	N
	C4591001 1016 10161020	Musculoskeletal and connective tissue disorders	Back pain	01JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01SEP2010		Y
	C4591001 1016 10161021	Surgical and medical procedures	Hysterectomy	01AUG2015	31AUG2015	N
	C4591001 1016 10161028	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JUL2017	31JUL2017	N
	C4591001 1016 10161029	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2014		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01MAR2020		Y
		Vascular disorders	Hypertension	01APR2014		Y
	C4591001 1016 10161031	Surgical and medical procedures	Hysterectomy	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	03AUG2020		Y
	C4591001 1016 10161043	Immune system disorders	Seasonal allergy	01MAR2005		Y
		Psychiatric disorders	Anxiety	01FEB2018		Y
			Attention deficit hyperactivity disorder	01MAY2011		Y
			Depression	01FEB2018		Y
			Insomnia	01FEB2018		Y
		Vascular disorders	Hypertension	01FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161047	Immune system disorders	Seasonal allergy	01APR2010		Y
	C4591001 1016 10161048	Immune system disorders	Seasonal allergy	01MAR1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Anxiety	01AUG1998		Y
		Surgical and medical procedures	Bladder repair	01JUN2010	30JUN2010	N
			Carpal tunnel decompression	01JUN2008	30JUN2008	N
			Cholecystectomy	01JUN2010	30JUN2010	N
			Female sterilisation	01AUG1991	31AUG1991	N
			Rotator cuff repair	01FEB2012	29FEB2012	N
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1016 10161049	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
			Nausea	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01APR2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2015		Y
			Pain in extremity	01NOV2016		Y
		Pregnancy, puerperium and perinatal conditions	Postpartum haemorrhage	01MAR1999	31MAR1999	N
		Surgical and medical procedures	Hysterectomy	01MAR1999	31MAR1999	N
	C4591001 1016 10161051	Surgical and medical procedures	Female sterilisation	01JUN2004	30JUN2004	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1016 10161054	Immune system disorders	Seasonal allergy	01AUG1983		Y
		Injury, poisoning and procedural complications	Cranioerebral injury	01JUN2012	30JUN2012	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01AUG1997		Y
			Osteoarthritis	01AUG1997		Y
		Nervous system disorders	Sciatica	01AUG1997		Y
		Psychiatric disorders	Anxiety	01APR2015		Y
			Depression	01APR2015		Y
			Post-traumatic stress disorder	01APR2015		Y
		Surgical and medical procedures	Vasectomy	01MAY2011	31MAY2011	N
	C4591001 1016 10161057	Congenital, familial and genetic disorders	Methylenetetrahydrofolate reductase gene mutation	01JUN2015		Y
		Gastrointestinal disorders	Constipation	01MAY2019		Y
		Immune system disorders	Drug hypersensitivity	01JUN2015	30JUN2015	N
		Investigations	Vitamin D decreased	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2018		Y
		Surgical and medical procedures	Hysterectomy	01JUN2015	30JUN2015	N
			Joint surgery	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1016 10161060	Cardiac disorders	Tachycardia	01JUN2017	30JUN2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2000		Y
		Hepatobiliary disorders	Cholelithiasis	01APR2000	30APR2000	N
		Immune system disorders	Seasonal allergy	01APR1989		Y
		Psychiatric disorders	Depression	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1985		Y
		Surgical and medical procedures	Cardiac ablation	01JUN2017	30JUN2017	N
			Cholecystectomy	01APR2000	30APR2000	N
			Ligament operation	01OCT1991	31OCT1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01OCT1998	31OCT1998	N
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1016 10161064	Congenital, familial and genetic disorders	Factor V Leiden mutation	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01DEC2009	31DEC2009	N
		Vascular disorders	Hypertension	01DEC2018		Y
	C4591001 1016 10161065	Nervous system disorders	Migraine	01NOV2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01MAR2002		Y
	C4591001 1016 10161069	Immune system disorders	Seasonal allergy	01APR2004		Y
	C4591001 1016 10161071	Vascular disorders	Hypertension	01APR2015		Y
	C4591001 1016 10161073	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Hepatobiliary disorders	Cholecystitis	01JUN1994	30JUN1994	N
		Infections and infestations	Appendicitis	01JAN1990	31JAN1990	N
		Investigations	Vitamin D decreased	01JAN2020		Y
		Psychiatric disorders	Anxiety	01APR2016	31JUL2020	N
		Reproductive system and breast disorders	Polycystic ovaries	01JUN2000	30JUN2012	N
		Surgical and medical procedures	Appendectomy	01JAN1990	31JAN1990	N
			Cholecystectomy	01JUN1994	30JUN1994	N
			Hysterectomy	01JUN2012	30JUN2012	N
			Sinus operation	01JAN2020	31JAN2020	N
	C4591001 1016 10161076	Metabolism and nutrition disorders	Gout	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JUL2017		Y
		Psychiatric disorders	Anxiety	03JAN2018		Y
			Depression	03JAN2018		Y
		Renal and urinary disorders	Renal failure	01JUN2003	30JUN2003	N
		Surgical and medical procedures	Nephrectomy	01JUN2003	30JUN2003	N
			Spinal fusion surgery	01APR2018	30APR2018	N
	C4591001 1016 10161077	Psychiatric disorders	Anxiety	17JUN2020		Y
		Surgical and medical procedures	Female sterilisation	18AUG2009	18AUG2009	N
	C4591001 1016 10161078	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
		Surgical and medical procedures	Female sterilisation	01FEB2012	29FEB2012	N
	C4591001 1016 10161080	Gastrointestinal disorders	Gastrooesophageal reflux disease	14AUG2012		Y
		Immune system disorders	Hypersensitivity	01APR1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	22APR2014		Y
		Nervous system disorders	Migraine	01AUG2000		Y
		Psychiatric disorders	Anxiety	16JUL2009		Y
	C4591001 1016 10161081	Endocrine disorders	Hypothyroidism	01JUN2005		Y
		Immune system disorders	Seasonal allergy	01MAR2000		Y
		Psychiatric disorders	Anxiety	01JUN2015		Y
		Social circumstances	Postmenopause	11AUG2016		Y
	C4591001 1016 10161084	Surgical and medical procedures	Salpingectomy	01AUG2019	31AUG2019	N
	C4591001 1016 10161085	Psychiatric disorders	Attention deficit hyperactivity disorder	01MAY2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161087	Immune system disorders	Drug hypersensitivity	01APR2002		Y
			Seasonal allergy	01APR1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian fibroma	01JAN2015	30JUN2015	N
		Nervous system disorders	Migraine	01APR2010		Y
		Surgical and medical procedures	Hysterectomy	01JUN2015	30JUN2015	N
			Meniscus operation	01JUL2009	31JUL2009	N
	C4591001 1016 10161092	Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1016 10161093	Immune system disorders	Seasonal allergy	01APR2001		Y
		Reproductive system and breast disorders	Uterine prolapse	01MAY2019	31MAY2019	N
		Surgical and medical procedures	Cholecystectomy	01OCT2006	31OCT2006	N
			Hysterectomy	01MAY2019	31MAY2019	N
	C4591001 1016 10161094	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01APR2001		Y
	C4591001 1016 10161095	Nervous system disorders	Migraine	01MAR2017		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JUN2012	30JUN2012	N
		Surgical and medical procedures	Hysterectomy	01JUN2012	30JUN2012	N
	C4591001 1016 10161097	Immune system disorders	Seasonal allergy	01FEB2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161101	Immune system disorders	Seasonal allergy	01APR2010		Y
	C4591001 1016 10161102	Surgical and medical procedures	Metabolic surgery	01NOV2014	30NOV2014	N
	C4591001 1016 10161103	Congenital, familial and genetic disorders	Factor V Leiden mutation	01FEB2019		Y
		Metabolism and nutrition disorders	Obesity	01MAY2019		Y
		Nervous system disorders	Migraine	01JAN2020		Y
			Restless legs syndrome	01NOV2015		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Attention deficit hyperactivity disorder	01NOV2015		Y
	C4591001 1016 10161105	Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y
		Surgical and medical procedures	Female sterilisation	01NOV2016	30NOV2016	N
	C4591001 1016 10161106	Immune system disorders	Seasonal allergy	01MAR2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01SEP2014		Y
		Psychiatric disorders	Depression	01JUN2015		Y
			Insomnia	01MAR2010		Y
		Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 1016 10161107	Immune system disorders	Seasonal allergy	01APR2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2015		Y
		Psychiatric disorders	Depression	01APR2000		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1016 10161109	Immune system disorders	Drug hypersensitivity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1016 10161114	Immune system disorders	Seasonal allergy	01AUG2004		Y
		Surgical and medical procedures	Ligament operation	01MAR2016	31MAR2016	N
			Meniscus operation	01MAR2016	31MAR2016	N
	C4591001 1016 10161118	Musculoskeletal and connective tissue disorders	Back pain	01JUN2017		Y
		Surgical and medical procedures	Female sterilisation	01MAR2012	31MAR2012	N
			Intervertebral disc operation	01DEC2017	31DEC2017	N
	C4591001 1016 10161119	Investigations	Vitamin D decreased	01APR2017		Y
		Surgical and medical procedures	Female sterilisation	01JUN2008	30JUN2008	N
			Ligament operation	01JAN1999	31JAN1999	N
	C4591001 1016 10161120	Immune system disorders	Seasonal allergy	01MAR2006		Y
	C4591001 1016 10161122	Immune system disorders	Seasonal allergy	01APR1995		Y
		Injury, poisoning and procedural complications	Intervertebral disc injury	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2020		Y
		Nervous system disorders	Migraine	01JUN2001		Y
		Psychiatric disorders	Anxiety	01AUG2014		Y
	C4591001 1016 10161123	Immune system disorders	Seasonal allergy	01APR2000		Y
	C4591001 1016 10161125	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161126	Congenital, familial and genetic disorders	Atrial septal defect	01MAR2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01MAR2014		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01APR2015		Y
		Surgical and medical procedures	Myectomy	01APR2012	30APR2012	N
	C4591001 1016 10161128	Immune system disorders	Seasonal allergy	01MAR2005		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Bipolar disorder	01OCT1998		Y
		Surgical and medical procedures	Hysterectomy	01NOV2006	30NOV2006	N
	C4591001 1016 10161130	Immune system disorders	Seasonal allergy	01JUN2016		Y
		Nervous system disorders	Migraine	01OCT2019		Y
		Psychiatric disorders	Anxiety	01MAY2015		Y
		Surgical and medical procedures	Endometrial ablation	01JUN2016	30JUN2016	N
			Female sterilisation	01JUN2016	30JUN2016	N
	C4591001 1016 10161133	Psychiatric disorders	Depression	01SEP1995		Y
	C4591001 1016 10161136	Investigations	Blood testosterone decreased	01JUL2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2008		Y
			Type 2 diabetes mellitus	01JUL2008		Y
		Surgical and medical procedures	Vasectomy	01JUN2009	30JUN2009	N
		Vascular disorders	Hypertension	01JUL2008		Y
	C4591001 1016 10161139	Immune system disorders	Seasonal allergy	01MAR2018		Y
		Metabolism and nutrition disorders	Gout	01MAR2018		Y
			Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2019		Y
			Depression	01MAR2019		Y
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1016 10161140	Immune system disorders	Seasonal allergy	01FEB2018		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Anxiety	01AUG2007		Y
			Depression	01AUG2007		Y
			Insomnia	01JAN2012		Y
	C4591001 1016 10161143	Surgical and medical procedures	Female sterilisation	23SEP2005	23SEP2005	N
	C4591001 1016 10161145	Endocrine disorders	Hypothyroidism	01JUN2019		Y
		Immune system disorders	Seasonal allergy	01MAR2016		Y
		Psychiatric disorders	Depression	01JUN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	29MAR2020		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1016 10161147	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JUN2010		Y
		Nervous system disorders	Migraine	01AUG2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31JAN2014	N
	C4591001 1016 10161148	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JUN2019		Y
			Insomnia	01JUN2010		Y
		Vascular disorders	Hypertension	01JUN2008		Y
	C4591001 1016 10161152	Immune system disorders	Seasonal allergy	01MAR2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JUN2017		Y
			Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01MAR2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31JAN2010	N
			Inguinal hernia repair	01APR2017		Y
	C4591001 1016 10161154	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JUL2009		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2009	31JUL2009	N
	C4591001 1016 10161155	Immune system disorders	Seasonal allergy	01APR2005		Y
		Nervous system disorders	Migraine	01JUN2016		Y
	C4591001 1016 10161156	Cardiac disorders	Tachycardia	01APR2008		Y
		Immune system disorders	Drug hypersensitivity	01APR2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01OCT2013		Y
	C4591001 1016 10161159	Infections and infestations	Herpes simplex	01JAN2010		Y
		Psychiatric disorders	Depression	01FEB2015		Y
		Surgical and medical procedures	Endometrial ablation	01APR2018	30APR2018	N
			Female sterilisation	01APR2018	30APR2018	N
	C4591001 1016 10161160	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Peripheral swelling	01APR2018		Y
		Immune system disorders	Seasonal allergy	01APR2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01MAR1996	31MAR1996	N
		Vascular disorders	Varicose vein	01APR2018		Y
	C4591001 1016 10161163	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUN1999		Y
	C4591001 1016 10161164	Immune system disorders	Drug hypersensitivity	01DEC1997		Y
		Surgical and medical procedures	Pyloroplasty	(b) (6) 1993	(b) (6) 1993	N
	C4591001 1016 10161167	Endocrine disorders	Hyperthyroidism	01NOV2002		Y
		Immune system disorders	Drug hypersensitivity	01JUL2000		Y
			Seasonal allergy	01OCT1978		Y
		Infections and infestations	Herpes simplex	01AUG2012		Y
		Surgical and medical procedures	Endometrial ablation	01MAR1989		Y
	C4591001 1016 10161168	Immune system disorders	Seasonal allergy	01APR2019	30APR2019	N
		Surgical and medical procedures	Vasectomy	01MAR1980		Y
		Vascular disorders	Hypertension	01OCT2013	31OCT2013	N
	C4591001 1016 10161170	Immune system disorders	Seasonal allergy	01JUL2018		Y
		Psychiatric disorders	Social anxiety disorder	01MAR2005		Y
	C4591001 1016 10161171	Skin and subcutaneous tissue disorders	Acne	01JUN2010		Y
	C4591001 1016 10161172	Cardiac disorders	Supraventricular tachycardia	20JUN2019		Y
		Metabolism and nutrition disorders	Obesity	01NOV2015		Y
	C4591001 1016 10161176	Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2015		Y
				01MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JUL2013		Y
		Nervous system disorders	Migraine	01JUL2013		Y
			Restless legs syndrome	01JUL2013		Y
		Psychiatric disorders	Depression	01MAR2018		Y
		Surgical and medical procedures	Hysterectomy	01MAR2010		Y
	C4591001 1016 10161177	Surgical and medical procedures	Hysterectomy	01AUG2014	31AUG2014	N
	C4591001 1016 10161178	Immune system disorders	Seasonal allergy	01MAR2000		Y
		Nervous system disorders	Migraine	01MAR2000		Y
	C4591001 1016 10161181	Immune system disorders	Seasonal allergy	01AUG2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2012		Y
	C4591001 1016 10161183	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1016 10161184	Injury, poisoning and procedural complications	Nerve injury	01JUL2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2015		Y
		Vascular disorders	Hypertension	01JUL2015		Y
	C4591001 1016 10161185	Immune system disorders	Seasonal allergy	01JUL2014		Y
	C4591001 1016 10161189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01APR2018		Y
	C4591001 1016 10161190	Psychiatric disorders	Insomnia	01JAN2012		Y
		Cardiac disorders	Right ventricular failure	01FEB2020		Y
		Infections and infestations	Sepsis	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Female sterilisation	01AUG2018	31AUG2018	N
	C4591001 1016 10161192	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG2006		Y
		Psychiatric disorders	Anxiety	01JUN2005		Y
			Depression	01JUN2020		Y
		Surgical and medical procedures	Female sterilisation	29JAN2011	29JAN2011	N
	C4591001 1016 10161193	Immune system disorders	Seasonal allergy	01APR2016		Y
	C4591001 1016 10161196	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01AUG2008		Y
		Nervous system disorders	Migraine	01MAR1998		Y
		Psychiatric disorders	Anxiety	01SEP2016		Y
	C4591001 1016 10161204	Immune system disorders	Seasonal allergy	01MAR2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1016 10161206	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	22APR2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	07JAN2020		Y
			Obesity	29DEC2008		Y
		Psychiatric disorders	Anxiety	12JAN2017		Y
			Attention deficit hyperactivity disorder	18DEC2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar I disorder	21JUN2007		Y
			Major depression	21DEC2016		Y
	C4591001 1016 10161208	Musculoskeletal and connective tissue disorders	Back pain	01MAR2016		Y
		Psychiatric disorders	Depression	01APR2000		Y
		Surgical and medical procedures	Female sterilisation	19JUN2009	19JUN2009	N
	C4591001 1016 10161209	Immune system disorders	Seasonal allergy	01AUG1990		Y
		Nervous system disorders	Migraine	01APR2015		Y
		Surgical and medical procedures	Female sterilisation	01JUL2009	31JUL2009	N
	C4591001 1016 10161210	Surgical and medical procedures	Female sterilisation	01AUG2019	31AUG2019	N
	C4591001 1016 10161213	Immune system disorders	Seasonal allergy	01AUG2018		Y
		Surgical and medical procedures	Jaw operation	01JUN2010	30JUN2010	N
	C4591001 1016 10161216	Endocrine disorders	Hyperthyroidism	01OCT2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01SEP2005		Y
		Immune system disorders	Seasonal allergy	01MAY2020		Y
		Infections and infestations	Folliculitis	27JUN2020		Y
		Injury, poisoning and procedural complications	Upper limb fracture	27JUN2020	06AUG2020	N
		Investigations	Biopsy breast	01NOV2019	30NOV2019	N
			Cardiac murmur	01JAN1971		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01SEP2013		Y
		Psychiatric disorders	Depression	01OCT1982		Y
		Reproductive system and breast disorders	Endometriosis	01OCT2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Polycystic ovaries	01JUN1995		Y
		Skin and subcutaneous tissue disorders	Hirsutism	01JUN1995		Y
		Surgical and medical procedures	Peripheral nerve decompression	01MAY2000	31MAY2000	N
			Tendon operation	01APR2000	30APR2000	N
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 1016 10161217	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2005		Y
		Immune system disorders	Drug hypersensitivity	01NOV2018		Y
			Seasonal allergy	01MAR2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1016 10161218	Immune system disorders	Seasonal allergy	01DEC2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2014		Y
		Psychiatric disorders	Depression	01OCT2014		Y
	C4591001 1016 10161223	Immune system disorders	Seasonal allergy	01MAR1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Meniscus operation	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1016 10161225	Immune system disorders	Seasonal allergy	01MAR1998		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01APR2015		Y
		Nervous system disorders	Tension headache	01APR2015		Y
		Psychiatric disorders	Anxiety	01SEP2019		Y
			Depression	01SEP2019		Y
		Surgical and medical procedures	Female sterilisation	01JUL2018	31JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161226	Surgical and medical procedures	Vasectomy	01MAR2003	31MAR2003	N
	C4591001 1016 10161228	Immune system disorders	Drug hypersensitivity	21SEP2006		Y
			Seasonal allergy	01MAR2016		Y
		Metabolism and nutrition disorders	Fluid retention	17MAY2019		Y
	C4591001 1016 10161229	Immune system disorders	Hypersensitivity	01APR2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01MAR2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAR2020		Y
		Surgical and medical procedures	Mammoplasty	01JUL2020	31JUL2020	N
	C4591001 1016 10161230	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2018		Y
		Psychiatric disorders	Anxiety	01DEC2001		Y
	C4591001 1016 10161231	Surgical and medical procedures	Vasectomy	01JUN2015	30JUN2015	N
	C4591001 1016 10161232	Investigations	Cardiac murmur	01AUG1991		Y
	C4591001 1016 10161233	Immune system disorders	Hypersensitivity	01OCT2015		Y
	C4591001 1016 10161235	Surgical and medical procedures	Vasectomy	02JUL2020	02JUL2020	N
	C4591001 1016 10161237	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP1997		Y
		Immune system disorders	Seasonal allergy	01MAR1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2000		Y
		Surgical and medical procedures	Vasectomy	01SEP2001	30SEP2001	N
	C4591001 1016 10161242	Hepatobiliary disorders	Gallbladder disorder	01JUL2005	31JUL2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUL2010		Y
			Attention deficit hyperactivity disorder	01JUN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2015	31OCT2015	N
		Surgical and medical procedures	Cholecystectomy	01JUL2005	31JUL2005	N
		Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 1016 10161243	Immune system disorders	Drug hypersensitivity	01MAY2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR1986		Y
	C4591001 1016 10161244	Endocrine disorders	Hypothyroidism	01JUN2010		Y
		Gastrointestinal disorders	Constipation	01JUN2020		Y
			Gastric ulcer	01NOV2018	30NOV2019	N
			Gastroesophageal reflux disease	01NOV2018		Y
			Hiatus hernia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV2008		Y
		Surgical and medical procedures	Female sterilisation	01JUN2006	30JUN2006	N
	C4591001 1016 10161245	Immune system disorders	Seasonal allergy	09JUN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	15APR2019		Y
		Psychiatric disorders	Anxiety	10DEC2019		Y
			Attention deficit hyperactivity disorder	30JAN2020		Y
			Depression	10DEC2019		Y
			Insomnia	03JAN2020		Y
		Surgical and medical procedures	Mammoplasty	01JUN2016	30JUN2016	N
	C4591001 1016 10161249	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG1985		Y
		Immune system disorders	Seasonal allergy	01MAR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2017		Y
			Scoliosis	01MAR1991		Y
		Nervous system disorders	Headache	01NOV1991		Y
		Surgical and medical procedures	Vasectomy	01MAY2015	31MAY2015	N
	C4591001 1016 10161252	Endocrine disorders	Basedow's disease	01SEP2005		Y
			Hypothyroidism	01SEP2006		Y
		Immune system disorders	Drug hypersensitivity	01MAR1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2012		Y
		Surgical and medical procedures	Thyroidectomy	01MAY2006	31MAY2006	N
	C4591001 1016 10161253	Immune system disorders	Seasonal allergy	01APR2010		Y
		Social circumstances	Menopause	01FEB2018		Y
	C4591001 1016 10161255	Gastrointestinal disorders	Gastroesophageal reflux disease	14AUG2013		Y
		Immune system disorders	Drug hypersensitivity	01SEP2018		Y
			Seasonal allergy	01APR2010		Y
		Infections and infestations	Herpes simplex	12JUL2007		Y
		Investigations	Weight increased	01DEC2019		Y
		Nervous system disorders	Restless legs syndrome	08JUN2009		Y
	C4591001 1016 10161258	Immune system disorders	Seasonal allergy	01MAY1985		Y
		Surgical and medical procedures	Vasectomy	01JUL2009	31JUL2009	N
	C4591001 1016 10161259	Immune system disorders	Seasonal allergy	01MAR2006		Y
		Nervous system disorders	Migraine	01SEP2000		Y
		Psychiatric disorders	Anxiety	01JUN2000		Y
		Surgical and medical procedures	Hysterectomy	03JUL2014	03JUL2014	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1016 10161261	Endocrine disorders	Hypothyroidism	01DEC2019		Y
		Immune system disorders	Drug hypersensitivity	01APR2016		Y
	C4591001 1016 10161265	Immune system disorders	Seasonal allergy	01MAR2003		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Uterine dilation and curettage	01MAR2020	31MAR2020	N
	C4591001 1016 10161268	Metabolism and nutrition disorders	Gout	01MAR2020	31MAR2020	N
	C4591001 1016 10161269	Immune system disorders	Seasonal allergy	01MAR1985		Y
	C4591001 1016 10161273	Cardiac disorders	Pulmonary valve stenosis	27MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01AUG2020		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
	C4591001 1016 10161275	Immune system disorders	Seasonal allergy	01MAR2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01MAY2018		Y
	C4591001 1016 10161276	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01MAR1999		Y
		Investigations	Blood thyroid stimulating hormone decreased	20AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01AUG2001		Y
				01SEP2011		Y
		Nervous system disorders	Migraine	01APR2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1016 10161277	Cardiac disorders	Mitral valve incompetence	01JUN2012		Y
		Endocrine disorders	Hypothyroidism	01JUN1995		Y
		Immune system disorders	Seasonal allergy	01JUN1985		Y
		Psychiatric disorders	Depression	01JUN1987		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JUN1987		Y
	C4591001 1016 10161279	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01MAR2000		Y
	C4591001 1016 10161280	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Herpes simplex	01JUL2019		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Renal and urinary disorders	Bladder spasm	01OCT2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1016 10161281	Endocrine disorders	Hypothyroidism	01JUN2013		Y
		Immune system disorders	Seasonal allergy	01SEP1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2017		Y
		Nervous system disorders	Migraine	01OCT1995		Y
			Restless legs syndrome	01JUN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1016 10161284	Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01FEB2017	28FEB2017	N
	C4591001 1016 10161285	Gastrointestinal disorders	Constipation	12MAY2014		Y
			Gastroesophageal reflux disease	01JUN2019		Y
			Irritable bowel syndrome	24SEP2018		Y
		Hepatobiliary disorders	Gallbladder disorder	06MAR2018	29MAR2018	N
		Immune system disorders	Seasonal allergy	20NOV2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020		Y
		Psychiatric disorders	Anger	13AUG2013		Y
			Attention deficit hyperactivity disorder	08MAY2013		Y
			Depression	11DEC2018		Y
			Oppositional defiant disorder	22SEP2015	30JUN2020	N
		Reproductive system and breast disorders	Ovarian cyst	10JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	30NOV2015		Y
		Surgical and medical procedures	Cholecystectomy	29MAR2018	29MAR2018	N
			Umbilical hernia repair	01SEP2003	30SEP2003	N
	C4591001 1016 10161286	Immune system disorders	Seasonal allergy	01MAR2006		Y
	C4591001 1016 10161287	Immune system disorders	Hypersensitivity	01OCT2008		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01NOV2016		Y
		Psychiatric disorders	Anxiety	01JUL2018	31MAR2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2016	31JAN2017	N
		Skin and subcutaneous tissue disorders	Acne	14JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1016 10161288	Gastrointestinal disorders	Gastroesophageal reflux disease	15MAY2017		Y
		Nervous system disorders	Migraine	18SEP2019		Y
	C4591001 1016 10161289	Immune system disorders	Seasonal allergy	01MAY2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2010		Y
	C4591001 1016 10161290	Congenital, familial and genetic disorders	Cerebral palsy	01JAN2005		Y
			Schizencephaly	04JUN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01APR2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	03MAY2012		Y
			Binge eating	17JUN2019		Y
			Depression	13MAR2019		Y
			Oppositional defiant disorder	29AUG2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26MAR2007	30APR2007	N
		Skin and subcutaneous tissue disorders	Eczema	31MAR2010	31DEC2012	N
	C4591001 1016 10161291	Immune system disorders	Seasonal allergy	29AUG2009		Y
		Psychiatric disorders	Obsessive-compulsive disorder	25MAR2019	31AUG2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	18DEC2008		Y
		Vascular disorders	Orthostatic hypotension	01JUL2019	01JUL2019	N
	C4591001 1016 10161292	Gastrointestinal disorders	Abdominal pain	08APR2013		Y
		Hepatobiliary disorders	Cholecystitis	20AUG2019	28AUG2019	N
		Psychiatric disorders	Anxiety	08APR2013		Y
		Surgical and medical procedures	Cholecystectomy	28AUG2019	28AUG2019	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1016 10161293	Immune system disorders	Seasonal allergy	01APR2006		Y
	C4591001 1016 10161294	Injury, poisoning and procedural complications	Meniscus injury	01MAR2018		Y
		Metabolism and nutrition disorders	Obesity	14AUG2013		Y
	C4591001 1016 10161295	Hepatobiliary disorders	Cholecystitis	09DEC2013	06FEB2015	N
		Immune system disorders	Seasonal allergy	01MAY2007		Y
		Surgical and medical procedures	Cholecystectomy	06FEB2015	06FEB2015	N
	C4591001 1016 10161296	Immune system disorders	Seasonal allergy	01APR2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2006	30JUN2010	N
	C4591001 1016 10161297	Metabolism and nutrition disorders	Hyperlipidaemia	28MAR2013		Y
		Nervous system disorders	Migraine	24FEB2016		Y
		Psychiatric disorders	Anxiety	05FEB2015		Y
			Attention deficit hyperactivity disorder	28MAR2013		Y
			Bipolar disorder	05FEB2015		Y
			Depression	05FEB2015		Y
			Insomnia	27AUG2009		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1016 10161298	Cardiac disorders	Mitral valve incompetence	22APR2016		Y
		Congenital, familial and genetic disorders	Neurofibromatosis	16JAN2014		Y
		Immune system disorders	Seasonal allergy	01MAR2008		Y
		Investigations	Cardiac murmur	23JAN2007		Y
		Psychiatric disorders	Anxiety disorder	17AUG2016		Y
			Attention deficit hyperactivity disorder	23NOV2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	17AUG2016		Y
			Insomnia	27AUG2018		Y
		Skin and subcutaneous tissue disorders	Cafe au lait spots	12JAN2007		Y
	C4591001 1016 10161299	Immune system disorders	Seasonal allergy	05JUN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07OCT2010		Y
	C4591001 1016 10161300	Musculoskeletal and connective tissue disorders	Scoliosis	12JUN2012		Y
	C4591001 1016 10161301	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01MAR2008		Y
	C4591001 1016 10161302	Gastrointestinal disorders	Constipation	27JUN2017		Y
		Infections and infestations	Pilonidal cyst	10JUN2019	11JUN2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	16SEP2010		Y
		Skin and subcutaneous tissue disorders	Acne	14NOV2016		Y
		Surgical and medical procedures	Cyst removal	10JUN2019	11JUN2019	N
	C4591001 1016 10161303	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN1990		Y
		Immune system disorders	Hypersensitivity	01APR2005		Y
		Psychiatric disorders	Insomnia	01JUN2008		Y
	C4591001 1016 10161304	Immune system disorders	Seasonal allergy	01MAY2000		Y
		Surgical and medical procedures	Female sterilisation	10FEB2020	10FEB2020	N
	C4591001 1016 10161305	Musculoskeletal and connective tissue disorders	Pain in extremity	10OCT2020		Y
	C4591001 1016 10161306	Immune system disorders	Seasonal allergy	01APR2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	06DEC2019		Y
		Psychiatric disorders	Anxiety	29NOV2017		Y
			Attention deficit hyperactivity disorder	01SEP2012		Y
			Tic	19AUG2013	30JUN2018	N
		Skin and subcutaneous tissue disorders	Acne	23SEP2019		Y
	C4591001 1016 10161312	Endocrine disorders	Hypothyroidism	01JUN1990		Y
		Metabolism and nutrition disorders	Hypokalaemia	07AUG2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	20JUN2020		Y
			Back pain	01MAR2007		Y
		Psychiatric disorders	Anxiety	01JUN2018		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1016 10161313	Immune system disorders	Seasonal allergy	01APR2010		Y
		Investigations	Blood testosterone decreased	01JUN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2015		Y
		Vascular disorders	Hypertension	10AUG2020		Y
	C4591001 1016 10161317	Immune system disorders	Seasonal allergy	29JUL2008		Y
	C4591001 1016 10161321	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2006		Y
		Immune system disorders	Drug hypersensitivity	01SEP2006		Y
			Seasonal allergy	01APR2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2009		Y
			Type 2 diabetes mellitus	01SEP2006		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
	C4591001 1016 10161328	Gastrointestinal disorders	Gastroesophageal reflux disease	19OCT2010		Y
		Immune system disorders	Seasonal allergy	06MAR2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	29FEB2012		Y
			Behaviour disorder	27MAR2012		Y
			Oppositional defiant disorder	13MAY2016		Y
	C4591001 1016 10161341	Immune system disorders	Seasonal allergy	01APR2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2015		Y
		Surgical and medical procedures	Hysterectomy	01JUN2014	30JUN2014	N
		Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 1016 10161342	Ear and labyrinth disorders	Cerumen impaction	14OCT2020		Y
		Gastrointestinal disorders	Abdominal pain	12NOV2019		Y
		Immune system disorders	Seasonal allergy	01APR2005		Y
		Psychiatric disorders	Anxiety	12NOV2019		Y
	C4591001 1016 10161345	Hepatobiliary disorders	Cholelithiasis	22NOV2017	22NOV2017	N
		Immune system disorders	Drug hypersensitivity	01JUN2006		Y
			Hypersensitivity	01APR2014		Y
			Rubber sensitivity	01JUN2006		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JUN2017	31JUL2017	N
		Nervous system disorders	Hemiplegic migraine	24JUL2018		Y
			Seizure	01JUN2004	30JUN2016	N
		Psychiatric disorders	Behaviour disorder	05AUG2014		Y
			Bipolar disorder	24JUL2018		Y
			Insomnia	01JUN2007		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	15JUL2020		Y
	C4591001 1016 10161346	Surgical and medical procedures	Cholecystectomy	22NOV2017	22NOV2017	N
		Metabolism and nutrition disorders	Obesity	19SEP2011		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	25AUG2020		Y
	C4591001 1016 10161347	Infections and infestations	Plantar fascial fibromatosis Pyelonephritis	23SEP2020 01APR2020	30APR2020	Y N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2013		Y
		Psychiatric disorders	Back pain Anxiety	01MAY2013 13MAR2019		Y Y
		Reproductive system and breast disorders	Depression Menstruation irregular	13MAR2019 23FEB2018		Y Y
	C4591001 1016 10161348	Endocrine disorders	Hyperthyroidism	23JUL2019		Y
		Immune system disorders	Hypothalamo-pituitary disorder Hypersensitivity	01DEC2003 07JUL2015		Y Y
		Metabolism and nutrition disorders	Obesity	13FEB2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01APR2015		Y
		Vascular disorders	Essential hypertension	13FEB2019	30NOV2019	N
	C4591001 1016 10161349	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 2003		Y
			Seasonal allergy	01AUG2013		Y
		Vascular disorders	Orthostatic hypertension	01AUG2013		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1016 10161355	Immune system disorders	Seasonal allergy	01APR2016		Y
	C4591001 1016 10161359	Immune system disorders	Seasonal allergy	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2019		Y
	C4591001 1016 10161360	Immune system disorders	Seasonal allergy	01APR2010		Y
		Injury, poisoning and procedural complications	Joint dislocation	01SEP2019	30SEP2019	N
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Renal and urinary disorders	Nephrolithiasis	01SEP2012	30SEP2012	N
	C4591001 1018 10181001	Eye disorders	Myopia	01JAN2015		Y
			Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Skin laceration	01MAY2020	31MAY2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1018 10181009	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005	31DEC2006	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2017		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric banding	01JAN2006	31DEC2006	N
			Gastric banding reversal	01JAN2014	31DEC2014	N
		Vascular disorders	Varicose vein	01JAN2016		Y
	C4591001 1018 10181010	Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Infections and infestations	Tonsillitis	01JAN1981	31DEC2017	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Ligament operation	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1018 10181011	Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01NOV2019		Y
	C4591001 1018 10181012	Immune system disorders	Hypersensitivity	01JAN2002		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1994		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2003	31DEC2003	N
	C4591001 1018 10181013	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal obstruction	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Nasal operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181014	Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Influenza	01JAN1982		Y
			Influenza	01JAN2007	31DEC2007	N
			Oral herpes	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1018 10181015	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2014		Y
	C4591001 1018 10181016	Endocrine disorders	Hypothyroidism	01OCT2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	17JUN2018	N
		Immune system disorders	Food allergy	01SEP2015		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	02JUL1996	02JUL1996	N
				11FEB1999	11FEB1999	N
			Cholecystectomy	17JUN2018	17JUN2018	N
			Gastrectomy	05JAN2018	05JAN2018	N
	C4591001 1018 10181017	Ear and labyrinth disorders	Hypoacusis	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Musculoskeletal stiffness	01JAN2018		Y
		Nervous system disorders	Tension headache	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181018	Eye disorders	Myopia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1993	01JAN1993	N
			Traumatic arthritis	01JAN1993		Y
		Investigations	Biopsy breast normal	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	27JUN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2003	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
		Surgical and medical procedures	Liposuction	01FEB2016	29FEB2016	N
	C4591001 1018 10181019	Injury, poisoning and procedural complications	Limb fracture	01JAN2017	31DEC2017	N
	C4591001 1018 10181020	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1985	31DEC1985	N
			Ligament operation	01JAN2008	31DEC2008	N
			Loop electrosurgical excision procedure	01JAN2003	31DEC2003	N
			Mammoplasty	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1018 10181021	Metabolism and nutrition disorders	Obesity	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstruation irregular	01MAY2020		Y
		Surgical and medical procedures	Caesarean section	01JUL2013	01JUL2013	N
				04APR2005	04APR2005	N
				10APR2010	10APR2010	N
			Female sterilisation	01JAN2013	31DEC2013	N
			Seasonal allergy	01JAN2000		Y
	C4591001 1018 10181022	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1018 10181024	Psychiatric disorders	Perinatal depression	01MAY2017		Y
	C4591001 1018 10181026	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1018 10181027	Eye disorders	Astigmatism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1018 10181028	Injury, poisoning and procedural complications	Tendon injury	01SEP2011	30SEP2011	N
		Nervous system disorders	Nerve compression	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Tenoplasty	01SEP2011	30SEP2011	N
	C4591001 1018 10181029	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2016	N
		Surgical and medical procedures	Endometrial ablation	01JAN2016	31DEC2016	N
	C4591001 1018 10181030	Psychiatric disorders	Anxiety	01NOV2018		Y
			Depression	01NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep disorder	01NOV2018		Y
		Surgical and medical procedures	Sinus operation	12MAY2015	12MAY2015	N
	C4591001 1018 10181031	Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1018 10181032	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2018		Y
			Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Sinus congestion	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2017	31OCT2017	N
	C4591001 1018 10181033	Infections and infestations	Oral herpes	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2009		Y
	C4591001 1018 10181037	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Gout	01JAN2001		Y
	C4591001 1018 10181038	Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Vitamin D deficiency	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1985		Y
			Rosacea	01JAN1979	31DEC1990	N
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
			Meniscus operation	01JAN2019	31DEC2019	N
			Muscle operation	01JAN2015	31DEC2015	N
	C4591001 1018 10181039	Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1018 10181040	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01MAY2009	31MAY2009	N
			Female sterilisation	01MAY2011	31MAY2011	N
			Mammoplasty	01AUG2009	31AUG2009	N
			Tonsillectomy	01MAY2020	31MAY2020	N
	C4591001 1018 10181042	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2013	31DEC2013	N
			Radius fracture	01JAN2007	31DEC2007	N
			Ulna fracture	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1018 10181046	Musculoskeletal and connective tissue disorders	Back pain	01AUG2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2014		Y
			Generalised anxiety disorder	01MAR2017		Y
			Panic attack	01JAN2015		Y
	C4591001 1018 10181047	Psychiatric disorders	Depression	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181048	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984	31DEC1988	N
		Surgical and medical procedures	Vasectomy	01FEB2019	28FEB2019	N
	C4591001 1018 10181049	Immune system disorders	Seasonal allergy	01JAN1991		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2012	31DEC2012	N
			Ligament rupture	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Gynaecomastia	01JAN2002	31DEC2004	N
		Surgical and medical procedures	Cartilage operation	01JAN2012	31DEC2012	N
			Ligament operation	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1018 10181050	Infections and infestations	Oral herpes	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2016	31DEC2017	N
		Surgical and medical procedures	Caesarean section	01DEC2006	31DEC2006	N
			Salpingectomy	01DEC2006	31DEC2006	N
	C4591001 1018 10181051	Investigations	Cardiac murmur	(b) (6) 1983		Y
	C4591001 1018 10181052	Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2011	31DEC2011	N
	C4591001 1018 10181053	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
			Pyloroplasty	01JAN1987	31DEC1987	N
	C4591001 1018 10181054	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	04JUN2020		Y
	C4591001 1018 10181055	Metabolism and nutrition disorders	Overweight	01JAN2012	31DEC2014	N
		Psychiatric disorders	Insomnia	01AUG2019		Y
		Surgical and medical procedures	Gastric banding	01JAN2014	31DEC2014	N
	C4591001 1018 10181056	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2003		Y
	C4591001 1018 10181057	Immune system disorders	Seasonal allergy	(b) (6) 1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	26DEC2017	27DEC2017	N
		Psychiatric disorders	Sleep disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017	31DEC2018	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1997		Y
		Surgical and medical procedures	Meningioma surgery	27DEC2017	27DEC2017	N
	C4591001 1018 10181058	Eye disorders	Astigmatism	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN2003		Y
	C4591001 1018 10181059	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2002	31DEC2018	N
		Infections and infestations	Bronchitis	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
	C4591001 1018 10181062	Eye disorders	Astigmatism	01JAN1989	31DEC2018	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1992	31DEC1992	N
			Fibula fracture	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Overweight	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Panic attack	01JAN2007	31DEC2017	N
		Surgical and medical procedures	Eye laser surgery	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN1991	31DEC1991	N
	C4591001 1018 10181064	Immune system disorders	Seasonal allergy	01JAN1984		Y
		Infections and infestations	Genital herpes simplex	01JAN2000		Y
		Investigations	Biopsy endometrium normal	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2006	31DEC2006	N
			Menorrhagia	01JAN2004	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181066	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	27APR2012	27APR2012	N
	C4591001 1018 10181067	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2003	31DEC2003	N
	C4591001 1018 10181071	Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1018 10181072	Infections and infestations	Tinea pedis	01JAN2016	13FEB2019	N
		Injury, poisoning and procedural complications	Traumatic haematoma	01OCT2019	31DEC2019	N
		Nervous system disorders	Migraine	01OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1018 10181074	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1018 10181076	Immune system disorders	Seasonal allergy	01JAN2001		Y
	C4591001 1018 10181077	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2015	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000	31DEC2015	N
		Surgical and medical procedures	Cholecystectomy	01OCT2008	31OCT2008	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1018 10181079	Immune system disorders	Anaphylactic reaction	01JAN2014	31DEC2014	N
			Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1018 10181081	Ear and labyrinth disorders	Meniere's disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN1998		Y
			Seasonal allergy	01JAN1990		Y
		Reproductive system and breast disorders	Breast cyst	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2006	31DEC2006	N
	C4591001 1018 10181083	Endocrine disorders	Hypogonadism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1994		Y
		Surgical and medical procedures	Cholecystectomy	01APR2005	30APR2005	N
			Fasciotomy	01MAY2009	31MAY2009	N
				01OCT2015	31OCT2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia repair	01SEP2015	30SEP2015	N
	C4591001 1018 10181084	Infections and infestations	Oral herpes	01JAN1982		Y
		Psychiatric disorders	Depression	01OCT2017		Y
			Post-traumatic stress disorder	01OCT2017		Y
		Renal and urinary disorders	Bladder irritation	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1988		Y
			Dermatitis allergic	01JAN1995		Y
		Surgical and medical procedures	Blood donation	17JUL2020	17JUL2020	N
			Nasal septal operation	01JAN1989	31DEC1989	N
	C4591001 1018 10181085	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	06AUG2000		Y
	C4591001 1018 10181086	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
		Renal and urinary disorders	Haematuria	01JAN2009	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2010	N
	C4591001 1018 10181088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Haemorrhoids	01JAN2015	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Limb operation	01JAN1982	31DEC1982	N
		Vascular disorders	White coat hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181089	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1018 10181090	Injury, poisoning and procedural complications	Jaw fracture	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Jaw operation	01JAN2008	31DEC2008	N
	C4591001 1018 10181091	Infections and infestations	Tinea pedis	06JUN2020		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Fracture treatment	01JAN2008	31DEC2008	N
	C4591001 1018 10181093	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2012		Y
	C4591001 1018 10181094	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Initial insomnia	01JAN2017		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2007	31DEC2007	N
	C4591001 1018 10181095	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2013	N
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1018 10181098	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01AUG2010		Y
	C4591001 1018 10181100	Infections and infestations	Latent tuberculosis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01DEC2000		Y
	C4591001 1018 10181103	Blood and lymphatic system disorders	Anaemia	01AUG2008		Y
		Cardiac disorders	Tachycardia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	12AUG2019		Y
			Obesity	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	15AUG2008		Y
	C4591001 1018 10181104	Surgical and medical procedures	Caesarean section	10FEB2012	10FEB2012	N
				27DEC2014	27DEC2014	N
			Mammoplasty	01NOV2016	30NOV2016	N
	C4591001 1018 10181105	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2010		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2000	31DEC2010	N
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1018 10181106	Immune system disorders	Allergy to animal	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Female sterilisation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1018 10181107	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1994		Y
	C4591001 1018 10181108	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1018 10181109	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N
			Foot operation	01JAN2018	31DEC2018	N
			Gastrectomy	01JAN2017	31DEC2017	N
			Open reduction of fracture	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1018 10181111	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Psychiatric disorders	Generalised anxiety disorder	01APR2019		Y
	C4591001 1018 10181113	Eye disorders	Myopia	01JAN1999		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN1994		Y
			Seasonal allergy	01OCT2000		Y
		Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
	C4591001 1018 10181114	Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
		Eye disorders	Presbyopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1992	31DEC1992	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gestational trophoblastic tumour	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Knee operation	01JAN1992	31DEC1992	N
			Uterine dilation and curettage	01JAN2003	31DEC2003	N
	C4591001 1018 10181116	Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1987	31DEC2016	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01NOV2016	30NOV2016	N
			Female sterilisation	13SEP2000	13SEP2000	N
			Fracture treatment	01JAN2016	31DEC2016	N
	C4591001 1018 10181118	Immune system disorders	Food allergy	01JAN1990		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990	31DEC1996	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1018 10181119	Eye disorders	Optic disc drusen	01JAN2000		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1018 10181120	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1984		Y
		Surgical and medical procedures	Female sterilisation	23MAR2006	23MAR2006	N
	C4591001 1018 10181125	Infections and infestations	Appendicitis	01JAN2017	20DEC2017	N
		Psychiatric disorders	Anxiety	15JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2018	01AUG2018	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	20DEC2017	20DEC2017	N
			Pleurodesis	01AUG2018	01AUG2018	N
	C4591001 1018 10181127	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1018 10181128	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1018 10181131	Injury, poisoning and procedural complications	Meniscus injury	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Meniscus operation	01JAN2007	31DEC2007	N
	C4591001 1018 10181133	Infections and infestations	Infectious mononucleosis	01MAR2020	31MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2018		Y
	C4591001 1018 10181139	Social circumstances	Menopause	01MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JUN2001	30JUN2001	N
	C4591001 1018 10181141	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01SEP2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1987	31DEC1987	N
			Intra-uterine contraceptive device insertion	01APR2019		Y
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1018 10181142	Infections and infestations	Chlamydial infection	11MAY2018	07JUN2018	N
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
		Reproductive system and breast disorders	Cervical cyst	22JUN2018	27JUN2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
		Surgical and medical procedures	Bunion operation	01JAN2003	31DEC2003	N
	C4591001 1018 10181143	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004	15JAN2008	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006	15NOV2007	N
		Surgical and medical procedures	Gastrectomy	15JAN2008	15JAN2008	N
			Tonsillectomy	15NOV2007	15NOV2007	N
	C4591001 1018 10181144	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2020		Y
		Vascular disorders	Hypertension	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181145	Investigations	Mycobacterium tuberculosis complex test negative	01DEC2019	31MAR2020	N
			Mycobacterium tuberculosis complex test positive	01DEC2019	31MAR2020	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01FEB2019		Y
			Keratomileusis	01AUG2019	31AUG2019	N
	C4591001 1018 10181146	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1978		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1018 10181148	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2005	31DEC2005	N
			Peripheral nerve decompression	01JAN2011	31DEC2011	N
	C4591001 1018 10181149	Ear and labyrinth disorders	Tinnitus	01JAN1989		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Reaction to food additive	01JAN1993		Y
			Seasonal allergy	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1018 10181150	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2001		Y
	C4591001 1018 10181151	Immune system disorders	Seasonal allergy	01MAR2018		Y
		Surgical and medical procedures	Female sterilisation	15OCT2017	15OCT2017	N
	C4591001 1018 10181152	Eye disorders	Myopia	01JAN1985	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2018	31DEC2018	N
			Tonsillectomy	11MAY2017	11MAY2017	N
	C4591001 1018 10181154	Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2011	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1018 10181156	Blood and lymphatic system disorders	Anaemia	01JAN2006		Y
		Immune system disorders	Allergy to plants	01JAN2000		Y
			Drug hypersensitivity	01JAN1981		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Ear infection	01JAN1981	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign vascular neoplasm	01NOV2002	31DEC2002	N
		Psychiatric disorders	Insomnia	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1985	31AUG2019	N
		Surgical and medical procedures	Sinuplasty	01AUG2019	31AUG2019	N
			Vascular operation	01DEC2002	31DEC2002	N
	C4591001 1018 10181157	Skin and subcutaneous tissue disorders	Dermatitis atopic	01DEC1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181158	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC2006	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2006		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1018 10181159	Injury, poisoning and procedural complications	Joint dislocation	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2013	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
			Occipital neuralgia	01JAN2014		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1967	31DEC2017	N
		Surgical and medical procedures	Cyst removal	01JAN1993	31DEC2009	N
			Mammoplasty	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2008	31DEC2008	N
				01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2014	31DEC2014	N
	C4591001 1018 10181160	Infections and infestations	Coccidioidomycosis	01DEC2016	30APR2017	N
			Hordeolum	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1018 10181161	Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1018 10181162	Gastrointestinal disorders	Haemorrhoids	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1018 10181163	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Jaw operation	01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN2007	31DEC2007	N
				01JAN2016	31DEC2016	N
	C4591001 1018 10181164	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
			Gastric banding	01JAN2009	31DEC2009	N
			Intrauterine contraception	01JAN2017		Y
	C4591001 1018 10181165	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1018 10181166	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2011		Y
	C4591001 1018 10181167	Musculoskeletal and connective tissue disorders	Exostosis	01JAN1993	31DEC1993	N
				01JAN2012	31DEC2012	N
		Surgical and medical procedures	Bone lesion excision	01JAN1993	31DEC1993	N
				01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181170	Ear and labyrinth disorders	Vertigo positional	01MAR2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Myopia	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1983	31DEC1983	N
		Psychiatric disorders	Anxiety disorder	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN2004	31DEC2004	N
			Tenotomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1018 10181171	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Cardiac murmur	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1018 10181173	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Rosacea	24JUL2020		Y
	C4591001 1018 10181174	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Cyst removal	15DEC2005	15DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181176	Immune system disorders	Food allergy	01AUG2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2013		Y
		Surgical and medical procedures	Keratomileusis	01DEC2006	31DEC2006	N
	C4591001 1018 10181178	Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1018 10181180	Hepatobiliary disorders	Cholelithiasis	01JAN2019	28FEB2019	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN2000	31OCT2002	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Obesity	01JAN1999		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2019	31JAN2019	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	01JAN2019	31JAN2019	N
				01NOV2014	30NOV2014	N
			Cholecystectomy	01FEB2019	28FEB2019	N
			Tonsillectomy	01OCT2002	31OCT2002	N
	C4591001 1018 10181181	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
	C4591001 1018 10181182	Immune system disorders	Mite allergy	01JAN2014		Y
			Seasonal allergy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181184	Eye disorders	Myopia	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1018 10181185	Eye disorders	Myopia	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Obsessive-compulsive disorder	01JAN1999		Y
			Panic attack	01JAN1999	31DEC2015	N
		Skin and subcutaneous tissue disorders	Acne	12JUN2020		Y
	C4591001 1018 10181186	Cardiac disorders	Supraventricular tachycardia	01JAN2011	31DEC2011	N
		Eye disorders	Uveitis	01JAN2017		Y
		Infections and infestations	Hepatitis A	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01MAR2007	31MAR2007	N
	C4591001 1018 10181187	Eye disorders	Myopia	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
				01JAN2003	31DEC2003	N
			Female sterilisation	01JAN2003	31DEC2003	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1018 10181188	Infections and infestations	Appendicitis	24NOV2010	24NOV2013	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Appendicectomy	24NOV2010	24NOV2010	N
			Caesarean section	19NOV2013	19NOV2013	N
	C4591001 1018 10181189	Surgical and medical procedures	Hernia repair	01OCT2017	31OCT2017	N
			Ligament operation	01APR2014	30APR2014	N
			Rotator cuff repair	01JUN2002	30JUN2002	N
				01OCT2010	31OCT2010	N
			Sinus operation	01JAN2009	31DEC2009	N
			Vasectomy	01AUG2016	31AUG2016	N
	C4591001 1018 10181191	Investigations	Vitamin D decreased	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1977	31DEC1977	N
	C4591001 1018 10181193	Immune system disorders	Food allergy	01JUN2019	30JUN2019	N
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Herpes simplex	01JAN2011	31DEC2011	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
	C4591001 1018 10181195	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Onychomycosis	01DEC2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
	C4591001 1018 10181196	Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2019		Y
	C4591001 1018 10181197	Gastrointestinal disorders	Constipation	01JUN2019	31OCT2019	N
		General disorders and administration site conditions	Precancerous condition	01SEP2019	30SEP2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Large intestinal polypectomy	01SEP2019	30SEP2019	N
			Polypectomy	01SEP2019	30SEP2019	N
	C4591001 1018 10181198	Eye disorders	Presbyopia	01JAN2020		Y
		General disorders and administration site conditions	Cyst	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Ear infection	10MAY2020	31MAY2020	N
			Oral herpes	01JAN1980		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2013	31DEC2013	N
	C4591001 1018 10181199	Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2008		Y
	C4591001 1018 10181200	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980	31DEC2017	N
		Surgical and medical procedures	Caesarean section	25JUN2010	25JUN2010	N
			Mammoplasty	01MAR2015	31MAR2015	N
	C4591001 1018 10181201	General disorders and administration site conditions	Fatigue	01MAR2020		Y
		Surgical and medical procedures	Finger amputation	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181202	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Food allergy	01AUG2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2013	31MAR2013	N
			Hand fracture	01APR2001	30JUN2001	N
			Lower limb fracture	01AUG1989	31OCT1989	N
		Surgical and medical procedures	Adenoidectomy	01SEP1994	30SEP1994	N
			Female sterilisation	09JAN2015	09JAN2015	N
			Tonsillectomy	01SEP1994	30SEP1994	N
			Uterine dilation and curettage	01APR2013	31AUG2013	N
	C4591001 1018 10181204	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2010		Y
			Hand fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN1988	31DEC1988	N
			Type 2 diabetes mellitus	01JAN2003		Y
			Vitamin D deficiency	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2014		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31MAY2018	N
				01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Caesarean section	01MAR2008	31MAR2008	N
				01MAY2010	31MAY2010	N
			Hysterectomy	01MAY2018	31MAY2018	N
	C4591001 1018 10181205	Psychiatric disorders	Insomnia	01JAN2013		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1018 10181206	Cardiac disorders	Mitral valve prolapse	01MAY1999	31AUG1999	N
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Pregnancy, puerperium and perinatal conditions	Eclampsia	01MAY1999	31AUG1999	N
		Surgical and medical procedures	Caesarean section	31AUG1999	31AUG1999	N
	C4591001 1018 10181207	Immune system disorders	Mite allergy	01JAN1995		Y
			Mycotic allergy	01JAN1995		Y
			Seasonal allergy	01JAN1993		Y
				01JAN1995		Y
	C4591001 1018 10181208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2000	31JUL2014	N
		Surgical and medical procedures	Scoliosis surgery	31JUL2014	31JUL2014	N
	C4591001 1018 10181211	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1018 10181214	Gastrointestinal disorders	Constipation	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181215	Psychiatric disorders	Insomnia	01AUG2018		Y
		Surgical and medical procedures	Vasectomy	01MAR2019	31MAR2019	N
	C4591001 1018 10181216	Eye disorders	Myopia	01JAN1980	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2010		Y
			Sinus polyp	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N
			Sinus operation	01JAN2012	31DEC2012	N
	C4591001 1018 10181218	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Ear infection	01JAN1979	31DEC1979	N
		Psychiatric disorders	Major depression	15JUN2020		Y
			Perinatal depression	01MAR2016	31DEC2018	N
		Surgical and medical procedures	Adenoidectomy	01JAN1979	31DEC1979	N
			Ear tube insertion	01JAN1979	31DEC1979	N
	C4591001 1018 10181219	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1989		Y
		Immune system disorders	Food allergy	01JAN1990		Y
			Seasonal allergy	01JUL2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2018	31DEC2018	N
		Investigations	Arthroscopy	01DEC2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989		Y
		Surgical and medical procedures	Bunion operation	29FEB1996	29FEB1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01DEC2018	31DEC2018	N
			Mammoplasty	01JUL2013	31JUL2013	N
	C4591001 1018 10181222	Eye disorders	Astigmatism	01JAN1999		Y
			Myopia	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1018 10181223	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN1983		Y
		Infections and infestations	Herpes simplex	01JAN2004		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1988	31DEC1988	N
			Hand fracture	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Shoulder operation	01JAN2009	31DEC2009	N
			Vasectomy	01NOV2016	30NOV2016	N
	C4591001 1018 10181224	Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Immune system disorders	Allergy to metals	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1018 10181225	Congenital, familial and genetic disorders	Phimosis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Circumcision	01JAN2006	31DEC2006	N
	C4591001 1018 10181226	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Psychiatric disorders	Anxiety	01OCT2016		Y
			Depression	01JAN2015		Y
			Panic attack	01OCT2016		Y
		Surgical and medical procedures	Mammoplasty	01DEC2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181227	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2005		Y
		Surgical and medical procedures	Ligament operation	01NOV2014	30NOV2014	N
			Uterine dilation and curettage	01NOV2008	30NOV2008	N
	C4591001 1018 10181228	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1018 10181230	Eye disorders	Presbyopia	01JAN2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Chondroplasty	01JAN1987	31DEC1987	N
	C4591001 1018 10181232	Metabolism and nutrition disorders	Obesity	01JAN1995	01MAR2019	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
		Surgical and medical procedures	Gastric banding	01JAN2005	31DEC2005	N
			Gastric banding reversal	01FEB2019	28FEB2019	N
			Gastric bypass	01FEB2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000	01MAY2019	N
	C4591001 1018 10181233	Eye disorders	Myopia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1018 10181234	Immune system disorders	Seasonal allergy	01JAN1991		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Obesity	01JAN2016		Y
		Surgical and medical procedures	Ligament operation	01JUN1986	30JUN1986	N
			Meniscus operation	01MAR2019	31MAR2019	N
				01NOV2015	30NOV2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1018 10181235	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1018 10181236	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Uvectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Prehypertension	01JAN2015		Y
	C4591001 1018 10181237	Psychiatric disorders	Anxiety	01JAN2017		Y
			Post-traumatic stress disorder	01JAN2017		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1018 10181238	Eye disorders	Myopia	01JAN1984		Y
			Presbyopia	01JAN2017		Y
		Immune system disorders	Allergy to plants	01JAN1980		Y
			Mite allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1018 10181240	Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2013	31DEC2013	N
			Caesarean section	01JAN2005	31DEC2005	N
				01JAN2011	31DEC2011	N
			Mammoplasty	01JAN2013	31DEC2013	N
			Metabolic surgery	01JAN2018	31DEC2018	N
	C4591001 1018 10181242	Immune system disorders	Mite allergy	01NOV2019		Y
		Infections and infestations	Pertussis	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2019		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2019		Y
	C4591001 1018 10181244	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2004	31DEC2005	N
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Meniscus operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2004	31DEC2009	N
	C4591001 1018 10181245	Surgical and medical procedures	Rectocele repair	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181246	Immune system disorders	Allergy to animal	01JAN1985		Y
			Food allergy	01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament sprain	12AUG2020	12AUG2020	N
	C4591001 1018 10181247	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Otitis media	15JUN2020	15JUN2020	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 1018 10181251	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
	C4591001 1018 10181252	Infections and infestations	Pilonidal cyst	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Joint injury	29JUN2018	29JUN2018	N
		Surgical and medical procedures	Female sterilisation	07MAR1992	07MAR1992	N
	C4591001 1018 10181254	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1998		Y
	C4591001 1018 10181255	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2003	31DEC2003	N
	C4591001 1018 10181256	Social circumstances	Alcohol use	01JAN1985	30APR2004	N
			Substance use	01JAN1985	30APR2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181257	Eye disorders	Astigmatism	01JAN2018		Y
			Myopia	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
			Rosacea	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
			Salpingectomy	01JAN2018	31DEC2018	N
	C4591001 1018 10181259	Immune system disorders	Food allergy	01JAN2014		Y
			Rubber sensitivity	01JAN2015		Y
		Reproductive system and breast disorders	Varicocele	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
	C4591001 1018 10181260	Gastrointestinal disorders	Necrotising colitis	01JAN1984	31DEC1984	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1997	31DEC1997	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraocular melanoma	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Intestinal resection	01JAN1984	31DEC1984	N
			Intraocular lens implant	01JAN2014	31DEC2014	N
	C4591001 1018 10181261	Immune system disorders	Drug hypersensitivity	01AUG2005		Y
				01JAN2012		Y
		Injury, poisoning and procedural complications	Foot fracture	01NOV2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hand fracture	01FEB1996		Y
				01MAR1995		Y
			Rib fracture	01AUG2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01MAY2005		Y
			Depression	01MAY2005		Y
		Reproductive system and breast disorders	Infertility	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2005		Y
	C4591001 1018 10181262	Reproductive system and breast disorders	Testicular torsion	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Orchidectomy	01JAN1990	31DEC1990	N
	C4591001 1018 10181263	Eye disorders	Presbyopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
			Vitamin D deficiency	01JAN2012		Y
		Surgical and medical procedures	Ligament operation	01JAN2003		Y
			Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1018 10181264	Metabolism and nutrition disorders	Decreased appetite	01JAN2008	31DEC2011	N
				01JAN2009	31DEC2011	N
	C4591001 1018 10181266	Reproductive system and breast disorders	Breast cyst	01JAN2020		Y
	C4591001 1018 10181267	Eye disorders	Myopia	01JAN1982		Y
			Presbyopia	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN1999	31DEC1999	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Cancer surgery	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	15JUN2020		Y
	C4591001 1018 10181268	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Infections and infestations	Oral herpes	01JAN1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Bone cyst	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2018	N
			Squamous cell carcinoma of skin	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1018 10181269	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2009		Y
		Surgical and medical procedures	Renal stone removal	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Retinal operation	01JUL2017	31OCT2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal laminectomy	01SEP2008	30SEP2008	N
	C4591001 1018 10181272	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1018 10181275	Gastrointestinal disorders	Haemorrhoids	01JAN2013		Y
	C4591001 1018 10181276	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	False positive investigation result	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981	31DEC1984	N
		Skin and subcutaneous tissue disorders	Dermatitis	22JUL2020	28JUL2020	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1983	31DEC1983	N
			Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1018 10181277	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1018 10181279	Eye disorders	Astigmatism	01JAN2002		Y
			Myopia	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
			Obsessive-compulsive disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
	C4591001 1018 10181282	Immune system disorders	Food allergy	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1991	31DEC1991	N
			Hand fracture	01JAN2012	31DEC2012	N
			Meniscus injury	01JAN1992	31DEC1992	N
			Upper limb fracture	01JAN2012	31DEC2012	N
		Investigations	Arthroscopy	01JUN2020	30JUN2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013	31OCT2018	N
		Surgical and medical procedures	Spinal fusion surgery	01OCT2018	31OCT2018	N
	C4591001 1018 10181283	Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Investigations	Hepatic enzyme increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2014	31DEC2014	N
	C4591001 1018 10181284	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Syncope	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
			Rosacea	01JAN2010		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01NOV2014	30NOV2019	N
				01NOV2019		Y
	C4591001 1018 10181286	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	19JUN2009	19JUN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	23MAR2018	23MAR2018	N
	C4591001 1018 10181287	Immune system disorders	Seasonal allergy	01SEP2019		Y
	C4591001 1018 10181288	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Social circumstances	Trans-sexualism	01SEP2019		Y
		Surgical and medical procedures	Breast prosthesis removal	12JUL2020		Y
			Mammoplasty	04JUN2020	04JUN2020	N
	C4591001 1018 10181289	Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Bone lesion excision	01JAN2016	31DEC2016	N
			Meniscus operation	01JAN2012	31DEC2012	N
	C4591001 1018 10181290	Immune system disorders	Dust allergy	01JAN2017		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Hepatitis A	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2015		Y
	C4591001 1018 10181292	Immune system disorders	Allergy to animal	01JAN2014		Y
			Dust allergy	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181293	Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1018 10181294	Infections and infestations	Diverticulitis	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	08SEP2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	04JUN2020	09JUL2020	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990	30JUN2019	N
		Surgical and medical procedures	Explorative laparotomy	01JAN1986	31DEC1986	N
	C4591001 1018 10181295	Immune system disorders	Food allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01SEP2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
			Drug eruption	01JAN1990		Y
				01JAN2010		Y
			Rosacea	01JAN2010		Y
	C4591001 1018 10181298	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma benign	01JUN2020	15JUL2020	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Oophorectomy	15JUL2020	15JUL2020	N
	C4591001 1018 10181299	Eye disorders	Astigmatism	01JAN2007		Y
		Immune system disorders	Rubber sensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Back pain	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1018 10181301	Injury, poisoning and procedural complications	Clavicle fracture	01JAN1998	31DEC1998	N
			Meniscus injury	01JAN1997	31DEC1999	N
			Muscle strain	01JAN1998	31DEC1998	N
			Stress fracture	01JAN1998	31DEC1998	N
			Tendon injury	01JAN2014	31DEC2014	N
		Investigations	Arthroscopy	01JAN1997	31DEC1997	N
				01JAN1999	31DEC1999	N
		Nervous system disorders	Muscle contractions involuntary	01JUN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
			Tenoplasty	01JAN2014	31DEC2014	N
	C4591001 1018 10181302	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1018 10181304	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN1974		Y
		Investigations	Discogram	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01SEP1994		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
			Radiculopathy	08MAY2017	31DEC2017	N
		Surgical and medical procedures	Foraminotomy	16JUN2017	16JUN2017	N
			Spinal laminectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181305	Immune system disorders	Drug hypersensitivity	16JUN2017	16JUN2017	N
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Concussion	01JAN2008	31DEC2008	N
			Wrist fracture	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2017	N
			Depression	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2018		Y
	C4591001 1018 10181306	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN2006	31DEC2006	N
	C4591001 1018 10181307	Eye disorders	Myopia	01JAN1990	31DEC2007	N
			Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01SEP2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
				01JAN2019	30SEP2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1990	31DEC1995	N
			Tendonitis	01JAN1990	31DEC2010	N
		Psychiatric disorders	Depression	01SEP1998		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Foot operation	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
			Keratomileusis	01JAN2007	31DEC2007	N
			Knee operation	01JAN2008	31DEC2008	N
				01SEP2019	30SEP2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1018 10181309	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1018 10181313	Injury, poisoning and procedural complications	Skin laceration	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Attention deficit hyperactivity disorder	01OCT2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1018 10181315	Surgical and medical procedures	Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1018 10181316	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2003	31DEC2004	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
			Eczema	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1018 10181317	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
	C4591001 1018 10181319	Eye disorders	Corneal disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1984		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181320	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2017	N
				01JUL2017	31JUL2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	30APR2016	N
					31OCT2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2018		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2017	31JUL2017	N
			Knee arthroplasty	01APR2016	30APR2016	N
				01OCT2016	31OCT2016	N
			Vasectomy	01JAN2011		Y
	C4591001 1018 10181322	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01SEP2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1018 10181323	Infections and infestations	Cystitis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
			Insomnia	01JAN2012	31DEC2016	N
	C4591001 1018 10181324	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181327	Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1018 10181329	Eye disorders	Myopia	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1018 10181333	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2004	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2008	31DEC2010	N
	C4591001 1018 10181334	Eye disorders	Hypermetropia	01JAN2017		Y
			Myopia	01JAN1987		Y
		Gastrointestinal disorders	Constipation	01JAN1985		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	31DEC2006	N
		Skin and subcutaneous tissue disorders	Dandruff	01JAN1988		Y
		Surgical and medical procedures	Caesarean section	14JUN2010	14JUN2010	N
				27MAY2014	27MAY2014	N
	C4591001 1018 10181335	Immune system disorders	Hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01SEP2018	30SEP2018	N
	C4591001 1018 10181336	Ear and labyrinth disorders	Conductive deafness	01DEC1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Middle ear effusion	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Flank pain	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Ear tube insertion	01JAN1997	31DEC1997	N
	C4591001 1018 10181338	Endocrine disorders	Hypogonadism male	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1985		Y
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1994	31DEC1994	N
	C4591001 1018 10181341	Immune system disorders	Allergy to animal	01JAN2000		Y
			Allergy to arthropod sting	01JAN2000		Y
			Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Eye laser surgery	01JAN2016	31JAN2016	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1018 10181342	Cardiac disorders	Aortic valve incompetence	01JAN2016		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1999	31DEC1999	N
			Lumbar vertebral fracture	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
			Sleep apnoea syndrome	01JAN1997		Y
		Surgical and medical procedures	Maxillofacial operation	01JAN2012	31DEC2012	N
			Nasal septal operation	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1998	31DEC1998	N
			Uvuloplasty	01JAN1998	31DEC1998	N
	C4591001 1018 10181344	Immune system disorders	Seasonal allergy	(b) (6) 1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996	31DEC2005	N
		Surgical and medical procedures	Ligament operation	01MAY2018	31MAY2018	N
			Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1018 10181345	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Upper respiratory tract infection	16OCT2020	24OCT2020	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Peripheral nerve decompression	01JAN2012	31DEC2012	N
	C4591001 1018 10181346	Surgical and medical procedures	Wisdom teeth removal	01JUN2020	31DEC2020	N
	C4591001 1018 10181347	Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
			Dermatitis allergic	01JAN2016		Y
	C4591001 1018 10181349	Skin and subcutaneous tissue disorders	Eczema	01JAN1990	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1018 10181351	Eye disorders	Hypermetropia	01JAN2002	31DEC2002	N
	C4591001 1018 10181352	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	13NOV2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010	31JAN2020	N
	C4591001 1018 10181353	Nervous system disorders	Syncope	01JAN2011	31DEC2011	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1019 10191002	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2006		Y
		Eye disorders	Myopia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
	C4591001 1019 10191005	Eye disorders	Myopia	01JAN1997		Y
		Infections and infestations	Pneumonia	01JAN2009	31DEC2009	N
			Sinusitis	01JAN2010		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1989	31DEC1989	N
			Foot fracture	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Wrist fracture	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191006	Eye disorders	Myopia	01JAN1988		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2002	01FEB2016	N
			Haemorrhoids	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Vitamin D deficiency	02JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Nervous system disorders	Tension headache	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1977		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1019 10191007	Eye disorders	Myopia	01JAN1971		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
	C4591001 1019 10191015	Ear and labyrinth disorders	Deafness unilateral	(b) (6) 1974		Y
		Eye disorders	Myopia	01JAN1983		Y
			Presbyopia	01JAN1983		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Rubber sensitivity	01JAN1974		Y
		Infections and infestations	Encephalomyelitis	01AUG1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JUL2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2001	28FEB2018	N
			Back pain	01JAN2001	28FEB2018	N
		Nervous system disorders	Seizure	01JAN1999	31DEC2000	N
		Psychiatric disorders	Anorexia nervosa	01JAN1984	31DEC2005	N
			Bulimia nervosa	01JAN1984	31DEC2005	N
		Reproductive system and breast disorders	Endometriosis	01JAN1999	31DEC2018	N
			Menorrhagia	01JAN1985	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978	31DEC1988	N
			Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	26FEB2018	26FEB2018	N
			Oophorectomy bilateral	01JAN2017	31DEC2017	N
			Open reduction of fracture	01JAN2001	31DEC2001	N
	C4591001 1019 10191018	Eye disorders	Myopia	01JAN1991		Y
		Injury, poisoning and procedural complications	Sternal fracture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1019 10191023	Immune system disorders	Iodine allergy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN2014	31DEC2014	N
		Investigations	Cardiac murmur	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	12AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteochondroma	01JAN2013		Y
				01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
	C4591001 1019 10191027	Gastrointestinal disorders	Abdominal pain	01JAN2005		Y
			Constipation	01JAN2005		Y
			Diarrhoea	01JAN2005		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2013	N
		Injury, poisoning and procedural complications	Snake bite	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1990		Y
			Tension headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1990	31DEC2000	N
			Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01NOV2014		Y
	C4591001 1019 10191028	Eye disorders	Myopia	01JUN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1989	31DEC1989	N
				01JAN2018	31DEC2018	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1989	31DEC1989	N
				01JAN2018	31DEC2018	N
			Vasectomy	01JUN1999	30JUN1999	N
	C4591001 1019 10191032	Gastrointestinal disorders	Constipation	01JAN2020	29FEB2020	N
			Dyspepsia	01JAN2012		Y
			Haemorrhoids	01JAN2014	31DEC2014	N
		Infections and infestations	Pneumonia	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Scoliosis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2011		Y
			Tension headache	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2010	N
			Rhinitis allergic	01JAN2000		Y
		Social circumstances	Substance use	01JAN2012	31DEC2015	N
	C4591001 1019 10191034	Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN1993		Y
			Depression	29JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Social circumstances	Substance use	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1019 10191036	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN1989		Y
				01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Jaw disorder	01JAN1989	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Keratomileusis	01JAN2005	31DEC2005	N
			Orthognathic surgery	01JAN2003	31DEC2003	N
	C4591001 1019 10191038	Eye disorders	Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Gastric ulcer	01NOV2005	31DEC2005	N
			Haemorrhoids	01NOV2005	31DEC2005	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01APR2006	31DEC2008	N
			Foot deformity	01JAN1993	31DEC1998	N
		Nervous system disorders	Sinus headache	01JAN2003	31DEC2004	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01FEB2003	31MAR2003	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rosacea	01JAN1999		Y
		Surgical and medical procedures	Bunion operation	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1019 10191041	Eye disorders	Myopia	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1019 10191044	Eye disorders	Myopia	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2018		Y
		Injury, poisoning and procedural complications	Foreign body	01MAR2020	31MAR2020	N
			Ligament rupture	01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N
			Removal of foreign body from joint	01MAR2020	31MAR2020	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1019 10191047	Eye disorders	Presbyopia	01JAN2006		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Haemorrhoids	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Pain in extremity	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	01JAN1990	31DEC1990	N
	C4591001 1019 10191050	Eye disorders	Presbyopia	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2011	31DEC2011	N
			Squamous cell carcinoma of skin	01JAN2011	31DEC2011	N
		Nervous system disorders	Tension headache	01JAN2014		Y
		Psychiatric disorders	Alcohol abuse	01JAN1979	31DEC1992	N
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2002	31DEC2002	N
			Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Substance use	01JAN1980	31DEC1992	N
		Surgical and medical procedures	Cancer surgery	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Maxillofacial operation	01JAN2001	31DEC2001	N
			Nephrectomy	01JAN2017	31DEC2017	N
			Sinus operation	01JAN2002	31DEC2002	N
			Skin neoplasm excision	01JAN2011	31DEC2011	N
	C4591001 1019 10191056	Eye disorders	Myopia	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Inguinal hernia	01JAN1993	31DEC1993	N
		Infections and infestations	Pneumonia	01JAN1968	31DEC1977	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968	31DEC1977	N
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191058	Eye disorders	Myopia	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
		Infections and infestations	Sinusitis	01JAN1980	31DEC2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1982		Y
			Sinus headache	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2000	N
			Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2000	31DEC2000	N
	C4591001 1019 10191059	Eye disorders	Myopia	01JAN1977		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2000	31DEC2017	N
			Gastrooesophageal reflux disease	01JAN1995		Y
			Hiatus hernia	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2007	31DEC2007	N
		Investigations	Arthroscopy	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN2015	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
	C4591001 1019 10191063	Blood and lymphatic system disorders	Iron deficiency anaemia	01JUN2020	31JUL2020	N
		Eye disorders	Myopia	01JAN1965	31DEC1999	N
			Presbyopia	01JAN1965		Y
			Strabismus	(b) (6) 1965	31DEC1972	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Foot fracture	01APR2020	30APR2020	N
			Thermal burns of eye	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2020		Y
		Surgical and medical procedures	Keratomileusis	01JAN1999	31DEC1999	N
			Strabismus correction	01JAN1967	31DEC1967	N
				01JAN1969	31DEC1969	N
				01JAN1972	31DEC1972	N
	C4591001 1019 10191068	Eye disorders	Myopia	01JAN2018		Y
			Presbyopia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2019	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Mammoplasty	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01DEC2019	31DEC2019	N
	C4591001 1019 10191073	Eye disorders	Myopia	01JAN1992		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Myalgia	01JAN2005		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
			Sinus headache	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1019 10191074	Eye disorders	Glaucoma	01JAN2019		Y
			Myopia	01JAN2014		Y
			Presbyopia	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
			Pain in jaw	01MAY2020		Y
		Nervous system disorders	Headache	01JAN2018		Y
			Migraine	01JAN2012		Y
			Restless legs syndrome	01JAN2012		Y
			Sinus headache	01JAN2015		Y
			Tension headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Oophorectomy bilateral	01JAN2013	31DEC2013	N
			Trabeculectomy	27JUL2020	27JUL2020	N
	C4591001 1019 10191076	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN1973		Y
			Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Osteopenia	30JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
			Rhinitis allergic	01JAN1975		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Open reduction of fracture	01JAN2012	31DEC2012	N
	C4591001 1019 10191077	Eye disorders	Myopia	01JAN1998		Y
			Strabismus	(b) (6) 1980	(b) (6) 1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01DEC2019		Y
	C4591001 1019 10191081	Endocrine disorders	Growth hormone deficiency	01JAN1981	31DEC1997	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1991	31DEC1991	N
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1991	31DEC1991	N
			Shoulder operation	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1019 10191083	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Myopia	01JAN1989		Y
		Infections and infestations	Sinusitis	01JAN2019	31DEC2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
			Tension headache	01JAN2013		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2017	N
			Depression	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2013		Y
			Ovarian cyst	01JAN2007		Y
			Polycystic ovaries	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1975		Y
			Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
				01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N
			Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1019 10191085	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Prostatectomy	01DEC2019	31DEC2019	N
	C4591001 1019 10191090	Ear and labyrinth disorders	Deafness unilateral	01JAN2003		Y
		Infections and infestations	Herpes zoster	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1999	31DEC1999	N
		Nervous system disorders	Disturbance in attention	01JAN2018		Y
			Restless legs syndrome	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01DEC2019		Y
			Rhinitis allergic	01JAN2008		Y
	C4591001 1019 10191098	Infections and infestations	Herpes zoster	01OCT2018	31OCT2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1019 10191100	Endocrine disorders	Hypothyroidism	01MAR2006		Y
		Eye disorders	Astigmatism	01JAN2001		Y
		Infections and infestations	Pneumonia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2006	31DEC2012	N
			Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1997	31DEC2009	N
			Depression	01JAN1997	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994	31DEC1994	N
			Nasal septum deviation	01JAN1999		Y
			Rhinitis allergic	01JAN2002		Y
	C4591001 1019 10191101	Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2002		Y
			Back pain	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN1996	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1993	31DEC1993	N
	C4591001 1019 10191102	Eye disorders	Dry eye	01JAN1986		Y
			Presbyopia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	04AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Sinus headache	01JAN2007		Y
			Tension headache	01JAN1984		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Urinary bladder suspension	01JAN2014	31DEC2014	N
			Uterine tumour excision	01JAN2000	31DEC2000	N
	C4591001 1019 10191106	Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Synovial cyst removal	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191108	Eye disorders	Astigmatism	01JAN2015		Y
			Myopia	01JAN1998		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Nervous system disorders	Sinus headache	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2003		Y
			Insomnia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
		Social circumstances	Substance use	01JAN2007	31DEC2007	N
	C4591001 1019 10191110	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Reaction to colouring	01JAN1998		Y
		Infections and infestations	Pneumonia	01APR2013	30APR2013	N
			Sinusitis	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
			Vitamin D deficiency	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Breast cyst	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hypotrichosis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2014	31DEC2014	N
	C4591001 1019 10191113	Eye disorders	Astigmatism	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1019 10191116	Injury, poisoning and procedural complications	Ankle fracture	01JAN2001	31DEC2001	N
			Jaw fracture	01JAN2003	31DEC2003	N
			Ligament rupture	01JAN2002	31DEC2002	N
			Wrist fracture	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	31DEC1995	N
	C4591001 1019 10191123	Eye disorders	Astigmatism	01JAN2004		Y
			Myopia	01JAN2004		Y
			Presbyopia	01JAN2004		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2015		Y
			Dyspepsia	01JAN2005		Y
			Haemorrhoids	01JAN2015		Y
			Irritable bowel syndrome	01JAN2015		Y
			Peptic ulcer	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01OCT2010	31OCT2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Herpes simplex	01JAN2018		Y
			Pneumonia	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinusitis	01JAN2016	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
				01JAN2017		Y
		Nervous system disorders	Osteoarthritis	01JAN2017		Y
			Carpal tunnel syndrome	01JAN2006	31DEC2006	N
			Tension headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2005	31DEC2008	N
			Ovarian cyst	01JAN2005	31DEC2008	N
			Uterine enlargement	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2016		Y
			Nasal septum deviation	01JAN2016	31DEC2017	N
			Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
			Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Cholecystectomy	01OCT2017	31OCT2017	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Mammoplasty	01JAN2012	31DEC2012	N
			Nasal septal operation	01JAN2017	31DEC2017	N
	C4591001 1019 10191124	Gastrointestinal disorders	Dyspepsia	01JAN1993		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Infections and infestations	Diverticulitis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	30NOV2019	N
			Muscle spasms	01MAR2019	30NOV2019	N
			Myalgia	01JAN2005		Y
		Nervous system disorders	Dizziness	01JAN2000		Y
			Tension headache	01JAN2017		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Depression	01OCT2019		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
			Chronic obstructive pulmonary disease	01JAN2005		Y
			Cough	01JAN2003		Y
			Rhinitis allergic	01JAN2009		Y
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Colectomy	01JAN2013	31DEC2013	N
			Urinary bladder suspension	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1019 10191125	Eye disorders	Myopia	01JAN2005		Y
	C4591001 1019 10191127	Eye disorders	Myopia	01JAN1987		Y
			Presbyopia	01JAN1987		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JUN2020	30JUN2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
			Lower limb fracture	01JAN2015	31DEC2015	N
		Investigations	Hepatic enzyme increased	01JAN2005		Y
		Nervous system disorders	Epilepsy	01JAN2019		Y
			Tremor	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1019 10191128	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2009	31DEC2015	N
		Eye disorders	Myopia	01JAN2015		Y
			Presbyopia	01JAN2004		Y
		Reproductive system and breast disorders	Endometriosis	01DEC2015	31DEC2015	N
			Menorrhagia	01JAN1996	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1019 10191129	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Infections and infestations	Herpes zoster	01JUL2019	31JUL2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191133	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2008		Y
			Diarrhoea	01JAN2008		Y
			Gastrooesophageal reflux disease	01JAN2008		Y
			Irritable bowel syndrome	01JAN2008		Y
		Hepatobiliary disorders	Biliary dyskinesia	01JAN2010	31DEC2010	N
		Immune system disorders	Allergy to vaccine	01JAN2016		Y
			Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2009	31DEC2018	N
		Injury, poisoning and procedural complications	Fractured coccyx	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2014		Y
			Sinus headache	01JAN2014		Y
			Tension headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1019 10191137	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Haemorrhoids	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01AUG2020		Y
			Tension headache	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1019 10191138	Endocrine disorders	Hypogonadism	01JAN2018		Y
			Hypothyroidism	01JAN2003		Y
		Eye disorders	Presbyopia	01JAN2017		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1019 10191140	Ear and labyrinth disorders	Deafness unilateral	01JAN2005		Y
		Eye disorders	Cataract	01JAN2014		Y
			Myopia	01JAN1977		Y
			Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
			Hiatus hernia	01JAN2019		Y
		Infections and infestations	Sinusitis	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2018		Y
		Nervous system disorders	Sinus headache	01JAN1983		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
			Rhinitis allergic	01JAN1973		Y
		Social circumstances	Substance use	01JAN1984	01JUN2020	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1019 10191141	Eye disorders	Presbyopia	01OCT2014		Y
		Injury, poisoning and procedural complications	Arthropod bite	01FEB2004	29FEB2004	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2013	31JUL2018	N
		Nervous system disorders	Sinus headache	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1977		Y
		Surgical and medical procedures	Debridement	01FEB2004	29FEB2004	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	29OCT2013		Y
	C4591001 1019 10191145	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2013		Y
		Eye disorders	Myopia	01JAN1990	31DEC2008	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2011		Y
		Infections and infestations	Herpes simplex	01JAN2018		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01MAR2020		Y
			Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN2005	31DEC2005	N
				01JAN2016	31DEC2016	N
			Nasal septal operation	01JAN2017	31DEC2017	N
			Spinal laminectomy	01AUG2013	31AUG2013	N
	C4591001 1019 10191147	Eye disorders	Presbyopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
			Cubital tunnel syndrome	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Peripheral nerve decompression	01JAN2015	31DEC2015	N
	C4591001 1019 10191154	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Nervous system disorders	Drug withdrawal headache	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1019 10191156	Eye disorders	Presbyopia	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
	C4591001 1019 10191157	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Arteriovenous fistula operation	01JAN1987	31DEC1987	N
			Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Arteriovenous fistula	01JAN1987	31DEC1987	N
			Hypertension	01JAN2015		Y
	C4591001 1019 10191159	Blood and lymphatic system disorders	Iron deficiency anaemia	01OCT2012		Y
		Eye disorders	Myopia	01JAN2009		Y
			Presbyopia	01JAN2009		Y
		Infections and infestations	Sinusitis	01JAN2012	31DEC2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Sinus headache	01JAN2010		Y
			Tension headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1019 10191161	Renal and urinary disorders	Nephrolithiasis	01AUG2020	01SEP2020	N
		Surgical and medical procedures	Lithotripsy	01SEP2020	01SEP2020	N
	C4591001 1019 10191164	Eye disorders	Astigmatism	01JAN1980		Y
			Myopia	01JAN1980		Y
			Presbyopia	01JAN1980		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1996	31DEC1996	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1989		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Open reduction of fracture	01JAN1996	31DEC1996	N
			Umbilical hernia repair	01JAN2019	31DEC2019	N
	C4591001 1019 10191166	Eye disorders	Myopia	01APR2015		Y
			Presbyopia	01APR2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Rubber sensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN2014	31DEC2014	N
		Nervous system disorders	Tension headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
			Rhinitis allergic	01MAR2017		Y
		Social circumstances	Postmenopause	01APR2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1019 10191168	Eye disorders	Myopia	01JAN1986		Y
		Infections and infestations	Onychomycosis	01MAR2019	14SEP2019	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01OCT2016		Y
	C4591001 1019 10191171	Eye disorders	Myopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2018	31DEC2018	N
		Nervous system disorders	Sinus headache	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1019 10191172	Eye disorders	Keratoconus	01JAN2000		Y
					31DEC2000	N
			Myopia	01JAN2019		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2012		Y
			Inguinal hernia	01JAN2016		Y
			Proctitis ulcerative	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Fractured coccyx	01JAN1992	31DEC1992	N
			Joint dislocation	01JAN1990	31DEC1990	N
				01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1994		Y
			Osteoarthritis	01JAN1994		Y
		Psychiatric disorders	Insomnia	01JAN1989	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Corneal transplant	01JAN2000	31DEC2000	N
			Knee operation	01JAN1990	31DEC1990	N
				01JAN2003	31DEC2003	N
	C4591001 1019 10191173	Eye disorders	Presbyopia	01JAN1982		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		General disorders and administration site conditions	Pain	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Genital herpes	01JAN2013		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
			Headache	01JAN1984		Y
			Migraine	01JAN2013		Y
			Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Breast mass	01JAN2012	31DEC2012	N
			Endometriosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191174	Eye disorders	Myopia	01JAN1981	31DEC2004	N
			Presbyopia	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN1995		Y
			Rubber sensitivity	01JAN2002		Y
		Infections and infestations	Sinusitis	01JAN1985	31DEC2018	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2011	31DEC2011	N
			Hand fracture	01JAN2007	31DEC2007	N
			Joint dislocation	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1986		Y
			Intervertebral disc degeneration	01JAN2011		Y
			Periarthritis	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
			Ostectomy	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Photorefractive keratectomy	01JAN2004	31DEC2004	N
	C4591001 1019 10191175	Eye disorders	Myopia	01JAN2005		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
			Radius fracture	01JAN2013	31DEC2013	N
		Nervous system disorders	Sinus headache	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
			Rhinitis allergic	01JAN2012		Y
	C4591001 1019 10191181	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018	31DEC2018	N
		Endocrine disorders	Gonadotrophin deficiency	01DEC2002		Y
		Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Haemorrhoids	01JAN2016		Y
			Irritable bowel syndrome	01JAN2000		Y
		Infections and infestations	Cellulitis	01JAN2017	28FEB2017	N
			Genital herpes	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2005		Y
		Nervous system disorders	Epilepsy	01JAN1977	31DEC1985	N
			Generalised tonic-clonic seizure	01JAN1977	31DEC1985	N
			Tension headache	01JAN2000		Y
		Renal and urinary disorders	Urethral prolapse	01DEC2011	31DEC2011	N
		Reproductive system and breast disorders	Breast cyst	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC1995	N
			Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
			Rhinoplasty	01JAN1995	31DEC1995	N
			Urethral repair	01DEC2011	31DEC2011	N
			Varicose vein operation	01JAN2019	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Thrombosis	01OCT2018	31DEC2018	N
			Varicose vein	01JAN2019		Y
			Venous thrombosis limb	01JAN2018	31JAN2019	N
		Eye disorders	Presbyopia	01JAN2014		Y
	C4591001 1019 10191184	Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Neck pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000		Y
		Nervous system disorders	Hypoaesthesia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
			Ligament operation	01JAN2010	31DEC2010	N
			Meniscus operation	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1019 10191186	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Toothache	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Muscle spasms	01JUN2020		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Alcohol abuse	01JAN2006	31DEC2016	N
			Anxiety	01JAN2003		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2003		Y
			Drug abuse	01JAN2006	31DEC2016	N
				01JAN2011	31DEC2012	N
			Insomnia	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JUN2019	30JUN2019	N
				01OCT2006	31OCT2006	N
				01OCT2010	31OCT2012	N
				01SEP2008	30SEP2008	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JUN2019	30JUN2019	N
		Eye disorders	Myopia	01JAN1988	31DEC2002	N
	C4591001 1019 10191187			01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Investigations	Human papilloma virus test positive	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Keratomileusis	01JAN2002	31DEC2002	N
	C4591001 1019 10191188	Eye disorders	Presbyopia	01JAN2013		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1019 10191189	Eye disorders	Myopia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1999	31DEC1999	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1992		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1019 10191192	Injury, poisoning and procedural complications	Renal surgery	01JAN1999	31DEC1999	N
			Wrist fracture	01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JUL2020		Y
			Bipolar disorder	01JAN2005		Y
	C4591001 1019 10191193	Congenital, familial and genetic disorders	Talipes	(b) (6) 1988		Y
		Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Rubber sensitivity	01JAN1998		Y
		Infections and infestations	Sinusitis	01JAN2005	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Surgical and medical procedures	Ankle arthroplasty	15OCT2008	15OCT2008	N
			Caesarean section	04MAY2010	04MAY2010	N
				18FEB2015	18FEB2015	N
			Female sterilisation	18FEB2015	18FEB2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191194	Endocrine disorders	Hypothyroidism	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01NOV2019	29FEB2020	N
	C4591001 1019 10191195	Eye disorders	Myopia	01JAN1995		Y
		Nervous system disorders	Sinus headache	01JAN2000	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1019 10191196	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
			Migraine	01JAN1996		Y
			Sinus headache	01JAN2000		Y
			Tension headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2017		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2004		Y
			Menorrhagia	01JAN2010	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1019 10191197	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Peripheral nerve injury	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Peripheral nerve operation	01JAN2019	31DEC2019	N
	C4591001 1019 10191198	Ear and labyrinth disorders	Deafness	01JAN1997		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019	31DEC2019	N
		Immune system disorders	Allergy to arthropod sting	01JAN1996		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
			Tonsillitis	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1993	31DEC1993	N
				01JAN1994	31DEC1994	N
			Facial bones fracture	01JAN1994	31DEC1994	N
				01JAN1997	31DEC1997	N
			Joint dislocation	01JAN1994	31DEC1994	N
			Tibia fracture	01JAN1995	31DEC1995	N
		Investigations	Arthroscopy	01JAN1991	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019	31DEC2019	N
			Obesity	01JAN2000	31DEC2019	N
			Type 2 diabetes mellitus	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990		Y
			Sleep apnoea syndrome	01SEP2019	30NOV2019	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Gastrectomy	01JAN2019	31DEC2019	N
			Nasal septal operation	01JAN1994	31DEC1994	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1997	31DEC1997	N
			Ostectomy	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1998	31DEC1998	N
			Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01SEP2019	31DEC2019	N
	C4591001 1019 10191205	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1970	31DEC1970	N
		Eye disorders	Myopia	01JAN1988		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1991		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1981		Y
		Surgical and medical procedures	Pyloroplasty	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1019 10191206	Endocrine disorders	Hypothyroidism	01DEC2016		Y
		Eye disorders	Dry eye	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2008	30JUN2013	N
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2016		Y
			Intervertebral disc protrusion	01JUN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01OCT2016	31DEC2016	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2002	30APR2020	N
					31DEC2019	N
			Sinus headache	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2007	31DEC2015	N
			Rhinitis allergic	01JAN2003		Y
		Surgical and medical procedures	Carpal tunnel decompression	01APR2020	30APR2020	N
			Thyroidectomy	01DEC2019	31DEC2019	N
		Vascular disorders	Deep vein thrombosis	01DEC2016	31DEC2016	N
	C4591001 1019 10191208	Eye disorders	Astigmatism	01JAN1998	31DEC1998	N
			Myopia	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Infections and infestations	Herpes zoster	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1019 10191209	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2014		Y
			Tension headache	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
	C4591001 1019 10191211	Eye disorders	Myopia	01JAN1976		Y
		Gastrointestinal disorders	Abdominal pain	01JAN2000		Y
			Constipation	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dyspepsia	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
		Injury, poisoning and procedural complications	Fibula fracture	01APR2020	31MAY2020	N
			Foot fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2010		Y
		Surgical and medical procedures	Photorefractive keratectomy	01JAN2014	31DEC2014	N
	C4591001 1019 10191212	Eye disorders	Astigmatism	01JAN2015		Y
			Myopia	01JAN2015		Y
			Presbyopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
	C4591001 1019 10191213	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
	C4591001 1019 10191214	Eye disorders	Myopia	01JAN1987		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1987		Y
			Gastric ileus	01JAN2005	31DEC2005	N
		Infections and infestations	Gastroenteritis norovirus	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1991		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1019 10191215	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Back pain	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2003		Y
	C4591001 1019 10191216	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Chlamydial infection	01JAN2004	31DEC2004	N
		Investigations	Human papilloma virus test positive	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2019	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2004	31DEC2004	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2005		Y
			Ovarian cyst	01JAN2006		Y
	C4591001 1019 10191217	Surgical and medical procedures	Salpingectomy	01JAN2004	31DEC2004	N
		Gastrointestinal disorders	Haemorrhoids	01JAN1992		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Caesarean section	01JUN1993	30JUN1993	N
	C4591001 1019 10191218	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Food allergy	01JAN2003		Y
		Infections and infestations	Pneumonia	01JAN2004	31DEC2004	N
			Sinusitis	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1019 10191220	Eye disorders	Myopia	01JAN1985	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
			Herpes zoster	01JAN1994	31DEC1994	N
			Sinusitis	01JAN2010	31DEC2015	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1982	31DEC1982	N
			Foot fracture	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982		Y
			Rhinitis allergic	01JAN1991		Y
			Sleep apnoea syndrome	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
			Keratomileusis	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1019 10191222	Congenital, familial and genetic disorders	Talipes	(b) (6) 1981	(b) (6) 1981	N
		Eye disorders	Presbyopia	01JAN2019		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2009	31DEC2009	N
			Hand fracture	01JAN2015	31DEC2015	N
			Traumatic lung injury	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Miliaria	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN2009	31DEC2009	N
			Pneumocentesis	01JUL2020	31JUL2020	N
			Talipes correction	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1019 10191225	Eye disorders	Presbyopia	01AUG2015		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	28FEB2010	N
		Immune system disorders	Rubber sensitivity	15JAN2009		Y
		Injury, poisoning and procedural complications	Burns third degree	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2009		Y
			Sinus headache	01JAN2007		Y
			Tension headache	01JAN2007		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
			Cholecystectomy	01FEB2010	28FEB2010	N
			Skin graft	01JAN1982	31DEC1982	N
	C4591001 1019 10191226	Eye disorders	Glaucoma	01JAN2018		Y
			Myopia	01JAN1987		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
			Muscle spasms	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1019 10191227	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Injury, poisoning and procedural complications	Radius fracture	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	01JAN2011	31DEC2011	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1019 10191230	Eye disorders	Myopia	01JAN1999	31DEC1999	N
			Presbyopia	01MAY2020		Y
		Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
		Immune system disorders	Iodine allergy	01JAN2002		Y
		Infections and infestations	Sinusitis	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1988		Y
			Menorrhagia	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2017		Y
		Surgical and medical procedures	Abortion induced	01JAN2001	31JAN2001	N
			Caesarean section	01JAN2001	31JAN2001	N
				01NOV2005	30NOV2005	N
			Hysterectomy	01NOV2005	31DEC2005	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Myomectomy	01JAN1991	31DEC1991	N
			Retinal operation	01JUL2020	31JUL2020	N
	C4591001 1019 10191232	Eye disorders	Myopia	01JAN1978		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01MAY2019	31MAY2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
			Type 2 diabetes mellitus	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Arthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1998		Y
			Tension headache	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01DEC2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2019	31MAY2019	N
			Female sterilisation	01NOV1992	30NOV1992	N
	C4591001 1019 10191234	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Nervous system disorders	Sinus headache	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Caesarean section	01JUN2003	30JUN2003	N
				01MAR2005	31MAR2005	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1019 10191235	Eye disorders	Astigmatism	01JAN2006		Y
			Myopia	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Allergy to animal	01JUL2020		Y
		Infections and infestations	Chlamydial infection	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Rhinitis allergic	01JAN1994		Y
		Social circumstances	Substance use	01JAN2013		Y
	C4591001 1019 10191236	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Tendon laxity	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01DEC1988	31DEC1988	N
				01MAR1990	31MAR1990	N
			Female sterilisation	01MAR1990	31MAR1990	N
			Sterilisation reversal	01JAN2000	31DEC2000	N
			Tenoplasty	01JAN2006	31DEC2006	N
	C4591001 1019 10191238	Eye disorders	Presbyopia	01JAN2015		Y
		Infections and infestations	Cellulitis	01JAN2000	31DEC2000	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016	31DEC2018	N
	C4591001 1019 10191242	Eye disorders	Myopia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1019 10191245	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2007		Y
		Eye disorders	Myopia	01JAN2010		Y
			Open angle glaucoma	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191246	Nervous system disorders	Migraine	01JAN2015		Y
			Tension headache	01JAN2015		Y
	C4591001 1019 10191247	Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Hepatitis C	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
			Coccydynia	01JAN2006		Y
			Muscle spasms	01JAN2007		Y
			Osteoarthritis	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2000		Y
			Tremor	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01APR1997	30APR1997	N
				01FEB2005	28FEB2005	N
				01NOV2006	30NOV2006	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1019 10191249	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2019	31DEC2019	N
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
			Thyroid calcification	01JAN2011	31DEC2011	N
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2019	31DEC2019	N
			Gastroesophageal reflux disease	01JAN2015		Y
			Hiatus hernia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Sinusitis	01JAN1999		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2014	31DEC2014	N
				01JUL2020	31JUL2020	N
			Ligament rupture	01JAN2002	31DEC2002	N
		Investigations	Laparoscopy	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
			Intervertebral disc protrusion	01JAN1991		Y
			Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Nervous system disorders	Tension headache	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN1999		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Caesarean section	05OCT2004	05OCT2004	N
			Foot operation	10AUG2020	10AUG2020	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Thyroidectomy	01JAN2011	31DEC2011	N
			Toe operation	01JAN2015	31DEC2015	N
	C4591001 1019 10191251	Metabolism and nutrition disorders	Vitamin D deficiency	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1019 10191252	Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1987	31DEC1987	N
			Clavicle fracture	01JAN1987	31DEC1987	N
			Foot fracture	01JAN1987	31DEC1987	N
			Hip fracture	01JAN1987	31DEC1987	N
			Limb injury	01JAN1987	31DEC1987	N
			Pelvic fracture	01JAN1987	31DEC1987	N
			Retinal injury	01JAN2019	31DEC2019	N
			Rib fracture	01JAN1987	31DEC1987	N
			Skin laceration	01JAN1991	31DEC1991	N
			Tibia fracture	01JAN1987	31DEC1987	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	01JAN2014	31DEC2014	N
		Nervous system disorders	Focal dyscognitive seizures	01JAN1994	31DEC2015	N
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Finger repair operation	01JAN1987	31DEC1987	N
			Intervertebral disc operation	01JAN1987	31DEC1987	N
			Neck surgery	01JAN2014	31DEC2014	N
			Open reduction of fracture	01JAN1987	31DEC1987	N
			Plastic surgery to the face	01JAN1991	31DEC1991	N
			Retinal operation	01JAN2019	31DEC2019	N
			Thyroidectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191254	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN1999		Y
		Eye disorders	Myopia	01JAN1995		Y
		Hepatobiliary disorders	Biliary colic	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1019 10191255	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Infections and infestations	Ear infection	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Social circumstances	Substance use	01JAN2006	31JUL2020	N
	C4591001 1019 10191256	Eye disorders	Myopia	01JAN1979	31DEC2001	N
		Hepatobiliary disorders	Gallbladder hypofunction	01JAN2006	31DEC2006	N
		Infections and infestations	Sinusitis	01JAN1994		Y
			Tonsillitis	01JAN1975	31DEC1975	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
			Meniscus injury	01JAN1995	31DEC1995	N
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Dehydration	01JAN1990	31DEC1990	N
			Obesity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1995		Y
			Back pain	01JAN1998		Y
		Nervous system disorders	Tension headache	01JAN1989		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Keratomileusis	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1975	31DEC1975	N
			Vasectomy	01JUL2020	31JUL2020	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1019 10191257	Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Back pain	01JAN2012		Y
			Osteoarthritis	01JAN2008		Y
			Spinal osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	05FEB2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012		Y
					31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2008	31DEC2008	N
			Myomectomy	05FEB2019	05FEB2019	N
	C4591001 1019 10191260	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2017	N
			Sinusitis	01JAN1993	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN1996		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
			Depression	01MAR2019		Y
			Drug abuse	01JAN2008	31DEC2012	N
				01MAR2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1991		Y
	C4591001 1019 10191262	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Myopia	01JAN1999		Y
		Infections and infestations	Sinusitis	01JAN2007	31DEC2018	N
			Tonsillitis	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Synovial cyst	01MAR2020	31MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Bipolar disorder	01JAN2016		Y
			Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Ovarian cyst	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Keratomileusis	01MAY2019	31MAY2019	N
			Synovial cyst removal	01MAR2020	31MAR2020	N
			Tonsillectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191264	Eye disorders	Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Haemorrhoids	01JAN1992		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Infections and infestations	Trichomoniasis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Tension headache	01JAN2010		Y
		Psychiatric disorders	Depression	10SEP2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1019 10191265	Injury, poisoning and procedural complications	Accidental poisoning	01JAN2018	31DEC2018	N
			Ulna fracture	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Substance use	01JAN2018	31JUL2020	N
	C4591001 1019 10191268	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN1965		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y
			Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
			Restless legs syndrome	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Coronary artery bypass	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191269	Eye disorders	Myopia	01JAN1971		Y
			Presbyopia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
			Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1019 10191270	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Myopia	01JAN1969		Y
			Presbyopia	01JAN2013		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Haemorrhoids	01JAN2012		Y
		Infections and infestations	Fungal skin infection	01OCT2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01MAR2020		Y
		Psychiatric disorders	Depression	01JAN2014	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1986	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1019 10191273	Metabolism and nutrition disorders	Rhinitis allergic	01JAN2015		Y
			Vitamin A deficiency	01AUG2020		Y
	C4591001 1019 10191276	Immune system disorders	Vitamin E deficiency	01AUG2000		Y
			Drug hypersensitivity	01JAN1991		Y
		Infections and infestations	Hepatitis A	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2011	31DEC2011	N
	C4591001 1019 10191279	Investigations	Cardiac murmur	01JAN1988		Y
		Eye disorders	Cataract	01JAN2019		Y
			Presbyopia	01JAN2010		Y
			Pterygium	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Gastric polyps	01JAN2017	31DEC2017	N
			Gastroesophageal reflux disease	01JAN2014		Y
			Inguinal hernia	01JAN1976	31DEC1978	N
		Infections and infestations	Helicobacter infection	01JAN2017		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2004	31DEC2004	N
			Femur fracture	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Intervertebral disc protrusion	01JAN2004		Y
			Muscle spasms	01JAN2018		Y
			Myalgia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2000		Y
				01SEP2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Chondroplasty	01JAN2004	31DEC2004	N
			Inguinal hernia repair	01JAN1978	31DEC1978	N
			Internal fixation of fracture	01JAN2016	31DEC2016	N
			Pterygium operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1019 10191280	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2013		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2011	31DEC2011	N
			Hand fracture	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1019 10191281	Eye disorders	Presbyopia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Pneumonia	01JAN2010	31DEC2010	N
		Investigations	Cardiac murmur	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Substance use	01JAN1991	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01OCT2000	31OCT2000	N
				01OCT2014	31OCT2014	N
	C4591001 1019 10191288	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Myopia	01JAN1981		Y
		Infections and infestations	Genital herpes	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1972		Y
	C4591001 1019 10191289	Eye disorders	Presbyopia	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Herpes simplex	01JAN1996		Y
			Pelvic inflammatory disease	01JAN2000	31DEC2001	N
			Urinary tract infection	01JAN1988		Y
		Investigations	Cardiac murmur	01JAN1968		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Gastrectomy	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salpingectomy	01JAN2001	31DEC2001	N
	C4591001 1019 10191290	Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Eye disorders	Myopia	01JAN1995		Y
		Infections and infestations	Sinusitis	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2017	31DEC2017	N
	C4591001 1019 10191292	Eye disorders	Cataract	01JAN2017		Y
			Myopia	01JAN1976		Y
			Presbyopia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1985	31DEC2017	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1998	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
			Carpal tunnel decompression	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Open reduction of fracture	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191293	Eye disorders	Myopia	01JAN1988	31DEC2011	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1992		Y
			Haemorrhoids	01JAN2010		Y
		Immune system disorders	Rubber sensitivity	01JAN2011		Y
		Infections and infestations	Herpes zoster	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1998	31DEC1998	N
			Foot fracture	01JAN2018	31DEC2018	N
			Hand fracture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Obesity	01JAN2008	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Neck pain	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Social circumstances	Substance use	01JAN1998	31DEC2003	N
			Tobacco user	01JAN1998	31DEC2012	N
		Surgical and medical procedures	Gastrectomy	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1019 10191295	Eye disorders	Myopia	01JAN1998		Y
			Presbyopia	01JAN2019		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191296	Eye disorders	Myopia	01JAN1988		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1019 10191301	Eye disorders	Myopia	01JAN2002		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
			Prognathism	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Contraception	01JAN2006		Y
			Mammoplasty	01JAN2005	31DEC2005	N
			Orthognathic surgery	01JAN2019	31DEC2019	N
			Tenoplasty	01JAN2019	31DEC2019	N
	C4591001 1019 10191304	Eye disorders	Myopia	01JAN1992		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N
	C4591001 1019 10191305	Congenital, familial and genetic disorders	Brachymetatarsia	01JAN2000	31DEC2004	N
		Eye disorders	Myopia	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	21FEB2019	21FEB2019	N
			Wrist fracture	21FEB2019	21FEB2019	N
		Nervous system disorders	Peroneal nerve palsy	01JAN2004	31DEC2010	N
		Psychiatric disorders	Depression	01FEB2019		Y
		Surgical and medical procedures	Bone operation	01JAN2004	31DEC2004	N
			Caesarean section	05SEP2010	05SEP2010	N
			Foot operation	01JAN2010	31DEC2010	N
	C4591001 1019 10191306	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Inguinal hernia	01JAN2015		Y
		Infections and infestations	Septic arthritis staphylococcal	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Skin laceration	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Nervous system disorders	Tension headache	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1019 10191312	Ear and labyrinth disorders	Deafness bilateral	01OCT2020		Y
		Eye disorders	Myopia	01JAN2016		Y
			Presbyopia	01JAN2016		Y
		Infections and infestations	Herpes zoster	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Concussion	01JAN1980	31DEC1980	N
			Craniocerebral injury	01JAN1980	31DEC1980	N
			Upper limb fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1993	31DEC1993	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2020		Y
	C4591001 1019 10191315	Surgical and medical procedures	Arthrodesis	01JAN2002	31DEC2002	N
		Eye disorders	Myopia	01JAN2010		Y
			Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011	31DEC2012	N
			Hiatus hernia	01JAN2012	31DEC2012	N
			Intestinal obstruction	01JAN2014	31DEC2014	N
			Pancreatitis	01JAN2010	31DEC2010	N
		Infections and infestations	Osteomyelitis	01JAN2017	31DEC2017	N
		Investigations	Aspiration pleural cavity	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Back pain	01JAN2000		Y
			Muscle spasms	01JAN1989		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	01JAN2018	31DEC2018	N
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Gastrectomy	01JAN2012	31DEC2012	N
			Hernia hiatus repair	01JAN2012	31DEC2012	N
			Intestinal operation	01JAN2014	31DEC2014	N
			Toe amputation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1019 10191318	Eye disorders	Myopia	01JAN2009		Y
		Hepatobiliary disorders	Cholecystitis	01JUN2015	30JUN2015	N
			Cholelithiasis	01JUN2015	30JUN2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Nervous system disorders	Sinus headache	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2015	30JUN2015	N
	C4591001 1019 10191321	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN1997		Y
	C4591001 1021 10211011	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1021 10211012	Gastrointestinal disorders	Umbilical hernia	01JAN1975	31DEC1977	N
		Investigations	Laparoscopy	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	30SEP2015	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1995	30SEP2015	N
		Surgical and medical procedures	Hysterectomy	01SEP2015	30SEP2015	N
			Umbilical hernia repair	01JAN1977	31DEC1977	N
	C4591001 1021 10211016	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211032	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Bipolar disorder	20JUL2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1021 10211040	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Perennial allergy	01JAN1981		Y
			Seasonal allergy	01JAN1981		Y
		Infections and infestations	Tuberculosis	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
	C4591001 1021 10211042	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1995	31DEC1995	N
		Nervous system disorders	Migraine	01JAN1989		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1995	31DEC1995	N
	C4591001 1021 10211061	Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2013		Y
		Surgical and medical procedures	Bunion operation	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211066	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2003	31DEC2003	N
	C4591001 1021 10211069	Congenital, familial and genetic disorders	Congenital anomaly	01JAN1966		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN1966		Y
		Immune system disorders	Food allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1978		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Cochlea implant	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2005	31DEC2005	N
			Nasal septal operation	01JAN1990	31DEC1990	N
			Plastic surgery to the face	01JAN1986	31DEC1986	N
				01JAN2008	31DEC2008	N
	C4591001 1021 10211083	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Insomnia	01JAN2019		Y
	C4591001 1021 10211092	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2004	31DEC2004	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2004	31DEC2004	N
			Caesarean section	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211097	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1988		Y
		Surgical and medical procedures	Vasectomy	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1021 10211099	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2009	31DEC2009	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	01JUL2020	N
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
			Brain operation	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2018	31DEC2018	N
			Hysterectomy	01JUL2020	01JUL2020	N
			Thyroidectomy	01JAN2009	31DEC2009	N
	C4591001 1021 10211101	Endocrine disorders	Hypothyroidism	01AUG2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Food allergy	01JAN1991		Y
			Seasonal allergy	01JAN2013		Y
		Investigations	Biopsy breast normal	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1021 10211104	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1021 10211112	Injury, poisoning and procedural complications	Thermal burn	01NOV2000	30NOV2000	N
		Surgical and medical procedures	Skin graft	01NOV2000	30NOV2000	N
	C4591001 1021 10211117	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Post-traumatic stress disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Vascular disorders	Hypotension	01JAN2000		Y
	C4591001 1021 10211119	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
			Rhinitis perennial	01JAN1996		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1021 10211123	Infections and infestations	Appendicitis perforated	28JUN2020	28JUN2020	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	28JUN2020	28JUN2020	N
	C4591001 1021 10211127	Cardiac disorders	Cardiac failure congestive	01JAN2016		Y
			Cardiomyopathy	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2013		Y
		Investigations	Heart rate irregular	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01DEC2019		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1021 10211130	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2008	31DEC2008	N
			Nasal septum deviation	01JAN1987	31DEC2008	N
			Rhinitis perennial	01JAN2005		Y
		Surgical and medical procedures	Nasal polypectomy	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211142	Respiratory, thoracic and mediastinal disorders	Pleurisy	01JAN2017		Y
		Surgical and medical procedures	Dental implantation	01JAN2017	31DEC2017	N
	C4591001 1021 10211146	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Myopia	01JAN1981		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Fungal infection	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
			Wrist fracture	01JAN2018	31DEC2018	N
		Investigations	Biopsy breast	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2019		Y
			Type 2 diabetes mellitus	16OCT2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
				01JAN2018		Y
				01JAN2019		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2003	31DEC2003	N
			Uterine leiomyoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Gastric banding	01JAN2013	31DEC2013	N
			Gastric banding reversal	01JAN2019	31DEC2019	N
			Hysterectomy	01DEC2009	31DEC2009	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Knee operation	01JAN2010	31DEC2010	N
			Oophorectomy	01DEC2009	31DEC2009	N
			Shoulder operation	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wrist surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1021 10211147	Eye disorders	Dry eye	01JAN2013		Y
		Gastrointestinal disorders	Gastrointestinal hypomotility	01NOV2018		Y
			Gastroesophageal reflux disease	01JAN2004		Y
			Hiatus hernia	01NOV2018		Y
		Hepatobiliary disorders	Cholelithiasis	01NOV2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Obesity	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2004		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2016	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
			Sleep apnoea syndrome	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2017		Y
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1021 10211149	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2015	31DEC2015	N
	C4591001 1021 10211152	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Insomnia	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
	C4591001 1021 10211154	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1021 10211156	Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1021 10211157	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1021 10211158	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
	C4591001 1021 10211168	Injury, poisoning and procedural complications	Gun shot wound	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Bone marrow donation	01JAN2010	31DEC2010	N
			Wound treatment	01JAN2000	31DEC2000	N
	C4591001 1021 10211182	Infections and infestations	Staphylococcal infection	01JAN1977	31DEC1977	N
		Injury, poisoning and procedural complications	Muscle injury	01JAN1977		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN1996		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
	C4591001 1021 10211185	Cardiac disorders	Pericarditis	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Oesophagitis	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Injury, poisoning and procedural complications	Gastrointestinal procedural complication	01JAN1997		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN1981	31DEC1981	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Lymphoma operation	01JAN1981	31DEC1981	N
			Splenectomy	01JAN1981	31DEC1981	N
	C4591001 1021 10211202	Immune system disorders	Food allergy	01JAN2016		Y
			Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Dental implantation	01JAN2010	31DEC2010	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1021 10211211	Eye disorders	Glaucoma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1021 10211212	Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Limb operation	01JAN1987	31DEC1987	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1021 10211213	Gastrointestinal disorders	Inguinal hernia	01JAN2002	31DEC2002	N
		Immune system disorders	Food allergy	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2002	31DEC2002	N
	C4591001 1021 10211219	Cardiac disorders	Ventricular tachycardia	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Surgical and medical procedures	Jaw operation	01JAN2003	31DEC2003	N
	C4591001 1021 10211220	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Spinal cord neoplasm	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211223	Eye disorders	Dacryostenosis acquired	01JAN1980	31DEC1980	N
		Gastrointestinal disorders	Oesophageal disorder	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
		Surgical and medical procedures	Lacrimal duct procedure	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1021 10211224	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
					31DEC2017	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
	C4591001 1021 10211230	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillolith	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Dental operation	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1021 10211239	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2005	31DEC2007	N
		Surgical and medical procedures	Ankle operation	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JAN2010	31DEC2010	N
			Tendon sheath incision	01JAN2007	31DEC2007	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1021 10211240	Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Tenoplasty	01JAN2015	31DEC2015	N
	C4591001 1021 10211242	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2019	31DEC2019	N
			Joint injury	01JAN1989	31DEC2014	N
			Meniscus injury	01JAN1990	31DEC1990	N
			Tendon rupture	01JAN1998	31DEC1998	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Knee operation	01JAN1989	31DEC2014	N
				01JAN1990	31DEC1990	N
			Limb operation	01JAN2019	31DEC2019	N
			Tenoplasty	01JAN1998	31DEC1998	N
	C4591001 1021 10211244	Investigations	Laparoscopy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
			Synovial cyst removal	01JAN2012	31DEC2012	N
	C4591001 1021 10211245	Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1021 10211246	Immune system disorders	Drug hypersensitivity	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1021 10211247	Injury, poisoning and procedural complications	Ligament rupture	01JAN1986	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN1993	31DEC1999	N
			Depression	01JAN2017		Y
		Surgical and medical procedures	Joint arthroplasty	01JAN1993	31DEC1993	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Knee operation	01JAN1986	31DEC1986	N
				01JAN1993	31DEC1993	N
				01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1021 10211248	Hepatobiliary disorders	Biliary tract disorder	01MAY2017	31DEC2017	N
			Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
				01JAN2010		Y
			Food allergy	01JAN2007		Y
		Infections and infestations	Breast abscess	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
		Surgical and medical procedures	Abscess drainage	01JAN2016	31DEC2016	N
			Bile duct stent removal	01AUG2017	31AUG2017	N
				01JUL2017	31JUL2017	N
			Biliary stent placement	01JUN2017	30JUN2017	N
				01MAY2017	31MAY2017	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Female sterilisation	01JAN2017	31DEC2017	N
			Tooth extraction	01JAN2016	31DEC2016	N
	C4591001 1021 10211252	Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2011	31DEC2011	N
			Gun shot wound	01JAN2002	31DEC2002	N
			Hip fracture	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2013		Y
		Surgical and medical procedures	Hip surgery	01JAN2007	31DEC2007	N
			Toe amputation	01JAN2002	31DEC2002	N
	C4591001 1022 10221004	Metabolism and nutrition disorders	Hyperglycaemia	15OCT2001		Y
			Obesity	15OCT2001		Y
	C4591001 1022 10221010	Musculoskeletal and connective tissue disorders	Back pain	17APR2017		Y
		Vascular disorders	Hypertension	05NOV2019		Y
	C4591001 1022 10221013	Injury, poisoning and procedural complications	Facial bones fracture	05MAR2015		Y
			Muscle strain	05MAR2015		Y
		Psychiatric disorders	Post-traumatic stress disorder	07MAY2012		Y
		Vascular disorders	Hypertension	24APR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221017	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	04SEP2017		Y
		Immune system disorders	Seasonal allergy	03NOV2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	03JUL2018		Y
			Sacroiliitis	04OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03FEB2006		Y
	C4591001 1022 10221018	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1022 10221019	Social circumstances	Menopause	01JAN2015		Y
	C4591001 1022 10221020	Hepatobiliary disorders	Cholelithiasis	12MAR2010		Y
		Immune system disorders	Seasonal allergy	06JUN2018		Y
		Metabolism and nutrition disorders	Obesity	07JUL2011		Y
		Psychiatric disorders	Adjustment disorder	30MAR2017		Y
		Vascular disorders	Hypertension	28JAN2019		Y
	C4591001 1022 10221023	Hepatobiliary disorders	Cholelithiasis	16JUN2014		Y
		Metabolism and nutrition disorders	Obesity	08MAY2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis reactive	24JUN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01SEP2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	15MAY2012		Y
	C4591001 1022 10221024	Metabolism and nutrition disorders	Obesity	23JAN2017		Y
		Nervous system disorders	Headache	23JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Migraine	21MAY2018		Y
		Psychiatric disorders	Anxiety	01DEC2016		Y
			Depression	06JUL2018		Y
	C4591001 1022 10221025	Gastrointestinal disorders	Gastroesophageal reflux disease	10DEC2011		Y
			Irritable bowel syndrome	10DEC2011		Y
		Metabolism and nutrition disorders	Obesity	10DEC2011		Y
			Vitamin D deficiency	21JAN2014		Y
		Musculoskeletal and connective tissue disorders	Neck pain	10DEC2011		Y
		Nervous system disorders	Migraine	17JAN2020		Y
			Tension headache	10DEC2011		Y
		Psychiatric disorders	Major depression	07NOV2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26NOV2013		Y
	C4591001 1022 10221027	Immune system disorders	Seasonal allergy	26JUN2013		Y
		Psychiatric disorders	Anxiety	10FEB2012		Y
			Depression	10FEB2012		Y
	C4591001 1022 10221028	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10APR2018		Y
	C4591001 1022 10221030	Endocrine disorders	Goitre	05MAY2003		Y
		Gastrointestinal disorders	Dysphagia	12MAY2020		Y
			Gastroesophageal reflux disease	27OCT2014		Y
			Pelvic floor dysfunction	15JUL2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	06DEC2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	29JUL2020		Y
			Back pain	18MAY2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck pain	18MAY2012		Y
			Tendonitis	15JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	09NOV2012		Y
		Psychiatric disorders	Insomnia	05AUG2013		Y
		Social circumstances	Menopause	25SEP2017		Y
		Surgical and medical procedures	Female sterilisation	01AUG2011		Y
		Vascular disorders	Hypertension	13MAY2014		Y
	C4591001 1022 10221031	Psychiatric disorders	Depression	17OCT2019		Y
	C4591001 1022 10221033	Cardiac disorders	Palpitations	06MAY2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	22JUN2009		Y
		Nervous system disorders	Migraine	12JUL2016		Y
		Reproductive system and breast disorders	Endometriosis	25JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	08JAN2008		Y
			Rhinitis allergic	25JAN2016		Y
		Social circumstances	Menopause	08AUG2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1022 10221035	Psychiatric disorders	Generalised anxiety disorder	05JAN2017		Y
			Insomnia	10SEP2002		Y
			Major depression	08MAY2018		Y
		Surgical and medical procedures	Intrauterine contraception	23APR2018		Y
	C4591001 1022 10221040	Metabolism and nutrition disorders	Hyperlipidaemia	29APR2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	29APR2013		Y
		Nervous system disorders	Headache	29APR2013		Y
			Sciatica	29APR2013		Y
		Renal and urinary disorders	Chronic kidney disease	21MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26JUN2013		Y
		Skin and subcutaneous tissue disorders	Psoriasis	20OCT2018		Y
		Vascular disorders	Hypertension	29APR2013		Y
	C4591001 1022 10221043	Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	18MAR2009		Y
	C4591001 1022 10221048	Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood glucose increased	29JUL2020		Y
	C4591001 1022 10221049	Nervous system disorders	Migraine	09OCT2017		Y
		Reproductive system and breast disorders	Infertility	15SEP2016		Y
	C4591001 1022 10221051	Nervous system disorders	Migraine	09SEP2010		Y
		Reproductive system and breast disorders	Menorrhagia	25APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	04OCT2017		Y
	C4591001 1022 10221052	Psychiatric disorders	Depression	10JUN2018		Y
			Insomnia	23SEP2019		Y
	C4591001 1022 10221054	Skin and subcutaneous tissue disorders	Acne	15AUG2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221055	Cardiac disorders	Palpitations	01MAY2020		Y
		Immune system disorders	Seasonal allergy	10NOV2019		Y
		Nervous system disorders	Arachnoid cyst	11NOV2019	11NOV2019	N
		Psychiatric disorders	Anxiety	12NOV2019		Y
			Depression	01JAN2003		Y
			Insomnia	11NOV2019		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	12NOV2019		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2015		Y
	C4591001 1022 10221062	Musculoskeletal and connective tissue disorders	Arthralgia	09JUL2014		Y
			Back pain	14JAN2019		Y
	C4591001 1022 10221064	Surgical and medical procedures	Intrauterine contraception	18OCT2019		Y
		Metabolism and nutrition disorders	Overweight	28MAY2020		Y
	C4591001 1022 10221066	Gastrointestinal disorders	Irritable bowel syndrome	05OCT2009		Y
		Immune system disorders	Seasonal allergy	01DEC2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	27NOV2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	23SEP2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1022 10221069	Congenital, familial and genetic disorders	Factor V Leiden mutation	23JAN2009		Y
			Type IIa hyperlipidaemia	12AUG2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	04DEC2012		Y
		Nervous system disorders	Cervical radiculopathy	10JUL2013		Y
		Psychiatric disorders	Generalised anxiety disorder	21MAR2018		Y
			Post-traumatic stress disorder	21MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	20JUL2008		Y
	C4591001 1022 10221070	Surgical and medical procedures	Hysterectomy	20JAN2009	20JAN2009	N
		Infections and infestations	Bronchitis	10JUL2015		Y
		Investigations	Hysteroscopy	19JUL2017	19JUL2017	N
		Metabolism and nutrition disorders	Obesity	04MAY2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	20MAY2019		Y
		Psychiatric disorders	Insomnia	13AUG2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JUL2000		Y
		Surgical and medical procedures	Intrauterine contraception	15SEP2018		Y
	C4591001 1022 10221076	Musculoskeletal and connective tissue disorders	Tendonitis	01APR2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1022 10221078	Endocrine disorders	Anovulatory cycle	01JAN1987		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1995		Y
	C4591001 1022 10221080	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN1989		Y
	C4591001 1022 10221081	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	10JAN2013		Y
		Nervous system disorders	Lumbar radiculopathy	31JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	15SEP2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	31AUG2017		Y
			Rhinitis allergic	10JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	06NOV2017		Y
		Skin and subcutaneous tissue disorders	Skin maceration	10JAN2013		Y
	C4591001 1022 10221083	Endocrine disorders	Adrenal insufficiency	28JUN2016		Y
			Hypothyroidism	28JUN2016		Y
		Metabolism and nutrition disorders	Hyponatraemia	27JUN2016	27JUN2016	N
			Vitamin D deficiency	27JUN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	16MAY2016	31MAY2016	N
		Psychiatric disorders	Depression	02JUN2020		Y
		Reproductive system and breast disorders	Infertility	05JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Snoring	28OCT2016		Y
	C4591001 1022 10221084	Musculoskeletal and connective tissue disorders	Arthritis	15MAY2012		Y
			Back pain	15MAY2012		Y
				18SEP2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	18SEP2012		Y
		Surgical and medical procedures	Intrauterine contraception	03JAN2017		Y
	C4591001 1022 10221093	Gastrointestinal disorders	Irritable bowel syndrome	10MAY2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	09MAR2018		Y
			Sacroiliitis	02JAN2019		Y
		Nervous system disorders	Migraine	28OCT2009		Y
			Neuropathy peripheral	29JUN2010		Y
		Psychiatric disorders	Insomnia	25OCT2011		Y
		Social circumstances	Menopause	21MAR2019		Y
		Surgical and medical procedures	Oophorectomy bilateral	01MAY2019	31MAY2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221094	Cardiac disorders	Mitral valve disease	20APR2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	15DEC2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1022 10221098	Gastrointestinal disorders	Gastrooesophageal reflux disease	07MAY2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	29APR2019		Y
		Skin and subcutaneous tissue disorders	Acne	26FEB2009		Y
		Surgical and medical procedures	Intrauterine contraception	10JAN2019		Y
		Vascular disorders	Orthostatic hypotension	07MAY2013		Y
	C4591001 1022 10221100	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25AUG2014		Y
	C4591001 1022 10221101	Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Hyperlipidaemia	13DEC2018		Y
			Obesity	22NOV2010		Y
			Type 2 diabetes mellitus	13DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Hypoxia	28OCT2015		Y
			Sleep apnoea syndrome	28OCT2015		Y
		Social circumstances	Menopause	13DEC2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
			Cholecystectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	23JUN2014		Y
	C4591001 1022 10221105	Gastrointestinal disorders	Constipation	26SEP2018		Y
			Gastrooesophageal reflux disease	26SEP2018		Y
			Irritable bowel syndrome	26SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Gastroenteritis	21JUN2018		Y
		Psychiatric disorders	Anxiety	21SEP2017		Y
			Depression	26SEP2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21SEP2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1022 10221106	Endocrine disorders	Hypothyroidism	11NOV2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30SEP2016		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	27MAY2015	16JUN2015	N
	C4591001 1022 10221108	Hepatobiliary disorders	Cholelithiasis	01JAN2018	01JUN2020	N
		Surgical and medical procedures	Cholecystectomy	01JUN2020	01JUN2020	N
	C4591001 1022 10221110	Psychiatric disorders	Depression	24NOV2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	10JUN2013		Y
			Rhinitis allergic	10JUN2013		Y
	C4591001 1022 10221111	Metabolism and nutrition disorders	Obesity	06AUG2008		Y
		Reproductive system and breast disorders	Amenorrhoea	01OCT2011		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	20JUL2012		Y
			Sleep apnoea syndrome	27AUG2002		Y
			Tonsillar hypertrophy	27AUG2002		Y
	C4591001 1022 10221115	Gastrointestinal disorders	Irritable bowel syndrome	08FEB2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Immune system disorders	Seasonal allergy	15MAR2016		Y
		Psychiatric disorders	Insomnia	15MAR2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	08FEB2005		Y
	C4591001 1022 10221117	Metabolism and nutrition disorders	Hyperlipidaemia	12AUG2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	22APR2014		Y
		Vascular disorders	Hypertension	20APR2014		Y
	C4591001 1022 10221120	Gastrointestinal disorders	Gastroesophageal reflux disease	06OCT2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	08MAY2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	08MAY2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	18FEB2002		Y
		Vascular disorders	Hypertension	08MAY2019		Y
	C4591001 1022 10221122	Cardiac disorders	Pulmonary valve stenosis	01JAN2011		Y
		Endocrine disorders	Hypothyroidism	01MAY2011		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12DEC2012		Y
	C4591001 1022 10221123	Endocrine disorders	Hypothyroidism	07JUN2012		Y
		Gastrointestinal disorders	Constipation	17JUL2015		Y
			Irritable bowel syndrome	03OCT2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01OCT2006		Y
			Osteoarthritis	05SEP2008		Y
		Social circumstances	Menopause	02MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221127	Gastrointestinal disorders	Haemorrhoids	01JAN2004		Y
	C4591001 1022 10221128	Nervous system disorders	Syncope	27MAR2014		Y
		Psychiatric disorders	Anxiety	10JUL2017		Y
			Insomnia	14MAY2020		Y
	C4591001 1022 10221129	Surgical and medical procedures	Intrauterine contraception	10JUL2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1022 10221131	Injury, poisoning and procedural complications	Rhinitis allergic Wrist fracture	01JAN1985 01SEP2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2006	31MAY2006	N
		Nervous system disorders	Cervical radiculopathy	24FEB2020		Y
		Renal and urinary disorders	Nephrolithiasis	01AUG2007	31AUG2007	N
	C4591001 1022 10221133	Immune system disorders	Seasonal allergy	17JUL2014		Y
	C4591001 1022 10221134	Blood and lymphatic system disorders	Anaemia	19APR2013		Y
		Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19APR2013		Y
		Nervous system disorders	Migraine	19APR2013		Y
			Restless legs syndrome	19APR2013		Y
		Vascular disorders	Hypertension	19APR2013		Y
	C4591001 1022 10221136	Endocrine disorders	Hypothyroidism	18JUL2018		Y
		Psychiatric disorders	Anxiety	18JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obsessive-compulsive disorder	24JUL2018		Y
	C4591001 1022 10221137	Congenital, familial and genetic disorders	Congenital cystic kidney disease	19FEB2016		Y
		Gastrointestinal disorders	Irritable bowel syndrome	02APR2009		Y
		Psychiatric disorders	Depression	13FEB2014		Y
			Generalised anxiety disorder	23MAR2007		Y
			Insomnia	19OCT2018		Y
		Surgical and medical procedures	Hysterectomy	01NOV2014	30NOV2014	N
		Vascular disorders	Hypertension	26JUN2015		Y
	C4591001 1022 10221138	Cardiac disorders	Atrial fibrillation	21JUL2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	21JUL2005		Y
		Nervous system disorders	Migraine	18FEB2011		Y
		Renal and urinary disorders	Calculus urinary	25FEB2004	25FEB2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	13SEP2013		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1022 10221139	Psychiatric disorders	Depression	20JUN2020		Y
		Reproductive system and breast disorders	Menstruation irregular	25FEB2019		Y
	C4591001 1022 10221142	Metabolism and nutrition disorders	Overweight	08DEC2015		Y
		Nervous system disorders	Migraine	08DEC2015		Y
	C4591001 1022 10221143	Immune system disorders	Seasonal allergy	16JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUN2011	30JUN2011	N
		Reproductive system and breast disorders	Cervical dysplasia	25JUL2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dysmenorrhoea	16JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10APR2016		Y
		Surgical and medical procedures	Female sterilisation	19MAY2004	19MAY2004	N
	C4591001 1022 10221147	Metabolism and nutrition disorders	Lactose intolerance	03JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2019		Y
	C4591001 1022 10221156	Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
	C4591001 1022 10221164	Blood and lymphatic system disorders	Anaemia	03AUG2020		Y
			Macrocytosis	23APR2018		Y
		Hepatobiliary disorders	Cholelithiasis	27AUG2019		Y
		Metabolism and nutrition disorders	Obesity	02FEB2010	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	13DEC2016	13DEC2016	N
		Psychiatric disorders	Depression	05JUL2012		Y
			Post-traumatic stress disorder	24JUN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	25AUG2010		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1022 10221179	General disorders and administration site conditions	Fatigue	24NOV2014		Y
	C4591001 1024 10241001	Nervous system disorders	Migraine	01AUG2006		Y
		Psychiatric disorders	Binge eating	01MAR2017		Y
			Depression	01MAR2017		Y
	C4591001 1024 10241002	Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241004	Psychiatric disorders	Depression	01JAN2003		Y
		Social circumstances	Drug abuser	01JAN2010	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
	C4591001 1024 10241011	Investigations	Blood cholesterol increased	01JUL2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JUN2020		Y
	C4591001 1024 10241012	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1024 10241021	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	08FEB2018	08FEB2018	N
	C4591001 1024 10241023	Surgical and medical procedures	Female sterilisation	19AUG2002	19AUG2002	N
	C4591001 1024 10241029	Surgical and medical procedures	Endometrial ablation	06JUN2019	06JUN2019	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1024 10241030	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1024 10241032	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1024 10241042	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
	C4591001 1024 10241046	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1024 10241051	Endocrine disorders	Hypothyroidism	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241052	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN2019	31JUL2019	N
		Surgical and medical procedures	Mastectomy	01JUN2019	31JUL2019	N
	C4591001 1024 10241054	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1024 10241056	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1024 10241058	Surgical and medical procedures	Vasectomy	01SEP2002	30SEP2002	N
	C4591001 1024 10241061	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1024 10241067	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
	C4591001 1024 10241070	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1024 10241073	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
	C4591001 1024 10241075	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1024 10241078	Investigations	Blood cholesterol increased	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1024 10241084	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241085	Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
	C4591001 1024 10241086	Psychiatric disorders	Depression	01JAN1995		Y
	C4591001 1024 10241088	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1024 10241090	Endocrine disorders	Depression Hypothyroidism	01JAN2019 01JAN2015		Y Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1024 10241092	Surgical and medical procedures	Hysterectomy	20MAY2007	20MAY2007	N
	C4591001 1024 10241098	Investigations	Blood cholesterol increased	01JAN2013		Y
	C4591001 1024 10241100	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1024 10241101	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2019		Y
		Hepatobiliary disorders	Cholecystitis	22AUG2017	22AUG2017	N
		Surgical and medical procedures	Gastrectomy	01DEC2019	30DEC2019	N
	C4591001 1024 10241102	Surgical and medical procedures	Hysterectomy	26AUG2011	26AUG2011	N
	C4591001 1024 10241104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1024 10241106	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241107	Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1024 10241108	Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1024 10241109	Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1024 10241114	Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1024 10241118†	General disorders and administration site conditions	Fatigue	14JAN2020		Y
			Oedema peripheral	14JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Investigations	HIV test positive	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	14JAN2020		Y
			Intervertebral disc degeneration	01JAN2015		Y
			Muscular weakness	14JAN2020		Y
		Nervous system disorders	Headache	14JAN2020		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2015	31DEC2015	N
	C4591001 1024 10241121†	Gastrointestinal disorders	Diarrhoea	15SEP2020		Y
			Irritable bowel syndrome	01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
			HIV test positive	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1024 10241123†	Investigations	HIV test positive	03JUN2015		Y
	C4591001 1024 10241124†	Investigations	HIV test positive	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1024 10241129	Investigations	Blood cholesterol increased	01MAR2020		Y
	C4591001 1027 10271005	Infections and infestations	Oral herpes	01JAN1977		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Micrographic skin surgery	01DEC2019	31DEC2019	N
	C4591001 1027 10271012	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
			Foot deformity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1027 10271017	Gastrointestinal disorders	Diverticulum intestinal	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
				01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN1987		Y
	C4591001 1027 10271019	Injury, poisoning and procedural complications	Ankle fracture	23JUN2020	24JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01SEP2019		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1027 10271026	Immune system disorders	Allergy to arthropod sting	01JAN1990		Y
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1984		Y
		Infections and infestations	Genital herpes	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1027 10271028	Immune system disorders	Allergy to arthropod bite	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN1996		Y
		Psychiatric disorders	Depression	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
	C4591001 1027 10271029	Injury, poisoning and procedural complications	Cartilage injury	01OCT2015	31OCT2015	N
			Road traffic accident	01JAN1968	31DEC1968	N
		Investigations	Arthroscopy	01OCT2015	31OCT2015	N
		Musculoskeletal and connective tissue disorders	Muscle atrophy	01JAN1968		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Mammoplasty	01JAN1998	31DEC1998	N
	C4591001 1027 10271032	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019	31OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Knee operation	01OCT2019	31OCT2019	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1027 10271033	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1027 10271037	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1027 10271040	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1027 10271041	Infections and infestations	Appendicitis	01JUN2020	30JUN2020	N
		Surgical and medical procedures	Appendicectomy	01JUN2020	30JUN2020	N
			Vasectomy	01JAN2020	31JAN2020	N
	C4591001 1027 10271046	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2002	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1027 10271049	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Gout	01JAN2008		Y
			Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1027 10271058	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
	C4591001 1027 10271059	Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
	C4591001 1027 10271061	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2020		Y
	C4591001 1027 10271079	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Orchidectomy	01JAN2003	31DEC2003	N
	C4591001 1027 10271083	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rash	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1027 10271086	Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1027 10271091	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1027 10271094	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2020	31JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2020	31JAN2020	N
			Thyroidectomy	01JAN2020	31JAN2020	N
	C4591001 1027 10271104	Renal and urinary disorders	Nephrolithiasis	01JUL2014		Y
	C4591001 1027 10271105	Cardiac disorders	Mitral valve prolapse	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN1996		Y
			Iodine allergy	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1027 10271107	Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Nausea	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Psychiatric disorders	Depression	01NOV1999		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1027 10271108	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Vulvovaginal mycotic infection	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Back pain	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Insomnia	01JAN1994		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1027 10271119	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Eye disorders	Dry eye	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
				01JAN1975		Y
				01JAN1982		Y
				01JAN1986		Y
			Hypersensitivity	01JAN1978		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
			Uterine leiomyoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1027 10271126	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
	C4591001 1027 10271127	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
	C4591001 1027 10271129	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
	C4591001 1027 10271145	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1027 10271152	Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1027 10271155	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JUN2020		Y
	C4591001 1027 10271157	Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1027 10271158	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Insomnia	01JAN2009		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Micrographic skin surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271162	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1027 10271163	Blood and lymphatic system disorders	Anaemia	01JAN1999	31DEC2001	N
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1027 10271172	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1027 10271173	Immune system disorders	Food allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
	C4591001 1027 10271182	Metabolism and nutrition disorders	Iron deficiency	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271183	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1027 10271192	Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1027 10271193	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Nervous system disorders	Syncope	01JAN2009	28FEB2019	N
		Psychiatric disorders	Anxiety	01JAN2001		Y
	C4591001 1027 10271199	Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1027 10271203	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
			Plantar fasciitis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2019	N
		Nervous system disorders	Migraine	01JAN1983		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Renal and urinary disorders	Haematuria	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2016		Y
	C4591001 1027 10271207†	Cardiac disorders	Coronary artery disease	01JAN2012		Y
			Myocardial infarction	01JAN2012	31DEC2012	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1975		Y
		Investigations	HIV test positive	01JAN1996		Y
		Metabolism and nutrition disorders	Gout	01JAN2011		Y
			Hyperlipidaemia	01JAN2006		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1027 10271208†	Injury, poisoning and procedural complications	Ulna fracture	01JAN2004	31DEC2004	N
		Investigations	HIV test positive	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Schizophrenia	01JAN2015	31DEC2018	N
		Renal and urinary disorders	Acute kidney injury	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Bone operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1027 10271212†	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Food allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JUL2020	15AUG2020	N
		Investigations	HIV test positive	01JUN2007		Y
		Psychiatric disorders	Tobacco abuse	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2013		Y
	C4591001 1027 10271214	Surgical and medical procedures	Open reduction of fracture	15AUG2020	15AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1027 10271215	Social circumstances	Postmenopause	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1027 10271216	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Seasonal allergy	01JAN1983		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1028 10281001	Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
	C4591001 1028 10281002	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Vasectomy	02DEC2019	02DEC2019	N
	C4591001 1028 10281003	Eye disorders	Myopia	01JAN1994		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Hypersensitivity	01JAN2013		Y
		Surgical and medical procedures	Abortion induced	01JUL2013	31JUL2013	N
			Haemorrhoid operation	01JAN2009	31DEC2009	N
	C4591001 1028 10281005	Psychiatric disorders	Drug abuse	01JAN1995	31DEC1996	N
			Nicotine dependence	01JAN1995	31DEC2010	N
		Social circumstances	Tobacco user	01JAN1995	31DEC2010	N
	C4591001 1028 10281007	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2010		Y
			Motion sickness	01JAN2006		Y
			Tinnitus	01JAN1975		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	13MAY2014	N
		Infections and infestations	Staphylococcal infection	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2017		Y
			Hand fracture	01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN1997	31DEC1997	N
				01JAN2009	31DEC2009	N
				14NOV2018	14NOV2018	N
			Hysteroscopy	06APR2017	06APR2017	N
				17NOV2017	17NOV2017	N
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2018		Y
			Obesity	01JAN2010	17AUG2020	N
			Vitamin B12 deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1997		Y
			Arthropathy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN1995		Y
			Exostosis	01JAN2009		Y
			Fibromyalgia	01JAN2006		Y
			Foot deformity	01JAN2007	31DEC2007	N
			Muscle spasms	01JAN2000		Y
			Neck pain	01JAN1997		Y
			Osteoarthritis	01JAN2005		Y
			Synovial cyst	01JAN2019		Y
			Tendonitis	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2018		Y
			Nicotine dependence	01JAN1988	31DEC2006	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1984	17NOV2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Bunion operation	01JAN2007	31DEC2007	N
			Cholecystectomy	13MAY2014	13MAY2014	N
			Gastric bypass	01JAN2011	31DEC2011	N
			Hysterectomy	17NOV2017	17NOV2017	N
			Intervertebral disc operation	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
			Large intestinal polypectomy	14NOV2019	14NOV2019	N
			Rotator cuff repair	01JAN2009	31DEC2018	N
			Uterine dilation and curettage	06APR2017	06APR2017	N
			Wrist surgery	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281009	Psychiatric disorders	Anxiety	01NOV2019		Y
			Depression	01NOV2019		Y
			Insomnia	01FEB2020		Y
	C4591001 1028 10281010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
			Onychomycosis	01JAN1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1028 10281013	Investigations	Colonoscopy	13MAR2019	13MAR2019	N
			Laparoscopy	01JAN1998	31DEC1998	N
			Nasoendoscopy	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	15AUG2018		Y
			Impaired fasting glucose	15AUG2018		Y
			Iron deficiency	15MAY2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2018	31DEC2019	N
			Skin papilloma	18SEP2019	18NOV2019	N
		Nervous system disorders	Migraine	01JAN2017	31DEC2018	N
		Reproductive system and breast disorders	Amenorrhoea	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Lentigo	18SEP2019		Y
			Photodermatosis	18SEP2019		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	17OCT2019	17OCT2019	N
			Nasal septal operation	01JAN1994	31DEC1994	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	15MAY2017		Y
	C4591001 1028 10281017	Endocrine disorders	Basedow's disease	01JAN2012		Y
			Hypothyroidism	01JAN2017		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JUN2020	30JUN2020	N
		Investigations	Arthroscopy	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2008	31DEC2008	N
		Psychiatric disorders	Insomnia	01JAN2020		Y
			Nicotine dependence	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN1992		Y
		Social circumstances	Tobacco user	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2008	31DEC2008	N
	C4591001 1028 10281018	Injury, poisoning and procedural complications	Ligament injury	01JAN2012	14DEC2018	N
			Ligament rupture	01JAN2015	14DEC2018	N
			Meniscus injury	01JAN2015	14DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	14DEC2018	14DEC2018	N
	C4591001 1028 10281019	Eye disorders	Dry eye	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Nervous system disorders	Dizziness	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Hirsutism	01JAN2007	31DEC2019	N
		Surgical and medical procedures	Adenoidectomy	01JAN1988	31DEC1988	N
			Caesarean section	05FEB2009	05FEB2009	N
				19JUN2006	19JUN2006	N
	C4591001 1028 10281022	Cardiac disorders	Palpitations	01NOV2019	30NOV2019	N
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Colonoscopy	25SEP2013	25SEP2013	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Neck pain	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1028 10281023	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Pancreatitis necrotising	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Alcohol poisoning	01OCT2019	31OCT2019	N
			Intentional overdose	01JAN2019	31DEC2019	N
		Investigations	Blood pressure increased	28MAY2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Surgical and medical procedures	Pancreatic stent placement	01JAN2017	31DEC2017	N
			Pancreatic stent removal	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1028 10281024	Cardiac disorders	Mitral valve incompetence	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Salivary gland calculus	01JAN2018	31DEC2018	N
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2006	N
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	13SEP2019		Y
			Impaired fasting glucose	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	09MAY2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2016	N
			Ovarian cyst	01JAN2014	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000	31DEC2006	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Knee arthroplasty	13JAN2020	13JAN2020	N
				20JAN2020	20JAN2020	N
			Salivary gland operation	01JAN2018	31DEC2018	N
			Salpingectomy	01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Raynaud's phenomenon	01JUL2019		Y
	C4591001 1028 10281025	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	19MAY2018	19MAY2018	N
		Nervous system disorders	Facial paralysis	01JAN2013	31DEC2013	N
		Psychiatric disorders	Nicotine dependence	01JAN1996	01JAN2007	N
				01JAN2007	31DEC2017	N
		Social circumstances	Tobacco user	01JAN1996	01JAN2007	N
				01JAN2007	31DEC2017	N
	C4591001 1028 10281026	Eye disorders	Exophthalmos	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2013		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
	C4591001 1028	Surgical and medical procedures	Lung lobectomy	01JAN1982	31DEC1982	N
	10281027	Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1988	31DEC1988	N
			Upper limb fracture	01JAN1982	31DEC1982	N
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1028		Vasectomy	01JAN2010	31DEC2010	N
	10281028	Infections and infestations	Otitis media	31DEC2019	08JAN2020	N
			Sinusitis	14JAN2020	04FEB2020	N
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Urethral operation	01JAN2008	31DEC2008	N
	C4591001 1028	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	10281029		Sinusitis	01JAN2002		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2017	31DEC2017	N
		Nervous system disorders	Febrile convulsion	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
			Sinus operation	30JUN2016	30JUN2016	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1028 10281030	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997	31DEC2010	N
		Immune system disorders	Allergy to metals	01JAN1996		Y
			Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	08MAR2010		Y
		Psychiatric disorders	Adjustment disorder	01JUN2019		Y
			Anxiety	01JAN1997		Y
			Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN1997		Y
			Obsessive-compulsive disorder	01JAN1997		Y
			Post-traumatic stress disorder	01JAN2010		Y
	C4591001 1028 10281031	Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Abdominal pain	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2018		Y
	C4591001 1028 10281033	Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
		Injury, poisoning and procedural complications	Tendon rupture	25JUN2018	07NOV2018	N
	C4591001 1028 10281035	Surgical and medical procedures	Tenoplasty	07NOV2018	07NOV2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2012	31DEC2016	N
			Migraine	01JAN2012		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2002	31DEC2016	N
			Menorrhagia	01JAN2002	31DEC2016	N
	C4591001 1028 10281036	Injury, poisoning and procedural complications	Ankle fracture	01AUG1991	31AUG1991	N
			Head injury	01AUG1991	31AUG1991	N
			Lower limb fracture	01AUG1991	31AUG1991	N
		Investigations	Arthroscopy	01JAN1994	31DEC1994	N
		Nervous system disorders	Headache	01JAN1997	31DEC2015	N
		Surgical and medical procedures	Adenoidectomy	01JAN1972	31DEC1972	N
			Appendectomy	01JAN1975	31DEC1975	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01AUG1991		Y
	C4591001 1028 10281038	Gastrointestinal disorders	Constipation	01JAN1970		Y
			Haemorrhoids	01JAN1994		Y
			Irritable bowel syndrome	01JAN1970		Y
		Immune system disorders	Reaction to colouring	01JAN2000		Y
		Infections and infestations	Diverticulitis	03JUN2019		Y
			Herpes simplex	01JAN1976		Y
		Investigations	Colonoscopy	03JUN2019	03JUN2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1994		Y
			Obesity	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Exostosis	25JUL2019		Y
			Tendonitis	25JUL2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2015	25SEP2015	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1981	25SEP2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01JUL1994	31JUL1994	N
			Hysterectomy	25SEP2015	25SEP2015	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1028 10281043	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Irritable bowel syndrome	01JAN2016		Y
		General disorders and administration site conditions	Hernia	01JAN1972	31DEC1972	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Herpes simplex	01JAN2018		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2004	31DEC2004	N
				01NOV2019	30NOV2019	N
				25JAN1997	25JAN1997	N
		Investigations	Angiogram	01JAN1992	31DEC1992	N
			Endoscopy upper gastrointestinal tract	06DEC2012	06DEC2012	N
				31DEC2012	31DEC2012	N
		Metabolism and nutrition disorders	Gout	01JAN2011		Y
			Hypercholesterolaemia	20SEP2017		Y
			Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
			Reflux laryngitis	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	29OCT2010		Y
		Surgical and medical procedures	Limb operation	01JAN1997	31DEC1997	N
			Oesophagogastric fundoplasty	01JAN2004	31DEC2004	N
				23JAN2013	23JAN2013	N
			Tenolysis	29DEC2015	29DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1028 10281044	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1028 10281047	Endocrine disorders	Hyperthyroidism	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Tooth abscess	10AUG2020	20AUG2020	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1993	31DEC2000	N
			Rhinitis allergic	01JAN1992		Y
	C4591001 1028 10281048	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Anxiety	29NOV2019		Y
	C4591001 1028 10281049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
			Hiatus hernia	28NOV2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Hand fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Oesophageal dilation procedure	24OCT2007		Y
			Open reduction of fracture	01JAN1990	31DEC1990	N
	C4591001 1028 10281050	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1994		Y
		Infections and infestations	Folliculitis	01JAN1995		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Obesity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1994		Y
		Surgical and medical procedures	Hydrocele operation	01JAN1989	31DEC1989	N
			Wisdom teeth removal	01JAN2008	31DEC2008	N
	C4591001 1028 10281052	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2005		Y
			Somnolence	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281053	Immune system disorders	Food allergy	01JAN2002		Y
			Multiple allergies	01JAN2002		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
		Nervous system disorders	Headache	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2011	N
	C4591001 1028 10281054	Gastrointestinal disorders	Haemorrhoids	07DEC2018		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2010	31DEC2010	N
			Wrist fracture	01JAN1983	31DEC1987	N
		Investigations	Colonoscopy	07DEC2018	07DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	17FEB2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
			Tendonitis	01JAN2017		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1983	31DEC1983	N
				01JAN1985	31DEC1985	N
				01JAN1987	31DEC1987	N
				01JAN2010	31DEC2010	N
	C4591001 1028 10281055	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Dust allergy	01JAN2001		Y
			Food allergy	01JAN2013		Y
			Seasonal allergy	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2007	31DEC2007	N
		Investigations	Hysteroscopy	14FEB2014	14FEB2014	N
			Laparoscopy	01JAN2005	31DEC2005	N
			Liver function test increased	01JAN2007	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
			Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	14FEB2014	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Irritability	18NOV2019		Y
		Reproductive system and breast disorders	Infertility female	01JAN2010	31DEC2010	N
			Menorrhagia	01JAN2013	14FEB2014	N
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
				25SEP2013	25SEP2013	N
			Endometrial ablation	14FEB2014	14FEB2014	N
			Female sterilisation	25SEP2013	25SEP2013	N
			Fracture treatment	01JAN2007	31DEC2007	N
				01JAN2011	31DEC2011	N
			Internal fixation of fracture	01JAN2008	31DEC2008	N
			Mammoplasty	22DEC2019	22DEC2019	N
			Myomectomy	01JAN2005	31DEC2005	N
			Rhinoplasty	01JAN2000	31DEC2000	N
			Uterine dilation and curettage	01JAN2008	31DEC2008	N
	C4591001 1028 10281059	Endocrine disorders	Hypothyroidism	30AUG2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN1998		Y
		Metabolism and nutrition disorders	Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01AUG2016	30NOV2016	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1994	31DEC1994	N
	C4591001 1028 10281060	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Infections and infestations	Genital herpes simplex	01JAN1990		Y
			Vaginal infection	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1989		Y
			Facet joint syndrome	01JAN2013		Y
			Intervertebral disc degeneration	01JAN2013		Y
			Intervertebral disc protrusion	01JAN2013		Y
			Osteoarthritis	01JAN2015		Y
			Spinal osteoarthritis	01JAN2014		Y
			Spondyloarthropathy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Drug abuse	01JAN1999	31DEC2005	N
			Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dyspareunia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1028 10281061	Blood and lymphatic system disorders	Anaemia	02JUL2020		Y
		Ear and labyrinth disorders	Vertigo	01JAN2000	31DEC2000	N
		Investigations	Colonoscopy	28AUG2017	28AUG2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	17JUL2020		Y
		Surgical and medical procedures	Hysterectomy	29DEC2015	29DEC2015	N
			Large intestinal polypectomy	01JAN2017	31DEC2017	N
			Uterine dilation and curettage	01JAN1994	31DEC1994	N
		Vascular disorders	Hot flush	01JAN2016		Y
			Hypertension	01JAN1992		Y
	C4591001 1028 10281062	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2019	31JAN2020	N
		Hepatobiliary disorders	Cholelithiasis	04DEC2013	04DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2016		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2016	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Plantar fasciitis	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine with aura	01JAN2000	31DEC2018	N
		Psychiatric disorders	Binge eating	01JAN2018		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2017	15AUG2020	N
			Dyspareunia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	14JUL2020	28JUL2020	N
		Social circumstances	Postmenopause	23JUL2020		Y
		Surgical and medical procedures	Cholecystectomy	04DEC2013	04DEC2013	N
			Female sterilisation	09NOV2016	09NOV2016	N
	C4591001 1028 10281065	Immune system disorders	Allergy to metals	01JAN2019		Y
			Drug hypersensitivity	01JAN2000		Y
			Milk allergy	01JAN1996		Y
			Seasonal allergy	01JAN1996		Y
		Investigations	Smear cervix abnormal	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	26AUG2020		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1028 10281066	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Infections and infestations	Otitis media acute	01JAN1987		Y
			Tonsillitis	01JAN1996	31DEC1996	N
			Upper respiratory tract infection	21MAR2020	26MAR2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Human papilloma virus test positive	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Intervertebral disc disorder	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Binge eating	01JAN2018		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2014		Y
			Post-traumatic stress disorder	01JAN2016		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2019	31DEC2019	N
			Polycystic ovaries	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1028 10281069	Injury, poisoning and procedural complications	Joint injury	01JAN2002	31DEC2002	N
			Upper limb fracture	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003	31DEC2009	N
		Surgical and medical procedures	Wrist surgery	01JAN2002		Y
	C4591001 1028 10281070	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1988	31DEC1992	N
		Investigations	Arthroscopy	01JAN1992	31DEC1992	N
				02JUN2016	02JUN2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1984	31DEC1984	N
			Vasectomy	27JAN2012	27JAN2012	N
	C4591001 1028 10281072	Blood and lymphatic system disorders	Iron deficiency anaemia	28JUL2017		Y
		General disorders and administration site conditions	Fatigue	01JAN2020		Y
		Infections and infestations	Tonsillitis	01JAN2013	12MAR2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	28MAY2008		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Hyperhidrosis	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	12MAR2018	12MAR2018	N
			Mammoplasty	01DEC2011	31DEC2011	N
			Tonsillectomy	12MAR2018	12MAR2018	N
	C4591001 1028 10281075	Cardiac disorders	Palpitations	01JAN2018		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Contrast media allergy	01JAN1984	31DEC1984	N
			Drug hypersensitivity	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN1977		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN1977		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2004	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Mammoplasty	01JUL2013	31JUL2013	N
			Nasal septal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1028 10281077	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2009		Y
		General disorders and administration site conditions	Dysplasia	01JAN1995	31DEC1995	N
		Hepatobiliary disorders	Hepatic lesion	01JAN2018	31DEC2018	N
		Infections and infestations	Herpes zoster	01FEB2019	28FEB2019	N
				16FEB2019	31MAR2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	01APR2018		Y
			Intervertebral disc degeneration	01APR2018		Y
			Intervertebral disc protrusion	01APR2018	30APR2018	N
			Temporomandibular joint syndrome	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Lumbar radiculopathy	01APR2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01DEC2010	31DEC2010	N
			Intervertebral disc operation	07SEP2018	07SEP2018	N
			Loop electrosurgical excision procedure	01JAN1995	31DEC1995	N
	C4591001 1028 10281078	Blood and lymphatic system disorders	Anaemia	01OCT2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2013		Y
			Haemorrhoids	01JAN2015		Y
		Immune system disorders	Reaction to food additive	01JAN1990		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1999	31DEC1999	N
			Rib fracture	01MAR2010	01MAR2010	N
		Investigations	Human papilloma virus test positive	15APR2009		Y
			Smear cervix abnormal	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007	17MAR2020	N
			Vitamin D deficiency	01OCT2017		Y
		Nervous system disorders	Headache	01JAN2003		Y
			Migraine	01JAN2004		Y
			Syncope	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN2002		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dyspareunia	01JAN2008	31MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
			Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	21JAN2019	21JAN2019	N
			Salpingectomy	21JAN2019	21JAN2019	N
			Wisdom teeth removal	01JAN2001	31DEC2001	N
	C4591001 1028 10281079	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	24SEP2009		Y
		Eye disorders	Eye swelling	29DEC2014		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2007	31DEC2007	N
			Peptic ulcer	01JAN1972	31DEC1972	N
		General disorders and administration site conditions	Pain	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2013		Y
		Infections and infestations	Infectious mononucleosis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2012	31DEC2012	N
		Investigations	Angiogram	01JAN2014	31DEC2014	N
			Endoscopy upper gastrointestinal tract	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Hypertriglyceridaemia	01JAN2017		Y
			Obesity	01JAN2014		Y
		Nervous system disorders	Speech disorder	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	24SEP2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nicotine dependence	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Social circumstances	Postmenopause	12DEC2014		Y
			Tobacco user	01JAN2018		Y
		Surgical and medical procedures	Cranial operation	29DEC2014	29DEC2014	N
			Eye operation	29DEC2014	29DEC2014	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1028 10281080	Eye disorders	Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Coeliac disease	07JUN2015	21JAN2016	N
			Haemorrhoids	11MAR2015		Y
			Irritable bowel syndrome	01JAN2016		Y
		General disorders and administration site conditions	Fatigue	10JUL2020	31JUL2020	N
		Immune system disorders	Seasonal allergy	01JUN2015		Y
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
			Diverticulitis	07OCT2019	09JUL2020	N
		Investigations	Arthroscopy	01JAN1997	31DEC1997	N
				01JAN2007	31DEC2007	N
			Colonoscopy	11MAR2015	11MAR2015	N
			Colposcopy	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
			Endoscopy upper gastrointestinal tract	11MAR2015	11MAR2015	N
			Smear cervix abnormal	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Gluten sensitivity	11MAR2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
			Neck pain	01JAN2016		Y
			Osteoarthritis	01JAN1997		Y
			Rotator cuff syndrome	01JUN2020	10AUG2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	19MAR2012	21JAN2016	N
		Nervous system disorders	Headache	01JAN2007		Y
			Migraine	01JAN2007		Y
		Renal and urinary disorders	Pollakiuria	01AUG2019	31AUG2019	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	10JUL2017	31JUL2017	N
				10JUN2017	31JUL2017	N
		Social circumstances	Postmenopause	01APR2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1974	31DEC1974	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Loop electrosurgical excision procedure	01JAN2007	31DEC2007	N
			Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1028 10281085	Ear and labyrinth disorders	Eustachian tube dysfunction	01NOV2019	31DEC2019	N
		Infections and infestations	Acute sinusitis	01DEC2019	31DEC2019	N
			Tonsillitis	01JAN2002	31DEC2002	N
		Nervous system disorders	Headache	01JAN2016		Y
			Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Nicotine dependence	01JAN2001	31DEC2015	N
		Social circumstances	Tobacco user	01JAN2001	31DEC2015	N
		Surgical and medical procedures	Keratomileusis	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281086	Gastrointestinal disorders	Inguinal hernia	01JAN1983	31DEC1983	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Eczema	05FEB2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1983	31DEC1983	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1028 10281087	Ear and labyrinth disorders	Cerumen impaction	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1995	31DEC1995	N
			Wrist fracture	01JAN1980	31DEC1980	N
		Investigations	Arthroscopy	01JAN1989	31DEC1989	N
				01JAN2013	31DEC2013	N
			Transaminases increased	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle tightness	01JAN2015		Y
			Osteoarthritis	01JAN2013		Y
			Plantar fasciitis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2010		Y
			Tenosynovitis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
			Seborrhoeic dermatitis	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1028 10281088	Eye disorders	Conjunctivitis allergic	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glaucoma	01JAN1999		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		General disorders and administration site conditions	Pain	01JAN1985		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	10MAY2016	N
		Investigations	Colonoscopy	19JUL2019	19JUL2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2014	31JUL2014	N
			Rotator cuff syndrome	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2002		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01DEC2019		Y
		Surgical and medical procedures	Bunion operation	31JUL2014	31JUL2014	N
			Cholecystectomy	10MAY2016	10MAY2016	N
			Female sterilisation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1979	31DEC1979	N
	C4591001 1028 10281090	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2004	31DEC2004	N
			Nasal operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1028 10281094	Metabolism and nutrition disorders	Lactose intolerance	01JUL2020		Y
		Renal and urinary disorders	Dysuria	07MAR2019	30APR2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281095	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2010		Y
			Seasonal allergy	(b) (6) 1991		Y
		Investigations	Colonoscopy	18JUL2012	18JUL2012	N
		Nervous system disorders	Intercostal neuralgia	23JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Attention deficit hyperactivity disorder	01JUN2018		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2015		Y
			Panic attack	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1028 10281096	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1997		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2020		Y
			Obesity	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01OCT2014	31OCT2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
			Sleep apnoea syndrome	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee arthroplasty	01JAN2000	31DEC2000	N
			Sinus operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypotension	01JAN2004		Y
	C4591001 1028 10281097	Musculoskeletal and connective tissue disorders	Bursitis	18JUL2017		Y
			Osteoarthritis	18JUL2017		Y
			Rotator cuff syndrome	18JUL2017		Y
	C4591001 1028 10281098	Cardiac disorders	Ventricular tachycardia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Pelvic floor dysfunction	01NOV2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1982	31DEC1985	N
		Investigations	Diagnostic procedure	05APR2017	05APR2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	15FEB2017	N
			Rotator cuff syndrome	04OCT2018	30NOV2018	N
		Nervous system disorders	Migraine	01JAN2017		Y
		Renal and urinary disorders	Stress urinary incontinence	10AUG2017		Y
			Urge incontinence	01JAN2014		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	20MAY2016		Y
			Menometrorrhagia	22AUG2013	05APR2017	N
			Vulvovaginal dryness	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	05APR2017	05APR2017	N
				06SEP2013	06SEP2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281100	Vascular disorders	Hot flush	01JAN2015		Y
		Endocrine disorders	Basedow's disease	01JAN2016		Y
		Immune system disorders	Allergy to metals	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Investigations	Laparoscopy	01JAN2000	31DEC2000	N
				01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01OCT2010		Y
			Depression	01OCT2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1997	31DEC2009	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
	C4591001 1028 10281101	Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1975	31DEC1975	N
			Wisdom teeth removal	01JAN1992	31DEC1992	N
		Gastrointestinal disorders	Constipation	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2017	31DEC2017	N
			Fracture	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Scoliosis	01JAN1995		Y
	Psychiatric disorders	Anxiety	01JAN2000		Y	
		Depression	01JAN2000		Y	
		Insomnia	01JAN2015	31DEC2015	N	
	Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281103	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Psychiatric disorders	Bipolar disorder	01JAN2004		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2010		Y
			Social anxiety disorder	01JAN2004		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2006		Y
	C4591001 1028 10281104	Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
		Gastrointestinal disorders	Diverticulum	31OCT2019		Y
		Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1988	31DEC1988	N
		Investigations	Biopsy breast normal	01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
			Colonoscopy	31OCT2019	31OCT2019	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1977		Y
		Social circumstances	Postmenopause	25OCT2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1987	31DEC1987	N
			Cervix cryotherapy	01JAN1993	31DEC1993	N
			Hysterectomy	25OCT2017	25OCT2017	N
			Limb operation	15JUL2014	15JUL2014	N
			Nasal septal operation	01JAN1988	31DEC1988	N
			Spinal operation	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1028 10281105	General disorders and administration site conditions	Fatigue	01JAN2017		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2018		Y
			Obesity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Limb operation	16SEP2014	16SEP2014	N
		Vascular disorders	Raynaud's phenomenon	01JAN2015		Y
	C4591001 1028 10281106	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2019	31JUL2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1028 10281110	Hepatobiliary disorders	Cholecystitis	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2004		Y
				01SEP2019		Y
		Infections and infestations	Fungal infection	01JAN2017		Y
			Herpes zoster	01JAN2014	31DEC2014	N
		Investigations	Smear cervix abnormal	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN1983	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Nervous system disorders	Morton's neuralgia	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01AUG2019		Y
		Social circumstances	Postmenopause	01AUG2019		Y
		Surgical and medical procedures	Cervix cautery	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Gastric bypass	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hot flush	01AUG2019		Y
	C4591001 1028 10281112	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Hypersensitivity	01JAN1985		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2000	31DEC2000	N
			Foot fracture	01JAN1999	31DEC1999	N
			Meniscus injury	01JAN1995	31DEC1995	N
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
			Colonoscopy	04NOV2015	04NOV2015	N
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Intervertebral disc degeneration	01JAN2004		Y
			Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Depression	01JAN1988		Y
			Obsessive-compulsive disorder	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2001	31DEC2010	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Gastric banding	01DEC2007	31DEC2007	N
			Intervertebral disc operation	01JAN2001	31DEC2001	N
				01JAN2004	31DEC2004	N
			Medical device battery replacement	01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N
			Spinal operation	01JAN2003	31DEC2003	N
	C4591001 1028 10281114	Gastrointestinal disorders	Abdominal pain	01JAN2015		Y
			Irritable bowel syndrome	01JAN2015		Y
		General disorders and administration site conditions	Fatigue	01JAN2000		Y
		Investigations	Colonoscopy	22AUG2018	22AUG2018	N
		Nervous system disorders	Headache	01JAN1992	31DEC1992	N
			Restless legs syndrome	01JAN2019	31DEC2019	N
		Psychiatric disorders	Alcoholism	01JAN1993	31DEC2001	N
			Anxiety	01JAN2018		Y
			Bipolar disorder	01JAN2000		Y
			Depression	01OCT2009		Y
			Eating disorder	01JAN1990	31DEC2000	N
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1989	31DEC1989	N
			Mammoplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1989	31DEC1989	N
			Uvulopalatopharyngoplasty	06DEC2012	06DEC2012	N
	C4591001 1028 10281116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Sinusitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Impaired fasting glucose	01JAN2019		Y
			Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1028 10281118	Congenital, familial and genetic disorders	Pyloric stenosis	(b) (6) 1987	(b) (6) 1987	N
		Gastrointestinal disorders	Diverticulum	15JUN2020	31JUL2020	N
			Epiploic appendagitis	15JUN2020		Y
			Inguinal hernia	01NOV2013	16DEC2013	N
		Injury, poisoning and procedural complications	Head injury	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
			Obesity	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2015		Y
			Migraine	01JAN2015		Y
			Periodic limb movement disorder	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Drug abuse	01JAN1991	31DEC2007	N
			Nicotine dependence	03MAY2003	16NOV2013	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Social circumstances	Tobacco user	03MAY2003	16NOV2013	N
		Surgical and medical procedures	Inguinal hernia repair	16DEC2013	16DEC2013	N
			Pyloroplasty	(b) (6) 1987	(b) (6) 1987	N
			Vasectomy	05JUL2013	05JUL2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1028 10281119	Gastrointestinal disorders	Diverticulum	05APR2016		Y
		Infections and infestations	Tinea versicolour	01JAN1995		Y
			Tonsillitis	01DEC2004	31DEC2004	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
			Colonoscopy	05APR2016	05APR2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2009	31DEC2009	N
			Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01DEC2004	31DEC2004	N
			Meniscus removal	01JAN2014	31DEC2014	N
			Tonsillectomy	01DEC2004	31DEC2004	N
			Vasectomy	01OCT2014	31OCT2014	N
	C4591001 1028 10281120	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1028 10281121	Gastrointestinal disorders	Haemorrhoids	01JAN2017		Y
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1028 10281122	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
			Rectal haemorrhage	01JAN2001	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1986	31DEC1986	N
		Investigations	Colonoscopy	01SEP2008	30SEP2008	N
			Cystoscopy	18MAY2020	18MAY2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2007	N
			Muscle spasms	01JAN2015		Y
			Neck pain	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAR2020	18MAY2020	N
		Nervous system disorders	Headache	01JAN1996		Y
		Pregnancy, puerperium and perinatal conditions	Postpartum haemorrhage	01JAN2001	31DEC2001	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Metrorrhagia	01MAR2020	18MAY2020	N
			Uterine haemorrhage	01MAR2020	18MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN2007	31DEC2007	N
			Hysterectomy	18MAY2020	18MAY2020	N
			Salpingectomy	18MAY2020	18MAY2020	N
			Transfusion	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Varicose vein	01JAN2001		Y
	C4591001 1028 10281124	Blood and lymphatic system disorders	Anaemia	01FEB2018	31JUL2018	N
			Splenomegaly	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Injury, poisoning and procedural complications	Procedural pain	01AUG2003	31AUG2003	N
		Investigations	Aspiration bone marrow	26FEB2018	26FEB2018	N
			Colonoscopy	06MAR2018	06MAR2018	N
		Metabolism and nutrition disorders	Gout	01JAN1994		Y
			Hyperlipidaemia	03OCT2003	31DEC2005	N
			Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
		Renal and urinary disorders	Renal cyst	01FEB2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2005		Y
		Surgical and medical procedures	Abdominal exploration	15AUG2003	15AUG2003	N
			Cholecystectomy	01AUG2003	31AUG2003	N
			Gastric bypass	01AUG2003	31AUG2003	N
			Intervertebral disc operation	10MAR2015	10MAR2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1028 10281125	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2020	29FEB2020	N
		Psychiatric disorders	Depression	01JAN2014	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Keratomileusis	01JAN2002	31DEC2002	N
			Uterine dilation and curettage	01MAR2006	31DEC2006	N
	C4591001 1028 10281126	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
			Scoliosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01APR2020	28AUG2020	N
		Nervous system disorders	Epilepsy	01JAN1990		Y
		Psychiatric disorders	Nicotine dependence	01JAN1981		Y
		Social circumstances	Tobacco user	01JAN1981		Y
	C4591001 1028 10281130	Investigations	Human papilloma virus test positive	27OCT2014		Y
		Metabolism and nutrition disorders	Obesity	19APR2017		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01FEB2017	28FEB2017	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N
	C4591001 1028 10281131	Gastrointestinal disorders	Aphthous ulcer	29MAY2020	05JUN2020	N
			Eosinophilic oesophagitis	20JUN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Urinary tract infection	24MAR2020	28MAR2020	N
		Investigations	Endoscopy upper gastrointestinal tract	20JUN2018	20JUN2018	N
				24OCT2018	24OCT2018	N
		Renal and urinary disorders	Dysuria	24MAR2020	28MAR2020	N
			Haematuria	24MAR2020	28MAR2020	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281133	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Investigations	Colposcopy	01JUN2019	30JUN2019	N
			Human papilloma virus test positive	06MAY2019	06AUG2020	N
		Reproductive system and breast disorders	Cervical dysplasia	06MAY2019	06AUG2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1028 10281134	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Papilloma viral infection	01JAN2007	31DEC2007	N
			Urinary tract infection	01JUL2020	31JUL2020	N
		Injury, poisoning and procedural complications	Ankle fracture	01APR2019	01APR2019	N
			Foot fracture	01APR2019	01APR2019	N
		Investigations	Colposcopy	01JAN2007	31DEC2007	N
			Smear cervix abnormal	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
			Cervical polypectomy	01JAN2013	31DEC2013	N
			Loop electrosurgical excision procedure	01JAN2007	31DEC2007	N
			Uterine dilation and curettage	08SEP2017	08SEP2017	N
	C4591001 1028 10281135	Gastrointestinal disorders	Inguinal hernia	01JAN2010	07AUG2010	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2017	01JAN2017	N
			Tonsillectomy	01JAN2017	01JAN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281138	Injury, poisoning and procedural complications	Fractured coccyx	01JAN2018	31DEC2018	N
		Investigations	Laparoscopy	15DEC2016	15DEC2016	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1995	31DEC1995	N
		Psychiatric disorders	Nicotine dependence	01JAN1998	13NOV2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN2005	10FEB2017	N
		Surgical and medical procedures	Adenoidectomy	01JAN1992	31DEC1992	N
			Bunion operation	01JAN1995	31DEC1995	N
			Female sterilisation	26JAN2009	26JAN2009	N
			Hysterectomy	10FEB2017	10FEB2017	N
			Salpingectomy	10FEB2017	10FEB2017	N
				15DEC2016	15DEC2016	N
				01JAN1992	31DEC1992	N
				01JAN2017		Y
				01JAN1990		Y
				01JAN1995		Y
			01JAN2019		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
			Synovial cyst	01JAN1979	31DEC1979	N
				01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1979	31DEC1979	N
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1979		Y
		Surgical and medical procedures	Appendectomy	01JAN1979	31DEC1979	N
			Mammoplasty	01JAN2005	31DEC2005	N
			Oophorectomy bilateral	01JAN1979	31DEC1979	N
	C4591001 1028 10281143	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Nasal discomfort	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
			Dyshidrotic eczema	01JAN2018		Y
	C4591001 1028 10281144	Gastrointestinal disorders	Dysphagia	01JAN2019		Y
			Peptic ulcer	01JAN2019	31DEC2019	N
		General disorders and administration site conditions	Pain	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2017		Y
			Cervical spinal stenosis	01JUL2017		Y
			Intervertebral disc degeneration	01JUL2017		Y
			Intervertebral disc protrusion	01JUL2017		Y
			Neck pain	01JUL2019		Y
			Spinal osteoarthritis	01JUL2017		Y
		Nervous system disorders	Cervical radiculopathy	01JUL2017		Y
			Migraine	01JAN1993	31DEC2015	N
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017	31MAR2020	N
	C4591001 1028 10281146	Immune system disorders	Seasonal allergy	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Smear cervix abnormal	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN1998		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2009	31DEC2009	N
			Nasal septal operation	01JAN2000	31DEC2000	N
			Renal stone removal	01JAN2012	31DEC2012	N
			Wisdom teeth removal	01JAN2001	31DEC2001	N
	C4591001 1028 10281150	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1028 10281152	General disorders and administration site conditions	Nodule	01JAN2018		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	10JUL2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1028 10281153	Gastrointestinal disorders	Gastroesophageal reflux disease	16MAY2020		Y
			Irritable bowel syndrome	16MAY2020		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Hypersensitivity	01APR2020		Y
			Reaction to food additive	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	23JUL2020	31AUG2020	N
		Psychiatric disorders	Anxiety	09JUL2020		Y
			Depression	09JUL2020		Y
	C4591001 1028 10281154	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2014	31DEC2014	N
			Upper limb fracture	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013		Y
			Menorrhagia	01JAN2013		Y
	C4591001 1028 10281155	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1989		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	06APR2016		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
			Tonsillitis	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2007	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2016	06APR2016	N
		Social circumstances	Postmenopause	06APR2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1988	31DEC1988	N
			Hysterectomy	06APR2016	06APR2016	N
			Mammoplasty	01JAN1991	31DEC1991	N
			Oophorectomy bilateral	06APR2016	06APR2016	N
			Salpingectomy	06APR2016	06APR2016	N
			Tonsillectomy	01JAN1984	31DEC1984	N
	C4591001 1028 10281158	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1985		Y
			Migraine	01JAN1991		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2016	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1991		Y
			Hirsutism	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
	C4591001 1028 10281159	Infections and infestations	Appendicitis	27DEC2010	27DEC2010	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Nicotine dependence	01JAN1996	31DEC2020	N
		Surgical and medical procedures	Appendicectomy	27DEC2010	27DEC2010	N
	C4591001 1028 10281161	Ear and labyrinth disorders	Deafness unilateral	01JAN1978		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1982	31DEC1982	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Acute sinusitis	01JUL2020	07JUL2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020	31AUG2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bursitis	01FEB2020	31AUG2020	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Libido decreased	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
		Social circumstances	Menopause	24APR2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
			Inguinal hernia repair	01JAN1982	31DEC1982	N
			Rhinoplasty	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1028 10281162	General disorders and administration site conditions	Pain	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Investigations	Smear cervix abnormal	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JUN2020		Y
			Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Myofascial pain syndrome	01JAN2005		Y
		Nervous system disorders	Disturbance in attention	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1977		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1977	31DEC1977	N
			Caesarean section	09APR2011	09APR2011	N
				19OCT2006	19OCT2006	N
			Female sterilisation	01JAN2017	31DEC2017	N
			Loop electrosurgical excision procedure	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1977	31DEC1977	N
			Turbinectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1028 10281165	Immune system disorders	Allergy to animal	01JAN2018		Y
			Seasonal allergy	01JAN1986		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1028 10281167	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Sensitive skin	01JAN1985		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1028 10281170	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281172	Surgical and medical procedures	Myomectomy	01JAN2013	31DEC2013	N
		Endocrine disorders	Hypothyroidism	28NOV2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JAN2007	31DEC2007	N
				01JAN2017	31DEC2017	N
				08MAR2020	08MAR2020	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1995	31DEC1995	N
			Foot fracture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	17JUL2020		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Reproductive system and breast disorders	Adnexa uteri cyst	02OCT2014	02OCT2014	N
			Premature menopause	04JUN2015		Y
		Surgical and medical procedures	Female sterilisation	02OCT2014	02OCT2014	N
	C4591001 1028 10281174		Ovarian cystectomy	02OCT2014	02OCT2014	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2020		Y
		Investigations	Colonoscopy	08JAN2020	08JAN2020	N
	C4591001 1028 10281176	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		General disorders and administration site conditions	Chest pain	07JUL2020	07JUL2020	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1982	31DEC1982	N
		Investigations	Arthroscopy	01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N
			01JAN1992	31DEC1992	N	
			01JAN1993	31DEC1993	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cardiac stress test	09JUL2020	09JUL2020	N
	C4591001 1028 10281177	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Investigations	Blood thyroid stimulating hormone abnormal	01NOV2014		Y
		Metabolism and nutrition disorders	Obesity	01FEB2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
			Seizure	01JAN2000		Y
		Psychiatric disorders	Anxiety	01NOV2014	30NOV2014	N
			Depression	01JAN2003		Y
			Seasonal affective disorder	01JAN2003		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
	C4591001 1028 10281183	Cardiac disorders	Palpitations	01JAN1997		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN2000	31DEC2015	N
			Wrist fracture	01JAN1981	31DEC1981	N
		Investigations	Colonoscopy	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Hyperlipidaemia	11SEP2019	11SEP2019	N
		Psychiatric disorders	Anxiety	22JAN2018		Y
			Depression	01JAN2012	31DEC2013	N
			Libido decreased	01JAN2012	31DEC2013	N
			Nicotine dependence	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1984	31DEC2015	N
			Tobacco user	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC2015	N
				07FEB1991	07FEB1991	N
				18MAY1999	18MAY1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				27JUL1993	27JUL1993	N
			Female sterilisation	01JAN1999	31DEC1999	N
			Large intestinal polypectomy	11SEP2019	11SEP2019	N
	C4591001 1028 10281184	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2011	31DEC2011	N
			Foot fracture	01JAN2010	31DEC2010	N
		Investigations	Colposcopy normal	21APR2020	21APR2020	N
			Smear cervix abnormal	01APR2020	30APR2020	N
				01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	27AUG2015	10DEC2015	N
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2019	31DEC2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
		Surgical and medical procedures	Tenotomy	11DEC2015	11DEC2015	N
	C4591001 1028 10281186	Hepatobiliary disorders	Cholecystitis	04APR2017	11MAY2017	N
		Infections and infestations	Varicella	01JAN1991	31DEC1991	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998	31DEC2005	N
		Nervous system disorders	Sciatica	01JAN2019		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	27JAN2017	30JAN2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	11MAY2017	11MAY2017	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratomileusis	01JAN2007	31DEC2007	N
			Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1028 10281188	Injury, poisoning and procedural complications	Fibula fracture	01JAN1999	31DEC1999	N
		Nervous system disorders	Restless legs syndrome	01NOV2018		Y
		Psychiatric disorders	Premature ejaculation	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	(b) (6) 1986	31DEC1991	N
		Surgical and medical procedures	Nasal septal operation	01JAN2002	01JAN2002	N
			Rhinoplasty	01MAY2017	01MAY2017	N
			Wisdom teeth removal	01JAN2008	31DEC2008	N
		Vascular disorders	Raynaud's phenomenon	01NOV2018		Y
	C4591001 1028 10281190	Infections and infestations	Ear infection	01JAN1977	31DEC1985	N
		Injury, poisoning and procedural complications	Upper limb fracture	01DEC2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1993		Y
			Migraine	01JAN1993	31DEC2003	N
		Surgical and medical procedures	Adenoidectomy	01JAN1985	31DEC1985	N
			Myringotomy	01JAN1982	31DEC1982	N
			Open reduction of fracture	01JAN2015	31JAN2015	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1028 10281191	Gastrointestinal disorders	Abdominal pain	31JUL2020	01AUG2020	N
		Musculoskeletal and connective tissue disorders	Back pain	31JUL2020		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
			Menorrhagia	01JAN2015		Y
	C4591001 1028 10281192	Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Infections and infestations	Pilonidal cyst	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypokalaemia	01JAN2007	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN2009	31DEC2009	N
			Wisdom teeth removal	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1028 10281197	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1985		Y
		Cardiac disorders	Arrhythmia	01JAN2015		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN1980		Y
			Goitre	01JAN1980		Y
			Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Fatigue	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Mycotic allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
			Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN1992	31DEC1992	N
				01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
			Biopsy breast normal	01JAN2014	31DEC2014	N
			Colonoscopy	02JUN2017	02JUN2017	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma of breast	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001		Y
			Insomnia	01JAN2017		Y
			Libido decreased	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1028 10281198	Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01DEC2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2013		Y
			Migraine	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009		Y
	C4591001 1028 10281200	Surgical and medical procedures	Brain operation	01DEC2018	31DEC2018	N
		Ear and labyrinth disorders	Aural polyp	01JAN2004	31DEC2004	N
		Eye disorders	Anisometropia	01JAN2001		Y
			Astigmatism	01JAN2001		Y
			Hypermetropia	01JAN2001		Y
			Refractive amblyopia	01JAN2001		Y
		Gastrointestinal disorders	Abdominal pain lower	01JAN2012	31DEC2012	N
			Constipation	01JAN2010		Y
		General disorders and administration site conditions	Fatigue	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2016		Y
			Drug hypersensitivity	01JAN2016		Y
			Dust allergy	01JAN2016		Y
			Food allergy	01JAN2016		Y
			Milk allergy	01JAN2016		Y
		Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
			Ovulation pain	01JAN2018		Y
			Vaginal discharge	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008		Y
			Rhinitis allergic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Eustachian tube operation	01JAN2004	31DEC2004	N
	C4591001 1028 10281202	Injury, poisoning and procedural complications	Wrist fracture	01JAN1992	31DEC1992	N
		Investigations	Laparoscopy	01SEP2002	30SEP2002	N
		Reproductive system and breast disorders	Infertility female	01SEP2002	30SEP2002	N
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
				01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2007	31DEC2007	N
			Fracture treatment	01JAN1992	31DEC1992	N
			Wrist surgery	01JAN1992	31DEC1992	N
	C4591001 1028 10281203	Immune system disorders	Hypersensitivity	01JAN2013		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	13MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Tendonitis	27APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y	
		Surgical and medical procedures	Finger amputation	01MAY1995	31MAY1995	N	
			Limb reattachment surgery	01MAY1995	31MAY1995	N	
			Nasal septal operation	01JAN2005	31DEC2005	N	
			Tonsillectomy	01JAN1983	31DEC1983	N	
			Turbinectomy	01JAN2005	31DEC2005	N	
			Uvulopalatopharyngoplasty	01JAN2005	31DEC2005	N	
			Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1028 10281205	Gastrointestinal disorders	Gastrooesophageal reflux disease	01OCT2018		Y	
				Irritable bowel syndrome	01JAN2006		Y
			Immune system disorders	Rectal haemorrhage	01MAR2020	31JUL2020	N
				Allergy to animal	01JAN1996		Y
				Drug hypersensitivity	01JAN2006		Y
				Rubber sensitivity	01JAN2006		Y
				Seasonal allergy	01JAN1996		Y
				Investigations	Colonoscopy	22APR2020	22APR2020
			Metabolism and nutrition disorders	Obesity	01DEC2017		Y
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	22APR2020	22APR2020	N
			Nervous system disorders	Headache	01JAN2001		Y
				Migraine	01JAN2001		Y
				Psychiatric disorders	Anxiety	01JUN2017	
		Renal and urinary disorders	Cystitis interstitial	01JAN2011		Y	
			Hypertonic bladder	01JAN2011		Y	
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2011		Y	

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
			Chronic spontaneous urticaria	01JAN2017		Y
		Surgical and medical procedures	Benign tumour excision	22APR2020	22APR2020	N
			Caesarean section	04JUN2017	04JUN2017	N
				23MAR2019	23MAR2019	N
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 1028 10281207	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Investigations	Biopsy endometrium normal	17APR2018	17APR2018	N
		Pregnancy, puerperium and perinatal conditions	Peripartum cardiomyopathy	01FEB2002	31AUG2002	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2003		Y
		Reproductive system and breast disorders	Menorrhagia	17APR2018	15MAY2018	N
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1028 10281208	Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
			Tooth infection	13JUN2020	23JUN2020	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	29APR2014		Y
			Neck pain	27MAY2015		Y
			Pain in jaw	25MAY2020	30JUN2020	N
		Nervous system disorders	Facial paralysis	01DEC2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	20DEC2016		Y
			Persistent depressive disorder	01DEC2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	09DEC2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenoidectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN2002	31DEC2002	N
	C4591001 1028 10281209	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Groin infection	01JAN2016		Y
		Injury, poisoning and procedural complications	Incisional hernia	01JAN1997		Y
		Investigations	Arthroscopy	01JAN1994	31DEC1994	N
			Biopsy liver normal	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Impaired fasting glucose	01JAN2017		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	11FEB2008	11FEB2008	N
				25JUL2011	25JUL2011	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1028 10281211	Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Epididymal cyst	27JUN2020		Y
		Surgical and medical procedures	Wisdom teeth removal	01DEC2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281213	Infections and infestations	Tonsillitis	10SEP2020	22SEP2020	N
		Investigations	Cardiac murmur	01JAN1998		Y
	C4591001 1028 10281216	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Overdose	01JAN2016	31DEC2016	N
			Tibia fracture	26JAN2017	26JAN2017	N
		Investigations	Human papilloma virus test positive	01JAN2018	31DEC2018	N
			Smear cervix abnormal	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Intentional self-injury	01JAN2016	31DEC2016	N
			Suicide attempt	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Intramedullary rod insertion	26JAN2017	26JAN2017	N
	C4591001 1028 10281221	Gastrointestinal disorders	Anal fissure	01JAN2010	31DEC2010	N
			Anal fistula	01JAN2010	31DEC2010	N
		General disorders and administration site conditions	Chest pain	01JAN2017		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1979	31DEC1979	N
			Foot fracture	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	14MAY2020		Y
			Hyperlipidaemia	01OCT2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
		Surgical and medical procedures	Anorectal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1028 10281222	Gastrointestinal disorders	Abdominal pain	01JAN2020	31DEC2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Infections and infestations	Herpes zoster	01JAN2005	31DEC2018	N
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2010		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Panic disorder	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Infertility female	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1028 10281223	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2002		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Conjunctivitis	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Muscle spasms	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
			Mole excision	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1028 10281224	Cardiac disorders	Bradycardia	16MAR2020		Y
		Infections and infestations	Lyme disease	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN2013		Y
			Melanocytic naevus	01JAN2013		Y
			Seborrhoeic keratosis	23AUG2019	23AUG2019	N
		Nervous system disorders	Muscle contractions involuntary	01JAN2017		Y
			Syncope	14MAR2020	14MAR2020	N
		Skin and subcutaneous tissue disorders	Actinic cheilitis	01APR2020		Y
			Eczema	01JAN1980		Y
			Lentigo	01JAN2013		Y
			Photodermatosis	01JAN2013		Y
		Surgical and medical procedures	Cryotherapy	21MAY2020	21MAY2020	N
				23AUG2020	23AUG2020	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1028 10281225	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	(b) (6) 1969		Y
		Injury, poisoning and procedural complications	Ligament rupture	27JUN2014	27JUN2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	27JUN2014	27JUN2014	N
			Colonoscopy	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Arthralgia	21MAY2015		Y
			Plantar fasciitis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteochondroma	01JAN1989		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2011	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	(b) (6) 1969		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N
			Muscle graft	27JUN2014	27JUN2014	N
	C4591001 1028 10281226	Investigations	Biopsy site unspecified normal	01JAN1992	31DEC1992	N
			Blood glucose increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2010		Y
			Fibrocystic breast disease	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1028 10281227	Infections and infestations	Streptococcal infection	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	20OCT2011		Y
			Insomnia	01JAN2011		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1028 10281228	Hepatobiliary disorders	Gallbladder disorder	01FEB2001	28FEB2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01SEP2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2013		Y
			Impaired fasting glucose	01AUG2013		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	01AUG2013		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2001	28FEB2001	N
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1028 10281229	Eye disorders	Giant papillary conjunctivitis	31JUL2014	31AUG2014	N
		Gastrointestinal disorders	Umbilical hernia	01JAN1998	31DEC1998	N
		Hepatobiliary disorders	Gallbladder polyp	01JAN2003		Y
		Investigations	Colonoscopy	17SEP2020	17SEP2020	N
		Psychiatric disorders	Alcohol problem	01JAN2001	31DEC2001	N
			Anxiety	01JAN1985		Y
			Insomnia	01JAN2014		Y
			Irritability	01JAN2014		Y
			Sleep disorder	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast enlargement	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal turbinate hypertrophy	01JAN2014		Y
			Rhinitis allergic	01JAN1985		Y
			Snoring	01JAN2014		Y
		Surgical and medical procedures	Large intestinal polypectomy	17SEP2020	17SEP2020	N
	C4591001 1028 10281231	Ear and labyrinth disorders	Vertigo	25JUL2018	18AUG2018	N
		General disorders and administration site conditions	Fatigue	01JAN2005		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	15SEP2015		Y
			Depression	15SEP2015	15SEP2015	N
			Insomnia	01JAN2005		Y
	C4591001 1028 10281236	Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
		Congenital, familial and genetic disorders	Corneal dystrophy	01JAN1990		Y
		Eye disorders	Corneal degeneration	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Investigations	Biopsy cervix normal	01JAN2008	31DEC2008	N
			Colonoscopy	19NOV2019	19NOV2019	N
			Colposcopy	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Vulvovaginal warts	01JAN2014	03SEP2014	N
		Nervous system disorders	Carpal tunnel syndrome	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2005		Y
		Social circumstances	Postmenopause	01OCT2019		Y
		Surgical and medical procedures	Cryotherapy	01JAN2008	31DEC2008	N
			Vulval operation	03SEP2014	03SEP2014	N
		Vascular disorders	Hot flush	01OCT2019		Y
	C4591001 1028 10281237	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Syncope	01JAN1995	31DEC1995	N
		Psychiatric disorders	Nicotine dependence	01JAN1999		Y
	C4591001 1028 10281240	Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	17MAY2018		Y
			Posterior tibial tendon dysfunction	20FEB2019		Y
	C4591001 1028 10281241	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Gastrointestinal disorders	Constipation	29JUL2020	31AUG2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Ilium fracture	29JUL2020	29JUL2020	N
			Procedural pain	29JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Depression	01JUN2020		Y
			Nicotine dependence	01JAN2009	21AUG2020	N
			Post-traumatic stress disorder	01JAN2001		Y
		Renal and urinary disorders	Urethral disorder	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Social circumstances	Substance use	01JAN2014		Y
		Surgical and medical procedures	Debridement	29JUL2020	29JUL2020	N
			Urethral operation	01JAN1989	31DEC1989	N
	C4591001 1028 10281242	Musculoskeletal and connective tissue disorders	Back pain	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Drug abuse	01JAN2018	31DEC2018	N
			Nicotine dependence	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JUL2019		Y
	C4591001 1028 10281243	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	23JUL2020		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31JAN2018	N
			Meniscus injury	01JAN2008	31DEC2008	N
		Investigations	Arthroscopy	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
			Keloid scar	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2018	31JAN2018	N
				23DEC2019	23DEC2019	N
			Ostectomy	23DEC2019	23DEC2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281244	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	11JUL2017	11JUL2017	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Infections and infestations	Chronic sinusitis	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Rhinitis allergic	01JAN1992		Y
			Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	11JUL2017	11JUL2017	N
	C4591001 1028 10281246	Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	04JAN2008		Y
			Hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Femoral neck fracture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	10FEB2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	18JUN2019		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	24JAN2008		Y
			Depression	24JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1028 10281247	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN1978		Y
		Infections and infestations	Herpes simplex	01JAN2009		Y
		Injury, poisoning and procedural complications	Foot fracture	01FEB2020	31MAR2020	N
				01JAN1993	31DEC1993	N
		Investigations	Biopsy breast normal	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
			Biopsy cervix normal	01JAN2010	31DEC2010	N
			Colposcopy	01JAN2010	31DEC2010	N
			Smear cervix abnormal	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Impaired fasting glucose	05JUL2018		Y
			Obesity	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1999		Y
				01JAN2009	31DEC2009	N
		Reproductive system and breast disorders	Breast calcifications	01JAN2007	31DEC2014	N
			Endometriosis	01JAN1992		Y
			Infertility female	01JAN2009		Y
			Polycystic ovaries	01JAN1992		Y
			Vulval disorder	16JUL2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Eczema	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	07JAN2014	07JAN2014	N
	C4591001 1028 10281248	Gastrointestinal disorders	Haemorrhoids	17AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1028 10281249	Eye disorders	Conjunctivitis allergic	01JAN2012		Y
		Immune system disorders	Food allergy	13MAR2017	13MAR2017	N
			Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Rotator cuff syndrome	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1028 10281250	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1028 10281251	Gastrointestinal disorders	Gastroesophageal reflux disease	28JUN2011		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2018		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2005	31DEC2005	N
		Investigations	Colonoscopy	11OCT2018	11OCT2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
			Bursitis	01JAN2005		Y
			Exostosis	01JAN2019	31DEC2019	N
			Muscle spasms	21AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	19OCT2005		Y
			Nicotine dependence	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	18MAR2005		Y
		Skin and subcutaneous tissue disorders	Acne	19OCT2005		Y
			Lichenification	19OCT2005		Y
			Neurodermatitis	19OCT2015		Y
			Urticaria	19OCT2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Large intestinal polypectomy	11OCT2018	11OCT2018	N
			Osteotomy	31DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1028 10281253	Gastrointestinal disorders	Gastrooesophageal reflux disease	03JUN2020		Y
		Immune system disorders	Allergy to metals	01JAN2006		Y
			Drug hypersensitivity	01JAN2012		Y
		Infections and infestations	Genital herpes	01JAN2007		Y
			Herpes zoster	01JAN2001		Y
			Varicella	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Fractured coccyx	01JAN2003	31DEC2003	N
				01JAN2012	31DEC2012	N
		Investigations	Smear cervix abnormal	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hyperlipidaemia	03JUN2020		Y
			Hypertriglyceridaemia	03JUN2020		Y
			Hypoglycaemia	01JAN1998		Y
			Obesity	03DEC2019		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	(b) (6) 1990		Y
			Temporomandibular joint syndrome	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2002	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Attention deficit hyperactivity disorder	01JAN1999		Y
			Depression	01JAN1999		Y
			Libido decreased	03JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2006	31DEC2006	N
	C4591001 1028 10281254	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Irritable bowel syndrome	01JAN2008		Y
			Malabsorption	03JUL2014	03JUL2014	N
		Hepatobiliary disorders	Cholecystitis	28JAN2015	28JAN2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	16APR2013	16APR2013	N
		Investigations	Colonoscopy	01OCT2008	31OCT2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01OCT2012		Y
			Depression	01JAN2000		Y
			Obsessive-compulsive disorder	09MAR2015		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	28JAN2015	28JAN2015	N
			Gastric bypass	03JUL2014	03JUL2014	N
			Tonsillectomy	16APR2013	16APR2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281255	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	17DEC2017	31DEC2018	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2010	N
			Ovarian cyst	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Caesarean section	14SEP1995	14SEP1995	N
				17JUL2001	17JUL2001	N
				20DEC1999	20DEC1999	N
			Female sterilisation	17JUL2001	17JUL2001	N
			Oophorectomy	01JAN2005	31DEC2005	N
			Salpingectomy	01JAN2005	31DEC2005	N
	C4591001 1028 10281256	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1028 10281257	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Enterobiasis	30AUG2020	13SEP2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	30AUG2020	29SEP2020	N
		Nervous system disorders	Hypoaesthesia	30AUG2020	29SEP2020	N
		Psychiatric disorders	Anxiety	01SEP2018		Y
			Attention deficit hyperactivity disorder	01JAN1998		Y
			Depression	01SEP2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281258	Injury, poisoning and procedural complications	Clavicle fracture	(b) (6) 1995	(b) (6) 1995	N
			Hand fracture	01JAN2009	31DEC2009	N
			Wrist fracture	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
	C4591001 1028 10281259	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Back pain	20JUL2000		Y
			Mobility decreased	20JUL2020		Y
			Muscle tightness	20JUN2000		Y
			Myofascial pain syndrome	20JUL2020		Y
		Nervous system disorders	Balance disorder	20JUL2000		Y
			Restless legs syndrome	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	16MAY2019	16MAY2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Finger amputation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Oophorectomy	01JAN2019	31DEC2019	N
	C4591001 1028 10281261	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Investigations	Prostatic specific antigen increased	01JAN2016	25NOV2016	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01NOV2015		Y
	C4591001 1028 10281262	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2016		Y
			Fatigue	01SEP2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Seizure	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002		Y
		Surgical and medical procedures	Abdominal panniculectomy	24SEP2018	24SEP2018	N
			Abdominoplasty	24SEP2018	24SEP2018	N
			Appendicectomy	01JAN1995	31DEC1995	N
			Caesarean section	31DEC2014	31DEC2014	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1028 10281265	Gastrointestinal disorders	Haemorrhoids	01SEP2020		Y
			Pancreatitis	15JUL2018	15JUL2018	N
		Immune system disorders	Allergy to animal	01JAN1975		Y
			Mite allergy	01JAN1975		Y
		Infections and infestations	Appendicitis	07OCT2018	07OCT2018	N
			Tonsillitis	01JAN1977	31DEC1977	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1975	31DEC1975	N
			Tendon rupture	01MAY2015	02JUN2015	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				07OCT2016	07OCT2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	07OCT2018	07OCT2018	N
			Ligament operation	01JAN1998	31DEC1998	N
				01JAN2005	31DEC2005	N
			Tendon transfer	02JUN2015	02JUN2015	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1028 10281267	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN1995		Y
		General disorders and administration site conditions	Fatigue	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Investigations	Colonoscopy	01DEC2012	01DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN1993	31DEC1993	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016		Y
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN2012	31DEC2018	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Wrist surgery	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1028 10281269	Ear and labyrinth disorders	Eustachian tube dysfunction	05JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	19FEB2019	30APR2019	N
		Infections and infestations	Urinary tract infection	07JUN2020	11JUN2020	N
		Injury, poisoning and procedural complications	Animal bite	19FEB2019	02MAR2019	N
			Wrist fracture	01JAN2005	31DEC2005	N
		Investigations	Streptococcus test positive	17APR2019	19APR2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15AUG2017		Y
		Pregnancy, puerperium and perinatal conditions	Gestational hypertension	17APR2019	30APR2019	N
		Renal and urinary disorders	Dysuria	07JUN2020	11JUN2020	N
			Pollakiuria	07JUN2020	11JUN2020	N
		Surgical and medical procedures	Adenoidectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1995	31DEC1995	N
			Wisdom teeth removal	01JAN2011	31DEC2011	N
	C4591001 1028 10281271	Endocrine disorders	Hypothyroidism	01AUG1999		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Fatigue	01AUG1999		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Chronic sinusitis	01JAN2015		Y
			Oral herpes	01JAN2010		Y
			Tonsillitis	01JAN1990	31DEC1990	N
		Investigations	Aspiration joint	01JAN2009	31DEC2009	N
			Nasoendoscopy	21JUN2016	21JUN2016	N
				27OCT2015	27OCT2015	N
			Smear cervix abnormal	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Iron deficiency	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01JAN1990		Y
			Hypersomnia	01JAN2012		Y
			Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Nicotine dependence	01JAN1995		Y
		Renal and urinary disorders	Haematuria	01JAN2015	31DEC2015	N
			Hypertonic bladder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Surgical and medical procedures	Debridement	21JUN2016	21JUN2016	N
				27OCT2015	27OCT2015	N
			Sinus operation	21JUN2016	21JUN2016	N
			Tonsillectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01SEP2008		Y
			Peripheral venous disease	01AUG1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281274	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Infections and infestations	Vulvitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Bursitis	10SEP2020		Y
			Osteoarthritis	01JAN2019		Y
			Patellofemoral pain syndrome	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1986		Y
			Menometrorrhagia	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2010		Y
		Surgical and medical procedures	Pharyngeal polypectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hot flush	01JAN2018		Y
			Hypertension	01JAN2016		Y
	C4591001 1028 10281275	Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Iliotibial band syndrome	01MAY2014	11NOV2014	N
			Mallet finger	22MAR2019		Y
			Muscle strain	02MAY2012	21JUN2012	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2014	11NOV2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281276	Immune system disorders	Hypersensitivity	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008	31DEC2008	N
			Depression	01JAN2008	31DEC2008	N
			Nicotine dependence	01JAN1994	31DEC1996	N
	C4591001 1028 10281279	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Exostosis	08JUL2014		Y
			Tendonitis	01JAN2014		Y
		Reproductive system and breast disorders	Cervical dysplasia	16JUL2015	08OCT2020	N
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1028 10281280	Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cutaneous T-cell lymphoma	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1028 10281282	Metabolism and nutrition disorders	Vitamin B12 deficiency	01JUL2020		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1028 10281284	Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Depression	01JAN2016		Y
		Renal and urinary disorders	Dysuria	25SEP2020	28SEP2020	N
	C4591001 1028 10281285	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2011	14AUG2012	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2011		Y
		Surgical and medical procedures	Bunion operation	14AUG2012	14AUG2012	N
	C4591001 1028 10281286	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Orthognathic surgery	03DEC2019	03DEC2019	N
			Osteotomy	03DEC2019	03DEC2019	N
	C4591001 1028 10281287	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nausea	01OCT2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Investigations	Hysteroscopy	21OCT2019	21OCT2019	N
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2001		Y
		Surgical and medical procedures	Endometrial ablation	21OCT2019	21OCT2019	N
			Salpingectomy	21OCT2019	21OCT2019	N
			Uterine dilation and curettage	21OCT2019	21OCT2019	N
	C4591001 1028 10281290	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1990		Y
				01JAN1999		Y
				01JAN2001		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2001	31DEC2001	N
			Tibia fracture	01JAN1999	31DEC1999	N
				01JAN2011	31DEC2011	N
		Investigations	Colonoscopy	01JAN2005	31DEC2005	N
				08JUN2018	08JUN2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN1980		Y
			Idiopathic generalised epilepsy	01JAN1967		Y
		Renal and urinary disorders	Urethral dilatation	01JAN1972	31DEC1972	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	18MAY2017		Y
		Surgical and medical procedures	Ankle operation	01JAN2001	31JAN2001	N
			Hysterectomy	18MAY2017	18MAY2017	N
			Salpingectomy	18MAY2017	18MAY2017	N
	C4591001 1028 10281291	Blood and lymphatic system disorders	Anaemia	30JUL2020	01AUG2020	N
		Endocrine disorders	Hypothyroidism	01DEC2007		Y
		Eye disorders	Keratoconus	10DEC2014	10DEC2014	N
		Gastrointestinal disorders	Diverticulum	30JUL2020		Y
			Gastroesophageal reflux disease	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN2013		Y
				01JAN2014		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Foot fracture	01FEB2020	29FEB2020	N
			Humerus fracture	01JAN1992	31DEC1992	N
			Wrist fracture	01JAN1991	31DEC1991	N
		Investigations	Colonoscopy	01JAN2000	31DEC2000	N
			Endoscopy upper gastrointestinal tract	10JUN2019	10JUN2019	N
			Smear cervix abnormal	01JAN1997	31DEC1997	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2004	31DEC2008	N
			Intervertebral disc degeneration	30JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Binge eating	01JAN2019		Y
			Depression	04JUN2014		Y
			Insomnia	01JAN2003		Y
			Nicotine dependence	01JAN1996	01JUN2001	N
		Reproductive system and breast disorders	Menorrhagia	01DEC2018	29JUL2020	N
			Polycystic ovaries	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	29JUL2020		Y
		Surgical and medical procedures	Bunion operation	01JAN2008	31DEC2008	N
			Caesarean section	04JUN2014	04JUN2014	N
				08FEB2017	08FEB2017	N
				22AUG2018	22AUG2018	N
			Corneal transplant	10DEC2014	10DEC2014	N
			Hysterectomy	29JUL2020	29JUL2020	N
			Oesophagogastric fundoplasty	01DEC2000	31DEC2000	N
			Salpingectomy	29JUL2020	29JUL2020	N
			Tonsillectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hot flush	01DEC2019		Y
			Hypertension	01FEB2020		Y
			Varicose vein	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281294	Blood and lymphatic system disorders	Anaemia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2014		Y
			Reaction to food additive	01JAN2016		Y
			Rubber sensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2003	31DEC2003	N
			Wrist fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Post-traumatic stress disorder	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2017		Y
			Seborrhoeic dermatitis	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1030 10301001	Investigations	Blood cholesterol increased	14AUG2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	14AUG2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1030 10301005	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Social circumstances	Menopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1030 10301012	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01FEB2014		Y
	C4591001 1030 10301013	Psychiatric disorders	Depression	01MAR2019		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1030 10301014	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Psychiatric disorders	Depression	01JUN2020		Y
	C4591001 1030 10301015	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
	C4591001 1030 10301019	Gastrointestinal disorders	Dyspepsia	01JUL2020		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1030 10301026	Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JUL2019		Y
	C4591001 1030 10301030	Endocrine disorders	Hypothyroidism	01SEP2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
	C4591001 1030 10301039	Metabolism and nutrition disorders	Hyperlipidaemia	23MAY2020		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2010		Y
		Social circumstances	Organ donor	07JUN2005		Y
	C4591001 1030 10301041	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01DEC2017		Y
		Vascular disorders	Hypertension	01OCT2016		Y
	C4591001 1030 10301043	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1030 10301044	Psychiatric disorders	Anxiety	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1030 10301045	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1030 10301048	Psychiatric disorders	Depression	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1030 10301049	Immune system disorders	Multiple allergies	01FEB2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1030 10301050	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer stage IV	13AUG2013	01APR2015	N
		Nervous system disorders	Neuropathy peripheral	01AUG2013		Y
		Surgical and medical procedures	Hysterectomy	15AUG2013	15AUG2013	N
	C4591001 1030 10301054	Nervous system disorders	Migraine	01JAN1985		Y
	C4591001 1030 10301055	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1983	01JAN2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	01JAN2018	N
	C4591001 1030 10301056	Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1030 10301057	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1030 10301063	Nervous system disorders	Migraine	01JUL2020		Y
	C4591001 1030 10301069	Gastrointestinal disorders	Coeliac disease	01JAN2012		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	27JAN2019	27JAN2019	N
	C4591001 1030 10301070	Investigations	Blood cholesterol increased	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1030 10301081	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2005		Y
	C4591001 1030 10301082	Investigations	Blood cholesterol increased	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2019		Y
	C4591001 1030 10301083	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Infections and infestations	Herpes virus infection	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2019		Y
	C4591001 1030 10301087	Surgical and medical procedures	Thyroidectomy	01JAN2005	01JAN2005	N
	C4591001 1030 10301095	Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1030 10301097	Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1030 10301099	Infections and infestations	Herpes simplex	01SEP2010		Y
	C4591001 1030 10301100	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1030 10301101	Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	01JAN2009	N
	C4591001 1030 10301106	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1030 10301107	Injury, poisoning and procedural complications	Muscle rupture	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016	01JAN2016	N
		Renal and urinary disorders	Urinary retention	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018		Y
	C4591001 1030 10301120	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1030 10301123	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2013		Y
	C4591001 1030 10301124	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
	C4591001 1030 10301127	Investigations	Blood cholesterol increased	01JAN2019		Y
		Social circumstances	Menopause	01JAN2016	01JAN2016	N
	C4591001 1030 10301128	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1030 10301136	Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1030 10301137	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
	C4591001 1030 10301139	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1030 10301142	Psychiatric disorders	Obsessive-compulsive disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1030 10301145	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1030 10301146	Surgical and medical procedures	Female sterilisation	01JAN2012	01JAN2012	N
	C4591001 1030 10301148	Psychiatric disorders	Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1030 10301152	Psychiatric disorders	Anxiety	01JAN1999		Y
	C4591001 1030 10301153	Psychiatric disorders	Depression	01JAN2004		Y
	C4591001 1030 10301155	Social circumstances	Menopause	01JAN2017		Y
	C4591001 1036 10361004	Ear and labyrinth disorders	Deafness bilateral	01JAN1998		Y
		Immune system disorders	Allergy to animal	01JAN1994		Y
			Allergy to arthropod sting	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN1994	31DEC1994	N
		Skin and subcutaneous tissue disorders	Eczema	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361006	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Hypoaesthesia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1036 10361009	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Nervous system disorders	Anosmia	01JAN1975		Y
			Migraine	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1036 10361012	Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1036 10361014	Investigations	Blood triglycerides	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JUL2020		Y
	C4591001 1036 10361017	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Investigations	Cardiac murmur	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1036 10361018	Immune system disorders	Anaphylactic reaction	01JAN2017		Y
			Drug hypersensitivity	01JAN2017		Y
	C4591001 1036 10361020	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1036 10361021	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	09SEP2016	09SEP2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				13APR2012	13APR2012	N
				16JAN2010	16JAN2010	N
				29MAY2008	29MAY2008	N
	C4591001 1036 10361022	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1036 10361023	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1036 10361026	Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
	C4591001 1036 10361027	Surgical and medical procedures	Sinus operation	01JAN2013	31DEC2013	N
	C4591001 1036 10361029	Nervous system disorders	Seizure	30JAN2020		Y
		Psychiatric disorders	Bipolar disorder	01JAN1986		Y
	C4591001 1036 10361030	Endocrine disorders	Hypothyroidism	01JAN2006	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Psychiatric disorders	Bipolar disorder	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1036 10361032	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1036 10361033	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
	C4591001 1036 10361038	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
			Sterilisation reversal	01JAN2000	31DEC2000	N
	C4591001 1036 10361039	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	23MAR2017	23MAR2017	N
			Female sterilisation	23MAR2017	23MAR2017	N
	C4591001 1036 10361040	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1036 10361042	Eye disorders	Blindness unilateral	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2016	N
				01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
			Female sterilisation	01JAN2019	31DEC2019	N
	C4591001 1036 10361043	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1036 10361047	Ear and labyrinth disorders	Vertigo	22OCT2018		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Head injury	22OCT2018	22OCT2018	N
	C4591001 1036 10361048	Nervous system disorders	Headache	22OCT2018		Y
		Investigations	Cardiac murmur	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014		Y
	C4591001 1036 10361053	Nervous system disorders	Nystagmus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1036 10361055	Vascular disorders	Hypertension	01JAN2019		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1998		Y
	C4591001 1036 10361056	Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
	C4591001 1036 10361061	Surgical and medical procedures	Female sterilisation	10JAN2019	10JAN2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Scoliosis	(b) (6) 1998		Y
	C4591001 1036 10361064	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361065	Reproductive system and breast disorders	Polycystic ovaries	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Female sterilisation	30DEC2015	30DEC2015	N
	C4591001 1036 10361068	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1036 10361069	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Social circumstances	Woman of childbearing potential	01JAN2003		Y
		Surgical and medical procedures	Chemical contraception	01JAN2003		Y
			Contraception	01JAN2003		Y
	C4591001 1036 10361070	Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2016	31DEC2016	N
			Female sterilisation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1036 10361072	Immune system disorders	Seasonal allergy	01JAN1994		Y
	C4591001 1036 10361073	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1036 10361074	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1036 10361076	Immune system disorders	Drug hypersensitivity	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361084	Immune system disorders	Allergy to animal	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Psychiatric disorders	Back pain	01JAN2016		Y
			Anxiety	01JAN2008		Y
	C4591001 1036 10361086	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1036 10361093	Surgical and medical procedures	Intrauterine contraception	01JUN2020		Y
	C4591001 1036 10361095	Immune system disorders	Food allergy	01JAN2005		Y
	C4591001 1036 10361096	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
		Vascular disorders	Embolism	01JAN1998	31DEC1998	N
				01JAN2004	31DEC2004	N
	C4591001 1036 10361097	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
	C4591001 1036 10361098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Nervous system disorders	Epilepsy	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
	C4591001 1036 10361099	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361102	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2001		Y
	C4591001 1036 10361103	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN2017	31DEC2017	N
	C4591001 1036 10361104	Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01FEB2020		Y
	C4591001 1036 10361105	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2011	31DEC2018	N
	C4591001 1036 10361107	Infections and infestations	Diverticulitis	01JAN2018		Y
	C4591001 1036 10361110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361112	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1036 10361117	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1991		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN1973		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Ligament operation	01JAN2011		Y
	C4591001 1036 10361119	Hepatobiliary disorders	Hepatic cirrhosis	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
			Female sterilisation	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1036 10361125	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1036 10361126	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Renal necrosis	01JAN2010		Y
	C4591001 1036 10361127	Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1036 10361131	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01MAR2019	31MAR2019	N
	C4591001 1036 10361135	Gastrointestinal disorders	Diarrhoea	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1036 10361137	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Hearing aid user	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1036 10361141	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361144	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
			Post-traumatic stress disorder	01JAN2017		Y
	C4591001 1036 10361145	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2002		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
				01JAN2007		Y
		Infections and infestations	Pyelonephritis	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
			Intervertebral disc protrusion	01JAN2012	31DEC2012	N
			Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Nerve compression	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypotension	01JAN2018		Y
	C4591001 1037 10371007	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
	C4591001 1037 10371008	Endocrine disorders	Hyperthyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371010	Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1037 10371017	Endocrine disorders	Autoimmune thyroiditis	01JUN2015		Y
			Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2012		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01SEP1993		Y
			Vitamin D deficiency	31JAN2012		Y
		Psychiatric disorders	Major depression	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01AUG2000		Y
			Keratosis pilaris	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01NOV2018	30NOV2018	N
		Vascular disorders	Hypertension	01SEP2012		Y
	C4591001 1037 10371018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371024	Immune system disorders	Seasonal allergy	01APR2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2019		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01OCT2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2019		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	02JAN2020	02JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371026	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1037 10371028	Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1037 10371029	Surgical and medical procedures	Abdominal hernia repair	01NOV2018	30NOV2018	N
	C4591001 1037 10371037	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31AUG2015	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1037 10371038	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2019	31DEC2019	N
	C4591001 1037 10371041	Gastrointestinal disorders	Irritable bowel syndrome	01MAR2013		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1037 10371042	Immune system disorders	Seasonal allergy	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1037 10371043	Immune system disorders	Food allergy	01JAN2006		Y
			Seasonal allergy	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
		Surgical and medical procedures	Oophorectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1037 10371044	Surgical and medical procedures	Oophorectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371045	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1037 10371046	Metabolism and nutrition disorders	Obesity	01AUG1998		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01OCT2012	31OCT2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1037 10371047	Nervous system disorders	Migraine	01JAN2000		Y
		Vascular disorders	Deep vein thrombosis	01JAN2018	31DEC2018	N
	C4591001 1037 10371050	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2000		Y
	C4591001 1037 10371051	Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Splenic rupture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Myalgia	14APR2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01SEP2013	30SEP2013	N
		Psychiatric disorders	Generalised anxiety disorder	01APR2013		Y
		Surgical and medical procedures	Hysterectomy	01SEP2013	30SEP2013	N
			Splenectomy	01JAN2016	31DEC2016	N
	C4591001 1037 10371052	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
		Reproductive system and breast disorders	Uterine disorder	01JAN2011	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1037 10371054	Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1037 10371056	Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	21JUL2008	21AUG2008	N
			Female sterilisation	01DEC2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371058	Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1037 10371060	Gastrointestinal disorders	Constipation	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1999		Y
			Neck pain	01JAN1999		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
	C4591001 1037 10371061	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1037 10371065	Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Seizure	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371067	General disorders and administration site conditions	Hernia	01JAN1995	31JAN1995	N
		Immune system disorders	Seasonal allergy	01OCT2000		Y
		Surgical and medical procedures	Hernia repair	01JAN1995	31JAN1995	N
			Intervertebral disc operation	01MAY2017	31MAY2017	N
			Spinal fusion surgery	01OCT2015	31OCT2015	N
			Vasectomy	01FEB2012	29FEB2012	N
	C4591001 1037 10371068	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2013	N
		Nervous system disorders	Diabetic neuropathy	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Mastectomy	01JAN2013	31DEC2013	N
	C4591001 1037 10371072	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371073	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
			Generalised anxiety disorder	01JAN2015		Y
			Major depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1037 10371074	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1037 10371076	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01FEB2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2000		Y
	C4591001 1037 10371077	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1037 10371081	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JUL2019		Y
		Surgical and medical procedures	Gastrectomy	21DEC2017	21DEC2017	N
	C4591001 1037 10371082	Psychiatric disorders	Major depression	01JAN2000		Y
	C4591001 1037 10371083	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1037 10371087	Surgical and medical procedures	Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1037 10371088	Immune system disorders	Contrast media allergy	01JAN2005		Y
			Seasonal allergy	01JAN1982		Y
	C4591001 1037 10371092	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2007		Y
	C4591001 1037 10371096	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1037 10371097	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371104	Infections and infestations	Herpes simplex	01JAN2017		Y
	C4591001 1037 10371109	Immune system disorders	Seasonal allergy	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01SEP2019		Y
		Nervous system disorders	Migraine	01JAN2009		Y
	C4591001 1037 10371110	Psychiatric disorders	Depression	01APR2014		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1037 10371115	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1997		Y
	C4591001 1037 10371116	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1037 10371124	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1037 10371125	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		General disorders and administration site conditions	Oedema peripheral	01JUL2000		Y
		Metabolism and nutrition disorders	Obesity	01MAR2014		Y
		Surgical and medical procedures	Female sterilisation	26AUG2020	26AUG2020	N
	C4591001 1037 10371126	Ear and labyrinth disorders	Hypoacusis	01JAN1983		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
	C4591001 1037 10371130	Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2010		Y
				01JUL1998		Y
		Metabolism and nutrition disorders	Obesity	01DEC2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Thyroidectomy	01JUL2016	31JUL2016	N
	C4591001 1037 10371131	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Spinal laminectomy	01JAN2016	31DEC2016	N
	C4591001 1037 10371138	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
	C4591001 1037 10371140	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Investigations	Blood iron decreased	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2001	31DEC2005	N
	C4591001 1037 10371142	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01DEC2012	31DEC2012	N
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
			Major depression	01JAN2015		Y
		Social circumstances	Menopause	01DEC2010		Y
		Surgical and medical procedures	Hysterectomy	01DEC2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371145	Surgical and medical procedures	Oophorectomy bilateral	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1037 10371148	Gastrointestinal disorders	Abdominal hernia	01JAN2006		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2009	31DEC2009	N
			Ligament rupture	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2006	31DEC2006	N
			Chondroplasty	01JAN2009	31DEC2009	N
			Ligament operation	01JAN1997	31DEC1997	N
	C4591001 1037 10371152	Congenital, familial and genetic disorders	Congenital myopathy	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1037 10371154	Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1037 10371155	Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371157	Injury, poisoning and procedural complications	Ulna fracture	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Bone operation	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN2006	31DEC2006	N
	C4591001 1037 10371168	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1037 10371169	Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Joint dislocation	01JUL2020	31JUL2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1998	31DEC1998	N
		Social circumstances	Menopause	01JUL2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Joint surgery	01JUL2020	31DEC2020	N
			Spinal operation	01JAN1998	31DEC1998	N
	C4591001 1037 10371170	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1037 10371172	Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01FEB2020	29FEB2020	N
		Psychiatric disorders	Major depression	01JAN1991		Y
		Skin and subcutaneous tissue disorders	Hirsutism	01JAN1992		Y
		Surgical and medical procedures	Ligament operation	01JAN1997	31DEC1997	N
			Synovial cyst removal	01FEB2020	29FEB2020	N
	C4591001 1037 10371176	Investigations	Biopsy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sarcoma	01JAN2015	31DEC2015	N
			Skin cancer	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	01JAN1977	31DEC1977	N
		Social circumstances	Menopause	01JUN2018		Y
		Surgical and medical procedures	Mastectomy	01JAN2014	31DEC2014	N
			Sarcoma excision	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1037 10371179	Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
	C4591001 1037 10371180	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
	C4591001 1037 10371183	Congenital, familial and genetic disorders	Congenital joint malformation	(b) (6) 1970		Y
		Gastrointestinal disorders	Constipation	01JAN2005		Y
			Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1971		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN2011		Y
			Vitamin D deficiency	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN2011		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	08MAY2003	08MAY2003	N
			Joint dislocation reduction	30SEP2005	30SEP2005	N
			Salpingectomy	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1995	31DEC1995	N
		Hypertension		01JAN2011		Y
	C4591001 1037 10371192	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Appendicitis	01AUG2006	31AUG2006	N
		Psychiatric disorders	Major depression	01AUG1990		Y
		Surgical and medical procedures	Appendicectomy	01AUG2006	31AUG2006	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371198	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01SEP2020		Y
	C4591001 1037 10371199	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1037 10371200	Gastrointestinal disorders	Constipation	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
	C4591001 1037 10371201	Immune system disorders	Drug hypersensitivity	(b) (6) 1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371202	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31MAY2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Social circumstances	Tobacco user	01MAY1989		Y
		Surgical and medical procedures	Knee arthroplasty	01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1037 10371208	Endocrine disorders	Hypothyroidism	01MAR2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY1990		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1037 10371209	Immune system disorders	Seasonal allergy	01MAR1987		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2000		Y
	C4591001 1037 10371210	Gastrointestinal disorders	Abdominal hernia	01OCT2017	31OCT2017	N
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01OCT2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Abdominal hernia repair	01OCT2017	31OCT2017	N
			Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01DEC2005		Y
	C4591001 1037 10371214	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371215	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Nervous system disorders	Epilepsy	01OCT2019		Y
			Migraine	01OCT2019		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
	C4591001 1037 10371219	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1980		Y
	C4591001 1037 10371220	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371221	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2014	31DEC2014	N
			Oophorectomy	01JAN2008	31DEC2008	N
			Salpingectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1037 10371222	Surgical and medical procedures	Benign breast lump removal	01JAN2014	31DEC2014	N
	C4591001 1037 10371223	Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2015		Y
	C4591001 1037 10371230	Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN2020	31MAY2020	N
		Surgical and medical procedures	Functional endoscopic sinus surgery	01MAY2020	31MAY2020	N
			Meniscus operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2008	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371231	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371232	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1037 10371236	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAY2015	31DEC2019	N
			Depression	01MAY2015	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Dysphonia	01JAN2019		Y
			Vocal cord polyp	01JAN2019	13NOV2020	N
		Surgical and medical procedures	Female sterilisation	01JAN2007	31JAN2007	N
	C4591001 1037 10371238	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN2000		Y
	C4591001 1037 10371240	Psychiatric disorders	Anxiety	01MAY2019		Y
			Depression	01MAY2019		Y
	C4591001 1037 10371241	Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
	C4591001 1037 10371245	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1037 10371246	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371249	Immune system disorders	Seasonal allergy	01APR1995		Y
		Infections and infestations	Herpes simplex	01JAN2011		Y
		Investigations	Heart rate increased	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01SEP2020	08SEP2020	N
	C4591001 1037 10371250	Immune system disorders	Seasonal allergy	01JAN1985		Y
	C4591001 1037 10371253	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01MAY2014	31MAY2014	N
	C4591001 1037 10371254	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1037 10371255	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Abdominal injury	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Abdominal operation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371256	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1037 10371257	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1037 10371258	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
		Psychiatric disorders	Tobacco abuse	01MAY2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1037 10371259	Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01SEP2010		Y
		Surgical and medical procedures	Meniscus operation	01JAN2015	31DEC2015	N
	C4591001 1037 10371262	Gastrointestinal disorders	Constipation	01JUN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Tobacco abuse	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371265	Cardiac disorders	Supraventricular tachycardia	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01MAR2000		Y
	C4591001 1037 10371266	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1037 10371269	Eye disorders	Cataract	01JAN2014		Y
			Retinal detachment	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Retinopexy	01JAN2014	31DEC2014	N
	C4591001 1037 10371271	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1037 10371277	Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1037 10371284	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Trichotillomania	01JAN2006		Y
	C4591001 1037 10371286	Infections and infestations	Tinea pedis	01SEP2020		Y
		Vascular disorders	Hypertension	01SEP2015		Y
	C4591001 1037 10371287	Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371288	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1037 10371290	Immune system disorders	Drug hypersensitivity	01MAR1984		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1037 10371291	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1997		Y
			Major depression	01JAN1997		Y
		Social circumstances	Menopause	01JAN2020		Y
		Vascular disorders	Hot flush	01JAN2020		Y
	C4591001 1037 10371298	Immune system disorders	Food allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01APR2005	30APR2013	N
		Surgical and medical procedures	Uterine dilation and curettage	01APR2013	30APR2013	N
	C4591001 1037 10371300	General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1037 10371301	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
			Obesity	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1037 10371302	Congenital, familial and genetic disorders	Pectus carinatum	01MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01FEB2020		Y
	C4591001 1037 10371306	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1037 10371307	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1037 10371308	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
			Tobacco abuse	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Night sweats	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01MAR2000	31MAR2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1037 10371309	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01FEB1999		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1037 10371312	Cardiac disorders	Myocardial infarction	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01FEB2010		Y
		Social circumstances	Postmenopause	01JUL2017		Y
		Surgical and medical procedures	Gastrectomy	01JAN2016	31JAN2016	N
			Percutaneous coronary intervention	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371313	Metabolism and nutrition disorders	Obesity	01JAN1983		Y
		Psychiatric disorders	Schizophrenia	01JAN1986		Y
	C4591001 1037 10371314	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31MAR2010	N
		Surgical and medical procedures	Hysterectomy	01MAR2010	31MAR2010	N
	C4591001 1037 10371315	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1037 10371316	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1037 10371317	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
			Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Major depression	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371319	Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1037 10371321	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Gastrointestinal disorders	Constipation	01JAN1999		Y
			Gastric ulcer	01APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1037 10371323	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1037 10371324	Blood and lymphatic system disorders	Anaemia	01MAR1998		Y
		Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2012		Y
			Irritable bowel syndrome	01APR2006		Y
		Immune system disorders	Seasonal allergy	01AUG2001		Y
		Metabolism and nutrition disorders	Hypokalaemia	01FEB2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAY2015		Y
			Spinal osteoarthritis	01AUG2010		Y
		Psychiatric disorders	Major depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2006		Y
		Vascular disorders	Hypertension	01OCT2012		Y
	C4591001 1037 10371325	Skin and subcutaneous tissue disorders	Keloid scar	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371327	Metabolism and nutrition disorders	Obesity	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1995	31DEC2002	N
		Surgical and medical procedures	Gastrectomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1037 10371328	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1037 10371331	Endocrine disorders	Hypothyroidism	01OCT2018		Y
			Thyroid mass	01JAN2017	31OCT2018	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1983		Y
		Surgical and medical procedures	Thyroidectomy	01OCT2018	31OCT2018	N
	C4591001 1037 10371336	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2019		Y
			Obesity	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01MAY2013	31MAY2013	N
			Oophorectomy bilateral	01JAN2007	31JAN2007	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1037 10371337	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Infections and infestations	Urinary tract infection	07OCT2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371340	Injury, poisoning and procedural complications	Jaw fracture	01APR2019	30APR2019	N
		Surgical and medical procedures	Jaw operation	01APR2019	30APR2019	N
	C4591001 1037 10371341	Immune system disorders	Seasonal allergy	13OCT1986		Y
	C4591001 1037 10371342	Endocrine disorders	Hyperprolactinaemia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Rubber sensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Major depression	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371344	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1037 10371347	Psychiatric disorders	Tobacco abuse	01MAY1992		Y
	C4591001 1037 10371350	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01MAY2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1037 10371351	Immune system disorders	Seasonal allergy	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1037 10371352	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Tobacco abuse	01JAN2017		Y
	C4591001 1037 10371353	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1037 10371355	Nervous system disorders	Cerebrovascular accident	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1037 10371357	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Bipolar disorder	01SEP2020		Y
			Major depression	01JAN2012		Y
	C4591001 1037 10371359	Metabolism and nutrition disorders	Hyperlipidaemia	17JUL2016		Y
		Nervous system disorders	Cerebrovascular accident	17JUL2016	17JUL2016	N
			Epilepsy	01NOV1993		Y
	C4591001 1037 10371360	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1038 10381002	Congenital, familial and genetic disorders	Gene mutation	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1038 10381004	Surgical and medical procedures	Fracture treatment	01AUG1989	31AUG1989	N
		Vascular disorders	Hypertension	30OCT2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381005	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Investigations	Blood glucose abnormal	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
	C4591001 1038 10381008	Endocrine disorders	Hypogonadism male	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2012		Y
			Hyperlipidaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
	C4591001 1038 10381010	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01SEP2016		Y
	C4591001 1038 10381012	Endocrine disorders	Hypothyroidism	24APR2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01DEC2000		Y
		Psychiatric disorders	Depression	23AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	31AUG2017		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01DEC2015	31DEC2015	N
			Endometrial ablation	01MAY2015	31MAY2015	N
			Female sterilisation	01MAY1994	31MAY1994	N
			Mammoplasty	01FEB2019	28FEB2019	N
		Vascular disorders	Essential hypertension	01AUG2017		Y
	C4591001 1038 10381013	Endocrine disorders	Hypothyroidism	02SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	29DEC2014		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Major depression	18MAY2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Surgical and medical procedures	Vasectomy	28APR2011		Y
	C4591001 1038 10381014	Immune system disorders	Drug hypersensitivity	01DEC1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	07APR2018	07APR2018	N
			Female sterilisation	07APR2018	07APR2018	N
			Fracture treatment	01JAN2009	31JAN2009	N
	C4591001 1038 10381016	Ear and labyrinth disorders	Meniere's disease	01JAN2015		Y
		Endocrine disorders	Goitre	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JUN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1981	31DEC1981	N
	C4591001 1038 10381018	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01DEC2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1992	31DEC1992	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N
	C4591001 1038 10381022	Ear and labyrinth disorders	Vertigo	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
				01JAN1990		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN2008		Y
			Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
			Migraine	01JAN1980		Y
			Transient ischaemic attack	31JAN2020	31JAN2020	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN1999		Y
			Insomnia	01JAN2014		Y
			Major depression	01JAN1999		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Shoulder operation	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1038 10381023	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	17AUG2011		Y
		Endocrine disorders	Hypogonadism male	07DEC2012		Y
			Hypothyroidism	22DEC2017		Y
		Gastrointestinal disorders	Coeliac disease	19MAR2020		Y
			Gastroesophageal reflux disease	30AUG2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	22AUG2018		Y
		Psychiatric disorders	Insomnia	21OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17MAR2017		Y
	C4591001 1038 10381024	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Nervous system disorders	Sciatica	01DEC2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1999		Y
	C4591001 1038 10381027	Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1038 10381028	Vascular disorders	Hypertension	01JAN2015		Y
		Gastrointestinal disorders	Constipation	15MAR2012		Y
		Investigations	Hiatus hernia	01JAN2015		Y
		Reproductive system and breast disorders	Cardiac murmur functional	25JUL2012		Y
			Endometriosis	25MAR2011		Y
			Menstrual disorder	17MAY2013		Y
			Metrorrhagia	15MAR2012		Y
			Pelvic pain	23SEP2014		Y
			Polycystic ovaries	04JAN2013		Y
	C4591001 1038 10381029	Skin and subcutaneous tissue disorders	Hirsutism	25FEB2010		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1994		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01MAR2020		Y
	C4591001 1038 10381036	Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2003		Y
			Depression	01JAN2003		Y
		Social circumstances	Tobacco user	01JAN1996		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN2019	31DEC2019	N
	C4591001 1038 10381038	Infections and infestations	Onychomycosis	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01NOV2013		Y
	C4591001 1038 10381042	Blood and lymphatic system disorders	Anaemia	08MAY2020		Y
		Endocrine disorders	Goitre	19OCT2015		Y
			Hypothyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Investigations	Blood uric acid increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperhomocysteinaemia	01JAN2015		Y
			Hyperinsulinism	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	06SEP2011		Y
			Attention deficit hyperactivity disorder	25MAR2020		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Metrorrhagia	01JAN2006		Y
			Oligomenorrhoea	01JAN2006		Y
			Polycystic ovaries	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
		Vascular disorders	Essential hypertension	01JAN2015		Y
	C4591001 1038 10381043	Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	13DEC2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cerebellar infarction	23DEC2019		Y
		Psychiatric disorders	Anxiety	01NOV2007		Y
			Depression	01JAN2004		Y
		Surgical and medical procedures	Intrauterine contraception	01APR2020		Y
	C4591001 1038 10381044	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
	C4591001 1038 10381045	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Endocrine disorders	Hypogonadism	01JAN2010		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2015		Y
			Impaired gastric emptying	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Investigations	Catheterisation cardiac	01OCT2015	31OCT2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Hypoglycaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Oesophageal adenocarcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Oesophagogastrectomy	25NOV2015	25NOV2015	N
			Vasectomy	01SEP2015	30SEP2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Essential hypertension	01JAN2015		Y
	C4591001 1038 10381048	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01DEC2016		Y
	C4591001 1038 10381049	Psychiatric disorders	Insomnia	23MAR2020		Y
	C4591001 1038 10381052	Gastrointestinal disorders	Constipation	14FEB2013		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1038 10381053	Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1038 10381057	Endocrine disorders	Hypothyroidism	25APR2017		Y
		Metabolism and nutrition disorders	Gout	21MAR2014		Y
			Hyperlipidaemia	14AUG2009		Y
			Impaired fasting glucose	13MAR2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	15DEC2012		Y
	C4591001 1038 10381059	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Presyncope	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1038 10381061	General disorders and administration site conditions	Oedema peripheral	18JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Investigations	Mammogram abnormal	01SEP2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	26JAN2016		Y
			Type 2 diabetes mellitus	07MAR2011		Y
			Vitamin D deficiency	18JAN2017		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	17AUG2016		Y
			Spinal osteoarthritis	15JUL2017		Y
		Nervous system disorders	Cervical radiculopathy	28AUG2020		Y
		Psychiatric disorders	Anxiety	11AUG2019		Y
			Attention deficit hyperactivity disorder	12NOV2019		Y
			Depression	07MAR2011		Y
			Insomnia	27MAR2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Mammoplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	27MAR2015		Y
	C4591001 1038 10381063	Cardiac disorders	Atrial fibrillation	10APR2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	04JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	02SEP2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04JAN2006		Y
			Sleep apnoea syndrome	18FEB2011		Y
	C4591001 1038 10381065	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
	C4591001 1038 10381067	Investigations	Hysteroscopy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	07AUG2017		Y
		Surgical and medical procedures	Mammoplasty	01JAN1997	31DEC1997	N
		Vascular disorders	Essential hypertension	06OCT2014		Y
	C4591001 1038 10381069	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01APR2020		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01DEC1995	31DEC1995	N
			Thyroidectomy	01AUG2017	31AUG2017	N
	C4591001 1038 10381070	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	30APR2019		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	17JAN2019		Y
	C4591001 1038 10381075	Musculoskeletal and connective tissue disorders	Back pain	07OCT2015		Y
		Psychiatric disorders	Anxiety	17JUN2020		Y
			Major depression	17JUN2020		Y
	C4591001 1038 10381076	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2018		Y
			Polycystic ovaries	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381077	Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Lithotripsy	01JAN2006	31DEC2006	N
	C4591001 1038 10381078	Metabolism and nutrition disorders	Glucose tolerance impaired	10DEC2019		Y
			Hyperlipidaemia	10DEC2019		Y
			Obesity	10DEC2019		Y
		Vascular disorders	Hypertension	10DEC2019		Y
	C4591001 1038 10381079	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	11FEB2020		Y
			Insomnia	01APR2020		Y
		Surgical and medical procedures	Limb operation	12NOV2013	12NOV2013	N
	C4591001 1038 10381080	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Gout	01JAN2002		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
	C4591001 1038 10381082	Injury, poisoning and procedural complications	Foot fracture	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Foot operation	01JAN2011	31DEC2011	N
	C4591001 1038 10381083	Endocrine disorders	Goitre	01AUG2019		Y
			Hyperthyroidism	01AUG2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1986		Y
			Tension headache	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JUN2017		Y
			Insomnia	01JAN2005		Y
			Sleep disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG2020		Y
	C4591001 1038 10381085	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01MAR2012	31DEC2012	N
			Hepatic steatosis	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Surgical and medical procedures	Abscess drainage	01JAN2011	31DEC2011	N
			Cholecystectomy	01MAR2012	31DEC2012	N
			Umbilical hernia repair	01JAN2011	31DEC2011	N
	C4591001 1038 10381088	Infections and infestations	Oral herpes	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1038 10381091	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Generalised anxiety disorder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01DEC2005	31DEC2005	N
			Mammoplasty	01JAN2013	31DEC2013	N
	C4591001 1038 10381093	Congenital, familial and genetic disorders	Umbilical malformation	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	14JUL2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1038 10381094	Surgical and medical procedures	Intra-uterine contraceptive device insertion	22MAR2017	22MAR2017	N
	C4591001 1038 10381095	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008		Y
			Rhinitis allergic	01JAN2005		Y
	C4591001 1038 10381096	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1038 10381098	Immune system disorders	Drug hypersensitivity	31MAR2013		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2010		Y
	C4591001 1038 10381102	Eye disorders	Chorioretinopathy	09JUN2016		Y
		Gastrointestinal disorders	Constipation	24AUG2009		Y
		Immune system disorders	Seasonal allergy	19MAY2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05FEB2017		Y
			Obesity	04NOV2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	07AUG2013		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spondylolysis	01JUL1983		Y
		Nervous system disorders	Hypoaesthesia	08FEB2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	02MAY2014		Y
			Oropharyngeal pain	06APR2018		Y
			Sleep apnoea syndrome	09MAY2018		Y
			Snoring	14FEB2018		Y
		Surgical and medical procedures	Intervertebral disc operation	01MAY1992	31MAY1992	N
		Vascular disorders	Essential hypertension	23DEC2013		Y
	C4591001 1038 10381103	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAY2017	30NOV2017	N
		Surgical and medical procedures	Hysterectomy	01NOV2017	30NOV2017	N
	C4591001 1038 10381105	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1038 10381109	Gastrointestinal disorders	Umbilical hernia	01JUN2018	30JUN2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Muscle spasms	11OCT2019		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2010		Y
			Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	26AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Umbilical hernia repair	01JUN2018	30JUN2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Varicose vein	01JAN2010		Y
	C4591001 1038 10381111	Endocrine disorders	Hypogonadism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990		Y
		Surgical and medical procedures	Ureteral stent insertion	01JAN2000	31DEC2000	N
	C4591001 1038 10381112	Vascular disorders	Hypertension	01JAN2015		Y
		Gastrointestinal disorders	Dysphagia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2006		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Insomnia	01JAN2010		Y
	C4591001 1038 10381115	Gastrointestinal disorders	Gastroesophageal reflux disease	06MAY2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Major depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1038 10381117	Musculoskeletal and connective tissue disorders	Scoliosis	29JUL2010		Y
		Psychiatric disorders	Anxiety disorder	17JUN2011		Y
			Attention deficit hyperactivity disorder	26APR2005		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381119	Gastrointestinal disorders	Gastroesophageal reflux disease	11SEP2013		Y
		Nervous system disorders	Headache	14NOV2017		Y
			Restless legs syndrome	08FEB2017		Y
		Psychiatric disorders	Depression	11SEP2013		Y
	C4591001 1038 10381120	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Mammoplasty	01JAN2015	31DEC2015	N
			Salpingectomy	09JUL2020	09JUL2020	N
	C4591001 1038 10381121	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1038 10381127	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
			Blood testosterone decreased	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1038 10381128	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1038 10381130	Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381131	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1038 10381133	Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Hyperlipidaemia	01JAN2009		Y
	C4591001 1038 10381136	Metabolism and nutrition disorders	Obesity	01JAN1998		Y
			Type 2 diabetes mellitus	01DEC2018		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Therapeutic nerve ablation	01JAN2010	31DEC2010	N
	C4591001 1038 10381138	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
			Urge incontinence	01JAN2016		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1038 10381140	Vascular disorders	Hypertension	01JAN2005		Y
		Endocrine disorders	Hypogonadism male	14NOV2011		Y
			Hypothyroidism	07AUG2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23APR2014		Y
		Vascular disorders	Hypertension	14NOV2011		Y
	C4591001 1038 10381141	Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1039 10391002	Immune system disorders	Seasonal allergy	01JAN2010	31DEC2020	N
		Infections and infestations	Papilloma viral infection	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dandruff	(b) (6) 1989		Y
	C4591001 1039 10391004	Social circumstances	Denture wearer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Eye laser surgery	01JAN2012	31DEC2012	N
	C4591001 1039 10391009	Eye disorders	Myopia	21AUG2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1985		Y
			Nasal septum deviation	01JAN2005		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2012		Y
	C4591001 1039 10391011	Blood and lymphatic system disorders	Anaemia	01JAN2012	31DEC2018	N
		Congenital, familial and genetic disorders	Developmental hip dysplasia	(b) (6) 1967	15JAN2008	N
		Endocrine disorders	Hypothyroidism	01JAN2005	31DEC2010	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
			Hiatus hernia	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2019	28FEB2019	N
			Muscle spasms	01JAN1982	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1982	31DEC2000	N
		Psychiatric disorders	Bipolar I disorder	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	(b) (6) 1967	15JAN2008	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1039 10391014	Eye disorders	Presbyopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Injury, poisoning and procedural complications	Concussion	24DEC2019	01MAR2020	N
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391016	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	07DEC2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Cranial operation	01JAN1997	31DEC1997	N
	C4591001 1039 10391017	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Eye disorders	Myopia	01JAN2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
	C4591001 1039 10391021	Immune system disorders	Drug hypersensitivity	(b) (6) 1994		Y
			Seasonal allergy	01JAN2004		Y
		Nervous system disorders	Carpal tunnel syndrome	01JUN2019	31MAY2020	N
		Psychiatric disorders	Anxiety	01OCT2017		Y
		Surgical and medical procedures	Carpal tunnel decompression	01MAY2020	31MAY2020	N
	C4591001 1039 10391022	Injury, poisoning and procedural complications	Sports injury	01JAN2016	31DEC2016	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN2001	31DEC2008	N
		Surgical and medical procedures	Caesarean section	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2016	31DEC2016	N
	C4591001 1039 10391025	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Onychomycosis	25AUG2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
	C4591001 1039 10391026	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN1996		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
		Surgical and medical procedures	Abdominoplasty	01JUL2018	31JUL2018	N
			Caesarean section	01AUG2016	31AUG2016	N
				01JUL2013	31JUL2013	N
			Female sterilisation	01AUG2016	31AUG2016	N
				01JAN2016	31DEC2016	N
			Mammoplasty	01JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN2013	31DEC2016	N
	C4591001 1039 10391036	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1991		Y
		Investigations	Liver function test increased	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN1994		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
	C4591001 1039 10391045	Vascular disorders	Hypertension	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1039 10391057	Surgical and medical procedures	Vasectomy	06MAR2020	06MAR2020	N
		Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2016	N
				01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
	C4591001 1039 10391058	Eye disorders	Myopia	01JAN1985		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Immune system disorders	Allergy to plants	01JAN2016		Y
			Seasonal allergy	01JAN2016		Y
		Infections and infestations	Herpes zoster	01JAN1989	31DEC2018	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Eye laser surgery	01JAN2001	31DEC2001	N
			Oophorectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	26MAR2016		Y
	C4591001 1039 10391065	Eye disorders	Myopia	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1039 10391067	Eye disorders	Conjunctivitis allergic	01JAN2018		Y
			Myopia	01JAN1983		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoid cystic carcinoma	01JAN2009	31DEC2009	N
			Vulval cancer	01JAN2009	31DEC2009	N
		Social circumstances	Corrective lens user	01JAN1983		Y
		Surgical and medical procedures	Bartholin's cyst removal	01JAN2009	31DEC2009	N
			Mammoplasty	01JAN2003	31DEC2003	N
			Vulvectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Raynaud's phenomenon	01JAN2003		Y
	C4591001 1039 10391068	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2018		Y
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1039 10391071	Eye disorders	Presbyopia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Rubber sensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2003	31DEC2003	N
			Hernia repair	01JAN2012	31DEC2012	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
			Skin cyst excision	01JAN2020	31DEC2020	N
			Transfusion	01JAN2016	31DEC2016	N
	C4591001 1039 10391076	Congenital, familial and genetic disorders	Protein S deficiency	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2003	31DEC2003	N
				01JAN2017	31DEC2017	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1039 10391080	Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1039 10391085	Eye disorders	Retinal degeneration	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	(b) (6) 1979		Y
	C4591001 1039 10391086	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Social circumstances	Blood donor	01JAN2000		Y
			Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	03FEB1999	03FEB1999	N
				09JUL1996	09JUL1996	N
			Female sterilisation	03FEB1999	03FEB1999	N
			Thyroidectomy	01JAN2002	31DEC2002	N
	C4591001 1039 10391087	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2016	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01JAN2006	31DEC2007	N
	C4591001 1039 10391088	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2008		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Intrauterine contraception	01JAN2019		Y
	C4591001 1039 10391090	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01APR2017	30APR2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1039 10391091	Eye disorders	Myopia	01JAN1988		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1994		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
			Tonsillitis	01JAN2018	31DEC2018	N
		Nervous system disorders	Hypersomnia	01JAN2018		Y
		Social circumstances	Tobacco user	04SEP2007	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN1990	31DEC1990	N
			Appendicectomy	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1039 10391093	Social circumstances	Corrective lens user	01JAN2013		Y
	C4591001 1039 10391096	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast pain	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Breast operation	01JAN2011	31DEC2011	N
			Exeresis	01JAN2014	31DEC2014	N
	C4591001 1039 10391097	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN1979		Y
			Umbilical hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	(b) (6) 1979		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2002	31DEC2006	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2014	31DEC2014	N
	C4591001 1039 10391099	General disorders and administration site conditions	Hernia	01JAN2009	31DEC2009	N
		Infections and infestations	Tinea versicolour	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Hernia repair	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1039 10391104	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391108	Endocrine disorders	Hypothyroidism	01JAN2013	31DEC2017	N
		Investigations	Human papilloma virus test positive	01JAN1994	31DEC2015	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1983		Y
		Nervous system disorders	Sinus headache	01JAN1997	31DEC1997	N
		Psychiatric disorders	Bipolar II disorder	01JAN2008		Y
			Sleep disorder	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1039 10391109	Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2010	31DEC2010	N
			Endometrial ablation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1039 10391110	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Social circumstances	Blood donor	01JAN2018		Y
			Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Hernia repair	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391112	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Trigger finger	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1039 10391114	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Social circumstances	Blood donor	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2006	31DEC2006	N
			Sinuplasty	01MAR2019	31MAR2019	N
	C4591001 1039 10391115	Eye disorders	Pinguecula	01JAN2020	31DEC2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2020		Y
			Dermatitis	01JAN2020		Y
		Social circumstances	Blood donor	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1039 10391118	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011	31DEC2011	N
		Infections and infestations	Herpes virus infection	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Rhinitis allergic	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Eye operation	01JAN2010	31DEC2010	N
			Uterine dilation and curettage	01JAN1994	31DEC1994	N
	C4591001 1039 10391119	Eye disorders	Myopia	01JAN1978		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Colonoscopy	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1978		Y
		Surgical and medical procedures	Hernia repair	01JAN2002	31DEC2002	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1039 10391120	Immune system disorders	Seasonal allergy	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 1039 10391124	Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
		Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Diverticulitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1997		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1039 10391128	Infections and infestations	Ear infection	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
	C4591001 1039 10391133	Blood and lymphatic system disorders	Microcytosis	01DEC2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Investigations	Cardiac murmur	01JAN1980	31DEC1998	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01FEB2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Insomnia	01JAN2018		Y
			Obsessive-compulsive disorder	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Hernia repair	01JAN1984	31DEC1984	N
			Knee operation	01JAN1999	31DEC1999	N
			Limb operation	01JAN1999	31DEC1999	N
			Uterine dilation and curettage	01JAN2000	31DEC2000	N
	C4591001 1039 10391134	Blood and lymphatic system disorders	Anaemia	01JAN1975	31DEC1978	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Infections and infestations	Hepatitis A	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Peripheral nerve operation	01JUL2020	31JUL2020	N
			Vasectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1039 10391136	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1039 10391140	Surgical and medical procedures	Thyroidectomy	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN1993		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1039 10391145	Surgical and medical procedures	Sinuplasty	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Biopsy cervix	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014		Y
			Headache	01JAN2003		Y
			Migraine	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Insomnia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1039 10391150	Social circumstances	Corrective lens user	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1990	31DEC1990	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN1996	31DEC1996	N
		Eye disorders	Presbyopia	01JAN2016	31DEC2016	N
	C4591001 1039 10391151			01JAN2017		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1974	31DEC1974	N
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
			Dyspnoea	01SEP2019	31MAR2020	N
			Sleep apnoea syndrome	01SEP2019	31MAR2020	N
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Hernia repair	01JAN1974	31DEC1974	N
			Knee operation	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
				01JAN2017	31DEC2017	N
			Limb operation	01JAN1983	31DEC1983	N
			Lymphadenectomy	01JAN1986	31DEC1986	N
			Shoulder operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1979	31DEC1979	N
			Vasectomy	01JAN2014	31JAN2014	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1039 10391152	Infections and infestations	Chronic sinusitis	01JAN2005	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Amenorrhoea	01JAN1996	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1981		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2012	31DEC2012	N
			Cardiac operation	01JAN2015	31DEC2015	N
	C4591001 1039 10391153	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2002		Y
			Dermatitis	01JAN2015		Y
		Social circumstances	Blood donor	01JAN2000	31DEC2017	N
		Surgical and medical procedures	Hair transplant	14FEB2020	14FEB2020	N
	C4591001 1039 10391156	Eye disorders	Myopia	01JAN1978		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1967		Y
		Investigations	Biopsy breast	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Nephrolithiasis	01AUG2015	31AUG2015	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Endometrial ablation	01JAN2014	31DEC2014	N
			Hysterectomy	01DEC2016	31DEC2016	N
			Retinal operation	26JUL2018	26JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	24JUN2019	24JUN2019	N
	C4591001 1039 10391157	Eye disorders	Myopia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01MAY2020		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Spinal operation	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1039 10391162	Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
			Menopause	01JAN2016		Y
		Surgical and medical procedures	Photorefractive keratectomy	01JAN1989	31DEC1989	N
	C4591001 1039 10391165	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2011	31DEC2011	N
	C4591001 1039 10391166	Gastrointestinal disorders	Malocclusion	01JAN2016	31MAY2020	N
		Psychiatric disorders	Insomnia	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	(b) (6) 1994		Y
	C4591001 1039 10391167	Surgical and medical procedures	Orthognathic surgery	01MAY2020	31MAY2020	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1981		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1987		Y
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
			Endoscopy upper gastrointestinal tract	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Social circumstances	Blood donor	01JAN1991	31DEC2019	N
			Corrective lens user	01JAN1988		Y
		Surgical and medical procedures	Abdominal operation	01JAN2012	31DEC2012	N
			Appendectomy	01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Nail operation	01JAN2017	31DEC2017	N
			Small intestine operation	01JAN2012	31DEC2012	N
			Spinal operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1039 10391168	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Large intestine polyp	01JAN2005		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1993		Y
		Surgical and medical procedures	Dental operation	01JAN2019	31DEC2019	N
			Knee operation	01JAN2010	31DEC2010	N
	C4591001 1039 10391171	Ear and labyrinth disorders	Hypoacusis	01JAN2002		Y
			Tympanic membrane perforation	01JAN2007		Y
		Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977	31DEC1995	N
		Social circumstances	Corrective lens user	01JAN2004		Y
		Surgical and medical procedures	Dental operation	01JAN1993	31DEC1993	N
			Eye laser surgery	01JAN2004	31DEC2004	N
			Meniscus operation	01JAN2018	31DEC2018	N
			Tympanoplasty	01JAN2002	31DEC2002	N
				01JAN2007		Y
					31DEC2007	N
	C4591001 1039 10391172	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1978	31DEC1978	N
			Eye laser surgery	01JAN1996	31DEC1996	N
			Mammoplasty	01JAN2014	31DEC2014	N
	C4591001 1039 10391175	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2018	31DEC2018	N
			Sinuplasty	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391176	Surgical and medical procedures	Shoulder operation	01JAN2019	31DEC2019	N
			Tendon operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2016	31DEC2016	N
	C4591001 1039 10391177	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN2001		Y
		Investigations	Colonoscopy	01MAR2020	31MAR2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Social circumstances	Blood donor	01JAN1996	30SEP2020	N
		Surgical and medical procedures	Eye laser surgery	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1996	31DEC1996	N
			Wisdom teeth removal	01JAN1994	31DEC1994	N
	C4591001 1039 10391178	Endocrine disorders	Hypothyroidism	01NOV2019		Y
		Hepatobiliary disorders	Cholecystitis	01OCT2017	31OCT2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01NOV2019		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2017	31OCT2017	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1039 10391179	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2018	07JUN2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1039 10391180	Surgical and medical procedures	Hernia repair	07JUN2018	07JUN2018	N
		Cardiac disorders	Mitral valve prolapse	01JAN2006		Y
		Ear and labyrinth disorders	Vertigo	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Herpes simplex	01JAN2004		Y
		Investigations	Papilloma viral infection	01JAN2005	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Biopsy lymph gland	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Back pain	01JAN2004		Y
			Malignant melanoma	01JAN2008	31DEC2008	N
	C4591001 1039 10391181	Psychiatric disorders	Anxiety	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Peritonitis	01JAN2005	31DEC2005	N
		Nervous system disorders	Carpal tunnel syndrome	29SEP2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Abdominal operation	01JAN2005	31DEC2005	N
			Appendectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391182	Ear and labyrinth disorders	Hypoacusis	01JAN1973		Y
			Vertigo	01JAN2018	31DEC2018	N
		Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
	C4591001 1039 10391183	Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Neck pain	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Skin discolouration	01JAN2012	31DEC2012	N
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Meniscus operation	01JAN1992	31DEC1992	N
	C4591001 1039 10391185	Gastrointestinal disorders	Abdominal hernia	01JAN1973	31DEC1973	N
			Large intestine polyp	01FEB2020	29FEB2020	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN1990		Y
		Investigations	Colonoscopy	01FEB2020	29FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2000	31DEC2000	N
				01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2018	31DEC2018	N
			Nasal polypectomy	01JAN2000	31DEC2000	N
				01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1039 10391186	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN1997		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2019	31DEC2019	N
	C4591001 1039 10391187	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2010		Y
		Endocrine disorders	Testicular failure	01JAN2014		Y
		Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01APR2004	30APR2004	N
		Psychiatric disorders	Adjustment disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2015	31DEC2015	N
			Skin atrophy	01JAN2018		Y
			Skin hypertrophy	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Circumcision	01DEC2018	31DEC2018	N
			Orchidectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391190	Eye disorders	Presbyopia	01JAN1987		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Transient ischaemic attack	01MAY2015	31MAY2015	N
		Social circumstances	Corrective lens user	01JAN1987		Y
		Surgical and medical procedures	Dental implantation	01NOV2019	30NOV2019	N
	C4591001 1039 10391196	Blood and lymphatic system disorders	Anaemia	01JUN2020		Y
		Ear and labyrinth disorders	Deafness	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	02APR2020	31MAY2020	N
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1039 10391198	Injury, poisoning and procedural complications	Radius fracture	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012	31JUL2020	N
	C4591001 1039 10391199	Ear and labyrinth disorders	Deafness unilateral	01JAN1988		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN1995		Y
		Investigations	Colonoscopy	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391200	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Eye disorders	Myopia	01JAN1994		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Herpes simplex	01SEP2007		Y
			Herpes zoster	01JAN2018	31DEC2018	N
			Otitis media chronic	01JAN2010	31DEC2015	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1039 10391203	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anogenital warts	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01OCT2018	31OCT2018	N
		Surgical and medical procedures	Eye laser surgery	01JAN2013	31DEC2013	N
			Ligament operation	01JAN1999	31DEC1999	N
	C4591001 1039 10391205	Eye disorders	Astigmatism	01JAN1992		Y
			Hypermetropia	01JAN1987		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Infections and infestations	Diverticulitis	01JAN2007	31DEC2007	N
			Herpes zoster	01JAN2012	31DEC2012	N
		Investigations	Colonoscopy	01JAN2007	31DEC2007	N
		Social circumstances	Corrective lens user	01JAN1987		Y
		Surgical and medical procedures	Hernia repair	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2016		Y
		Eye disorders	Astigmatism	01JAN2016		Y
	C4591001 1039 10391207	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN1990		Y
		Social circumstances	Blood donor	01JAN2000	31DEC2015	N
			Corrective lens user	01JAN1997		Y
		Surgical and medical procedures	Dental operation	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Vasectomy	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JAN1995	31DEC1995	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2016		Y
	C4591001 1039 10391208	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1984	31DEC1984	N
		Congenital, familial and genetic disorders	Thalassaemia minor	01JAN2000		Y
	C4591001 1039 10391209					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	(b) (6) 1976		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Radial nerve compression	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Infertility	01JAN2011		Y
			Menorrhagia	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Peripheral nerve decompression	01JAN2014	31DEC2014	N
	C4591001 1039 10391212	Immune system disorders	Seasonal allergy	(b) (6) 1993		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
			Herpes zoster	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
	C4591001 1039 10391214	Ear and labyrinth disorders	Hypoacusis	01JAN1998	31DEC2006	N
		Eye disorders	Myopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1986		Y
		Infections and infestations	Otitis media	01JAN1998	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01JAN2006	31DEC2006	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN1998		Y
	C4591001 1039 10391218†	Surgical and medical procedures	Tympanoplasty	01JAN2006	31DEC2006	N
		Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN1993		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1967	31DEC1967	N
			Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Investigations	HIV test positive	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007	31DEC2014	N
		Social circumstances	Corrective lens user	01JAN1993		Y
	C4591001 1039 10391220	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Presyncope	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Social circumstances	Corrective lens user	01JAN2006		Y
	C4591001 1039 10391222	Eye disorders	Hypermetropia	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Investigations	Colonoscopy	01MAR2007	31MAR2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1982		Y
		Surgical and medical procedures	Hysterectomy	01JUL2007	31JUL2007	N
	C4591001 1039 10391224	Cardiac disorders	Sinus tachycardia	25JUL2020	30JUL2020	N
		Ear and labyrinth disorders	Ear deformity acquired	01JAN2006		Y
			Hypoacusis	01OCT2019		Y
		Eye disorders	Myopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01DEC2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Nervous system disorders	Syncope	01SEP2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01OCT2019		Y
		Social circumstances	Corrective lens user	01JAN1998		Y
	C4591001 1039 10391225	Endocrine disorders	Hypothyroidism	01JAN2009	31DEC2016	N
		Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Investigations	Biopsy skin	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Hypomagnesaemia	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2019	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Dyspareunia	01JAN2010		Y
	C4591001 1039 10391226	Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
	C4591001 1039 10391232	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN1998		Y
			Insomnia	01JAN2006		Y
	C4591001 1039 10391233	Surgical and medical procedures	Permanent contraceptive tubal implant	01JAN2011		Y
		Cardiac disorders	Tachycardia	01JAN2017		Y
		Eye disorders	Myopia	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN1994		Y
		Infections and infestations	Urinary tract infection	01JAN2012	31DEC2015	N
		Social circumstances	Corrective lens user	01MAY2020		Y
	C4591001 1039 10391234†	Surgical and medical procedures	Tympanoplasty	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1999	31DEC1999	N
		Investigations	HIV test positive	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Back pain	01AUG2020		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Insomnia	01AUG2020		Y
		Surgical and medical procedures	Vascular operation	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391235	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2013		Y
		Social circumstances	Corrective lens user	01JAN2004		Y
	C4591001 1039 10391237	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Obsessive-compulsive disorder	01JAN1998		Y
		Reproductive system and breast disorders	Cystocele	01JAN2017		Y
			Polycystic ovaries	01JAN2019		Y
			Rectocele	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
	C4591001 1039 10391239	Cardiac disorders	Angina pectoris	01MAR2020		Y
			Palpitations	01MAR2020		Y
		Congenital, familial and genetic disorders	Congenital uterine anomaly	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Colonoscopy	01JAN2004	31DEC2004	N
			Sigmoidoscopy	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Caesarean section	26APR2009	26APR2009	N
				26SEP2012	26SEP2012	N
	C4591001 1039 10391240	Cardiac disorders	Pulmonary valve stenosis	01JAN1970	31DEC1971	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN2013		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2015	31DEC2015	N
		General disorders and administration site conditions	Cyst	01JAN1982	31DEC1982	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Chronic hepatitis B	01JAN1991		Y
			Fungal infection	01JAN2010	31DEC2017	N
		Investigations	Biopsy skin	01JAN1982	31DEC1982	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN1994	31DEC1995	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1991		Y
		Surgical and medical procedures	Commissurotomy of pulmonary valve	01JAN1971	31DEC1971	N
			Hernia repair	01JAN2015	31DEC2015	N
			Lithotripsy	01FEB2020	29FEB2020	N
			Renal stone removal	01JAN2002	31DEC2002	N
	C4591001 1039 10391241	Gastrointestinal disorders	Colitis ulcerative	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Surgical and medical procedures	Colectomy	01JAN2005	31DEC2005	N
	C4591001 1039 10391242	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391243	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
			Chronic spontaneous urticaria	01JAN2004		Y
	C4591001 1039 10391244	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1039 10391245	Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
	C4591001 1039 10391248	Congenital, familial and genetic disorders	Hypospadias	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Circumcision	01JAN2005	31DEC2005	N
	C4591001 1039 10391249	Eye disorders	Myopia	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Oesophagitis	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Autism spectrum disorder	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391254	Social circumstances	Vegan	01APR2020		Y
	C4591001 1039 10391257	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
			Menorrhagia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2017	31DEC2017	N
			Tenoplasty	01MAY2020	31MAY2020	N
	C4591001 1039 10391261	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Splenorrhaphy	01JAN2015	31DEC2015	N
	C4591001 1042 10421001	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1042 10421003	Infections and infestations	Tonsillitis	01JAN2005	01JAN2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2005		Y
	C4591001 1042 10421008	General disorders and administration site conditions	Hernia	01JUN1996	30JUN1996	N
		Surgical and medical procedures	Hernia repair	01JUN1996	30JUN1996	N
	C4591001 1042 10421014	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2018	31DEC2018	N
				01JUL2016	31JUL2016	N
			Salpingectomy	01DEC2018	31DEC2018	N
			Hypercholesterolaemia	01JAN2019		Y
	C4591001 1042 10421017	Metabolism and nutrition disorders				
	C4591001 1042 10421020	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Rubber sensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Otitis media chronic	01JAN1997	31DEC1999	N
		Nervous system disorders	Tension headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016	31DEC2020	N
		Surgical and medical procedures	Adenoidectomy	01JAN2000	31DEC2000	N
	C4591001 1042 10421021	Infections and infestations	Tonsillitis	01JUN1972	30JUN1972	N
		Social circumstances	Postmenopause	01FEB2018	28FEB2018	N
		Surgical and medical procedures	Female sterilisation	17JUL2003	17JUL2003	N
		Vascular disorders	Hot flush	01FEB2018		Y
	C4591001 1042 10421022	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Rheumatoid arthritis	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421024	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1042 10421027	Immune system disorders	Allergy to animal	01JAN1990		Y
		Psychiatric disorders	Anxiety	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	31MAR2020	31MAR2020	N
	C4591001 1042 10421028	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2002	31DEC2002	N
	C4591001 1042 10421029	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1042 10421031	Skin and subcutaneous tissue disorders	Drug eruption	01JAN1982		Y
		Surgical and medical procedures	Caesarean section	09MAY2002	09MAY2002	N
				12AUG1991	12AUG1991	N
				21DEC1982	21DEC1982	N
				21JUL1994	21JUL1994	N
				21MAY2003	21MAY2003	N
				31OCT1988	31OCT1988	N
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1042 10421034	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JUL2016		Y
			Panic attack	01JUL2016		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1042 10421035	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2004		Y
			Gastroesophageal reflux disease	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Intervertebral disc protrusion	01JAN2012	31DEC2012	N
			Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN1979		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Bipolar II disorder	01JAN2010		Y
			Depression	01JAN1986		Y
			Drug dependence	01JAN2001	31DEC2010	N
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Adenoidectomy	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN2012	31DEC2012	N
			Spinal laminectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421039	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Nervous system disorders	Migraine	01MAR2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2018		Y
	C4591001 1042 10421041	Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1042 10421043	Metabolism and nutrition disorders	Obesity	01JAN1978		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
			Panic attack	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31JAN2018	N
			Female sterilisation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1042 10421044	Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 1042 10421045	Endocrine disorders	Hypothyroidism	01JUN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Gastrectomy	01JUL2016	01JUL2016	N
	C4591001 1042 10421050	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421051	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
		Surgical and medical procedures	Orchidectomy	01JAN2008	31DEC2008	N
	C4591001 1042 10421057	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1042 10421059	Hepatobiliary disorders	Cholelithiasis	04JUN2020	04JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1042 10421061	Injury, poisoning and procedural complications	Cartilage injury	01JAN2004		Y
		Surgical and medical procedures	Chondroplasty	01JAN2004	31DEC2004	N
	C4591001 1042 10421063	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
	C4591001 1042 10421065	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1996		Y
			Hiatus hernia	01JAN2000		Y
			Mouth ulceration	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	03FEB2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
	C4591001 1042 10421068	Vascular disorders	Hypertension	01JAN2006		Y
		Immune system disorders	Food allergy	01JAN1993		Y
			Seasonal allergy	01JAN1993		Y
		Investigations	Blood testosterone decreased	23FEB2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Renal and urinary disorders	Pollakiuria	23FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Vascular disorders	Hypertension	23FEB2020		Y
	C4591001 1042 10421069	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1042 10421070	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1042 10421071	Surgical and medical procedures	Caesarean section	12JAN2015	12JAN2015	N
	C4591001 1042 10421073	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1042 10421076	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2006	N
		Reproductive system and breast disorders	Endometriosis	01JAN2005	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1042 10421077	General disorders and administration site conditions	Hernia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Surgery	01JAN2010	31DEC2010	N
	C4591001 1042 10421079	Psychiatric disorders	Attention deficit hyperactivity disorder	07AUG2016		Y
			Depression	07AUG2016		Y
		Surgical and medical procedures	Female sterilisation	27MAR2020	27MAR2020	N
	C4591001 1042 10421080	Gastrointestinal disorders	Femoral hernia	01JAN2003	31DEC2003	N
		Infections and infestations	Tonsillitis	01JAN1978	31DEC1978	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Femoral hernia repair	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1042 10421081	Gastrointestinal disorders	Inguinal hernia	01JAN1972	31DEC1972	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Nervous system disorders	Essential tremor	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
		Surgical and medical procedures	Hernia repair	01JAN1972	31DEC1972	N
	C4591001 1042 10421082	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01APR2014	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
		Surgical and medical procedures	Fracture treatment	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421088	Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Caesarean section	23JAN2002	23JAN2002	N
			Female sterilisation	23JAN2002	23JAN2002	N
	C4591001 1042 10421092	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
	C4591001 1042 10421093	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01MAR2015	31MAR2015	N
	C4591001 1042 10421095	Hepatobiliary disorders	Cholelithiasis	01OCT1995	31OCT1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
				01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Nervous system disorders	Headache	01JAN1984		Y
		Surgical and medical procedures	Caesarean section	02AUG1995	02AUG1995	N
				22FEB1994	22FEB1994	N
				31JUL2000	31JUL2000	N
			Cholecystectomy	01OCT1995	31OCT1995	N
			Female sterilisation	31JUL2000	31JUL2000	N
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1042 10421100	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Tooth abscess	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Head injury	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN2005	31DEC2005	N
			Unintended pregnancy	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Panic attack	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Craniectomy	01JAN1979	31DEC1979	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1042 10421103	Gastrointestinal disorders	Toothache	01FEB2006	28FEB2006	N
		Immune system disorders	Allergic oedema	01JAN2010		Y
			Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Tendon rupture	01OCT2019	31OCT2019	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1994		Y
		Surgical and medical procedures	Caesarean section	13DEC2011	13DEC2011	N
			Knee operation	01OCT2019	31OCT2019	N
			Wisdom teeth removal	01FEB2006	28FEB2006	N
	C4591001 1042 10421105	Nervous system disorders	Migraine	01JAN1997		Y
	C4591001 1042 10421106	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2012		Y
	C4591001 1042 10421109	Investigations	Blood testosterone decreased	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1042 10421111	Immune system disorders	Food allergy	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1042 10421120	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
	C4591001 1042 10421121	Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1042 10421123	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Skin graft	01JAN1993	31DEC1993	N
	C4591001 1042 10421124	Infections and infestations	Sinusitis	01APR2019	30APR2019	N
			Tonsillitis	01JAN1986	31DEC1986	N
		Injury, poisoning and procedural complications	Meniscus injury	01MAY2000	31MAY2000	N
		Surgical and medical procedures	Keratomileusis	01AUG2004	31AUG2004	N
			Meniscus operation	01MAY2000	31MAY2000	N
			Sinus operation	01APR2019	30APR2019	N
			Tonsillectomy	01JAN1986	31DEC1986	N
	C4591001 1042 10421125	Immune system disorders	Food allergy	01JAN1993		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2020		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	31JUL2019	31JUL2019	N
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Insomnia	01FEB2020		Y
	C4591001 1042 10421126	Surgical and medical procedures	Parathyroidectomy	31JUL2019	31JUL2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1993	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Eagle's syndrome	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Gastrectomy	01JAN2012	31DEC2012	N
			Ostectomy	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1042 10421128	Gastrointestinal disorders	Aphthous ulcer	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Mycotic allergy	01JAN2010	31DEC2010	N
			Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2010	31DEC2010	N
			Asthma	01JAN1971		Y
			Nasal polyps	01JAN2010	31DEC2010	N
			Rhinitis allergic	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Nasal operation	01JAN2010	31DEC2010	N
	C4591001 1042 10421130	Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
	C4591001 1042 10421131	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1042 10421140	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Gout	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
	C4591001 1042 10421142	Pregnancy, puerperium and perinatal conditions	Abnormal cord insertion	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Spinal decompression	01JAN2002	31DEC2002	N
	C4591001 1042 10421143	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Bone hypertrophy	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Nasal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1042 10421144	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
				01JAN2008		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2008		Y
	C4591001 1042 10421148	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Nasal septal operation	01JAN2005	31DEC2005	N
	C4591001 1042 10421151	Investigations	Aspiration pleural cavity	01JAN1999	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	01JAN1999	31DEC1999	N
	C4591001 1042 10421155	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1042 10421157	Hepatobiliary disorders	Gallbladder disorder	01JAN2019	31DEC2019	N
		Infections and infestations	Herpes simplex	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
			Sinus congestion	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	27APR2004	27APR2004	N
			Gallbladder operation	01JAN2019	31DEC2019	N
			Mammoplasty	01JAN2015	31DEC2015	N
			Nasal sinus irrigation	01JAN2018	31DEC2018	N
	C4591001 1042 10421158	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1993	31DEC1994	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN1994	31DEC1994	N
	C4591001 1042 10421161	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1042 10421162	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1042 10421163	Congenital, familial and genetic disorders	Congenital jaw malformation	01JAN1990	31DEC1994	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Surgical and medical procedures	Maxillofacial operation	01JAN1994	31DEC1994	N
	C4591001 1042 10421165	Ear and labyrinth disorders	Deafness bilateral	01MAR2020		Y
	C4591001 1042 10421169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31JAN2006	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Reproductive system and breast disorders	Endometriosis	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Endometrial ablation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1042 10421170	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Injury, poisoning and procedural complications	Tibia fracture	12JAN2019	15JAN2019	N
		Nervous system disorders	Headache	01JAN2009		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
			Obsessive-compulsive disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
		Surgical and medical procedures	Fracture treatment	15JAN2019	15JAN2019	N
			Mammoplasty	01JAN1996	31DEC1996	N
	C4591001 1042 10421175	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1996		Y
	C4591001 1042 10421176	Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Insomnia	01JAN1980		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Menstruation irregular	01APR2017	30APR2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Endometrial ablation	01APR2017	30APR2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1980	31DEC1980	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
	C4591001 1042 10421177	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Abortion induced	05DEC2019	05DEC2019	N
	C4591001 1042 10421180	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
			Pilonidal cyst	01AUG2009	31AUG2009	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Surgical and medical procedures	Pilonidal sinus repair	01AUG2009	31AUG2009	N
	C4591001 1042 10421181	General disorders and administration site conditions	Application site vesicles	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1042 10421185	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Bipolar II disorder	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	11APR2014	11APR2014	N
				16FEB2016	16FEB2016	N
				17FEB2011	17FEB2011	N
			Gastrectomy	22JAN2020	22JAN2020	N
			Mammoplasty	01NOV2012	30NOV2012	N
	C4591001 1042 10421188	Congenital, familial and genetic disorders	Pectus excavatum	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1042 10421190	Gastrointestinal disorders	Abdominal pain	01JAN1985	31DEC1985	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Fibromyalgia	01JAN2006		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2009		Y
			Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
			Intestinal operation	01JAN1985	31DEC1985	N
	C4591001 1042 10421193	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1990		Y
		Immune system disorders	Allergy to plants	01JAN1987		Y
			Seasonal allergy	01JAN1987		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	22MAR1998	22MAR1998	N
			Female sterilisation	01DEC1999	31DEC1999	N
			Shoulder operation	01MAY2020	01MAY2020	N
		Vascular disorders	Hot flush	01JAN2005		Y
			Hypertension	01JAN2017		Y
	C4591001 1042 10421194	Immune system disorders	Allergy to animal	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1042 10421196	Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Meniscus operation	01JAN2017	31DEC2017	N
	C4591001 1042 10421197	Gastrointestinal disorders	Mouth ulceration	01JAN1983		Y
	C4591001 1042 10421198	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2010	31DEC2010	N
		Immune system disorders	Milk allergy	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Myomectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1042 10421204	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
		Surgical and medical procedures	Mammoplasty	01JAN1996	31DEC1996	N
	C4591001 1042 10421205	Immune system disorders	Allergy to plants	01JAN1993		Y
			Dust allergy	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
			Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1042 10421206	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1042 10421207	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC2019	N
		Surgical and medical procedures	Nasal septal operation	01DEC2019	31DEC2019	N
	C4591001 1042 10421209	Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2015		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	01JAN2010		Y
	C4591001 1042 10421210	Cardiac disorders	Arrhythmia	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JUN2017	30JUN2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Panic attack	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	05MAR2017	05MAR2017	N
				10NOV2010	10NOV2010	N
			Cholecystectomy	01JUN2017	30JUN2017	N
			Keratomileusis	01MAY2015	31MAY2015	N
	C4591001 1042 10421213	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Noninfective sialoadenitis	01JAN1992	31DEC1992	N
		Immune system disorders	Food allergy	01JAN1990		Y
		Infections and infestations	Sinusitis	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Salivary gland resection	01JAN1993	31DEC1993	N
			Sinus operation	01JAN1993	31DEC1993	N
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1042 10421216	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1042 10421217	Gastrointestinal disorders	Peptic ulcer	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Milk allergy	01JAN1998		Y
			Seasonal allergy	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteonecrosis	01JAN2018	19FEB2020	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Bipolar II disorder	01JAN2015		Y
			Insomnia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1991		Y
		Surgical and medical procedures	Knee operation	19FEB2019	19FEB2019	N
		Vascular disorders	Thrombosis	01APR2019		Y
	C4591001 1042 10421219	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421222	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Mastectomy	01JAN2010	31DEC2010	N
	C4591001 1042 10421228	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1042 10421229	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Grief reaction	01JUN2020		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01MAR2020		Y
		Surgical and medical procedures	Cancer surgery	01JAN2012	31DEC2012	N
	C4591001 1042 10421231	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Lymphoma operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2012		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
	C4591001 1042 10421232	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Swollen tongue	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01NOV1987	01NOV1987	N
			Female sterilisation	01NOV1987		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1042 10421233	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1042 10421234	Gastrointestinal disorders	Umbilical hernia	01DEC2019	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01DEC2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01DEC2019	31DEC2019	N
			Female sterilisation	01DEC2011	31DEC2011	N
	C4591001 1042 10421235	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Bipolar I disorder	01JAN2002		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1996		Y
	C4591001 1042 10421237	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1972		Y
	C4591001 1042 10421238	Cardiac disorders	Palpitations	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
			Rhinitis allergic	01JAN2012		Y
	C4591001 1042 10421239	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis perforated	01JAN2002	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neurofibroma	01DEC2019	31DEC2019	N
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Affective disorder	01JAN2010		Y
			Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Panic attack	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Nervous system neoplasm surgery	01DEC2019	31DEC2019	N
	C4591001 1042 10421243	Gastrointestinal disorders	Umbilical hernia	01JAN1976	31DEC1976	N
		Immune system disorders	Dust allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
			Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421245	Cardiac disorders	Arrhythmia	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1042 10421246	Surgical and medical procedures	Female sterilisation	01JAN2015		Y
	C4591001 1042 10421247	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1042 10421249	Immune system disorders	Allergy to animal	01JAN2015		Y
			Allergy to plants	01JAN2015		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2014	31DEC2014	N
			Tenoplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1042 10421250	Gastrointestinal disorders	Dyspepsia	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia	01JAN1977	31DEC1977	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Tenoplasty	01JAN2000	31DEC2000	N
			Umbilicoplasty	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1042 10421251	Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1042 10421252	Psychiatric disorders	Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1042 10421253	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Arthritis bacterial	01JUN2016	30JUN2016	N
			Tonsillitis	01JUN2020	30JUN2020	N
		Investigations	Arthroscopy	01JUN2016	30JUN2016	N
			Laparoscopy	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2020	31DEC2020	N
	C4591001 1042 10421255	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1042 10421256	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1042 10421259	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Gastrooesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN2020		Y
		Immune system disorders	Dust allergy	01JAN1988		Y
			Seasonal allergy	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Breast prosthesis removal	16SEP2019	16SEP2019	N
			Caesarean section	03APR2007	03APR2007	N
			Hernia repair	27APR2002	27APR2002	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1042 10421260	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Vasectomy	08SEP2020	08SEP2020	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1042 10421261	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Knee operation	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1042 10421262	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1042 10421264	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1042 10421265	Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
	C4591001 1042 10421266	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Surgical and medical procedures	Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1042 10421267	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Dust allergy	01JAN1987		Y
		Injury, poisoning and procedural complications	Arthropod bite	01JAN2015		Y
			Lumbar vertebral fracture	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hot flush	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441001	Musculoskeletal and connective tissue disorders	Back pain	01JUN2018		Y
	C4591001 1044 10441009	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Hepatobiliary disorders	Biliary dyskinesia	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Serum ferritin decreased	01JAN2017		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
	C4591001 1044 10441011	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1044 10441021	Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN1983		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1044 10441024	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01DEC2005		Y
	C4591001 1044 10441028	Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Weight control	25NOV2019		Y
	C4591001 1044 10441029	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
	C4591001 1044 10441030	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1044 10441034	Immune system disorders	Drug hypersensitivity	30DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441035	Immune system disorders	Drug hypersensitivity	01JAN1988	31DEC1988	N
		Psychiatric disorders	Anxiety	01NOV2016		Y
	C4591001 1044 10441038	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Nervous system disorders	Restless legs syndrome	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
	C4591001 1044 10441042	Congenital, familial and genetic disorders	Arteriovenous malformation	01JUL1984		Y
		Nervous system disorders	Seizure	01JUL1984	31JUL1984	N
		Vascular disorders	Hypertension	01MAY2014		Y
	C4591001 1044 10441043	Immune system disorders	Drug hypersensitivity	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Surgical and medical procedures	Contraception	01JAN2008		Y
	C4591001 1044 10441045	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01OCT2009		Y
	C4591001 1044 10441050	Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1044 10441051	Immune system disorders	Drug hypersensitivity	01JAN1995	31DEC1995	N
				01JUL2020	31DEC2020	N
		Infections and infestations	Herpes simplex	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Contraception	01JAN2007		Y
	C4591001 1044 10441052	Reproductive system and breast disorders	Premenstrual syndrome	01JAN2019		Y
	C4591001 1044 10441054	Immune system disorders	Drug hypersensitivity	01JAN1988	31DEC1988	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Insomnia	01JAN2013		Y
		Surgical and medical procedures	Contraception	01JAN2016		Y
	C4591001 1044 10441058	Metabolism and nutrition disorders	Hyperlactacidaemia	01JAN2019		Y
	C4591001 1044 10441059	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2017		Y
		Psychiatric disorders	Insomnia	01MAR2018		Y
	C4591001 1044 10441060	Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1044 10441061	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
	C4591001 1044 10441063	Immune system disorders	Drug hypersensitivity	01JAN1986	31DEC1986	N
	C4591001 1044 10441065	Immune system disorders	Drug hypersensitivity	01JAN1997	31DEC1997	N
	C4591001 1044 10441068	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
	C4591001 1044 10441069	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1044 10441076	Skin and subcutaneous tissue disorders	Alopecia	01JAN2006		Y
	C4591001 1044 10441077	Social circumstances	Ex-tobacco user	01JUN2020		Y
		Surgical and medical procedures	Contraception	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1044 10441079	Infections and infestations	Cellulitis	02SEP2020		Y
		Surgical and medical procedures	Contraception	01JAN2020		Y
	C4591001 1044 10441081	Psychiatric disorders	Anxiety	01JAN2013		Y
		Surgical and medical procedures	Contraception	01JAN2011		Y
	C4591001 1044 10441088	Cardiac disorders	Mitral valve prolapse	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01AUG2020		Y
	C4591001 1044 10441099	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1044 10441101	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01SEP2016		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Surgical and medical procedures	Weight control	01DEC2019		Y
	C4591001 1044 10441102	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JUL2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441103	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1044 10441119	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN2005		Y
	C4591001 1044 10441122	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01DEC2019	31DEC2019	N
		Nervous system disorders	Migraine	01JAN1997		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
		Surgical and medical procedures	Micrographic skin surgery	01DEC2019	31DEC2019	N
	C4591001 1044 10441126	Cardiac disorders	Tachycardia	01JAN2018		Y
	C4591001 1044 10441127	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
	C4591001 1044 10441129	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1044 10441132	Endocrine disorders	Hypothyroidism	15SEP1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	15SEP2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15SEP2018		Y
		Vascular disorders	Hypertension	15SEP2018		Y
	C4591001 1044 10441133	Metabolism and nutrition disorders	Haemochromatosis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Prostatectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1044 10441136	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Rubber sensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
	C4591001 1044 10441137	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2000		Y
				01JAN2004		Y
				01JAN2015		Y
		Infections and infestations	Onychomycosis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1990	03SEP2020	N
			Migraine	03SEP2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002		Y
		Surgical and medical procedures	Oophorectomy	01MAR2013	03MAR2013	N
	C4591001 1044 10441142	Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974	31DEC2007	N
		Surgical and medical procedures	Contraception	01JUN2020		Y
	C4591001 1044 10441143	General disorders and administration site conditions	Oedema peripheral	01AUG2019		Y
	C4591001 1044 10441144	Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441146	Infections and infestations	Pneumonia	15FEB2020	29FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1044 10441151	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1044 10441152†	General disorders and administration site conditions	Drug intolerance	01JAN2016		Y
		Investigations	HIV test positive	01JAN2001		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	24AUG2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
				01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
		Psychiatric disorders	Generalised anxiety disorder	07OCT2016		Y
			Major depression	26MAY2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2020		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
			Chemotherapy	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Radiotherapy to breast	01JAN2013	31DEC2013	N
	C4591001 1044 10441153	Cardiac disorders	Palpitations	01AUG2019		Y
		Immune system disorders	Drug hypersensitivity	01OCT2015		Y
	C4591001 1044 10441155	Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2006		Y
			Bipolar II disorder	01JAN2016		Y
	C4591001 1044 10441156	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrointestinal hypomotility	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
	C4591001 1044 10441157	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Meniscus injury	01AUG2007	31AUG2007	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2016		Y
			Hysterectomy	01MAY2016	31MAY2016	N
	C4591001 1044 10441158	Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1044 10441159	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	03SEP2020	07SEP2020	N
		Surgical and medical procedures	Hysterectomy	01NOV2010	31DEC2010	N
	C4591001 1044 10441162	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	(b) (6) 1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2011		Y
		Nervous system disorders	Autonomic nervous system imbalance	01FEB2020		Y
		Surgical and medical procedures	Female sterilisation	01AUG2017	31AUG2017	N
	C4591001 1044 10441163	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Drug intolerance	01SEP2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUN2020		Y
			Temporomandibular joint syndrome	01JAN2010	31JAN2020	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
	C4591001 1044 10441164	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1044 10441165	Congenital, familial and genetic disorders	Adrenogenital syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01APR2019		Y
				01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2001		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Attention deficit hyperactivity disorder	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Rhinitis allergic	01JAN1983		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1044 10441166	Immune system disorders	Drug hypersensitivity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1044 10441167	Reproductive system and breast disorders	Menstruation irregular	01SEP2020		Y
		Surgical and medical procedures	Salpingectomy	01MAR2015	31MAR2015	N
	C4591001 1044 10441168	Immune system disorders	Seasonal allergy	01JAN1987		Y
	C4591001 1044 10441170	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1044 10441171	Reproductive system and breast disorders	Erectile dysfunction	01SEP2020		Y
	C4591001 1044 10441173	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
	C4591001 1044 10441174	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	01JAN1986		Y
	C4591001 1044 10441177	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
			Insomnia	01JAN2016		Y
	C4591001 1044 10441181	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
	C4591001 1044 10441185	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1044 10441186	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2010		Y
	C4591001 1044 10441187	Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
	C4591001 1044 10441188	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1044 10441190	General disorders and administration site conditions	Fatigue	01SEP2020		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016		Y
	C4591001 1044 10441191	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Surgical and medical procedures	Intervertebral disc operation	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01NOV2012		Y
	C4591001 1044 10441192	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441193	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1044 10441198	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
	C4591001 1044 10441199	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Contraception	01MAR2019		Y
	C4591001 1044 10441203	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1044 10441204	Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
	C4591001 1044 10441207	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nephroblastoma	01JAN1972	31DEC1974	N
		Surgical and medical procedures	Contraception	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1044 10441210	Surgical and medical procedures	Contraception	01JAN2013		Y
	C4591001 1044 10441211	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1044 10441213	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01MAR2015	31MAR2015	N
	C4591001 1044 10441215	Psychiatric disorders	Anxiety	15JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441218	Nervous system disorders	Epilepsy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1044 10441219	Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1044 10441224	Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1044 10441227	Endocrine disorders	Hypogonadism	01JAN2018		Y
	C4591001 1044 10441229	Reproductive system and breast disorders	Erectile dysfunction	01OCT2020		Y
	C4591001 1044 10441230	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
	C4591001 1044 10441232	Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
	C4591001 1044 10441234	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1044 10441237	Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
	C4591001 1044 10441238	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2004		Y
	C4591001 1044 10441239	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441241	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1044 10441242	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1044 10441243	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1044 10441244	General disorders and administration site conditions	Drug intolerance	01SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1044 10441245	Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Rhinitis allergic	01JAN2018		Y
	C4591001 1044 10441246	Psychiatric disorders	Autism spectrum disorder	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1044 10441249	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1044 10441250	Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441254	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1044 10441269	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1044 10441287	Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1046 10461001	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1046 10461002	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461005	Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
	C4591001 1046 10461006	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2018	31DEC2018	N
	C4591001 1046 10461010	Endocrine disorders	Thyroid mass	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN1994	31DEC1994	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Caesarean section	08DEC2008	08DEC2008	N
				19AUG2003	19AUG2003	N
			Female sterilisation	08DEC2008	08DEC2008	N
			Limb operation	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1046 10461011	Psychiatric disorders	Obsessive-compulsive disorder	01JAN1990		Y
	C4591001 1046 10461014	Cardiac disorders	Supraventricular tachycardia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Lipoma excision	01JAN2018	31DEC2018	N
	C4591001 1046 10461016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1988	31DEC1988	N
			Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1046 10461018	Gastrointestinal disorders	Tooth impacted	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Hernia	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
			Wisdom teeth removal	01JAN1993	31DEC1993	N
	C4591001 1046 10461020	Injury, poisoning and procedural complications	Hand fracture	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Fracture treatment	01JAN1999	31DEC1999	N
	C4591001 1046 10461023	Congenital, familial and genetic disorders	Congenital jaw malformation	01JAN1993	31DEC1993	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal adenoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Adrenalectomy	01JAN2019	31DEC2019	N
			Jaw operation	01JAN1993	31DEC1993	N
	C4591001 1046 10461024	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1985	31DEC1985	N
		Nervous system disorders	Restless legs syndrome	01JAN1990		Y
		Reproductive system and breast disorders	Testicular torsion	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Fracture treatment	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Testes exploration	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1046 10461026	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
	C4591001 1046 10461027	Endocrine disorders	Thyroid mass	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2008	31DEC2008	N
			Parathyroidectomy	01JAN2005	31DEC2005	N
	C4591001 1046 10461028	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1998		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1998	31DEC1998	N
		Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Neck pain	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	19JAN2002	19JAN2002	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1046 10461029	Congenital, familial and genetic disorders	Anomalous pulmonary venous connection	01JAN1990	31DEC1990	N
		General disorders and administration site conditions	Hernia	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac operation	01JAN1990	31DEC1990	N
			Hernia repair	01JAN2007	31DEC2007	N
	C4591001 1046 10461030	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Reproductive system and breast disorders	Breast mass	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Nasal septal operation	01JAN2015	31DEC2015	N
	C4591001 1046 10461031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461034	Gastrointestinal disorders	Tooth impacted	01JAN2018	31DEC2018	N
		Infections and infestations	Ear infection	01JAN1999	31DEC1999	N
			Tonsillitis	01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1046 10461039	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Allergy to chemicals	01JAN1995		Y
			Drug hypersensitivity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1046 10461040	Blood and lymphatic system disorders	Anaemia	01JAN2007		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Menstrual disorder	01APR2020	30APR2020	N
		Surgical and medical procedures	Caesarean section	01OCT2002	01OCT2002	N
				09AUG2011	09AUG2011	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Endometrial ablation	01APR2020	30APR2020	N
			Female sterilisation	01JAN2011	31DEC2011	N
			Gastric bypass	01JAN2007	31DEC2007	N
			Rotator cuff repair	01JAN2002	31DEC2002	N
	C4591001 1046 10461042	General disorders and administration site conditions	Hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2011	31DEC2011	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	10AUG2010	10AUG2010	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				15SEP2008	15SEP2008	N
				23APR2013	23APR2013	N
			Female sterilisation	23APR2013	23APR2013	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Rhinoplasty	01JAN2011	31DEC2011	N
	C4591001 1046 10461043	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Tremor	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461044	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Chronic sinusitis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Sinus operation	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1046 10461046	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998	31DEC1998	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Shoulder operation	01JAN1998	31DEC1998	N
	C4591001 1046 10461049	Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	12JUL2019	12JUL2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Uterine dilation and curettage	12JUL2019	12JUL2019	N
	C4591001 1046 10461050	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461051	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1046 10461052	Congenital, familial and genetic disorders	Renal fusion anomaly	01JAN2019		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Open reduction of fracture	01JAN2012	31DEC2012	N
			Uvulopalatopharyngoplasty	01JAN2007	31DEC2007	N
	C4591001 1046 10461053	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1046 10461054	Gastrointestinal disorders	Tooth impacted	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Sinus operation	01JAN1994	31DEC1994	N
			Wisdom teeth removal	01JAN1988	31DEC1988	N
	C4591001 1046 10461055	Gastrointestinal disorders	Tooth impacted	01JAN2014	31DEC2014	N
		Nervous system disorders	Tremor	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2014	31DEC2014	N
	C4591001 1046 10461058	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2009	31DEC2009	N
	C4591001 1046 10461063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck pain	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Chondroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Intervertebral disc operation	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1046 10461066	Gastrointestinal disorders	Crohn's disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1046 10461067	Gastrointestinal disorders	Inguinal hernia	01JAN1968	31DEC1968	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2003		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1968	31DEC1968	N
			Spinal decompression	01JAN2003	31DEC2003	N
			Tenoplasty	01JAN2018	31DEC2018	N
	C4591001 1046 10461068	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
			Chronic sinusitis	01JAN2003	31DEC2003	N
			Pilonidal cyst	01JAN1988	31DEC1988	N
			Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Pilonidal sinus repair	01JAN1988	31DEC1988	N
			Sinus operation	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461069	Gastrointestinal disorders	Tooth impacted	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
			Wrist surgery	01JAN2002	31DEC2002	N
	C4591001 1046 10461070	Reproductive system and breast disorders	Menstrual disorder	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1046 10461071	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	25APR2020	25APR2020	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Lymphadenectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN2015	31DEC2015	N
			Uterine dilation and curettage	25APR2020	25APR2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461072	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Tuberculosis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
	C4591001 1046 10461081	Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2019	31DEC2019	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2003		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2003	31DEC2003	N
			Gastrectomy	01JAN2019	31DEC2019	N
	C4591001 1046 10461091	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
			Tonsillitis	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
			Muscle rupture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2013		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC2009	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Carpal tunnel decompression	01JAN2017	31DEC2017	N
			Fracture treatment	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Muscle operation	01JAN2018	31DEC2018	N
			Thoracic operation	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1046 10461092	Injury, poisoning and procedural complications	Hand fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461093	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Salpingectomy	01JAN2017	31DEC2017	N
	C4591001 1046 10461097	Hepatobiliary disorders	Cholecystitis	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
	C4591001 1046 10461098	Reproductive system and breast disorders	Female sterilisation	01JAN2019	31DEC2019	N
			Menstrual disorder	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Exeresis	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1046 10461099	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2020		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2009	31DEC2009	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Urinary bladder suspension	01JAN2009	31DEC2009	N
	C4591001 1046 10461100	Hepatobiliary disorders	Cholecystitis	01JAN1990	31DEC1990	N
		Infections and infestations	Oral herpes	01JAN2010		Y
			Tonsillitis	01JAN2002	31DEC2002	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1998	31DEC1998	N
			Rectocele	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Face lift	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Rectocele repair	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2002	31DEC2002	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Transplant	01JAN2017	31DEC2017	N
			Vaginal prolapse repair	01JAN2017	31DEC2017	N
	C4591001 1046 10461101	Surgical and medical procedures	Fracture treatment	01JAN2017	31DEC2017	N
			Sebaceous cyst excision	01JAN2008	31DEC2008	N
	C4591001 1046 10461104	Eye disorders	Amblyopia	01JAN1999	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Ureteral disorder	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Amblyopia therapy	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
			Caesarean section	30OCT2017	30OCT2017	N
			Tonsillectomy	01JAN2005	31DEC2005	N
			Ureteric operation	01JAN2015	31DEC2015	N
	C4591001 1046 10461105	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
			Eye muscle operation	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2004	31DEC2004	N
			Oophorectomy	01JAN2009	31DEC2009	N
			Renal stone removal	01JAN2010	31DEC2010	N
			Synovial cyst removal	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1998	31DEC1998	N
			Ureteric repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461107	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01JAN2003		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2009	31DEC2009	N
	C4591001 1046 10461108	Hepatobiliary disorders	Cholecystitis	01FEB2007	28FEB2007	N
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2007	28FEB2007	N
	C4591001 1046 10461109	Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 1046 10461111	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Weight increased	01JAN2018		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1046 10461112	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1046 10461115	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2013	31DEC2015	N
			Type 2 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN2011	31DEC2016	N
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Caesarean section	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2011	31DEC2011	N
			Gastrectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Mammoplasty	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1046 10461116	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2017		Y
		Ear and labyrinth disorders	Inner ear disorder	01JAN2019	31DEC2019	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Gastrectomy	01JAN2016	31DEC2016	N
			Inner ear operation	01JAN2019	31DEC2019	N
			Nasal polypectomy	01JAN2018	31DEC2018	N
			Renal stone removal	01JAN2014	31DEC2014	N
			Skin operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461117	Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Cyclothymic disorder	01JAN2016		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2019		Y
	C4591001 1046 10461118	Gastrointestinal disorders	Pancreatitis	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholecystitis	01JAN2019	31DEC2019	N
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1046 10461119	Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
	C4591001 1046 10461120	Investigations	Arthroscopy	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008	31DEC2008	N
	C4591001 1046 10461123	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2000	31DEC2000	N
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1046 10461124	Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2012	31DEC2012	N
			Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Organ donor	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN2012	31DEC2012	N
	C4591001 1046 10461125	Infections and infestations	Pilonidal cyst	20OCT2017	20OCT2017	N
		Surgical and medical procedures	Pilonidal sinus repair	20OCT2017	20OCT2017	N
	C4591001 1046 10461127	Surgical and medical procedures	Drug rehabilitation	01JAN2018		Y
			Female sterilisation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461130	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Endometriosis	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Appendectomy	01JAN2005	31DEC2005	N
			Uterine dilation and curettage	01JAN2017	31DEC2017	N
			Wrist surgery	01JAN2013	31DEC2013	N
	C4591001 1046 10461131	Congenital, familial and genetic disorders	Talipes	01JAN1969		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2007	31DEC2008	N
			Gastrointestinal scarring	01JAN2006	31DEC2012	N
		Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Scar	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
			Ankle arthroplasty	01JAN2014	31DEC2014	N
			Caesarean section	08SEP2004	08SEP2004	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Colectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Colon operation	01JAN2012	31DEC2012	N
			Female sterilisation	08SEP2004	08SEP2004	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Scar excision	01JAN2005	31DEC2005	N
			Talipes correction	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461133	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Cyst removal	01JAN2003	31DEC2003	N
	C4591001 1046 10461134	Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
	C4591001 1046 10461135	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1046 10461137	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2020	31JAN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2018		Y
			Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2020	31DEC2020	N
	C4591001 1046 10461139	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1046 10461140	Gastrointestinal disorders	Coeliac disease	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Hernia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2006	31DEC2006	N
			Trigger finger	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Bunion operation	01JAN2006	31DEC2006	N
			Chest tube insertion	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Tendon sheath incision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1046 10461142	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Surgical and medical procedures	Epididymal cyst removal	01JAN2003	31DEC2003	N
			Nasal septal operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1046 10461143	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine dilation and curettage	01JAN1997	31DEC1997	N
	C4591001 1046 10461145	Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1046 10461146	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013	14FEB2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2004	31DEC2004	N
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Intervertebral disc operation	14FEB2020	14FEB2020	N
			Thyroidectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1046 10461147	Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
		Surgical and medical procedures	Ligament operation	01JAN2011	31DEC2011	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1046 10461148	Infections and infestations	Otitis media	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Cholesteatoma removal	01JAN2003	31DEC2003	N
	C4591001 1046 10461149	Investigations	Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2010	N
				01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2009		Y
		Surgical and medical procedures	Shoulder operation	01JAN2010	31DEC2010	N
	C4591001 1046 10461150	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN1993	31DEC1993	N
			Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1046 10461151	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2016		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Chondroplasty	01JAN2019	31DEC2019	N
			Ear tube insertion	01JAN1996	31DEC1996	N
			Knee operation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2003	31DEC2003	N
			Urinary tract operation	01JAN1999	31DEC1999	N
	C4591001 1046 10461152	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Genital herpes	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	04FEB2019	04FEB2019	N
				06APR2015	06APR2015	N
				11NOV2010	11NOV2010	N
			Mammoplasty	01JUN2003	30JUN2003	N
			Nasal septal operation	01FEB2010	28FEB2010	N
	C4591001 1046 10461153	Injury, poisoning and procedural complications	Facial bones fracture	01JAN1997	31DEC1998	N
		Investigations	Blood testosterone decreased	01JUN2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2020		Y
		Social circumstances	Andropause	01JAN2018		Y
		Surgical and medical procedures	Plastic surgery to the face	01DEC1997	31DEC1997	N
				01FEB1998	28FEB1998	N
				01JAN1998	31JAN1998	N
		Vascular disorders	Prehypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461154	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461155	Ear and labyrinth disorders	Excessive cerumen production	01JAN1993	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Schizophrenia	01JAN1995		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1993	31DEC1993	N
				01JAN1994	31DEC1994	N
				01JAN1995	31DEC1995	N
				01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
				01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
	C4591001 1046 10461159	Gastrointestinal disorders	Nausea	01JUN2020		Y
		Hepatobiliary disorders	Cholecystitis	01AUG2018	31AUG2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2018	31AUG2018	N
			Wisdom teeth removal	01JUL2019	31JUL2019	N
	C4591001 1046 10461162	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Arthroscopy	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Cranial nerve decompression	01JAN2001	31DEC2001	N
			Middle ear operation	01JAN1966	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septal operation	01JAN2018	31DEC2018	N
	C4591001 1046 10461163	Reproductive system and breast disorders	Menstrual disorder	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2018	31DEC2018	N
	C4591001 1046 10461164	Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2015	N
			Menstrual disorder	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Drug rehabilitation	01JAN2019	31DEC2019	N
			Endometrial ablation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461167	Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
	C4591001 1046 10461168	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Dependence	01JAN2007		Y
		Surgical and medical procedures	Fracture treatment	01JAN2016	31DEC2016	N
	C4591001 1046 10461171	Skin and subcutaneous tissue disorders	Urticaria	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	08JUN2020	08JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461172	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Chest tube insertion	01JAN2018	31DEC2018	N
	C4591001 1046 10461174	Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Umbilical hernia repair	01JAN2004	31DEC2004	N
	C4591001 1046 10461175	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Vitamin D deficiency	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2009		Y
	C4591001 1046 10461176	Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1046 10461177	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Renal and urinary disorders	Bladder spasm	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Caesarean section	01JAN1991	31DEC1991	N
				01JAN2000	31DEC2000	N
				01JAN2002	31DEC2002	N
			High frequency ablation	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1046 10461186	Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstrual disorder	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Gastrectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1046 10461188	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2001	31DEC2001	N
			Breast conserving surgery	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Joint debridement	01JAN2012	31DEC2012	N
			Toe operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1046 10461191	Injury, poisoning and procedural complications	Facial bones fracture	01JAN1985	31DEC1985	N
			Hand fracture	01JAN1995	31DEC1995	N
		Nervous system disorders	Neuropathy peripheral	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Fracture treatment	01JAN1995	31DEC1995	N
			Peripheral nerve operation	01JAN1991	31DEC1991	N
			Rhinoplasty	01JAN1985	31DEC1985	N
	C4591001 1046 10461192	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Nervous system disorders	Hypersomnia	01JAN2018		Y
			Migraine	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstrual disorder	01JAN2015	09MAY2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Hysterectomy	09MAY2019	09MAY2019	N
	C4591001 1046 10461193	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1046 10461194	Infections and infestations	Tonsillitis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1046 10461197	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	13DEC2001	13DEC2001	N
			Shoulder operation	01JAN2012	31DEC2012	N
	C4591001 1046 10461198	Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Infections and infestations	Tonsillitis	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1046 10461199	Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Caesarean section	20AUG2010	20AUG2010	N
			Chest tube insertion	05SEP1995	31DEC1995	N
	C4591001 1046 10461200	General disorders and administration site conditions	Hernia	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Hernia repair	01JAN2011	31DEC2011	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461202	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Psychiatric disorders	Depression	01APR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1046 10461203	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Immune system disorders	Contrast media reaction	01JAN1990		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	29JAN2008	29JAN2008	N
			Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1046 10461204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1046 10461210	Gastrointestinal disorders	Gastric disorder	01JAN2016	31DEC2016	N
			Gastroesophageal reflux disease	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstrual disorder	01JAN1995	31DEC1998	N
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Hormone replacement therapy	01MAY2020		Y
			Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461217	Gastrointestinal disorders	Gastric disorder	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1046 10461218	Surgical and medical procedures	Keratomileusis	01JAN2007	31DEC2017	N
	C4591001 1046 10461219	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1046 10461221	Immune system disorders	Seasonal allergy	01JAN2020		Y
	C4591001 1046 10461223	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1046 10461227	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2016	31DEC2016	N
	C4591001 1046 10461232	Gastrointestinal disorders	Colitis ulcerative	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Adenoiditis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Adenoidectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461234	Congenital, familial and genetic disorders	Ear malformation	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Otoplasty	01JAN2001	31DEC2001	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1046 10461236	General disorders and administration site conditions	Hernia	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2005	31DEC2005	N
			Hernia repair	01JAN2015	31DEC2015	N
	C4591001 1046 10461237	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2019	31DEC2019	N
	C4591001 1046 10461240	Nervous system disorders	Headache	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Endometriosis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Urinary bladder suspension	01JAN2019	31DEC2019	N
	C4591001 1046 10461242	Gastrointestinal disorders	Tooth impacted	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461246	Surgical and medical procedures	Wisdom teeth removal	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Lower limb fracture	13FEB1997	13FEB1997	N
			Traumatic ear amputation	01JAN1981	31DEC1981	N
			Upper limb fracture	01JAN1983	31DEC1983	N
		Nervous system disorders	Headache	01JAN1993		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Ear operation	01JAN1981	31DEC1981	N
			Fracture treatment	01JAN1983	31DEC1983	N
				13FEB1997	13FEB1997	N
				Ovarian cystectomy	01JAN2003	31DEC2003
	C4591001 1046 10461248	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1046 10461252	Surgical and medical procedures	Myomectomy	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2020	31MAY2020	N
	C4591001 1046 10461254	Surgical and medical procedures	Spinal fusion surgery	01MAY2020	31MAY2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
			Borderline personality disorder	01JAN2010		Y
			Depression	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461255	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Bladder prolapse	01JAN2006	31DEC2010	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Appendectomy	01JAN1974	31DEC1974	N
			Caesarean section	01JAN1989	31DEC1989	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
			Urinary bladder suspension	01JAN2006	31DEC2006	N
				01JAN2010	31DEC2010	N
				01SEP2009	30SEP2009	N
	C4591001 1046 10461256	Infections and infestations	Appendicitis	01SEP2009	30SEP2009	N
		Respiratory, thoracic and mediastinal disorders	Tonsillitis	07OCT2000	07OCT2000	N
			Adenoidal hypertrophy	07OCT2000	07OCT2000	N
		Surgical and medical procedures	Adenoidectomy	07OCT2000	07OCT2000	N
			Appendectomy	01SEP2009	30SEP2009	N
			Caesarean section	04APR2006	04APR2006	N
				07DEC2012	07DEC2012	N
				16JUL2010	16JUL2010	N
				21MAY2008	21MAY2008	N
				07OCT2000	07OCT2000	N
	C4591001 1046 10461257	Infections and infestations	Tonsillitis	01AUG2003	31AUG2003	N
		Nervous system disorders	Headache	01JAN2010		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Gynaecomastia	01MAR2003	31MAR2003	N
		Surgical and medical procedures	Breast operation	01MAR2003	31MAR2003	N
			Tonsillectomy	01AUG2003	31AUG2003	N
	C4591001 1046 10461261	Gastrointestinal disorders	Crohn's disease	01JAN2009		Y
		Surgical and medical procedures	Abscess drainage	01JAN2009	31DEC2009	N
	C4591001 1046 10461263	Gastrointestinal disorders	Impaired gastric emptying	01OCT2019		Y
		Infections and infestations	Chronic sinusitis	04APR2019	04APR2019	N
		Psychiatric disorders	Anxiety	01MAY2020		Y
		Surgical and medical procedures	Sinus operation	04APR2019	04APR2019	N
	C4591001 1046 10461265	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2003	31DEC2003	N
				01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2018		Y
			Obesity	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1982	31DEC1982	N
			Fracture treatment	01JAN2003	31DEC2003	N
				01JAN2009	31DEC2009	N
			Gastrectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1982	31DEC1982	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461266	Investigations	Blood cholesterol increased	01JAN2012		Y
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Skin graft	01JAN1977	31DEC1977	N
			Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1046 10461268	Vascular disorders	Hypertension	01JAN2012		Y
		Cardiac disorders	Pulmonary valve stenosis	01JAN1988		Y
		Congenital, familial and genetic disorders	Falot's tetralogy	01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Varicocele	01JAN2015	31DEC2015	N
	C4591001 1046 10461269	Surgical and medical procedures	Varicocele repair	01JAN2015	31DEC2015	N
		Eye disorders	Visual impairment	01JAN2018		Y
		Investigations	Precancerous cells present	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2019		Y
			Tendonitis	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N
	C4591001 1046 10461270		Loop electrosurgical excision procedure	01JAN2017	31DEC2017	N
		Immune system disorders	Iodine allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAY2020	31MAY2020	N
		Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01MAY2020	31MAY2020	N
			Fascia release	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461272	Injury, poisoning and procedural complications	Peripheral nerve injury	01FEB2020	29FEB2020	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Peripheral nerve operation	01FEB2020	29FEB2020	N
	C4591001 1046 10461273	Surgical and medical procedures	Jaw operation	01JAN1998	31DEC1998	N
	C4591001 1046 10461274	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1987	31DEC1987	N
		Infections and infestations	Adenoiditis	01JAN1985	31DEC1985	N
			Ear infection	01JAN1987	31DEC1987	N
			Tonsillitis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Adenoidectomy	01JAN1985	31DEC1985	N
			Ear tube insertion	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1985	31DEC1985	N
			Tympanoplasty	01JAN1987	31DEC1987	N
	C4591001 1046 10461275	General disorders and administration site conditions	Hernia	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Tardive dyskinesia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2014		Y
			Sleep terror	01JAN2015		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01DEC1987	31DEC1987	N
				01DEC1989	31DEC1989	N
				01JAN1987	31JAN1987	N
			Hernia repair	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1046 10461276	Infections and infestations	Osteomyelitis	01JUN2016	30JUN2016	N
		Injury, poisoning and procedural complications	Ankle fracture	01JUN2016	30JUN2016	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Surgical and medical procedures	Leg amputation	01JUN2016	30JUN2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1046 10461280	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Oesophagogastric fundoplasty	01JAN2007	31DEC2007	N
	C4591001 1046 10461281	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461284	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1046 10461285	Surgical and medical procedures	Bone lesion excision	01JAN2012	31DEC2012	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y	
		General disorders and administration site conditions	Pain	01JAN2018		Y	
		Surgical and medical procedures	Appendicectomy		01JAN2011	31DEC2011	N
			Cholecystectomy		01JAN2010	31DEC2010	N
			Foot operation		01APR2020	30APR2020	N
			Spinal operation		01APR2020	30APR2020	N
	C4591001 1046 10461287	Therapeutic procedure		01JAN2015	31DEC2015	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y	
	C4591001 1046 10461288	Investigations	Vitamin D decreased	01JAN2018		Y	
		Metabolism and nutrition disorders	Obesity	01MAY2020		Y	
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y	
		Psychiatric disorders	Depression	01JAN2005	31DEC2019	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y	
		Immune system disorders	Seasonal allergy	01JAN1994		Y	
		Investigations	Blood cholesterol increased		01JAN2010		Y
			Blood triglycerides increased		01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus		01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms		01JAN2001		Y
	Renal and urinary disorders	Nephrolithiasis		01JAN2014	31DEC2014	N	
	Reproductive system and breast disorders	Prostatomegaly		01JAN2018		Y	
	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome		01JAN2011		Y	
	Surgical and medical procedures	Coronary arterial stent insertion		01JAN2013	31DEC2013	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lithotripsy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1046 10461289	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2008	15FEB2009	N
		Psychiatric disorders	Alcoholism	01SEP2019		Y
			Insomnia	01AUG2020		Y
	C4591001 1046 10461290	Surgical and medical procedures	Intervertebral disc operation	15FEB2009	15FEB2009	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1046 10461291	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1046 10461292	Eye disorders	Dacryostenosis acquired	01JAN1999	31DEC1999	N
		Hepatobiliary disorders	Cholecystitis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Lacrimal duct procedure	01JAN1999	31DEC1999	N
	C4591001 1046 10461294	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Infections and infestations	Ear infection	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1993		Y
		Surgical and medical procedures	Caesarean section	18AUG2006	18AUG2006	N
				24JUN2002	24JUN2002	N
			Temporomandibular joint surgery	01JAN1993	31DEC1993	N
			Tympanoplasty	01JAN2008	31DEC2008	N
	C4591001 1046 10461295	Eye disorders	Cataract	01JAN2020	31JUL2020	N
			Eyelid ptosis	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cataract operation	01JUL2020	31JUL2020	N
			Endometrial ablation	01JAN2014	31DEC2014	N
			Eyelid operation	01JAN1989	31DEC1989	N
	C4591001 1046 10461297	Hepatobiliary disorders	Cholelithiasis	01SEP2020	30SEP2020	N
		Surgical and medical procedures	Cholecystectomy	01SEP2020	30SEP2020	N
			Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1046 10461298	Ear and labyrinth disorders	Vertigo	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1046 10461300	Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
	C4591001 1046 10461302	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
	C4591001 1046 10461303	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Food allergy	01JAN1997		Y
			Seasonal allergy	01JAN1997		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1046 10461304	Metabolism and nutrition disorders	Obesity	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2006		Y
			Muscle spasms	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			External fixation of fracture	01JAN2008	31DEC2008	N
			Gastric bypass	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Joint surgery	01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN2006	31DEC2006	N
	C4591001 1046 10461306	Infections and infestations	Appendicitis	16JAN2017	16JAN2017	N
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Appendectomy	16JAN2017	16JAN2017	N
			Caesarean section	24MAR2015	24MAR2015	N
	C4591001 1046 10461307	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1983		Y
		Surgical and medical procedures	Gastrectomy	20MAY2020	20MAY2020	N
	C4591001 1046 10461308	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Dystonia	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461312	Immune system disorders	Drug hypersensitivity	01JAN1995		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Caesarean section	06OCT2009	06OCT2009	N
				15JUL2008	15JUL2008	N
				16JUN2015	16JUN2015	N
	C4591001 1046 10461313	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1046 10461314	Gastrointestinal disorders	Abdominal fat apron	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal cyst	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Abdominal panniculectomy	01JAN2017	31DEC2017	N
			Sinus operation	01JAN2017	31DEC2017	N
	C4591001 1046 10461315	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2020		Y
	C4591001 1046 10461318	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	02APR1996	02APR1996	N
				17JUN1992	17JUN1992	N
			Female sterilisation	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461319	Gastrointestinal disorders	Tooth impacted	01JAN2017	31JAN2017	N
		Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31JAN2017	N
	C4591001 1046 10461321	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Ear infection	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	15FEB2007	15FEB2007	N
				27FEB2004	27FEB2004	N
			Female sterilisation	01JAN2008	31DEC2008	N
			Myringotomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461323	Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
				01JAN1989	31DEC1989	N
				01JAN1996	31DEC1996	N
			Hysterectomy	01JAN2004	31DEC2004	N
			Meniscus operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2019	31DEC2019	N
			Shoulder operation	01JAN2015	31DEC2015	N
			Thyroid nodule removal	01JAN2016	31DEC2016	N
	C4591001 1046 10461324	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendectomy	01JAN2004	31DEC2004	N
			Knee operation	01JAN2019	31DEC2019	N
	C4591001 1046 10461325	Infections and infestations	Hepatitis C	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2003		Y
	C4591001 1046 10461327	Infections and infestations	Appendicitis perforated	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Surgical and medical procedures	Appendectomy	01JAN2017	31DEC2017	N
	C4591001 1046 10461329	Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Ankle arthroplasty	01JAN2005	31DEC2005	N
			Surgery	01JAN2011	31DEC2011	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1046 10461330	Immune system disorders	Seasonal allergy	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2008	31DEC2008	N
				01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
			Arthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Knee operation	01JAN2009	31DEC2009	N
	C4591001 1046 10461331	Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1046 10461332	Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1046 10461333	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002		Y
			Polycystic ovaries	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Endometriosis ablation	01JAN2005	31DEC2005	N
				01JAN2016	31DEC2016	N
	C4591001 1046 10461334	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Injury, poisoning and procedural complications	Fractured coccyx	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2001		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Caesarean section	03NOV1994	03NOV1994	N
				15MAR2000	15MAR2000	N
			Carpal tunnel decompression	01JAN2017	31DEC2017	N
			Coccygectomy	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1046 10461336	Psychiatric disorders	Bipolar disorder	01JAN2019		Y
			Generalised anxiety disorder	01JAN2019		Y
			Major depression	01JAN2019		Y
			Panic disorder	01JAN2019		Y
	C4591001 1046 10461337	Surgical and medical procedures	Wisdom teeth removal	01JUN2020	30JUN2020	N
		Infections and infestations	Urinary tract infection	01JAN2019		Y
		Renal and urinary disorders	Bladder diverticulum	01JAN1990	31DEC1990	N
			Bladder obstruction	01JAN1990	31DEC1990	N
	C4591001 1046 10461338	Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1046 10461339	Pregnancy, puerperium and perinatal conditions	Delivery	01JUN1996	30JUN1996	N
		Renal and urinary disorders	Nephrolithiasis	01AUG2014	31AUG2014	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Caesarean section	01JUN1996	30JUN1996	N
				Endometrial ablation	01JAN2003	31DEC2003

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Renal surgery	01AUG2014	31AUG2014	N
	C4591001 1046 10461341	Infections and infestations	Adenoiditis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
	C4591001 1046 10461342	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1046 10461343	Congenital, familial and genetic disorders	Albinism	(b) (6) 2003		Y
		Eye disorders	Blindness	(b) (6) 2003		Y
	C4591001 1046 10461344	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1046 10461346	Infections and infestations	Tonsillitis	01MAR2017	31MAR2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01MAR2017	31MAR2017	N
	C4591001 1046 10461347	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1046 10461348	Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2017		Y
	C4591001 1047 10471009	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Headache	01JAN2006		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
		Surgical and medical procedures	Female sterilisation	01DEC2011	31DEC2011	N
	C4591001 1047 10471010	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1047 10471015	Cardiac disorders	Cardiac disorder	01JAN2011		Y
		Ear and labyrinth disorders	Meniere's disease	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		General disorders and administration site conditions	Hernia	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2010	10MAR2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Hernia repair	01JAN2001	31DEC2001	N
			Knee arthroplasty	10MAR2010	10MAR2010	N
			Leg amputation	04AUG2012		Y
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1047 10471017	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1047 10471018	Congenital, familial and genetic disorders	Spina bifida occulta	(b) (6) 1979		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>							
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>	
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN1988	31DEC2019	N	
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N	
			Caesarean section	01JAN2009	31DEC2009	N	
				01JAN2011	31DEC2011	N	
				Hysterectomy	01JAN2019	31DEC2019	N
				Mammoplasty	01JAN2013	31DEC2013	N
				Spinal fusion surgery	01JAN1980	31DEC1980	N
					01JAN1983	31DEC1983	N
	C4591001 1047 10471020	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01APR2018		Y	
				Spinal stenosis	01APR2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y	
				Depression	01JAN2018		Y
		Surgical and medical procedures	Meniscus operation	01JAN2007	31DEC2007	N	
				Vasectomy	01MAY2020	31MAY2020	N
	C4591001 1047 10471021	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y	
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2020	N	
	C4591001 1047 10471025	Immune system disorders	Drug hypersensitivity	01JAN1984		Y	
				Seasonal allergy	01JAN1987		Y
		Infections and infestations	Tonsillitis streptococcal	01JAN1984	31DEC2015	N	
		Investigations	Biopsy breast	01MAY2018	31MAY2018	N	
		Psychiatric disorders	Anxiety	01JAN2004		Y	
				Depression	01JAN2004		Y
		Surgical and medical procedures	Cervical polypectomy	01JAN2016	30JUN2016	N	
				Tonsillectomy	01APR2015	30APR2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471028	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Adenoidectomy	01JAN1983	31DEC1983	N
	C4591001 1047 10471029	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Nervous system disorders	Seizure	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31DEC2018	N
			Vaginal haemorrhage	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Thyroid nodule removal	01JAN2017	31DEC2017	N
	C4591001 1047 10471030	Cardiac disorders	Ventricular extrasystoles	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
			Human papilloma virus test positive	01JAN2017		Y
		Nervous system disorders	Migraine	01JUN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471033	Pregnancy, puerperium and perinatal conditions	Delivery	09MAR1996	09MAR1996	N
				17JUL2001	17JUL2001	N
				20APR2004	20APR2004	N
				21DEC2005	21DEC2005	N
				26DEC1999	26DEC1999	N
	C4591001 1047 10471034	Hepatobiliary disorders	Gallbladder disorder	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471035	Congenital, familial and genetic disorders	Cleft lip	(b) (6) 1985	31DEC2004	N
			Cleft palate	(b) (6) 1985	31DEC2004	N
		Hepatobiliary disorders	Cholelithiasis	01SEP2010	30SEP2010	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2020		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2016	31DEC2017	N
	C4591001 1047 10471037	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN2006	31DEC2006	N
			Post-traumatic neck syndrome	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1991		Y
		Reproductive system and breast disorders	Pelvic pain	01JAN2006		Y
	C4591001 1047 10471038	Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
			Tonsillitis	01JAN1979	31DEC1980	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Back pain	01JAN2012	31DEC2012	N
			Intervertebral disc degeneration	01JAN2012	31DEC2012	N
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N
		Nervous system disorders	Sleep deficit	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471040	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Infections and infestations	Sepsis	01JAN2019	31DEC2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Metabolic acidosis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2004		Y
		Renal and urinary disorders	Acute kidney injury	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1047 10471041	Gastrointestinal disorders	Gastritis	01JAN2019		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
		Surgical and medical procedures	Spinal laminectomy	01OCT2015	31OCT2015	N
			Tonsillectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471042	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1976	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1047 10471046	Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471047	Psychiatric disorders	Depression	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2015		Y
	C4591001 1047 10471048	Congenital, familial and genetic disorders	Kyphosis congenital	(b) (6) 1971	31MAR2019	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	(b) (6) 1971	31MAR2019	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Spinal fusion surgery	01MAR2019	31MAR2019	N
	C4591001 1047 10471049	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2017		Y
			Oesophagitis	24JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Intervertebral disc degeneration	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
			Rheumatoid arthritis	01JAN2016		Y
			Spinal osteoarthritis	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01FEB2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1047 10471051	Gastrointestinal disorders	Anal fissure	01JAN1999	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Rectal abscess	01JAN1999	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2019	05MAY2020	N
		Investigations	Arthroscopy	05MAY2020	05MAY2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Abscess drainage	01JAN2000	31DEC2000	N
			Caesarean section	04OCT2002	04OCT2002	N
				10MAR2004	10MAR2004	N
				24AUG2006	24AUG2006	N
			Endometrial ablation	01JAN2015	31DEC2015	N
	C4591001 1047 10471052	Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	07FEB2020	07FEB2020	N
				12MAR2013	12MAR2013	N
		Surgical and medical procedures	Caesarean section	12MAR2013	12MAR2013	N
			Female sterilisation	03AUG2020	03AUG2020	N
	C4591001 1047 10471054	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Bipolar disorder	01JAN2016		Y
			Insomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471056	Gastrointestinal disorders	Umbilical hernia	01JAN1983	31MAR2020	N
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Psychiatric disorders	Anxiety	01APR2019		Y
			Attention deficit hyperactivity disorder	01JAN1996		Y
			Post-traumatic stress disorder	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
	C4591001 1047 10471057	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Infections and infestations	Tonsillitis	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2006	31DEC2006	N
		Psychiatric disorders	Bipolar disorder	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1994	31DEC1994	N
			Chondroplasty	01JAN2006	31DEC2006	N
			Nasal septal operation	01JAN2005	31DEC2005	N
	C4591001 1047 10471058	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1997	31DEC2003	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2003	31DEC2003	N
	C4591001 1047 10471059	Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	30APR2020	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01APR2020	30APR2020	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Endoscopic sleeve gastropasty	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2015	31DEC2015	N
	C4591001 1047 10471061	Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1047 10471064	Gastrointestinal disorders	Abdominal mass	01OCT2017	31OCT2017	N
			Dyspepsia	01JAN2012		Y
			Irritable bowel syndrome	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Bipolar disorder	01JAN2005		Y
			Depression	01JAN1999		Y
			Post-traumatic stress disorder	01JAN1999		Y
		Renal and urinary disorders	Hypertonic bladder	01MAY2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Abdominal operation	01JAN2001	31DEC2014	N
				01JAN2012	31DEC2012	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	06NOV2005	06NOV2005	N
				16MAR1999	16MAR1999	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1047 10471065	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN1986		Y
			Depression	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1047 10471067	Immune system disorders	Allergy to vaccine	01JAN2001		Y
			Drug hypersensitivity	01JAN1994		Y
				01JAN2019		Y
			Food allergy	01JAN2001		Y
		Infections and infestations	Chronic sinusitis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Skull fractured base	10DEC2018	10DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Ovarian cyst	18AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Bronchitis chronic	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	07FEB2014	07FEB2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				13DEC2007	13DEC2007	N
				24JUN2003	24JUN2003	N
				26AUG2002	26AUG2002	N
			Cranioplasty	10DEC2018	10DEC2018	N
			Mastoidectomy	10DEC2018	10DEC2018	N
			Sinus operation	01JAN2010	31DEC2010	N
			Gastritis	01JAN2015		Y
	C4591001 1047 10471068	Gastrointestinal disorders				
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1991	31DEC1991	N
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1047 10471069	Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2009		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2008	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Neck injury	26MAY2015		Y
			Patella fracture	01JAN2001	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2017	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2003	31DEC2003	N
			Neck pain	26MAY2015		Y
			Rotator cuff syndrome	01JAN1998	31DEC1998	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1997	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Bone lesion excision	01JAN2003	31DEC2003	N
			Caesarean section	03FEB1995	03FEB1995	N
				26MAY1999	26MAY1999	N
			Carpal tunnel decompression	01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Gastrectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2004	31DEC2004	N
			Knee operation	01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
			Mammoplasty	01JUN2019	30JUN2019	N
			Plastic surgery	01JUN2019	30JUN2019	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1047 10471070	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN2012		Y
			Seasonal allergy	01JAN1989		Y
		Investigations	Laparoscopy	01JAN2002	31DEC2002	N
		Nervous system disorders	Sinus headache	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1972	31DEC1972	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1047 10471071	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1047 10471074	Gastrointestinal disorders	Gingival recession	01JUL2019	31JUL2019	N
		Metabolism and nutrition disorders	Lactose intolerance	(b) (6) 1980		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	25SEP2013	25SEP2013	N
				29MAR2012	29MAR2012	N
			Gingival graft	01JUL2019	31JUL2019	N
			Mammoplasty	01JUL2017	31JUL2017	N
	C4591001 1047 10471075	Congenital, familial and genetic disorders	Ankyloglossia congenital	(b) (6) 1979	31DEC1984	N
		Surgical and medical procedures	Tongue tie operation	01JAN1984	31DEC1984	N
	C4591001 1047 10471076	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2019		Y
			Nervous system disorder	01JAN2006		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2019	31DEC2019	N
	C4591001 1047 10471077	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Keratomileusis	01JAN2003	31DEC2003	N
	C4591001 1047 10471078	Gastrointestinal disorders	Inguinal hernia	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Psychiatric disorders	Anxiety	01MAR2019	31MAR2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1993	31DEC1994	N
		Social circumstances	Postmenopause	04JUL2019	04JUL2019	N
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
			Inguinal hernia repair	01JAN1969	31DEC1969	N
			Nasal septal operation	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1983	31DEC1983	N
			Seasonal allergy	01JAN2015		Y
	C4591001 1047 10471079	Immune system disorders				
	C4591001 1047 10471080	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN1989		Y
		Surgical and medical procedures	Mammoplasty	01JAN1998	31DEC1998	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
			Tenotomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1047 10471081	Gastrointestinal disorders	Umbilical hernia	01FEB2015	28FEB2015	N
		Metabolism and nutrition disorders	Vitamin D deficiency	29JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JUL2018	19DEC2018	N
		Psychiatric disorders	Anxiety	01AUG2018		Y
		Surgical and medical procedures	Nephrectomy	08AUG2018	08AUG2018	N
				19DEC2018	19DEC2018	N
			Umbilical hernia repair	01FEB2015	28FEB2015	N
	C4591001 1047 10471082	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
				01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Arthritis	01JAN2010	31DEC2010	N
	C4591001 1047 10471083	Musculoskeletal and connective tissue disorders				
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
	C4591001 1047 10471084	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Streptococcal infection	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1047 10471085	Cardiac disorders	Myocardial infarction	01SEP2018	30SEP2018	N
		Infections and infestations	Herpes simplex	01JUL2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Narcolepsy	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Myomectomy	01JAN2001		Y
	C4591001 1047 10471086	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN1980		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
				01JAN2004		Y
			Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Scoliosis	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1996	31DEC1997	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Fracture treatment	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Oophorectomy bilateral	01JAN1997	31DEC1997	N
	C4591001 1047 10471087	Eye disorders	Ocular hypertension	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2002		Y
		Injury, poisoning and procedural complications	Femur fracture	05NOV1996	31DEC1996	N
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Fracture treatment	01JAN1996	31DEC1996	N
			Medical device removal	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Hiatus hernia	01JAN2000	31DEC2000	N
			Small intestinal obstruction	01APR2020	30APR2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of bladder	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Pelvic pain	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1999	31DEC2019	N
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			Gastrectomy	01JAN2018	31DEC2018	N
			Hernia hiatus repair	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2019	31DEC2019	N
			Lower oesophageal sphincter magnetic augmentation	01APR2020	30APR2020	N
			Nasal septal operation	01JAN2019	31DEC2019	N
	C4591001 1047 10471089	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471093	Psychiatric disorders	Anxiety	01JAN2006		Y
			Insomnia	01JAN2004		Y
	C4591001 1047 10471094	Surgical and medical procedures	Caesarean section	02OCT2013	02OCT2013	N
		Infections and infestations	Staphylococcal infection	01JAN2009	31DEC2009	N
			Tonsillitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1992	31DEC1992	N
			Wrist fracture	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Fracture reduction	01JAN1992	31DEC1992	N
			Incisional drainage	01JUN1992	30JUN1992	N
			Tonsillectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1970	31DEC1970	N
	C4591001 1047 10471095	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006		Y
		Immune system disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Infections and infestations	Seasonal allergy	01JAN2000		Y
			Chronic sinusitis	01JAN2000		Y
			Ear infection	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2006		Y
			Periarthritis	01JAN2018	31DEC2018	N
			Temporomandibular joint syndrome	01JAN1986		Y
		Nervous system disorders	Tarsal tunnel syndrome	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN1984		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septum deviation	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Endometrial ablation	01JAN2014	31DEC2014	N
			Lithotripsy	01JAN2017	31DEC2017	N
			Nasal septal operation	01JAN2017	31DEC2017	N
			Sclerotherapy	01JAN2006	31DEC2006	N
			Appendicitis	01JAN2005	31DEC2005	N
	C4591001 1047 10471100	Infections and infestations				
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1047 10471106	Congenital, familial and genetic disorders	Spina bifida	(b) (6) 1976		Y
		Musculoskeletal and connective tissue disorders	Back pain	(b) (6) 1976		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2008	31DEC2008	N
			Spinal fusion surgery	01JAN2008	31DEC2008	N
	C4591001 1047 10471107	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2011	31DEC2016	N
			Polycystic ovaries	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	10JUN1998	10JUN1998	N
				24OCT1995	24OCT1995	N
			Hysterectomy	04APR2016	04APR2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471109	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1986		Y
		Surgical and medical procedures	Ankle operation	01JAN1997	31DEC1997	N
	C4591001 1047 10471111	Blood and lymphatic system disorders	Thrombocytosis	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Skin lesion	27AUG2020	27AUG2020	N
		Surgical and medical procedures	Facial lesion excision	27AUG2020	27AUG2020	N
			Ovarian cystectomy	01JAN2003	31DEC2003	N
	C4591001 1047 10471112	Surgical and medical procedures	Caesarean section	04FEB2007	04FEB2007	N
				04NOV2004	04NOV2004	N
				25AUG2003	25AUG2003	N
				25FEB2002	25FEB2002	N
	C4591001 1047 10471115	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Lipoma excision	01JAN2014	31DEC2014	N
	C4591001 1047 10471118	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Epilepsy	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01MAY2020	31MAY2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471119	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Pharyngitis streptococcal	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1047 10471120	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN1996	31DEC2006	N
			Uterine leiomyoma	01JAN2005	31DEC2011	N
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1047 10471124	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
			Obsessive-compulsive disorder	01JAN2016		Y
	C4591001 1047 10471125	Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2016		Y
			Post-traumatic stress disorder	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1989		Y
		Surgical and medical procedures	Caesarean section	25JUN1993	25JUN1993	N
				26JUN1989	26JUN1989	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
	C4591001 1047 10471126	Immune system disorders	Food allergy	01JAN1992	31DEC2004	N
		Infections and infestations	Tonsillitis	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Cartilage injury	01MAY2016	31MAY2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1994	31DEC1994	N
			Caesarean section	28SEP2017	28SEP2017	N
			Hip surgery	01MAY2016	31MAY2016	N
			Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1047 10471127	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastrectomy	01JAN2016	31DEC2016	N
	C4591001 1047 10471128	Gastrointestinal disorders	Anal fistula	01JAN2004	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1047 10471129	Surgical and medical procedures	Anal fistula repair	01JAN2004	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN1982	31DEC1982	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Caesarean section	01JAN1992	31DEC1992	N
				01JAN1996	31DEC1996	N
			Nephrectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471133	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2003		Y
			Insomnia	01JAN2003		Y
			Social anxiety disorder	01JAN2003		Y
	C4591001 1047 10471134	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
			Tonsillitis	01JAN1993	31DEC1993	N
			Upper respiratory tract infection	01JAN1978	31DEC1993	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck pain	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1047 10471143	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Surgical and medical procedures	Spinal operation	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1047 10471144	Cardiac disorders	Coronary artery disease	01OCT2015		Y
			Myocardial infarction	01OCT2015	31OCT2015	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
			Pneumonia	01FEB2020	29FEB2020	N
				01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01OCT2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Muscle operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01OCT2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Infections and infestations	Epstein-Barr virus infection	01JAN1988	31DEC1998	N
			Mastitis	01JAN2017	31DEC2017	N
		Investigations	Gene mutation identification test positive	(b) (6) 1969		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	(b) (6) 1969		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01AUG2000	31AUG2000	N
		Surgical and medical procedures	Breast reconstruction	01JAN2017	31DEC2017	N
			Caesarean section	02AUG2001	02AUG2001	N
				22MAR2004	22MAR2004	N
			Hysterectomy	15AUG2015	15AUG2015	N
			Liposuction	01JAN2014	31DEC2014	N
			Mastectomy	30NOV2016	30NOV2016	N
			Oophorectomy bilateral	01APR2016	30APR2016	N
			Tonsillectomy	01JAN1998	31DEC1998	N
			Uterine dilation and curettage	01AUG2000	31AUG2000	N
	C4591001 1047 10471148	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Fracture treatment	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471149	Injury, poisoning and procedural complications	Ankle fracture	01JAN1998	31DEC1998	N
		Investigations	Arthroscopy	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2003	31DEC2003	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1047 10471150	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Cardiac disorders	Atrial fibrillation	01JAN2013		Y
		Endocrine disorders	Autoimmune thyroiditis	01JUL2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1992		Y
			Pancreatic failure	01JAN2014		Y
			Pancreatitis	01JUN2014	30JUN2014	N
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Rubber sensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN1973		Y
			Vitamin D deficiency	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01SEP2013	30SEP2013	N
			Cholecystectomy	01JUL2018	31JUL2018	N
			Jejunostomy	01MAY2004	31MAY2004	N
	C4591001 1047 10471151	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Orthognathic surgery	01JAN2016	31DEC2016	N
	C4591001 1047 10471155	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAY2020	31DEC2020	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
			Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2020		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1047 10471159	Ear and labyrinth disorders	Tinnitus	01JAN2018	31DEC2018	N
	C4591001 1047 10471162	Psychiatric disorders	Anxiety	01MAY2020		Y
			Depression	01MAY2020		Y
	C4591001 1047 10471163	Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
			Major depression	01JAN2014		Y
	C4591001 1047 10471166	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Foot fracture	01JAN2016	31DEC2016	N
			Forearm fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01MAR2019		Y
			Myalgia	01MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Fracture treatment	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
				01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
	C4591001 1047 10471167	Infections and infestations	Tonsillitis	01JAN1999	31DEC1999	N
		Psychiatric disorders	Depression	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
				01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1047 10471168	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Renal stone removal	01JAN2019	31DEC2019	N
	C4591001 1047 10471171	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN1997		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2017		Y
			Temporomandibular joint syndrome	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN1997	31DEC1997	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1994		Y
		Surgical and medical procedures	Knee operation	01JAN2017	31DEC2017	N
			Pituitary tumour removal	01JAN1997	31DEC1997	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471172	Eye disorders	Dry eye	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Genital herpes	01JAN2000		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
			Neck pain	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1047 10471176	Cardiac disorders	Tachycardia	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Investigations	Blood testosterone decreased	01FEB2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2011		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1047 10471180	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN1991		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Gastric bypass	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471186	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1047 10471189	Infections and infestations	Tonsillitis	09MAY2020	09MAY2020	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	09MAY2019	09MAY2019	N
	C4591001 1047 10471192	Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Nervous system disorders	Neuralgia	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Cholecystectomy	01JAN1999	31DEC1999	N
			Foot amputation	01JAN2011	31DEC2011	N
				01JAN2018	31DEC2018	N
			Spinal operation	01JAN1998	31DEC1998	N
				01JAN2004	31DEC2004	N
	C4591001 1047 10471198	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Hand fracture	01NOV2011	30NOV2011	N
		Reproductive system and breast disorders	Premenstrual syndrome	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Fracture treatment	01NOV2011	30NOV2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471199	Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Surgical and medical procedures	Renal stone removal	01JAN2010	31DEC2010	N
	C4591001 1047 10471201	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2008	31DEC2008	N
			Hepatic cirrhosis	01JUN2020		Y
			Nonalcoholic fatty liver disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
		Investigations	Blood potassium decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1999		Y
			Osteoarthritis	01JAN2014		Y
			Osteoporosis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2020	29FEB2020	N
		Reproductive system and breast disorders	Ovarian cyst	28FEB2003	28FEB2003	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	24DEC1993	24DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric bypass	22SEP2011	22SEP2011	N
			Hysterectomy	25FEB2003	25FEB2003	N
			Oophorectomy	25FEB2003	25FEB2003	N
			Rotator cuff repair	01APR2012	30APR2012	N
				01JAN2012	31DEC2012	N
	C4591001 1047 10471202	Musculoskeletal and connective tissue disorders	Rhabdomyolysis	01AUG2017	31AUG2017	N
			Spinal osteoarthritis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hip surgery	01JAN1995	31DEC1995	N
	C4591001 1047 10471203	Hepatobiliary disorders	Gallbladder hypofunction	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN1999		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN1999		Y
			Obsessive-compulsive disorder	01JAN2015		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Tenotomy	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
	C4591001 1047 10471207	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1047 10471210	Immune system disorders	Drug hypersensitivity	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Iodine allergy	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Fracture treatment	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471211	Congenital, familial and genetic disorders	Congenital lymphoedema	01JAN1984		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986	31DEC1986	N
			Seasonal allergy	01JAN1992	31DEC1992	N
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
			Female sterilisation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1047 10471212	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	20JUL2019	22JUL2019	N
		Vascular disorders	Thrombosis	20JUL2019	20JUL2019	N
	C4591001 1047 10471217	Nervous system disorders	Nerve compression	01JAN1989	31DEC1989	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Peripheral nerve operation	01JAN1989	31DEC1989	N
	C4591001 1047 10471219	Renal and urinary disorders	Cystitis interstitial	30SEP1991		Y
		Surgical and medical procedures	Caesarean section	15JUN2009	15JUN2009	N
				26OCT2012	26OCT2012	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				28APR2014	28APR2014	N
			Female sterilisation	28APR2014	28APR2014	N
	C4591001 1047 10471220	Infections and infestations	Appendicitis	01SEP2019	30SEP2019	N
		Surgical and medical procedures	Appendicectomy	01SEP2019	30SEP2019	N
	C4591001 1047 10471221	Gastrointestinal disorders	Female sterilisation	01JAN2018	31DEC2018	N
			Dyspepsia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Scoliosis	(b) (6) 1970		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
			Ovarian cystectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471223	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010	31DEC2010	N
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1999	31DEC2000	N
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1999	31DEC1999	N
			Spinal fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Uterine leiomyoma	01JAN2011	31DEC2011	N
		Nervous system disorders	Epilepsy	01JAN1975		Y
			Migraine	01JAN1975		Y
		Psychiatric disorders	Bipolar disorder	01JAN1993		Y
			Insomnia	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N
				01JAN2013	31DEC2013	N
	C4591001 1047 10471225	General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1991	31DEC1991	N
		Psychiatric disorders	Affective disorder	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
			Generalised anxiety disorder	01JAN2019		Y
			Insomnia	01JAN2000		Y
			Major depression	01JAN2019		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	21MAY2012	21MAY2012	N
				27OCT2002	27OCT2002	N
			Female sterilisation	21MAY2012	21MAY2012	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1047 10471226	Injury, poisoning and procedural complications	Tibia fracture	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
			Vitamin D deficiency	01AUG2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01JUL2019	09JAN2020	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Dyspareunia	01JAN2020		Y
			Menorrhagia	01JAN2017	31DEC2019	N
		Social circumstances	Electronic cigarette user	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	05NOV2002	05NOV2002	N
			Carpal tunnel decompression	09JUN2020	09JUN2020	N
			Endometrial ablation	15MAY2019	15MAY2019	N
			Fracture treatment	01JAN1988	31DEC1988	N
	C4591001 1047 10471227	Endocrine disorders	Hypothyroidism	01FEB2017	31MAR2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Vesicoureteric reflux	(b) (6) 1987	31DEC2000	N
	C4591001 1047 10471229	Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
				01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
	C4591001 1047 10471231	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2001	31DEC2001	N



16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471232	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Pneumothorax spontaneous	10AUG2014	10AUG2014	N
	C4591001 1047 10471233	Gastrointestinal disorders	Abdominal hernia	01JAN1983	31DEC1983	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Seasonal affective disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN1984	31DEC1985	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN1983	31DEC1983	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1047 10471236	Congenital, familial and genetic disorders	Patent ductus arteriosus	01JAN1971	31DEC1971	N
				(b) (6) 1969	31DEC1971	N
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Food allergy	01JAN1992		Y
			Seasonal allergy	01JAN1979		Y
		Infections and infestations	Chronic sinusitis	01JAN2001		Y
			Tonsillitis	01JAN1972	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	11AUG2002	11AUG2002	N
				19MAY2004	19MAY2004	N
			Hysterectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy bilateral	01JAN2008	31DEC2008	N
			Sinus operation	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1047 10471237	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Umbilical hernia repair	01JAN2000	31DEC2000	N
	C4591001 1047 10471238	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic adenoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
			Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
		Surgical and medical procedures	Hepatectomy	01JAN2016	31DEC2016	N
	C4591001 1047 10471240	Gastrointestinal disorders	Pancreatitis	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholecystitis	01JAN2001	31DEC2001	N
		Infections and infestations	Diverticulitis	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Breast cyst	01JAN1997	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Paranasal cyst	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Breast cyst excision	01JAN1997	31DEC1997	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN1999	31DEC1999	N
			Sinus operation	01JAN1993	31DEC1993	N
	C4591001 1047 10471241	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Arthritis	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Caesarean section	08AUG2007	08AUG2007	N
			Cholecystectomy	30APR2002	30APR2002	N
			Myomectomy	01JAN1999	31DEC1999	N
			20NOV2019	20NOV2019	N	
	C4591001 1047 10471243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
			Impaired gastric emptying	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1047 10471244	Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Bursitis	01MAR2020	31MAR2020	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
	C4591001 1047 10471245	Infections and infestations	Tonsillitis	01MAY2020	31MAY2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN1998	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01MAY2020	31MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471246	Hepatobiliary disorders	Gallbladder disorder	01JAN2009	30SEP2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1991	30JUN1991	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN1987	30APR1987	N
		Surgical and medical procedures	Ankle arthroplasty	01JUN1991	30JUN1991	N
			Appendectomy	01JAN1996	31DEC1996	N
			Cholecystectomy	01SEP2009	30SEP2009	N
			Tonsillectomy	01APR1987	30APR1987	N
	C4591001 1047 10471251	Gastrointestinal disorders	Umbilical hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Biopsy cervix	01JAN2002	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basosquamous carcinoma	01JAN2014	31DEC2015	N
			Basosquamous carcinoma of skin	01JAN2014	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Reproductive system and breast disorders	Cervix disorder	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN2014	31DEC2014	N
	C4591001 1047 10471253	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				01JAN1995	31DEC1995	N
			Female sterilisation	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN2020	31JAN2020	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
	C4591001 1047 10471254	Endocrine disorders	Goitre	01JAN2009	31DEC2009	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JUL2020		Y
			Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1047 10471255	Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
	C4591001 1047 10471256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471257	Metabolism and nutrition disorders	Obesity	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	05JUN1995	05JUN1995	N
			Female sterilisation	05JUN1995	05JUN1995	N
	C4591001 1047 10471258	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Caesarean section	01DEC2014	31DEC2014	N
				01JUN2011	30JUN2011	N
			Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1047 10471259	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nasal septal operation	01NOV2010	30NOV2010	N
			Rhinoplasty	01NOV2010	30NOV2010	N
	C4591001 1047 10471262	Eye disorders	Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		Nervous system disorders	Brachial plexopathy	01JAN2018	31DEC2018	N
	C4591001 1047 10471264	Cardiac disorders	Ventricular extrasystoles	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2011		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1996		Y
			Transient ischaemic attack	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Endometriosis	01JAN2006	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1047 10471266	Congenital, familial and genetic disorders	Klippel-Feil syndrome	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				01JAN2010		Y
				01JAN2016		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Chronic sinusitis	01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	28FEB2020	28FEB2020	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
			Sleep disorder	01JAN2010		Y
		Social circumstances	Postmenopause	28FEB2020	28FEB2020	N
		Surgical and medical procedures	Hysterectomy	28FEB2020	28FEB2020	N
			Oophorectomy bilateral	28FEB2020	28FEB2020	N
			Sinus operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1047 10471267	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2003		Y
		Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471270	Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1995	31DEC2013	N
			Ovarian cyst	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2013	31DEC2013	N
			Oophorectomy	01JAN2016	31DEC2016	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1047 10471271	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1992		Y
	C4591001 1047 10471275	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
					31DEC2008	N
		Infections and infestations	Pharyngitis streptococcal	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2002	31DEC2002	N
			Tonsillar hypertrophy	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1047 10471278	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Renal stone removal	01JAN2011	31DEC2011	N
	C4591001 1047 10471279	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1047 10471284	Immune system disorders	Seasonal allergy	01JAN2016		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1047 10471285	Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
				01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
	C4591001 1047 10471288	Surgical and medical procedures	Female genital operation	01JAN2017	31DEC2017	N
			Hormone replacement therapy	01JAN2015	31DEC2015	N
			Transgender operation	08AUG2018	08AUG2018	N
	C4591001 1047 10471289	Immune system disorders	Food allergy	01JAN1966		Y
	C4591001 1047 10471291	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1047 10471292	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1987	31DEC1987	N
	C4591001 1047 10471294	Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471295	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005	31DEC2005	N
	C4591001 1047 10471296	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1047 10471297	Ear and labyrinth disorders	Deafness bilateral	14JUL1971		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
			Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
			Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2005	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Cochlea implant	01JAN2008	31DEC2008	N
				01JAN2014		Y
			Endometrial ablation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1047 10471301	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Infections and infestations	Helicobacter infection	01NOV2019	30NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Biopsy breast	01JUN2015	30JUN2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JUN2015	30JUN2015	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1992	31DEC1992	N
		Psychiatric disorders	Anxiety	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Caesarean section	22JAN2005	22JAN2005	N
			Female sterilisation	01JAN2005	31DEC2005	N
			Uterine dilation and curettage	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2019	31DEC2020	N
	C4591001 1047 10471303	Gastrointestinal disorders	Gastric ulcer	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1985	31JAN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN2019	31JAN2019	N
	C4591001 1047 10471304	Surgical and medical procedures	Caesarean section	01MAY2019	31MAY2019	N
	C4591001 1047 10471305	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
	C4591001 1047 10471306	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1047 10471307	Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2004		Y
			Upper limb fracture	01JAN2003	31DEC2003	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
			Vitamin B12 deficiency	01JAN2019		Y
			Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
			Diabetic neuropathy	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
			Post-traumatic stress disorder	01JAN2009		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Fracture treatment	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1047 10471308	Cardiac disorders	Cardiac failure congestive	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1987		Y
			Irritable bowel syndrome	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN1999		Y
				01JAN2001		Y
				01JAN2017		Y
		Injury, poisoning and procedural complications	Forearm fracture	27SEP2018	27SEP2018	N
			Lumbar vertebral fracture	01JAN1989		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1988		Y
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
		Nervous system disorders	Nerve compression	01JAN2009	31DEC2009	N
			Neuropathy peripheral	01JAN1994		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
			Rapid eye movements sleep abnormal	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Fracture treatment	01JUN1997	30JUN1997	N
				01OCT1993	31OCT1993	N
				27SEP2018	27SEP2018	N
			Peripheral nerve decompression	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471310	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Epilepsy	14JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1047 10471312	Immune system disorders	Seasonal allergy	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1047 10471314	Psychiatric disorders	Depression	01MAR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1989	31DEC1989	N
			Tonsillar hypertrophy	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Adenoidectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1047 10471316	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC1995	N
	C4591001 1047 10471317	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1047 10471318	Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
	C4591001 1047 10471319	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Renal and urinary disorders	Urge incontinence	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	15JUN1988	15JUN1988	N
				20MAR2004	20MAR2004	N
			Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471321	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471322	Immune system disorders	Food allergy	01JAN1991		Y
	C4591001 1047 10471325	Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
	C4591001 1047 10471326	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	17JUL1998	17JUL1998	N
				21OCT2002	21OCT2002	N
				30SEP1999	30SEP1999	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1047 10471329	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1987		Y
		Psychiatric disorders	Bipolar I disorder	01JAN2019		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2013	31DEC2013	N
			Ovarian haemorrhage	08JAN2020	08JAN2020	N
		Surgical and medical procedures	Female sterilisation	07JAN2020	07JAN2020	N
			Oophorectomy	08JAN2020	08JAN2020	N
	C4591001 1047 10471331	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
			Obesity	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1047 10471332	Metabolism and nutrition disorders	Obesity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2014		Y
	C4591001 1048 10481001	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
	C4591001 1048 10481004	Injury, poisoning and procedural complications	Nasal injury	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Nervous system disorders	Sinus headache	01JAN2015		Y
		Psychiatric disorders	Depression	01OCT2019		Y
	C4591001 1048 10481011	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Renal and urinary disorders	Bladder stenosis	01JAN2018	31DEC2018	N
			Urinary retention	01JAN2017		Y
		Surgical and medical procedures	Transurethral incision of prostate	01JAN2018	31DEC2018	N
	C4591001 1048 10481017	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Eye disorders	Myopia	01JAN1976		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1996		Y
	C4591001 1048 10481019	Congenital, familial and genetic disorders	Familial tremor	01JAN1990		Y
		Eye disorders	Myopia	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481021	Immune system disorders	Drug hypersensitivity	01SEP2012		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Nervous system disorders	Headache	01OCT2008		Y
	C4591001 1048 10481024	Injury, poisoning and procedural complications	Meniscus injury	01JUN2019		Y
		Investigations	Blood testosterone decreased	01AUG2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
			Obesity	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Piriformis syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1048 10481025	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
			Irritable bowel syndrome	01JAN2016		Y
		Infections and infestations	Diverticulitis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Surgical and medical procedures	Intestinal resection	01JAN2016		Y
	C4591001 1048 10481027	Endocrine disorders	Hypothyroidism	07AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	01JUN2020	07AUG2020	N
		Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Thyroidectomy	07AUG2020	07AUG2020	N
	C4591001 1048 10481030	Investigations	Precancerous cells present	01JAN2017	31AUG2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481032	Surgical and medical procedures	Hysterectomy	01AUG2017	31AUG2017	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastritis	01MAY2020		Y
			Hiatus hernia	01MAY2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Muscle spasms	01JAN2015		Y
		Nervous system disorders	Akathisia	01JAN2015		Y
			Tardive dyskinesia	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2001		Y
			Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		C4591001 1048 10481037	Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017
	C4591001 1048 10481040	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2019	31JUL2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Obesity	01JAN2000		Y
			Vitamin D deficiency	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2020		Y
			Sleep apnoea syndrome	01JAN2020		Y
		Surgical and medical procedures	Myomectomy	21MAY2020	21MAY2020	N
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1048 10481044	Gastrointestinal disorders	Diarrhoea	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1048 10481046	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Type 1 diabetes mellitus	01JAN1983		Y
			Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1987		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1980	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1048 10481048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481052	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01DEC2016		Y
	C4591001 1048 10481054	Metabolism and nutrition disorders	Vitamin A deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Vulvovaginal pain	15AUG2020	15AUG2020	N
	C4591001 1048 10481055	Endocrine disorders	Hyperthyroidism	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN2019	31JUL2019	N
			Uterine leiomyoma	01JAN2012	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01JUL2019	31JUL2019	N
			Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1048 10481056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2000	31DEC2002	N
			Spinal fracture	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2006		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481057	Endocrine disorders	Goitre	01JAN2015		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2013		Y
		Infections and infestations	Infected dermal cyst	23AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Type 2 diabetes mellitus	21MAY2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	13AUG2020	23AUG2020	N
		Social circumstances	Tobacco user	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1048 10481061	Eye disorders	Glaucoma	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Psychiatric disorders	Intermittent explosive disorder	01JAN2019		Y
	C4591001 1048 10481064	Gastrointestinal disorders	Diarrhoea	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Injury, poisoning and procedural complications	Limb injury	12AUG2020	14AUG2020	N
		Metabolism and nutrition disorders	Obesity	01SEP2000		Y
		Psychiatric disorders	Insomnia	01JAN1996		Y
		Renal and urinary disorders	Polyuria	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Apnoea	01JAN2005		Y
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2005		Y
			Hysterectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Haemorrhage	01JAN2011	31DEC2013	N
			Hypertension	01JAN2000		Y
	C4591001 1048 10481070	Reproductive system and breast disorders	Prostatomegaly	01JUN2020		Y
	C4591001 1048 10481075	Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1048 10481079	Cardiac disorders	Supraventricular tachycardia	06AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	06AUG2020		Y
	C4591001 1048 10481083	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
	C4591001 1048 10481085	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Infections and infestations	Herpes zoster	01SEP2019	31OCT2019	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1992		Y
		Nervous system disorders	Headache	01JAN1992		Y
	C4591001 1048 10481086	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01DEC2014	31DEC2014	N
		Surgical and medical procedures	Medical device implantation	01DEC2015	31DEC2015	N
	C4591001 1048 10481092	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Depression	01FEB2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1048 10481094	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2017		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1048 10481095	Ear and labyrinth disorders	Vertigo	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1999		Y
			Syncope	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1048 10481097	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Eczema	01JAN1982		Y
	C4591001 1048 10481101	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01NOV2005		Y
		Nervous system disorders	Headache	01APR2020		Y
	C4591001 1048 10481103	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Generalised anxiety disorder	01JAN2000		Y
			Insomnia	01JAN2000		Y
			Panic attack	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Mastectomy	01JAN2012	31DEC2012	N
			Skin graft	03SEP2020	03SEP2020	N
	C4591001 1048 10481106	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1048 10481107	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood triglycerides increased	01JAN2017		Y
	C4591001 1048 10481108	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1048 10481110	Gastrointestinal disorders	Diarrhoea	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1048 10481116	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1978		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y
			Rotator cuff syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1990		Y
			Post-traumatic stress disorder	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1048 10481125	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1982		Y
	C4591001 1048 10481126	Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Psychiatric disorders	Anxiety	01DEC2018		Y
			Insomnia	01MAR2019		Y
	C4591001 1048 10481132	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	10JUL2020	12JUL2020	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	12JUL2020	12JUL2020	N
	C4591001 1052 10521013	Respiratory, thoracic and mediastinal disorders	Asthma	01APR2020		Y
	C4591001 1052 10521017	Surgical and medical procedures	Hip arthroplasty	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1052 10521028	Surgical and medical procedures	Hysterectomy	01JUN2017	30JUN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1052 10521032	Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1052 10521036	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine neoplasm	01DEC2018	31DEC2018	N
		Surgical and medical procedures	Tumour excision	01DEC2018	31DEC2018	N
	C4591001 1052 10521052	Investigations	Blood cholesterol increased	01JAN2002		Y
	C4591001 1052 10521058	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1052 10521070	Surgical and medical procedures	Appendicectomy	07SEP2014	07SEP2014	N
	C4591001 1052 10521091	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
	C4591001 1052 10521092	Surgical and medical procedures	Hip arthroplasty	01JUL2014	31DEC2014	N
				11MAY2020	30JUN2020	N
	C4591001 1052 10521096	Surgical and medical procedures	Appendicectomy	01OCT2000	01OCT2000	N
	C4591001 1052 10521100	Social circumstances	Postmenopause	01NOV2019		Y
	C4591001 1052 10521101	Surgical and medical procedures	Caesarean section	26JAN2014	26JAN2014	N
	C4591001 1052 10521105	Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
	C4591001 1052 10521109	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1999		Y
	C4591001 1052 10521113	Surgical and medical procedures	Hysterectomy	13MAR2019	13MAR2019	N
	C4591001 1052 10521117	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1052 10521125	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1052 10521126	Surgical and medical procedures	Appendicectomy	01MAY1998	31MAY1998	N
			Hysterectomy	05MAR2019	05MAR2019	N
	C4591001 1052 10521129	Gastrointestinal disorders	Coeliac disease	01JAN2012		Y
	C4591001 1052 10521131	Injury, poisoning and procedural complications	Jaw fracture	10FEB2015	30APR2015	N
	C4591001 1052 10521132	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2003		Y
	C4591001 1052 10521133	Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1052 10521139	Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
	C4591001 1052 10521140	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1052 10521141	Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tenoplasty	01JAN2006	31DEC2006	N
				01JAN2010	31DEC2010	N
	C4591001 1052 10521145	Social circumstances	Postmenopause	01FEB2020		Y
	C4591001 1052 10521150	General disorders and administration site conditions	Hernia	01JAN2004	08JAN2005	N
	C4591001 1052 10521152	Psychiatric disorders	Depression	30NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1052 10521159	Investigations	Colonoscopy	01JAN2015	31DEC2015	N
	C4591001 1052 10521160	Nervous system disorders	Migraine	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1052 10521161	Cardiac disorders	Arrhythmia	10SEP2007	10SEP2007	N
		Vascular disorders	Hypertension	10SEP2007		Y
	C4591001 1052 10521162	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1052 10521165	Nervous system disorders	Migraine	01JAN1996		Y
	C4591001 1052 10521174	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1052 10521177	Psychiatric disorders	Anxiety	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2020		Y
		Surgical and medical procedures	Ligament operation	01MAY1995	31DEC1995	N
				01NOV2016	31DEC2016	N
	C4591001 1054 10541001	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Female sterilisation	16SEP2004	16SEP2004	N
	C4591001 1054 10541002	Injury, poisoning and procedural complications	Scar	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1054 10541003	Injury, poisoning and procedural complications	Scar	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1991		Y
				07DEC2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1982	31DEC1982	N
				01JAN1991	31DEC1991	N
		Nervous system disorders	Postural tremor	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Surgical and medical procedures	Lipoma excision	07DEC2014	07DEC2014	N
			Shoulder operation	01JAN1982	31DEC1982	N
				01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1054 10541005	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1054 10541006	Injury, poisoning and procedural complications	Gun shot wound	01JAN1994	31DEC1994	N
			Scar	01JAN1994		Y
		Surgical and medical procedures	Hand repair operation	01JAN1994	31DEC1994	N
				01JAN1995	31DEC1995	N
	C4591001 1054 10541008	Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1054 10541011	Infections and infestations	Herpes simplex	01JAN2017		Y
			Tonsillitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1054 10541012	Psychiatric disorders	Anxiety	01JUL2019		Y
	C4591001 1054 10541013	Infections and infestations	Urinary tract infection	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Scar	01FEB2014		Y
		Surgical and medical procedures	Caesarean section	01FEB2014	28FEB2014	N
			Hysterectomy	01FEB2014	28FEB2014	N
	C4591001 1054 10541014	Injury, poisoning and procedural complications	Scar	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2018	31DEC2018	N
	C4591001 1054 10541016	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1054 10541017	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1054 10541018	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Injury, poisoning and procedural complications	Scar	18MAR2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Vitamin D deficiency	01JAN2020		Y
		Renal and urinary disorders	Hypertonic bladder	01MAY2020		Y
		Surgical and medical procedures	Caesarean section	18MAR2016	18MAR2016	N
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1054 10541019	Cardiac disorders	Cardiac failure congestive	01NOV2019	30NOV2019	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2017		Y
		General disorders and administration site conditions	Chest discomfort	09JUL2020	09JUL2020	N
		Investigations	Angiogram	09JUL2020	09JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Skin discolouration	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1054 10541022	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Injury, poisoning and procedural complications	Scar	08MAY2018		Y
		Surgical and medical procedures	Caesarean section	08MAY2018	08MAY2018	N
	C4591001 1054 10541023	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Scar	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
	C4591001 1054 10541026	Injury, poisoning and procedural complications	Scar	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010		Y
	C4591001 1054 10541027	Blood and lymphatic system disorders	Normocytic anaemia	01JAN2015		Y
		Eye disorders	Ocular hypertension	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2018		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Intervertebral disc degeneration	01OCT2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Carcinoid tumour of the gastrointestinal tract	01JAN2013	31DEC2013	N
		Nervous system disorders	Syncope	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Cancer surgery	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1054 10541028	Congenital, familial and genetic disorders	Congenital intestinal malformation	(b) (6) 1980	(b) (6) 1980	N
		Injury, poisoning and procedural complications	Scar	(b) (6) 1980		Y
		Nervous system disorders	Carpal tunnel syndrome	01AUG2020		Y
			Paraesthesia	01AUG2020		Y
	C4591001 1054 10541032	Cardiac disorders	Sinus tachycardia	01JAN2014		Y
		Social circumstances	Menopause	01JAN2019		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1054 10541033	Infections and infestations	Appendicitis	23MAY2013	23MAY2013	N
			COVID-19	01MAY2020	31MAY2020	N
			Onychomycosis	01JAN2017		Y
		Injury, poisoning and procedural complications	Scar	23MAY2013		Y
		Surgical and medical procedures	Appendicectomy	23MAY2013	23MAY2013	N
	C4591001 1054 10541034	Infections and infestations	Urinary tract infection	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	22JUN2020		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541035	Cardiac disorders	Mitral valve incompetence	01MAR2010		Y
		Congenital, familial and genetic disorders	Klinefelter's syndrome	01JAN2018		Y
		Eye disorders	Myopia	01JAN1998	23MAY2020	N
		Infections and infestations	Chronic sinusitis	01JUL2020		Y
			Pneumonia	01JAN1992	31DEC1992	N
		Investigations	Blood testosterone decreased	01FEB2015		Y
			Cardiac murmur	(b) (6) 1991		Y
		Metabolism and nutrition disorders	Lactose intolerance	(b) (6) 1991		Y
		Nervous system disorders	Headache	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993	31DEC1995	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1992		Y
		Surgical and medical procedures	Keratomileusis	23MAY2020	23MAY2020	N
	C4591001 1054 10541037	Injury, poisoning and procedural complications	Joint injury	01JAN2011	31DEC2011	N
			Road traffic accident	01JAN2011	31DEC2011	N
			Scar	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
	C4591001 1054 10541038	Surgical and medical procedures	Mammoplasty	01MAY2019	31MAY2019	N
	C4591001 1054 10541039	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1054 10541041	Immune system disorders	Food allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01MAR2017	31MAR2017	N
			Keratomileusis	01JAN2011	31DEC2011	N
			Large intestinal polypectomy	01JAN1980	31DEC1980	N
			Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1054 10541042	Infections and infestations	Onychomycosis	01JAN2000		Y
		Injury, poisoning and procedural complications	Scar	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1983	31DEC2000	N
		Surgical and medical procedures	Wound closure	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1054 10541043	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Reproductive system and breast disorders	Testicular pain	02DEC2019	02DEC2019	N
	C4591001 1054 10541044	Gastrointestinal disorders	Colitis ulcerative	01JAN2019	31JAN2020	N
		Infections and infestations	Oral herpes	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
			Scar	01JAN2010		Y
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1054 10541047	Infections and infestations	Urinary tract infection	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Scar	01JAN1995		Y
			Upper limb fracture	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Neck pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1981		Y
			Depression	01JAN1981		Y
	C4591001 1054 10541048	Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2020		Y
		Surgical and medical procedures	Hand repair operation	01JAN2005	31DEC2005	N
			Sinus operation	01JAN2017	31DEC2017	N
	C4591001 1054 10541049	Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
	C4591001 1054 10541051	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2003		Y
	C4591001 1054 10541053	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JUN2019		Y
	C4591001 1054 10541054	Injury, poisoning and procedural complications	Scar	01JAN2010		Y
			Wrist fracture	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Open reduction of fracture	01JAN2000	31DEC2000	N
	C4591001 1054 10541057	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
			Eczema	01JAN2019		Y
	C4591001 1054 10541058	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1054 10541060	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2010	31DEC2010	N
			Road traffic accident	01JAN2010	31DEC2010	N
			Wrist fracture	01JAN2007	31DEC2007	N
		Nervous system disorders	Headache	01JAN2017		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1054 10541061	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Injury, poisoning and procedural complications	Scar	01JAN1981		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN1981	31DEC1981	N
	C4591001 1054 10541065	Eye disorders	Amblyopia	01JAN1993		Y
		Gastrointestinal disorders	Abdominal hernia	01JUN2020	01AUG2020	N
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Scar	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Hernia repair	01AUG2020	01AUG2020	N
	C4591001 1054 10541066	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Scar	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
	C4591001 1054 10541067	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Hypersensitivity	01JAN2014		Y
		Injury, poisoning and procedural complications	Scar	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Salpingectomy	01JAN2018	31DEC2018	N
	C4591001 1054 10541068	Infections and infestations	Onychomycosis	01JAN2010		Y
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1993	31DEC1993	N
			Scar	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thermal burn	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN2006		Y
	C4591001 1054 10541069	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Lithotripsy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1054 10541070	Congenital, familial and genetic disorders	Supernumerary nipple	01JAN1993	31DEC1993	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1998	31DEC1998	N
			Scar	01JAN1993		Y
		Nervous system disorders	Headache	01JAN1997		Y
			Migraine	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
	C4591001 1054 10541073	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Nervous system disorders	Tremor	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1054 10541074	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2000	31DEC2000	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Scar	26FEB2008		Y
		Nervous system disorders	Cerebral haemorrhage	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hemiparesis	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	26FEB2008	26FEB2008	N
			Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1054 10541078	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Scar	01JAN2000	31DEC2000	N
			Tendon rupture	01JAN2000	31DEC2000	N
			Upper limb fracture	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Surgical and medical procedures	Tenoplasty	01JAN2000	31DEC2000	N
	C4591001 1054 10541080	Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1054 10541081	Infections and infestations	Urinary tract infection	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1987		Y
			Migraine	01JAN1987		Y
		Psychiatric disorders	Bipolar disorder	01JAN1997		Y
		Renal and urinary disorders	Renal impairment	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	18AUG2000		Y
	C4591001 1054 10541084	Injury, poisoning and procedural complications	Scar	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Colectomy	01JAN2015	31DEC2015	N
	C4591001 1054 10541085	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2014	28FEB2014	N
		Surgical and medical procedures	Prostatectomy	01FEB2014	28FEB2014	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1054 10541086	Injury, poisoning and procedural complications	Wrist fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	10AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1054 10541087	Gastrointestinal disorders	Pancreatitis	01JAN1989	31DEC1989	N
		Injury, poisoning and procedural complications	Scar	01JAN1989		Y
			Upper limb fracture	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Limb operation	01FEB2020	29FEB2020	N
	C4591001 1054 10541088	Infections and infestations	Onychomycosis	01JAN2017		Y
		Injury, poisoning and procedural complications	Scar	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013	31DEC2013	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Renal stone removal	01JAN2014	31DEC2014	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
	C4591001 1054 10541089	Immune system disorders	Seasonal allergy	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1054 10541091	Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Traumatic haematoma	01JAN2019		Y
			Upper limb fracture	01JAN2005	31DEC2005	N
	C4591001 1054 10541092	Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
		Infections and infestations	Onychomycosis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1991		Y
			Eczema	01JAN1998		Y
	C4591001 1054 10541094	General disorders and administration site conditions	Medical device site scar	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	01JAN2012	31DEC2012	N
	C4591001 1054 10541096	Surgical and medical procedures	Lung operation	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Constipation	01JAN1976		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		General disorders and administration site conditions	Hernia	01JAN1976	31DEC1976	N
		Immune system disorders	Multiple allergies	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1976		Y
		Injury, poisoning and procedural complications	Scar	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2011		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
			Testicular torsion	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
			Eczema	01JAN2015		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2005	31DEC2005	N
			Open reduction of fracture	01JAN2009	31DEC2009	N
			Spermatic cord operation	01JAN1989	31DEC1989	N
	C4591001 1054 10541097	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Infections and infestations	Urinary tract infection	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1054 10541098	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1054 10541100	Eye disorders	Myopia	01JAN1992	06MAR2020	N
		Infections and infestations	Appendicitis	01NOV2005	30NOV2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Keratomileusis	06MAR2020	06MAR2020	N
	C4591001 1054 10541101	Injury, poisoning and procedural complications	Foot fracture	01JAN1995	31DEC1995	N
	C4591001 1054 10541104	Blood and lymphatic system disorders	Iron deficiency anaemia	01APR2016	31MAY2016	N
		Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer stage III	01MAR2016	30APR2016	N
		Nervous system disorders	Migraine	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2005		Y
	C4591001 1054 10541106	Surgical and medical procedures	Colectomy	01APR2016	30APR2016	N
		Congenital, familial and genetic disorders	Polydactyly	(b) (6) 1987	(b) (6) 1987	N
		Injury, poisoning and procedural complications	Scar	01JAN1987		Y
				01JAN2005		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Finger amputation	01JAN1987	31DEC1987	N
			Pleural operation	01JAN2005	31DEC2005	N
	C4591001 1054 10541107	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	01JAN1988	31DEC1988	N
		Skin and subcutaneous tissue disorders	Dandruff	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	01JUL2019	31JUL2019	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1054 10541108	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1054 10541110	Injury, poisoning and procedural complications	Forearm fracture	01JAN2000	31DEC2000	N
			Scar	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1996		Y
			Migraine	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
				01JAN2007	31DEC2007	N
	C4591001 1054 10541111	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	23AUG2013	23AUG2013	N
	C4591001 1054 10541115	Nervous system disorders	Headache	01APR2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Mammoplasty	01JAN2018		Y
					31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541119	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1054 10541120	Gastrointestinal disorders	Umbilical hernia	01JAN2015		Y
		Infections and infestations	Tuberculosis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1054 10541121	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1054 10541122	Endocrine disorders	Hypothyroidism	01APR2017		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
	C4591001 1054 10541123	Gastrointestinal disorders	Abdominal hernia	01MAY1970	31MAY1970	N
		Injury, poisoning and procedural complications	Scar	01MAY1970		Y
		Surgical and medical procedures	Abdominal hernia repair	01MAY1970	31MAY1970	N
	C4591001 1054 10541125	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016	31DEC2019	N
		Psychiatric disorders	Depression	01JUN2020	31AUG2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2020		Y
	C4591001 1054 10541130	Eye disorders	Blindness unilateral	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Eye injury	01JAN2014	31DEC2014	N
			Scar	01JAN1999		Y
	C4591001 1054 10541131	Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
		Infections and infestations	Hepatitis A	01JAN1990	31DEC1990	N
			Pilonidal cyst	01JAN1997	31DEC1997	N
				01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Scar	01JAN1997		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1997	31DEC1997	N
				01JAN1999	31DEC1999	N
			Vasectomy	01JUN2019	30JUN2019	N
	C4591001 1054 10541135	Congenital, familial and genetic disorders	Pyloric stenosis	(b) (6) 1996	(b) (6) 1996	N
		Injury, poisoning and procedural complications	Scar	(b) (6) 1996		Y
		Surgical and medical procedures	Pyloromyotomy	(b) (6) 1996	(b) (6) 1996	N
	C4591001 1054 10541138	Infections and infestations	Pneumonia	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Abdominal injury	01JAN1981	31DEC1981	N
			Scar	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1054 10541140	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN2014		Y
		Infections and infestations	Lyme disease	01JAN2002	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01DEC2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1054 10541141	Infections and infestations	Pneumonia	01JAN2002	31DEC2002	N
			Urinary tract infection	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
	C4591001 1054 10541144	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Scar	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1054 10541145	Eye disorders	Strabismus	01JAN1990	31DEC1990	N
		General disorders and administration site conditions	Cyst	01JAN1989	31DEC1989	N
		Infections and infestations	Pneumonia	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Scar	01JAN1989		Y
		Surgical and medical procedures	Eye operation	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb operation	01JAN1989	31DEC1989	N
			Mammoplasty	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2011	31DEC2011	N
			Rhinoplasty	01JAN2008	31DEC2008	N
	C4591001 1054 10541148	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
		Surgical and medical procedures	Haemangioma removal	01JAN2017	31DEC2017	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1054 10541150	Infections and infestations	Onychomycosis	01JAN2015		Y
		Injury, poisoning and procedural complications	Scar	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1054 10541152	Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Scar	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Nervous system disorders	Radiculopathy	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2020		Y
			Depression	01JAN2010		Y
		Social circumstances	Menopause	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541153	Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
		Eye disorders	Blindness unilateral	01JAN1992		Y
	C4591001 1054 10541154		Retinal detachment	01JAN1992		Y
		Gastrointestinal disorders	Abdominal distension	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JUN2020		Y
		Surgical and medical procedures	Vitrectomy	01JAN1992	31DEC1992	N
	C4591001 1054 10541155	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Scar	01JAN2012		Y
	C4591001 1054 10541155	Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Congenital, familial and genetic disorders	Pectus excavatum	(b) (6) 1988	31DEC2004	N
		Injury, poisoning and procedural complications	Scar	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1054 10541157	Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2018		Y
		Surgical and medical procedures	Thoracoplasty	01JAN2004	31DEC2004	N
		Infections and infestations	Onychomycosis	01JAN2017		Y
	C4591001 1054 10541157	Injury, poisoning and procedural complications	Scar	01JUL2002		Y
				04AUG2020		Y
			Skin laceration	01JUL2002	31JUL2002	N
			Upper limb fracture	04AUG2020	04AUG2020	N
			Wrist fracture	04AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	01SEP2020		Y
	C4591001 1054 10541158	Surgical and medical procedures	Fracture treatment	04AUG2020	04AUG2020	N
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Scar	01JAN2015		Y
	C4591001 1054 10541160	Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2007	31DEC2007	N
			Scar	01JAN2007		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1054 10541161	Surgical and medical procedures	Fracture treatment	01JAN2007	31DEC2007	N
		Ear and labyrinth disorders	Tinnitus	01JAN2005		Y
		Injury, poisoning and procedural complications	Scar	01JAN2003		Y
		Investigations	Blood testosterone decreased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	04AUG2020		Y
			Osteoarthritis	01JAN2003	31DEC2003	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2005		Y
		Surgical and medical procedures	Ankle operation	04AUG2020	04AUG2020	N
			Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1054 10541171	Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1979		Y
	C4591001 1054 10541174	Gastrointestinal disorders	Umbilical hernia	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Scar	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981	31DEC1996	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2017		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1986	31DEC1986	N
	C4591001 1054 10541178	Infections and infestations	Onychomycosis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1054 10541179	Eye disorders	Dry eye	01JAN2004		Y
		Gastrointestinal disorders	Abdominal tenderness	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Scar	27FEB2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	27FEB2020	27FEB2020	N
	C4591001 1054 10541182	Surgical and medical procedures	Female sterilisation	25SEP2001	25SEP2001	N
	C4591001 1054 10541184	Injury, poisoning and procedural complications	Scar	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2010	31DEC2010	N
			Nerve block	01JAN2019	31DEC2019	N
	C4591001 1054 10541190	Infections and infestations	Onychomycosis	01JAN2016		Y
	C4591001 1054 10541192	Gastrointestinal disorders	Umbilical hernia	01JAN2017	31DEC2017	N
		Infections and infestations	Onychomycosis	01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2003	31DEC2003	N
			Scar	01JAN2017		Y
			Wrist fracture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Psychiatric disorders	Bipolar disorder	01FEB2003		Y
	C4591001 1054 10541197	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2016	30JUN2016	N
	C4591001 1054 10541200	Congenital, familial and genetic disorders	Cleft palate	(b) (6) 2003	30JUN2005	N
		Gastrointestinal disorders	Mouth ulceration	01MAR2020	31MAR2020	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Scar	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2019	30SEP2019	N
		Surgical and medical procedures	Cleft palate repair	01JUN2005	30JUN2005	N
			Knee operation	01JAN2016	31DEC2016	N
	C4591001 1054 10541201	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Injury, poisoning and procedural complications	Scar	01JAN2012		Y
				30JUL1994		Y
			Wrist fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
			Obesity	01JAN2004		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31JAN2014	N
			Caesarean section	10JAN2000	10JAN2000	N
				30JUL1994	30JUL1994	N
				31MAR2014	31MAR2014	N
			Skin cosmetic procedure	01JAN2014	31JAN2014	N
			Wrist surgery	01JAN2012	31DEC2012	N
	C4591001 1054 10541203	Eye disorders	Dry eye	01JAN2018		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
		Infections and infestations	Typhoid fever	01JAN1983	31DEC1983	N
			Urinary tract infection	10JUL2020	25JUL2020	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Injury, poisoning and procedural complications	Scar	01JAN1983		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Glucose tolerance impaired	01JAN2010		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1054 10541204†	Blood and lymphatic system disorders	Mastocytosis	01JAN2017		Y
			Polycythaemia	01JAN2016		Y
		Endocrine disorders	Hypogonadism male	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Genital herpes	01JAN1990		Y
			Hepatitis A	01JAN2000	31DEC2000	N
			Onychomycosis	01JAN2009		Y
		Injury, poisoning and procedural complications	Testicular injury	01JAN2015	31DEC2015	N
		Investigations	HIV test positive	01JAN2004		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005	31DEC2005	N
			Rhabdomyolysis	01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2016	N
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016	31DEC2016	N
			Orchidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1054 10541206	Infections and infestations	Onychomycosis	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1999		Y
	C4591001 1054 10541207	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Scar	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
	C4591001 1054 10541208	Gastrointestinal disorders	Constipation	01JAN2003		Y
			Diarrhoea	01JAN2005		Y
			Umbilical hernia	01JAN1997	31DEC1997	N
		General disorders and administration site conditions	Cyst	28SEP2020	28SEP2020	N
		Infections and infestations	Infectious mononucleosis	01NOV2014	30NOV2014	N
		Injury, poisoning and procedural complications	Scar	28SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Ingrown hair	28SEP2020	28SEP2020	N
		Surgical and medical procedures	Limb operation	28SEP2020	28SEP2020	N
			Umbilical hernia repair	01JAN1997	31DEC1997	N
	C4591001 1054 10541212†	Endocrine disorders	Hypogonadism	01JAN2016		Y
		Gastrointestinal disorders	Anal fistula	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Genital herpes	01JAN2011		Y
		Investigations	HIV test positive	01OCT2004		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014	31DEC2015	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
		Surgical and medical procedures	Rectal fistula repair	01JAN2012	31DEC2012	N
	C4591001 1054 10541214	Injury, poisoning and procedural complications	Scar	22JUL2020		Y
		Psychiatric disorders	Perinatal depression	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	22JUL2020	22JUL2020	N
	C4591001 1054 10541215	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Gastrointestinal disorders	Diaphragmatic hernia	12OCT2020		Y
			Gastritis	12OCT2020		Y
			Gastroesophageal reflux disease	12OCT2020		Y
			Irritable bowel syndrome	01JAN2008		Y
			Oesophagitis	12OCT2020		Y
		Infections and infestations	Gastrointestinal bacterial overgrowth	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
			Insomnia	01JAN2013		Y
	C4591001 1055 10551001	Psychiatric disorders	Insomnia	01JAN2008		Y
	C4591001 1055 10551003	Ear and labyrinth disorders	Deafness bilateral	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1055 10551007	Ear and labyrinth disorders	Deafness	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551012	Endocrine disorders	Hypothyroidism	06MAR2000		Y
		Immune system disorders	Drug hypersensitivity	01DEC1998		Y
			Seasonal allergy	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1055 10551013	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1055 10551016	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2003		Y
	C4591001 1055 10551020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1055 10551021	Nervous system disorders	Migraine	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1055 10551022	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Irritable bowel syndrome	01JAN1994		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
			Eczema	01JAN2012		Y
	C4591001 1055 10551025	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1055 10551026	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551028	Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1055 10551029	Gastrointestinal disorders	Gastroesophageal reflux disease	15FEB2018		Y
		Immune system disorders	Rubber sensitivity	01JAN2006		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1991		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1055 10551032	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	01JAN2010	N
	C4591001 1055 10551034	Immune system disorders	Allergy to animal	01JAN1978		Y
			Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Nail discolouration	01FEB2020		Y
	C4591001 1055 10551037	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Seizure	01JUN2005		Y
	C4591001 1055 10551040	Hepatobiliary disorders	Hepatic steatosis	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551042	Psychiatric disorders	Anxiety	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
	C4591001 1055 10551046	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551050	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Surgical and medical procedures	Female sterilisation	14OCT2008	14OCT2008	N
	C4591001 1055 10551051	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1990		Y
	C4591001 1055 10551054	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2017		Y
			Seasonal allergy	01JAN1975		Y
		Nervous system disorders	Headache	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	15OCT2019	15OCT2019	N
	C4591001 1055 10551056	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2005		Y
	C4591001 1055 10551058	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551061	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Lactose intolerance	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01OCT1997		Y
	C4591001 1055 10551063	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	23DEC2003	23DEC2003	N
	C4591001 1055 10551075	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1055 10551076	Endocrine disorders	Hypothyroidism	01JAN2019		Y
	C4591001 1055 10551077	Nervous system disorders	Migraine	01JAN2013		Y
	C4591001 1055 10551078	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
		Surgical and medical procedures	Vasectomy	01OCT2002	01OCT2002	N
	C4591001 1055 10551080	Immune system disorders	Seasonal allergy	(b) (6) 1972		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1972		Y
	C4591001 1055 10551082	Endocrine disorders	Thyroid mass	01JAN2017		Y
		Immune system disorders	Seasonal allergy	(b) (6) 1965		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 105510551086	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nephroblastoma	01JUN1977	30JUN1978	N
	C4591001 10551087	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 10551089	Immune system disorders	Allergy to animal	01JAN2003		Y
	C4591001 10551099	Endocrine disorders	Hypothyroidism	01JUN2014		Y
	C4591001 10551104	Psychiatric disorders	Depression	01MAR2020		Y
	C4591001 10551104	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 10551105	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
	C4591001 10551115	Endocrine disorders	Hypothyroidism	10OCT2007		Y
		Immune system disorders	Seasonal allergy	30APR2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	(b) (6) 1976		Y
		Skin and subcutaneous tissue disorders	Psoriasis	25OCT1988		Y
	C4591001 10551117	Eye disorders	Diabetic retinopathy	25AUG2019		Y
		Immune system disorders	Seasonal allergy	(b) (6) 1974		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	25AUG1997		Y
			Type 2 diabetes mellitus	09SEP1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1974		Y
		Vascular disorders	Hypertension	25AUG1993		Y
	C4591001 10551118	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 10551125	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551134	Endocrine disorders	Hypothyroidism	01DEC2008		Y
	C4591001 1055 10551136	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Reproductive system and breast disorders	Ovarian cyst	01MAY2020	28JAN2021	N
	C4591001 1055 10551139	Vascular disorders	Hypertension	01DEC2016		Y
	C4591001 1055 10551143	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y
	C4591001 1055 10551151	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1055 10551157	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
	C4591001 1055 10551161	Immune system disorders	Seasonal allergy	01JUN1978		Y
	C4591001 1055 10551162	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
	C4591001 1055 10551165	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Vascular disorders	Hypertension	02SEP2018		Y
	C4591001 1055 10551168	Skin and subcutaneous tissue disorders	Psoriasis	01MAR2015		Y
	C4591001 1055 10551169	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1055 10551171	Immune system disorders	Seasonal allergy	01APR2000		Y
	C4591001 1055 10551175	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551176	Cardiac disorders	Angina pectoris	24MAR2010	04FEB2016	N
			Arteriospasm coronary	24MAR2010	04FEB2016	N
			Sinus tachycardia	01APR2019		Y
		Congenital, familial and genetic disorders	Congenital coronary artery malformation	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01APR1982		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01APR2010		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01OCT2000		Y
	C4591001 1055 10551190	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551195	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Psychiatric disorders	Bipolar disorder	01MAY1995		Y
	C4591001 1055 10551200	Immune system disorders	Seasonal allergy	15MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15MAR2018		Y
	C4591001 1055 10551202	Endocrine disorders	Hypothyroidism	01DEC2010		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JUL2010	31MAY2013	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Surgical and medical procedures	Neck dissection	01JAN2013	31DEC2013	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1055 10551203	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JUN2002	31DEC2004	N
		Surgical and medical procedures	Orchidectomy	01JUN2002	30JUN2002	N
	C4591001 1055 10551204	Vascular disorders	Hypertension	08JAN2020		Y
	C4591001 1055 10551206	Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2013		Y
	C4591001 1055 10551208	Cardiac disorders	Atrial fibrillation	01JAN1999	31DEC2020	N
	C4591001 1055 10551211	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551221	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01OCT2019		Y
	C4591001 1055 10551232	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1055 10551233	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	01JAN1976		Y
	C4591001 1055 10551238	Metabolism and nutrition disorders	Hyperlipidaemia	24FEB2015		Y
			Hypertriglyceridaemia	24FEB2015		Y
	C4591001 1055 10551243	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	04JAN2009		Y
	C4591001 1056 10561001	Metabolism and nutrition disorders	Overweight	01JAN2007		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2012	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561002	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2005	N
			Humerus fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561003	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561004	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561006	Metabolism and nutrition disorders	Overweight	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
	C4591001 1056 10561007	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561009	Metabolism and nutrition disorders	Overweight	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
			Hysterectomy	01NOV2019	30NOV2019	N
	C4591001 1056 10561010	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2009	31DEC2009	N
	C4591001 1056 10561013	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Caesarean section	30JAN2007	30JAN2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561016	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Infections and infestations	Tonsillitis	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1971	31DEC1971	N
	C4591001 1056 10561019	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	23JUN1998	23JUN1998	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1056 10561020	Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
	C4591001 1056 10561021	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561022	Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561025	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561026	Gastrointestinal disorders	Haemorrhoids	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			Haemorrhoid operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1056 10561027	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1056 10561028	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561029	Surgical and medical procedures	Caesarean section	03DEC2002	03DEC2002	N
	C4591001 1056 10561031	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	21SEP2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	21SEP2008	21SEP2008	N
	C4591001 1056 10561039	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561042	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561046	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561050	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
	C4591001 1056 10561053	Metabolism and nutrition disorders	Underweight	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561058	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561059	Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2015	N
			Overweight	01JAN2015		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
			Gastrectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561060	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2016	N
			Uterine leiomyoma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Mastectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561061	Surgical and medical procedures	Caesarean section	01MAR2017	01MAR2017	N
	C4591001 1056 10561065	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1056 10561069	Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1056 10561071	Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561072	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561073	Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
	C4591001 1056 10561077	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561081	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2013	31DEC2013	N
			Haemorrhagic stroke	01JAN2012	31DEC2012	N
			Neuropathy peripheral	01JAN2013		Y
	C4591001 1056 10561082	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561087	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1056 10561098	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1056 10561100	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561102	Gastrointestinal disorders	Umbilical hernia	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561103	Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
	C4591001 1056 10561108	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	25JAN2008	N
		Surgical and medical procedures	Hysterectomy	25JAN2008	25JAN2008	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1056 10561110	Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Caesarean section	31DEC1996	31DEC1996	N
	C4591001 1056 10561111	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Surgical and medical procedures	Tympanoplasty	01JAN1985	31DEC1985	N
	C4591001 1056 10561112	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1056 10561113	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561115	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561116	Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561118	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2018		Y
	C4591001 1056 10561119	Surgical and medical procedures	Caesarean section	25JAN2016	25JAN2016	N
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561129	Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
	C4591001 1056 10561130	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561131	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	08AUG2013	08AUG2013	N
			Female sterilisation	08AUG2013	08AUG2013	N
			Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1056 10561132	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561135	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1056 10561145	Gastrointestinal disorders	Intestinal obstruction	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
	C4591001 1056 10561146	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561147	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561149	Injury, poisoning and procedural complications	Radius fracture	15AUG2019	15AUG2019	N
			Ulna fracture	15AUG2019	15AUG2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Open reduction of fracture	15AUG2019	15AUG2019	N
	C4591001 1056 10561152	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561153	Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	27OCT2015	27OCT2015	N
	C4591001 1056 10561154	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	21JAN1997	21JAN1997	N
			Female sterilisation	21JAN1997	21JAN1997	N
	C4591001 1056 10561156	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561157	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561158	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	04JUN2001	04JUN2001	N
			Female sterilisation	04JUN2001	04JUN2001	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561160	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1056 10561161	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	31MAR2015	31MAR2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	31MAR2015	31MAR2015	N
	C4591001 1056 10561165	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1056 10561170	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1056 10561171	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985	31DEC1990	N
		Surgical and medical procedures	Adenoidectomy	01JAN1990	31DEC1990	N
			Spinal laminectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1056 10561173	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1056 10561174	Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Infections and infestations	Hepatitis A	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561177	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561178	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561182	Eye disorders	Glaucoma	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561185	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
			Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN2003	31DEC2003	N
			Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1056 10561186	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	09AUG1994	09AUG1994	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	09AUG1994	09AUG1994	N
	C4591001 1056 10561187	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1056 10561188	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1056 10561189	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
	C4591001 1056 10561190	Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561191	Surgical and medical procedures	Appendectomy	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Overweight	01JAN2011		Y
	C4591001 1056 10561192	Injury, poisoning and procedural complications	Ankle fracture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	22NOV1999	22NOV1999	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Oophorectomy	01JAN2015	31DEC2015	N
			Open reduction of fracture	01JAN2009	31DEC2009	N
	C4591001 1056 10561193	Metabolism and nutrition disorders	Obesity	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1056 10561194	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1056 10561195	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN2010	31DEC2010	N
	C4591001 1056 10561197	Surgical and medical procedures	Caesarean section	24NOV2003	24NOV2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561203	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2000	31DEC2000	N
	C4591001 1056 10561205	Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1056 10561208	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561210	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1056 10561212	Cardiac disorders	Myocardial infarction	01AUG2019	31AUG2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Angioplasty	01AUG2019	31AUG2019	N
			Coronary arterial stent insertion	01AUG2019	31AUG2019	N
	C4591001 1056 10561213	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Varicocele	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1056 10561214	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
			Mammoplasty	01JAN1997	31DEC1997	N
	C4591001 1056 10561215	Metabolism and nutrition disorders	Underweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561219	Injury, poisoning and procedural complications	Ankle fracture	01NOV2019	01NOV2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	19APR2007	19APR2007	N
			Open reduction of fracture	01NOV2019	01NOV2019	N
	C4591001 1056 10561226	Gastrointestinal disorders	Umbilical hernia	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1991	31DEC1991	N
	C4591001 1056 10561228	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Lipoma excision	01JAN2005	31DEC2005	N
	C4591001 1056 10561230	Surgical and medical procedures	Caesarean section	12NOV2016	12NOV2016	N
			Female sterilisation	12NOV2016	12NOV2016	N
	C4591001 1056 10561233	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
	C4591001 1056 10561234	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561235	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1056 10561240	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561241	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561243	Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561244	Ear and labyrinth disorders	Deafness neurosensory	01JAN1995		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1995	31DEC1995	N
			Road traffic accident	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561245	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561246	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	10DEC2003	10DEC2003	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1056 10561251	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561252	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Oophorectomy	01JAN2004	31DEC2004	N
			Salpingectomy	01JAN2004	31DEC2004	N
	C4591001 1056 10561253	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1056 10561255	Metabolism and nutrition disorders	Obesity	16SEP2000		Y
	C4591001 1056 10561256	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561262	Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1056 10561264	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561268	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561271	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Nervous system disorders	Hydrocephalus	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Ventricular drainage	01JAN2007	31DEC2007	N
	C4591001 1056 10561273	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1056 10561274	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561278	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561282	Surgical and medical procedures	Caesarean section	24NOV1991	24NOV1991	N
	C4591001 1056 10561286	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2019	24JAN2020	N
		Surgical and medical procedures	Caesarean section	07DEC1995	07DEC1995	N
				29JAN1985	29JAN1985	N
			Cholecystectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2005	31DEC2005	N
			Hysterectomy	24JAN2020	24JAN2020	N
	C4591001 1056 10561288	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	04SEP2008	04SEP2008	N
				15JUN2010	15JUN2010	N
	C4591001 1056 10561289	Metabolism and nutrition disorders	Female sterilisation	15JUN2010	15JUN2010	N
			Overweight	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	25MAY2014	25MAY2014	N
	C4591001 1056 10561290	Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
	C4591001 1056 10561292	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1056 10561293	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
	C4591001 1056 10561295	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
			Umbilical hernia	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Gout	01JAN2015		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561299	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561300	Gastrointestinal disorders	Inguinal hernia	01JAN1974	31DEC1974	N
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Inguinal hernia repair	01JAN1974	31DEC1974	N
			Open reduction of fracture	01JAN2001	31DEC2001	N
	C4591001 1056 10561304	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561307	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561308	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561309	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1056 10561312	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1056 10561313	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	02MAY2008	02MAY2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	02MAY2008	02MAY2008	N
	C4591001 1056 10561314	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561315	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561316	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561319	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561320	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561322	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
	C4591001 1056 10561325	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561327	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561330	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561331	Eye disorders	Retinal detachment	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561332	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561333	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561338	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561340	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561341	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	29AUG2015	29AUG2015	N
	C4591001 1056 10561344	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2000	31DEC2000	N
	C4591001 1056 10561345	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1056 10561347	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561348	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561350	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561352	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561354	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561359	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561360	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561361	Injury, poisoning and procedural complications	Meniscus injury	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Meniscus operation	01JAN1992	31DEC1992	N
	C4591001 1056 10561363	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2008		Y
			Major depression	01JAN2008		Y
	C4591001 1056 10561364	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1056 10561365	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561366	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	04NOV2005	04NOV2005	N
				19OCT2009	19OCT2009	N
				22APR1997	22APR1997	N
			Female sterilisation	19OCT2009	19OCT2009	N
	C4591001 1056 10561367	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1056 10561369	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Major depression	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561373	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561375	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Caesarean section	12JUN1990	12JUN1990	N
				24AUG1997	24AUG1997	N
			Female sterilisation	24AUG1997	24AUG1997	N
	C4591001 1056 10561376	Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1056 10561377	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561378	Gastrointestinal disorders	Umbilical hernia	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1984	31DEC1984	N
	C4591001 1056 10561383	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561384	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1056 10561385	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561386	Congenital, familial and genetic disorders	Renal aplasia	(b) (6) 1991		Y
			Spina bifida	(b) (6) 1991		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Nervous system disorders	Hydrocephalus	(b) (6) 1991	(b) (6) 1991	N
			Paraplegia	(b) (6) 1991		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Renal and urinary disorders	Bladder disorder	(b) (6) 1991		Y
		Skin and subcutaneous tissue disorders	Decubitus ulcer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Debridement	01JAN2014	31DEC2014	N
			Spinal operation	(b) (6) 1991	(b) (6) 1991	N
			Ventriculo-peritoneal shunt	(b) (6) 1991	31DEC1991	N
	C4591001 1056 10561388	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561391	Infections and infestations	Hepatitis A	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561393	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561395	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
	C4591001 1056 10561396	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Major depression	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1056 10561397	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561398	Surgical and medical procedures	Caesarean section	05APR2001	05APR2001	N
				05AUG1994	05AUG1994	N
				25MAR1997	25MAR1997	N
			Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1056 10561400	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561401	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	10APR1993	10APR1993	N
	C4591001 1056 10561405	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561407	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561411	Metabolism and nutrition disorders	Underweight	01JAN2018		Y
	C4591001 1056 10561413	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1056 10561414	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	14NOV2015	14NOV2015	N
				15JAN2013	15JAN2013	N
	C4591001 1056 10561417	Metabolism and nutrition disorders	Overweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561419	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561421	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1056 10561422	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1999		Y
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
	C4591001 1056 10561425	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561432	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	04MAY1991	04MAY1991	N
				11FEB2004	11FEB2004	N
				23MAR1994	23MAR1994	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1056 10561434	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561437	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	11APR2010	11APR2010	N
				23AUG2000	23AUG2000	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561441	Metabolism and nutrition disorders	Obesity	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561444	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561445	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561448	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Caesarean section	10JUL1992	10JUL1992	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Oophorectomy bilateral	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561451	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561452	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561453	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561466	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561469	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561471	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	04DEC2012	04DEC2012	N
	C4591001 1056 10561472	Metabolism and nutrition disorders	Overweight	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561473	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561475	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561476	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561477	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561488	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561489	Infections and infestations	Appendicitis	05JAN2005	05JAN2005	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	05JAN2005	05JAN2005	N
			Caesarean section	28AUG2004	28AUG2004	N
	C4591001 1056 10561493	Eye disorders	Cataract	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1056 10561494	Gastrointestinal disorders	Inguinal hernia	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1994	31DEC1994	N
	C4591001 1056 10561495	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561499	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561503	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561505	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	19JUN2002	19JUN2002	N
	C4591001 1056 10561506	Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2004	31DEC2004	N
			Open reduction of fracture	01JAN2006	31DEC2006	N
	C4591001 1056 10561507	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
	C4591001 1056 10561508	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561510	Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1056 10561512	Infections and infestations	Laryngitis	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1986	31DEC1986	N
	C4591001 1056 10561513	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561514	Surgical and medical procedures	Caesarean section	01AUG2014	01AUG2014	N
			Mammoplasty	01JAN2016	31DEC2016	N
	C4591001 1056 10561517	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
			Caesarean section	10FEB2003	10FEB2003	N
				20JAN1998	20JAN1998	N
				27AUG2006	27AUG2006	N
			Cholecystectomy	01JAN1989	31DEC1989	N
	C4591001 1056 10561518	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1056 10561519	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	02JAN1998	02JAN1998	N
				25JAN1996	25JAN1996	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561520	Metabolism and nutrition disorders	Overweight	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1056 10561521	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561526	Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561528	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	05DEC2013	05DEC2013	N
	C4591001 1056 10561529	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561532	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561533	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561534	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561540	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561542	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	21MAR2007	21MAR2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561543	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1056 10561544	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	26MAR2008	26MAR2008	N
	C4591001 1056 10561545	Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
	C4591001 1056 10561547	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1056 10561548	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
	C4591001 1056 10561550	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561553	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561554	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561555	Surgical and medical procedures	Caesarean section	04JUN2019	04JUN2019	N
				12MAR2016	12MAR2016	N
				30NOV2014	30NOV2014	N
	C4591001 1056 10561558	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561559	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Major depression	01JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561560	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561562	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1056 10561563	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	20APR2007	20APR2007	N
	C4591001 1056 10561564	Surgical and medical procedures	Caesarean section	01FEB2013	01FEB2013	N
	C4591001 1056 10561565	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561566	Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Surgical and medical procedures	Mammoplasty	01JAN2019	31DEC2019	N
	C4591001 1056 10561572	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	07JAN2014	07JAN2014	N
				31JAN2013	31JAN2013	N
	C4591001 1056 10561579	Metabolism and nutrition disorders	Overweight	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1056 10561581	Surgical and medical procedures	Caesarean section	03MAR2006	03MAR2006	N
				14NOV2007	14NOV2007	N
				24JUL2011	24JUL2011	N
				30NOV2004	30NOV2004	N
	C4591001 1056 10561582	Injury, poisoning and procedural complications	Ulna fracture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Open reduction of fracture	01JAN2015	31DEC2015	N
	C4591001 1056 10561583	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561585	Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
		Vascular disorders	Arteriosclerosis	01JAN2017	31DEC2017	N
	C4591001 1056 10561586	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1056 10561587	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	05NOV2019	05NOV2019	N
				17AUG2015	17AUG2015	N
			Female sterilisation	05NOV2019	05NOV2019	N
	C4591001 1056 10561588	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1056 10561591	Surgical and medical procedures	Caesarean section	04JUL2005	04JUL2005	N
				07AUG2001	07AUG2001	N
			Female sterilisation	04JUL2005	04JUL2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561592	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1056 10561593	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1056 10561594	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561595	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Abdominoplasty	07DEC2019	07DEC2019	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1056 10561596	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1056 10561599	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561600	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1056 10561601	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561602	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561606	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561610	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561611	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	14APR2017	14APR2017	N
				17DEC1999	17DEC1999	N
	C4591001 1056 10561612	Hepatobiliary disorders	Cholelithiasis	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
	C4591001 1056 10561613	Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1056 10561617	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561618	Gastrointestinal disorders	Umbilical hernia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2017	31DEC2017	N
	C4591001 1056 10561621	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1056 10561622	Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1056 10561623	Metabolism and nutrition disorders	Overweight	01JAN2013		Y
	C4591001 1056 10561626	Congenital, familial and genetic disorders	Cryptorchism	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Surgical and medical procedures	Orchidopexy	01JAN1988	31DEC1988	N
	C4591001 1056 10561627	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561629	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1056 10561633	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561634	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561635	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561636	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561638	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1056 10561639	Endocrine disorders	Hypothyroidism	01JAN1982		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980	31DEC2010	N
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Caesarean section	08JAN1993	08JAN1993	N
				23APR1999	23APR1999	N
			Gastric bypass	01APR2003	30APR2003	N
			Mammoplasty	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1056 10561642	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561643	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1057 10571001	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
	C4591001 1057 10571002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1989		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
	C4591001 1057 10571005	Injury, poisoning and procedural complications	Joint injury	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1987	31DEC1987	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
			Orchidectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1057 10571006	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Injury, poisoning and procedural complications	Splenic rupture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2008		Y
			Osteoarthritis	01JAN2015	31DEC2015	N
		Nervous system disorders	Restless legs syndrome	01MAY2020		Y
		Surgical and medical procedures	Caesarean section	10AUG1994	10AUG1994	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Splenectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571007	Gastrointestinal disorders	Inguinal hernia	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1975	31DEC1975	N
	C4591001 1057 10571008	Congenital, familial and genetic disorders	Tourette's disorder	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2014	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Bipolar disorder	01NOV2019		Y
		Reproductive system and breast disorders	Varicocele	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Varicocele repair	01JAN2013	31DEC2013	N
			Wrist surgery	01JAN2014	31DEC2014	N
	C4591001 1057 10571009	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1057 10571012	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571013	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1057 10571014	Nervous system disorders	Migraine	01JUL2015		Y
	C4591001 1057 10571015	Injury, poisoning and procedural complications	Joint injury	01JAN1989	31DEC1989	N
	C4591001 1057 10571016	Surgical and medical procedures	Knee operation	01JAN1981	31DEC1981	N
	C4591001 1057 10571016	Psychiatric disorders	Bipolar disorder	01JAN1986		Y
	C4591001 1057 10571017	Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1057 10571018	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1057 10571019	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1057 10571019	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN1999	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1990		Y
		Surgical and medical procedures	Neurectomy	01JAN2009	31DEC2009	N
	C4591001 1057 10571024	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1057 10571025	Gastrointestinal disorders	Gastric disorder	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Reproductive system and breast disorders	Ovarian rupture	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Oesophagogastric fundoplasty	01JAN2000	31DEC2000	N
	C4591001 1057 10571027	Immune system disorders	Seasonal allergy	01AUG2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Headache	01AUG2017		Y
	C4591001 1057 10571028	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1057 10571030	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1993	16MAY1997	N
			Osteoarthritis	01NOV2018		Y
		Nervous system disorders	Transient ischaemic attack	26MAR2018	26MAR2018	N
		Surgical and medical procedures	Spinal laminectomy	16MAY1997	16MAY1997	N
	C4591001 1057 10571031	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2019	N
		Psychiatric disorders	Depression	01AUG2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571032	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Appendicitis	01JUN2016	30JUN2016	N
		Surgical and medical procedures	Appendicectomy	01JUN2016	30JUN2016	N
	C4591001 1057 10571033	Infections and infestations	Appendicitis	01JAN1968	31DEC1968	N
		Psychiatric disorders	Depression	01JAN1984		Y
		Surgical and medical procedures	Appendicectomy	01JAN1968	31DEC1968	N
			Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1057 10571035	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
			Wisdom teeth removal	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1057 10571036	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
			Uterine leiomyoma embolisation	01JAN2008	31DEC2008	N
	C4591001 1057 10571037	Infections and infestations	Tonsillitis	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1996	31DEC1996	N
			Meniscus injury	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1057 10571042	Hepatobiliary disorders	Cholecystitis	01JAN1980	31DEC1980	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
	C4591001 1057 10571043	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1990		Y
	C4591001 1057 10571044	Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1057 10571046	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	12DEC2014	12DEC2014	N
	C4591001 1057 10571048	Immune system disorders	Drug hypersensitivity	01JAN1980	31DEC1980	N
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Investigations	Cardiac murmur	19AUG2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
			Caesarean section	08DEC2001	08DEC2001	N
			Hysterectomy	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571049	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	24APR2012	24APR2012	N
				28OCT2014	28OCT2014	N
	C4591001 1057 10571050	Endocrine disorders	Hypothyroidism	01DEC2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01DEC2019		Y
		Psychiatric disorders	Depression	01DEC2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1993	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1057 10571051	Immune system disorders	Food allergy	01JAN1985		Y
	C4591001 1057 10571054	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1987	31DEC1987	N
			Female sterilisation	01JAN2001	31DEC2001	N
	C4591001 1057 10571056	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2019		Y
			Depression	01OCT2019		Y
		Surgical and medical procedures	Caesarean section	15JUL2011	15JUL2011	N
				20AUG2013	20AUG2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571058	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
		Vascular disorders	Obesity	01JAN1998		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1057 10571060	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1057 10571065	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1057 10571067	Cardiac disorders	Mitral valve prolapse	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1057 10571068	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Gastrectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1057 10571070	Cardiac disorders	Ventricular extrasystoles	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Appendicitis	01DEC2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Abortion incomplete	01JUN1991	30JUN1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Appendicectomy	01DEC2014	31DEC2014	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Intra-uterine contraceptive device insertion	01JAN2015	31DEC2015	N
			Uterine dilation and curettage	01JUN1991	30JUN1991	N
	C4591001 1057 10571071	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01AUG2019	31AUG2019	N
		Injury, poisoning and procedural complications	Joint injury	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Ankle arthroplasty	01JAN1998	31DEC1998	N
			Inguinal hernia repair	01AUG2019	31AUG2019	N
	C4591001 1057 10571074	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN1995	31DEC2011	N
		Psychiatric disorders	Major depression	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Gastric banding	01JAN2011	31DEC2011	N
			Hysterosalpingo-oophorectomy	01JAN2009	31DEC2009	N
	C4591001 1057 10571075	Endocrine disorders	Androgen deficiency	01JAN2016		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2017	31DEC2017	N
				01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01OCT2014		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JUL2017	31JUL2017	N
	C4591001 1057 10571078	Injury, poisoning and procedural complications	Femur fracture	01JAN2010		Y
			Femur fracture	01JAN1985	31DEC1985	N
			Upper limb fracture	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Bone operation	01JAN1985	31DEC1985	N
			Elbow operation	01JAN1980	31DEC1980	N
	C4591001 1057 10571079	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015		Y
			Scoliosis	01JAN1974		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1057 10571080	Metabolism and nutrition disorders	Obesity	01OCT2005		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1057 10571081	Nervous system disorders	Migraine	22MAR1999		Y
		Psychiatric disorders	Major depression	22MAR1992		Y
		Reproductive system and breast disorders	Menorrhagia	01JUL2007	01JUL2008	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	27MAR2007	27MAR2007	N
			Endometrial ablation	01JUL2008	01JUL2008	N
	C4591001 1057 10571082	Psychiatric disorders	Depression	15JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571083	Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1057 10571085	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1057 10571089	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1057 10571090	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1057 10571091	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Surgical and medical procedures	Female sterilisation	01SEP2005	30SEP2005	N
	C4591001 1057 10571092	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Infections and infestations	Ear infection	01JAN1971	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenoidectomy	01JAN1972	31DEC1972	N
			Temporomandibular joint surgery	01JAN2001	31DEC2001	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1057 10571095	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2017	31DEC2018	N
	C4591001 1057 10571100	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Wrist fracture	26JUL2020	12AUG2020	N
		Psychiatric disorders	Major depression	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1057 10571103	Psychiatric disorders	Major depression	01AUG2018		Y
	C4591001 1057 10571106	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Major depression	01JUN2018		Y
	C4591001 1057 10571109	Psychiatric disorders	Major depression	01JAN2013		Y
	C4591001 1057 10571111	Immune system disorders	Drug hypersensitivity	(b) (6) 1974		Y
		Nervous system disorders	Carpal tunnel syndrome	01OCT2016	01OCT2018	N
			Migraine	01AUG1997		Y
		Psychiatric disorders	Generalised anxiety disorder	01AUG1997		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Carpal tunnel decompression	01OCT2018	01OCT2018	N
	C4591001 1057 10571113	Eye disorders	Blindness unilateral	01JAN1993		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571117	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1057 10571118	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571120	Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
	C4591001 1057 10571121	Injury, poisoning and procedural complications	Ligament rupture	01JAN2004	31DEC2004	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1982		Y
		Surgical and medical procedures	Caesarean section	13NOV2014	13NOV2014	N
			Ligament operation	01JAN2004	31DEC2004	N
	C4591001 1057 10571122	Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2014		Y
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1057 10571123	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Inguinal hernia	01JAN2018	31DEC2018	N
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018		Y
					31DEC2018	N
		Psychiatric disorders	Depression	01JAN2000		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571124	Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01NOV2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
				01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2013	31DEC2017	N
		Injury, poisoning and procedural complications	Joint injury	01MAY2020	31MAY2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1057 10571125	Surgical and medical procedures	Ankle operation	01MAY2020	31MAY2020	N
			Sinus operation	01JAN2017	31DEC2017	N
		Immune system disorders	Hypersensitivity	31AUG2010		Y
	C4591001 1057 10571127	Social circumstances	Postmenopause	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571129	Psychiatric disorders	Generalised anxiety disorder	01JUN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1967		Y
	C4591001 1057 10571132	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01OCT2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Skin neoplasm excision	01DEC2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Fall	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus injury	01JAN2007	31DEC2007	N
			Upper limb fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2020		Y
		Surgical and medical procedures	Caesarean section	09MAR1990	09MAR1990	N
				22DEC1995	22DEC1995	N
			Elbow operation	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2007	31DEC2007	N
			Seasonal allergy	01JAN2005		Y
	C4591001 1057 10571136	Immune system disorders				
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2018	31JAN2018	N
	C4591001 1057 10571137	Endocrine disorders	Goitre	01JAN2011	31DEC2011	N
			Hypothyroidism	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign cardiac neoplasm	01NOV2008	30NOV2008	N
			Uterine leiomyoma	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Major depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	20MAY1994	20MAY1994	N
				24MAY1996	24MAY1996	N
				29NOV1999	29NOV1999	N
			Cardiac operation	01NOV2008	30NOV2008	N
			Female sterilisation	01JAN1999	31DEC1999	N
			Thyroidectomy	01JAN2011	31DEC2011	N
			Vasectomy	01FEB2008	29FEB2008	N
	C4591001 1057 10571140	Surgical and medical procedures				
	C4591001 1057 10571142	Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
	C4591001 1057 10571144	General disorders and administration site conditions	Calcinosis	01AUG1990	30SEP1990	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	04NOV2010	04NOV2010	N
				25OCT2016	25OCT2016	N
			Knee operation	01SEP1990	30SEP1990	N
	C4591001 1057 10571145	Immune system disorders	Seasonal allergy	01JAN1978		Y
	C4591001 1057 10571146	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019	31DEC2019	N
		Infections and infestations	Sinusitis	01JAN2013	31DEC2013	N
			Tonsillitis	01MAR2020	31MAR2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01DEC2007	31DEC2007	N
			Female sterilisation	01DEC2019	31DEC2019	N
			Sinus operation	01JAN2013	31DEC2013	N
			Tonsillectomy	01MAR2020	31MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571148	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	02MAR1997	02MAR1997	N
	C4591001 1057 10571152	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JUN2009	31AUG2009	N
		Surgical and medical procedures	Hysterectomy	01AUG2009	31AUG2009	N
	C4591001 1057 10571153	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2019	N
		Psychiatric disorders	Depression	01AUG2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
	C4591001 1057 10571154	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Major depression	01JAN2017		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1057 10571155	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2006		Y
		Psychiatric disorders	Major depression	01JAN2011	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Surgical and medical procedures	Caesarean section	11NOV2010	11NOV2010	N
			Female sterilisation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571156	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1057 10571158	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Obesity	01JAN2008		Y
		Psychiatric disorders	Major depression	01AUG2008		Y
	C4591001 1057 10571160	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1057 10571161	General disorders and administration site conditions	Cyst	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
	C4591001 1057 10571162	General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Iodine allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1057 10571163	Social circumstances	Postmenopause	01JUN2019		Y
	C4591001 1057 10571165	Cardiac disorders	Myocardial infarction	15AUG2017	15AUG2017	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2010	31DEC2010	N
		Investigations	Catheterisation cardiac	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				10JUL2020	10JUL2020	N
				15AUG2017	15AUG2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN2013		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1057 10571169	Gastrointestinal disorders	Haemorrhoids	01JAN2008	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN2000	31DEC2009	N
		Nervous system disorders	Headache	01JAN1996		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2009	31DEC2009	N
			Sinus operation	01JAN2009	31DEC2009	N
	C4591001 1057 10571170	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Intra-uterine contraceptive device insertion	01JAN2017		Y
	C4591001 1057 10571171	Infections and infestations	Genital herpes	01OCT2017		Y
		Injury, poisoning and procedural complications	Wrist fracture	01APR2014	31JUL2014	N
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1991	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Wrist surgery	01JUL2014	31JUL2014	N
	C4591001 1057 10571173	Psychiatric disorders	Major depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571176	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1057 10571177	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
	C4591001 1057 10571182	Infections and infestations	Chronic sinusitis	01JAN2000	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Nervous system disorders	Headache	01JAN1979		Y
		Surgical and medical procedures	Sinus operation	01JAN2005	31DEC2005	N
	C4591001 1057 10571185	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2006	N
		Surgical and medical procedures	Endometrial ablation	01JAN2006	31DEC2006	N
			Wrist surgery	01JAN2005	31DEC2005	N
	C4591001 1057 10571186	Endocrine disorders	Diabetes insipidus	01OCT2005		Y
	C4591001 1057 10571187	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1986		Y
	C4591001 1057 10571188	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2008	31DEC2008	N
			Gastric bypass	01JAN2018	31DEC2018	N
	C4591001 1057 10571191	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	15FEB2020		Y
		Nervous system disorders	Migraine	01MAR1999		Y
		Psychiatric disorders	Insomnia	01AUG2014		Y
			Major depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1057 10571193	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1057 10571194	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Desmoplastic melanoma	01JAN2010	31JUL2011	N
			Lipoma	01JAN2013		Y
		Surgical and medical procedures	Skin neoplasm excision	01JUL2011	31JUL2011	N
	C4591001 1057 10571195	Reproductive system and breast disorders	Ovarian cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Salpingo-oophorectomy unilateral	01JAN2018	31DEC2018	N
	C4591001 1057 10571198	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571200	Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1057 10571201	Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1057 10571202	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2017		Y
	C4591001 1057 10571203	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1057 10571204	Ear and labyrinth disorders	Deafness unilateral	(b) (6) 1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1057 10571205	Gastrointestinal disorders	Inguinal hernia	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01OCT2019	31OCT2019	N
		Psychiatric disorders	Schizophrenia	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	15SEP2019		Y
	C4591001 1057 10571208	Metabolism and nutrition disorders	Obesity	01OCT2019	31OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
				01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1057 10571210	Endocrine disorders	Autoimmune thyroiditis	01JAN2014		Y
	C4591001 1057 10571211	Endocrine disorders	Autoimmune thyroiditis	01OCT2019		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1057 10571212	Cardiac disorders	Rhinitis allergic Coronary artery disease	01JAN2018 01JAN2019		Y Y
		Immune system disorders	Hypersensitivity	01JAN2019		Y
	C4591001 1057 10571215	Surgical and medical procedures Metabolism and nutrition disorders	Coronary artery bypass Obesity	12FEB2020 01JAN2010	12FEB2020	N Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y
			Osteoarthritis	01JAN2017		Y
	C4591001 1057 10571217	Surgical and medical procedures Infections and infestations	Hip arthroplasty Herpes simplex	01JUN2020 01AUG2020	30JUN2020	N Y
	C4591001 1057 10571218	Skin and subcutaneous tissue disorders Metabolism and nutrition disorders	Keratosis pilaris Type 1 diabetes mellitus	01JAN2000 01APR2018		Y Y
	C4591001 1057 10571219	Psychiatric disorders Congenital, familial and genetic disorders	Depression Syndactyly	01JAN2010 (b) (6) 1984	31DEC1986	Y N
					31DEC1993	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
			Nicotine dependence	01JAN2012		Y
		Surgical and medical procedures	Foot operation	01JAN1993	31DEC1993	N
			Limb operation	01JAN1986	31DEC1986	N
	C4591001 1057 10571220	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Pain in extremity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1057 10571222	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1057 10571223	Injury, poisoning and procedural complications	Joint injury	01JAN2016	31DEC2016	N
			Ligament rupture	04MAR2020		Y
			Meniscus injury	04MAR2020		Y
		Investigations	Arthroscopy	04MAR2020	04MAR2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2016	N
				04MAR2020		Y
		Psychiatric disorders	Major depression	01JAN2003		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571226	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01OCT2018		Y
		Surgical and medical procedures	Caesarean section	27MAY1985	27MAY1985	N
	C4591001 1057 10571227	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1057 10571229	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Bipolar disorder	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2007		Y
		Surgical and medical procedures	Gastric banding	01JAN2010	31DEC2010	N
			Gastric banding reversal	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1057 10571230	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1057 10571232	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2007	31DEC2010	N
			Osteoarthritis	01JAN1982	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1992		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1991	31DEC1991	N
				01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Lithotripsy	01JAN1991	31DEC1991	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1057 10571233	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Intervertebral disc operation	01JAN2018	31DEC2018	N
	C4591001 1057 10571235	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1057 10571236	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1057 10571238	Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1984		Y
			Rosacea	01JAN2016		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAY2016	31MAY2016	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1057 10571239	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01FEB2013	28FEB2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571240	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
			Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01SEP2015		Y
			Intervertebral disc degeneration	01JAN2009		Y
			Spinal stenosis	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01OCT2015		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01SEP2000		Y
	C4591001 1057 10571241	Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2014	31DEC2014	N
		Psychiatric disorders	Bipolar disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
			Tonsillolith	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571243	Injury, poisoning and procedural complications	Joint injury	01JAN1998	31DEC1999	N
				01JAN2003	31DEC2005	N
			Limb injury	01JAN2018	29FEB2020	N
			Neck injury	01APR2020		Y
				01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01APR2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN1999	31DEC1999	N
				01JAN2005	31DEC2005	N
			Shoulder operation	01FEB2020	29FEB2020	N
				01MAY2019	31MAY2019	N
	C4591001 1057 10571244	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	11FEB2009	11FEB2009	N
				16JUL2003	16JUL2003	N
				23NOV1999	23NOV1999	N
			Female sterilisation	11FEB1999	11FEB1999	N
	C4591001 1057 10571245	Infections and infestations	Urinary tract infection	01JAN2016		Y
		Injury, poisoning and procedural complications	Neck injury	01JAN1998	31DEC1998	N
		Investigations	Human papilloma virus test positive	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2011	31DEC2011	N
	C4591001 1057 10571246	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
	C4591001 1057 10571247	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Social circumstances	Postmenopause	01JUL2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571248	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01FEB2017	28FEB2017	N
	C4591001 1057 10571249	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2010		Y
			Major depression	01FEB2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01APR2016		Y
	C4591001 1057 10571252	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571257	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01AUG2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1057 10571258	Psychiatric disorders	Depression	01JUL2017	30NOV2018	N
		Surgical and medical procedures	Caesarean section	29AUG2015	29AUG2015	N
	C4591001 1057 10571259	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2013		Y
		Surgical and medical procedures	Gastrectomy	01FEB2014	28FEB2014	N
		Vascular disorders	Hypertension	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571261	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	08MAR1995	08MAR1995	N
		Vascular disorders	Hypertension	01OCT2018		Y
	C4591001 1057 10571262	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1057 10571263	Metabolism and nutrition disorders	Obesity	01JAN1993		Y
	C4591001 1057 10571265	Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Investigations	Precancerous cells present	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	02JAN1997	02JAN1997	N
				16SEP1992	16SEP1992	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Gastric bypass	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1057 10571266	Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2010		Y
	C4591001 1057 10571267	Psychiatric disorders	Depression	01OCT2019		Y
	C4591001 1057 10571268	Metabolism and nutrition disorders	Obesity	01OCT2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Drug use disorder	01JAN2012		Y
	C4591001 1057 10571270	Cardiac disorders	Cardiac failure congestive	01JAN2004		Y
		Investigations	Coronary artery disease	01JAN2005		Y
		Vascular disorders	Blood cholesterol increased	01JAN2005		Y
	C4591001 1057 10571271	Social circumstances	Hypertension	01JAN2004		Y
	C4591001 1057 10571273	Blood and lymphatic system disorders	Postmenopause	01JAN2016		Y
			Iron deficiency anaemia	01JAN2010		Y
		Congenital, familial and genetic disorders	Thalassaemia beta	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1057 10571274	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Generalised anxiety disorder	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	08JAN2008	08JAN2008	N
	C4591001 1057 10571276	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	03MAR2000	03MAR2000	N
				19DEC1994	19DEC1994	N
				23NOV1990	23NOV1990	N
	C4591001 1057 10571277	Skin and subcutaneous tissue disorders	Keloid scar	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571278	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN1970		Y
			Rubber sensitivity	01JAN1978		Y
		Investigations	Laparoscopy	01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Endometriosis	01JAN1988		Y
		Social circumstances	Postmenopause	01DEC2019		Y
	C4591001 1057 10571279	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
	C4591001 1057 10571282	Injury, poisoning and procedural complications	Ankle fracture	01JAN2003	31DEC2003	N
			Patella fracture	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Fracture treatment	01JAN2003	31DEC2003	N
				01JAN2009	31DEC2009	N
	C4591001 1057 10571283	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01OCT2011		Y
	C4591001 1057 10571284	Immune system disorders	Rubber sensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01FEB2020	29FEB2020	N
			Spinal fusion surgery	01JAN2009	31DEC2009	N
	C4591001 1057 10571286	Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571287	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01OCT2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
	C4591001 1057 10571288	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Cholecystitis	01SEP2019	31OCT2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31OCT2018	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2019	31OCT2019	N
			Endometrial ablation	01OCT2018	31OCT2018	N
	C4591001 1057 10571291	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
	C4591001 1057 10571293	Immune system disorders	Hypersensitivity	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nasal polypectomy	01JAN2010	31DEC2010	N
	C4591001 1057 10571294	Immune system disorders	Seasonal allergy	01JAN2001		Y
	C4591001 1057 10571295	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Psychiatric disorders	Bipolar disorder	01JAN1987		Y
		Social circumstances	Postmenopause	01JUN2018		Y
		Vascular disorders	Hypertension	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571298	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	01OCT2019		Y
	C4591001 1057 10571299	Metabolism and nutrition disorders	Obesity	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1997		Y
		Surgical and medical procedures	Caesarean section	07JAN1994	07JAN1994	N
				07JUN2000	07JUN2000	N
				10JUN2006	10JUN2006	N
			Mammoplasty	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1057 10571304	Endocrine disorders	Autoimmune thyroiditis	01OCT2019		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1057 10571305	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Bone lesion excision	01JAN2008	31DEC2008	N
			Phlebectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Varicose vein	01JAN2008		Y
	C4591001 1057 10571309	Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2015		Y
		Psychiatric disorders	Major depression	01JAN2015		Y
	C4591001 1057 10571311	Hepatobiliary disorders	Cholecystitis	01JUN2019	30JUN2019	N
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cholecystectomy	01JUN2019	30JUN2019	N
			Endometrial ablation	01JAN2012	31DEC2012	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
	C4591001 1057 10571312	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Gastrectomy	01DEC2017	31DEC2017	N
	C4591001 1057 10571313	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Bipolar disorder	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1057 10571314	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2018		Y
	C4591001 1057 10571315	Metabolism and nutrition disorders	Obesity	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571316	Psychiatric disorders	Generalised anxiety disorder	01FEB2015		Y
			Major depression	01FEB2015		Y
	C4591001 1057 10571318	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1057 10571319	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1057 10571320	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
	C4591001 1057 10571322	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Female sterilisation	19NOV2011	19NOV2011	N
			Tonsillectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1057 10571324	Immune system disorders	Drug hypersensitivity	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571325	Endocrine disorders	Basedow's disease	01JUN2001	31DEC2007	N
			Hyperthyroidism	01JUN2001	31DEC2007	N
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31OCT2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Vocal cord thickening	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	03JUN2005	03JUN2005	N
				12JUN1997	12JUN1997	N
				20AUG2002	20AUG2002	N
				25JUN2001	25JUN2001	N
			Hysterectomy	01OCT2018	31OCT2018	N
			Vocal cord nodule removal	01JAN2007	31DEC2007	N
	C4591001 1057 10571326	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
			Depression	01FEB2020		Y
	C4591001 1057 10571328	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571329	Injury, poisoning and procedural complications	Meniscus injury	07SEP2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571331	Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2004	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Gastric bypass	01JAN2004	31DEC2004	N
			Intra-uterine contraceptive device insertion	01SEP2020	30SEP2020	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1057 10571332†	Infections and infestations	HIV infection	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
	C4591001 1057 10571333	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01SEP1997	30SEP1997	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571336	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2010		Y
			Major depression	01FEB2019		Y
	C4591001 1057 10571337	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1994		Y
	C4591001 1057 10571338	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Surgical and medical procedures	Female sterilisation	01NOV1999	30NOV1999	N
			Hysterectomy	01MAR2012	31MAR2012	N
		Vascular disorders	Hypertension	01OCT2017		Y
	C4591001 1057 10571339	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC2010	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
	C4591001 1057 10571340	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Vitamin D deficiency	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1985		Y
		Psychiatric disorders	Depression	01JUN2019		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hysterectomy	07FEB2019	07FEB2019	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1057 10571341	Infections and infestations	Tonsillitis	01JAN1981	31DEC1981	N
		Social circumstances	Postmenopause	01OCT2019		Y
		Surgical and medical procedures	Caesarean section	04MAR1992	04MAR1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1981	31DEC1981	N
	C4591001 1057 10571342	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571343	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Pilonidal cyst	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN1994		Y
		Psychiatric disorders	Binge eating	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2005	31DEC2005	N
			Pilonidal sinus repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1057 10571344†	Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Investigations	HIV test positive	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1057 10571345†	Investigations	HIV test positive	01JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01OCT2018		Y
	C4591001 1057 10571347†	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Investigations	HIV test positive	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2012	N
		Surgical and medical procedures	Cholecystectomy	05JUN2007	05JUN2007	N
			Gastric bypass	05JUN2007	05JUN2007	N
	C4591001 1057 10571348†	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2000		Y
		Gastrointestinal disorders	Hiatus hernia	01JUN2020	30JUN2020	N
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Infections and infestations	Herpes simplex	01JAN2015		Y
		Investigations	HIV test positive	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Gastric bypass	01JUL2020	31JUL2020	N
			Hernia hiatus repair	01JUN2020	30JUN2020	N
	C4591001 1057 10571352†	Infections and infestations	HIV infection	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571353	Eye disorders	Blindness unilateral	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Eye injury	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Ureteral stent insertion	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1057 10571355†	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	HIV infection	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Schizoaffective disorder	01JAN2006		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1057 10571356	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	09FEB2018	09FEB2018	N
				16AUG2013	16AUG2013	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Intra-uterine contraceptive device insertion	01MAY2018	31MAY2018	N
	C4591001 1057 10571357	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Psychiatric disorders	Major depression	01JAN1984		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2016	31JAN2016	N
	C4591001 1057 10571358	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1996		Y
		Surgical and medical procedures	Spinal laminectomy	01AUG1998	31AUG1998	N
	C4591001 1057 10571362†	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Investigations	HIV test positive	01FEB2009		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2001		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2008		Y
	C4591001 1057 10571363	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Surgical and medical procedures	Rhinoplasty	01JUN2020	01JUN2020	N
	C4591001 1057 10571366	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2019		Y
	C4591001 1057 10571367	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571368	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
	C4591001 1057 10571369	Immune system disorders	Food allergy	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2020		Y
			Depression	01NOV2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1057 10571370	Eye disorders	Strabismus	01JAN2005	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Strabismus correction	01JAN2007	31DEC2007	N
	C4591001 1057 10571371	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1057 10571372	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1057 10571373	Immune system disorders	Food allergy	01FEB2006		Y
			Seasonal allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571381	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1066 10661002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015	31DEC2018	N
		Immune system disorders	Seasonal allergy	01AUG2018		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1997	31DEC1997	N
			Wrist fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01AUG2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN1997	31DEC1997	N
			Wrist surgery	01JAN2016	31DEC2016	N
	C4591001 1066 10661015	Injury, poisoning and procedural complications	Joint injury	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2014		Y
		Social circumstances	Menopause	01JUL2019		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1066 10661019	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1066 10661020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y



16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1066 10661022	Gastrointestinal disorders	Gastritis	30JUL2019		Y
		Psychiatric disorders	Depression	01JAN1993		Y
			Insomnia	01JAN2006		Y
	C4591001 1066 10661025	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Infections and infestations	Oral herpes	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Alcohol abuse	01JAN2000	31DEC2000	N
			Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Drug abuse	01JAN2000	31DEC2006	N
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1066 10661026	Cardiac disorders	Bradycardia	01FEB2020		Y
	C4591001 1066 10661035	Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
			Tendonitis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Social circumstances	Ex-tobacco user	01FEB2019		Y
	C4591001 1066 10661036	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
	C4591001 1066 10661037	Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01FEB2020		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2010	31DEC2016	N
		Nervous system disorders	Migraine without aura	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JUL2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2002	31DEC2016	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
			Endometrial ablation	01DEC2016	31DEC2016	N
			Mammoplasty	01JAN2018	31DEC2018	N
			Salpingectomy	01DEC2016	31DEC2016	N
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1066 10661044	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2001		Y
	C4591001 1066 10661060	Cardiac disorders	Left ventricular failure	01JAN2017		Y
		Congenital, familial and genetic disorders	Protein C deficiency	01JAN2011		Y
		Endocrine disorders	Goitre	01JAN2018		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2014		Y
			Large intestine polyp	01JAN2011		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Hepatobiliary disorders	Hepatic cyst	01JAN2013		Y
			Hepatic steatosis	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
				01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01MAR2016	31MAR2016	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Gout	01JAN2017		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
			Osteoarthritis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Renal and urinary disorders	Proteinuria	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Testicular swelling	01AUG2019	31AUG2019	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
			Pulmonary embolism	01JAN2011	31DEC2011	N
			Sleep apnoea syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JUL2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
			Meniscus operation	01MAR2016	31MAR2016	N
		Vascular disorders	Deep vein thrombosis	01JAN2000	31DEC2000	N
			Hypertension	01JAN2001		Y
	C4591001 1066 10661062	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2009	31DEC2009	N
	C4591001 1066 10661064	Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
		Nervous system disorders	Headache	01JAN1992		Y
			Migraine	01JAN1992		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1066 10661071	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Arthritis infective	01NOV2019	30NOV2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
		Surgical and medical procedures	Incisional drainage	01NOV2019	30NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661072	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Nervous system disorders	Sciatica	01JAN2005		Y
		Psychiatric disorders	Drug dependence	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
	C4591001 1066 10661073	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1066 10661075	Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
			Smear cervix abnormal	01JUN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
	C4591001 1066 10661078	Investigations	Smear cervix abnormal	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1066 10661081	Injury, poisoning and procedural complications	Nerve injury	01DEC2016		Y
		Renal and urinary disorders	Ureteric stenosis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Ureteral stent insertion	01JAN2009	31DEC2009	N
	C4591001 1066 10661085	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2012	31DEC2012	N
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Nervous system disorders	Tension headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2008	31DEC2008	N
			Eczema	01JAN2000		Y
		Surgical and medical procedures	Cyst removal	01JAN2008	31DEC2008	N
			Shoulder operation	01JAN2012	31DEC2012	N
	C4591001 1066 10661086	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	09MAR2015	09MAR2015	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Surgical and medical procedures	Salpingectomy	01DEC2016	31DEC2016	N
			Uterine dilation and curettage	09MAR2015	09MAR2015	N
	C4591001 1066 10661090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Essential hypertension	01JAN2017		Y
	C4591001 1066 10661095	Immune system disorders	Drug hypersensitivity	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017	31DEC2018	N
			Obesity	01JAN2006	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
			Gastrectomy	01JAN2018	31DEC2018	N
	C4591001 1066 10661097	Investigations	Blood cholesterol increased	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Nasal septal operation	01JAN1996	31DEC1996	N
	C4591001 1066 10661098	Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JUN2020		Y
		Reproductive system and breast disorders	Breast cyst	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Breast cyst excision	01JAN1999	31DEC1999	N
	C4591001 1066 10661101	Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01NOV2019	30NOV2019	N
	C4591001 1066 10661106	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2010	31DEC2010	N
	C4591001 1066 10661121	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Overweight	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 1066 10661123	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Investigations	Arthroscopy	01JAN1984	31DEC1984	N
			Blood cholesterol increased	01JAN2015		Y
			Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1988		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
			Endometrial ablation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN2016	31DEC2016	N
			Knee operation	01JAN1985	31DEC1985	N
			Nasal septal operation	01JAN1999	31DEC1999	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinoplasty	01JAN1999	31DEC1999	N
	C4591001 1066 10661129	Infections and infestations	Ear infection	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Uterine prolapse	01JAN2000	31DEC2000	N
			Eczema	01JAN1981		Y
		Surgical and medical procedures	Fracture treatment	01JAN1992	31DEC1992	N
			Hysteropexy	01JAN2000	31DEC2000	N
			Phlebectomy	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Varicose vein	01JAN2016	31DEC2016	N
	C4591001 1066 10661130	Nervous system disorders	Carpal tunnel syndrome	01JAN2014		Y
	C4591001 1066 10661132	Psychiatric disorders	Depression	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUN2020		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN2007	31DEC2007	N
	C4591001 1066 10661133	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Spinal operation	01JAN2002	31DEC2002	N
	C4591001 1066 10661136	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31AUG2018	N
		Surgical and medical procedures	Gastrectomy	01AUG2018	31AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661138	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1066 10661139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01MAY2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2020		Y
	C4591001 1066 10661142	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Chronic tonsillitis	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1066 10661147	Immune system disorders	Seasonal allergy	01JUN1992		Y
		Infections and infestations	Chronic sinusitis	01JAN1995	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN1990		Y
		Surgical and medical procedures	Sinus operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1066 10661149	Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
			Joint injury	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Ligament operation	29OCT2019	29OCT2019	N
			Nasal septal operation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661151	Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Toe operation	01JAN2015	31DEC2015	N
	C4591001 1066 10661152	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1066 10661167	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661168	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1066 10661173	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2007		Y
		Psychiatric disorders	Anxiety	01MAY2011		Y
			Depression	01MAY2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Nasal septal operation	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1066 10661178	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2005		Y
	C4591001 1066 10661182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1066 10661183	Reproductive system and breast disorders	Endometriosis	01JAN1991	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Mammoplasty	01JAN1997	31DEC1997	N
	C4591001 1066 10661184	Eye disorders	Glaucoma	01JAN2017		Y
			Retinal detachment	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Nervous system disorders	Headache	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Bone operation	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Renal stone removal	01JAN2012	31DEC2012	N
			Retinopexy	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
	C4591001 1066 10661186	Hepatobiliary disorders	Gallbladder disorder	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
			Overweight	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN2002	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Endometrial ablation	01JAN2009	31DEC2009	N
			Female sterilisation	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2012	31DEC2012	N
	C4591001 1066 10661187	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
	C4591001 1066 10661190	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN1989		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
	C4591001 1066 10661192	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
	C4591001 1066 10661193	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1066 10661194	Surgical and medical procedures	Vasectomy	01OCT2004	31OCT2004	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Tenoplasty	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1066 10661195	Injury, poisoning and procedural complications	Road traffic accident	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
			Blood testosterone decreased	01JAN2012		Y
		Surgical and medical procedures	Plastic surgery to the face	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1066 10661197	Ear and labyrinth disorders	Meniere's disease	01JAN2000		Y
		Gastrointestinal disorders	Intestinal obstruction	01JAN2012	31DEC2012	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2003	31DEC2003	N
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Intestinal operation	01JAN2012	31DEC2012	N
			Spinal operation	01JAN2005	31DEC2005	N
	C4591001 1066 10661198	Congenital, familial and genetic disorders	Congenital aortic stenosis	01JAN1992		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2008	31DEC2008	N
		Vascular disorders	Essential hypertension	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661202	Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1066 10661203	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
	C4591001 1066 10661217	Infections and infestations	Chronic tonsillitis	01JAN2000	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1066 10661219	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1066 10661226	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
	C4591001 1066 10661233	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Surgical and medical procedures	Myomectomy	01JAN2010	31DEC2010	N
	C4591001 1066 10661235	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1994	31DEC2012	N
			Pelvic pain	01JAN2008	30JUN2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1984		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
			Hysterectomy	01JUN2018	30JUN2018	N
			Liposuction	01JAN2002	31DEC2002	N
			Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1066 10661242	Immune system disorders	Iodine allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Vascular disorders	Deep vein thrombosis	01JAN2016		Y
	C4591001 1066 10661243	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
			Clostridium difficile colitis	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2013	31DEC2013	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Endometrial thickening	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cancer surgery	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661246	Hepatobiliary disorders	Gallbladder disorder	01JAN1998	31DEC1998	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal deformity	01JAN1996	31DEC1996	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Spinal operation	01JAN1996	31DEC1996	N
	C4591001 1066 10661247	Psychiatric disorders	Depression	01MAR2011		Y
	C4591001 1066 10661251	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JUL2010		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2009	31DEC2009	N
	C4591001 1066 10661253	Infections and infestations	Appendicitis	01MAY2020	31MAY2020	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1978		Y
		Surgical and medical procedures	Appendicectomy	01MAY2020	31MAY2020	N
			Bone operation	01JAN2010	31DEC2010	N
	C4591001 1066 10661259	Immune system disorders	Seasonal allergy	01NOV2000		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2018		Y
		Psychiatric disorders	Depression	01JUN2018		Y
		Social circumstances	Menopause	01MAY2019		Y
	C4591001 1066 10661260	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Smear cervix abnormal	01JAN2009	31DEC2009	N
	C4591001 1066 10661261	Ear and labyrinth disorders	Deafness bilateral	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteochondroma	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Bone operation	01JAN2014	31DEC2014	N
			Peripheral nerve destruction	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1066 10661262	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661264	Congenital, familial and genetic disorders	Congenital eye disorder	(b) (6) 1992		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Surgical and medical procedures	Eye excision	01JAN1993	31DEC1993	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1066 10661265	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Investigations	Smear cervix abnormal	01JAN2018	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1066 10661267	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Thyroidectomy	01JAN2005	31DEC2005	N
	C4591001 1066 10661270	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1995	31DEC1995	N
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1995	31DEC1995	N
	C4591001 1066 10661272	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Gallbladder operation	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661273	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
	C4591001 1066 10661275	Congenital, familial and genetic disorders	Factor V Leiden carrier	01MAR2008		Y
		Immune system disorders	Contrast media allergy	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Tenoplasty	01JAN2017	31DEC2017	N
	C4591001 1066 10661276	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661277	Gastrointestinal disorders	Inguinal hernia	01JAN1992	31DEC1992	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN1992	31DEC1992	N
	C4591001 1066 10661279	Hepatobiliary disorders	Gallbladder disorder	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2011	31DEC2011	N
			Ligament rupture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2011		Y
		Surgical and medical procedures	Bone operation	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Ligament operation	01JAN2008	31DEC2008	N
	C4591001 1066 10661280	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1991	31DEC1991	N
			Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1991	31DEC1991	N
	C4591001 1066 10661282	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Sebaceous cyst excision	01JAN2015	31DEC2015	N
	C4591001 1066 10661284	Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
	C4591001 1066 10661285	Ear and labyrinth disorders	Ear disorder	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2004		Y
	C4591001 1066 10661287	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2001	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Breast reconstruction	01JAN2005	31DEC2005	N
			Intervertebral disc operation	01JAN2008	31DEC2008	N
			Mastectomy	01JAN2001	31DEC2001	N
	C4591001 1066 10661289	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		General disorders and administration site conditions	Fatigue	01JAN2020		Y
		Immune system disorders	Contrast media allergy	01JAN2015		Y
			Drug hypersensitivity	01JAN1987		Y
		Metabolism and nutrition disorders	Hypocalcaemia	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
	C4591001 1066 10661290	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2006	31DEC2010	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1066 10661291	Infections and infestations	Cellulitis	01DEC2016	31DEC2016	N
				01DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1066 10661293	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2019		Y
	C4591001 1066 10661295	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N
		Infections and infestations	Genital herpes	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
			Migraine	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Female sterilisation	01JAN1989	31DEC1989	N
			Knee arthroplasty	01APR2018	30APR2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1066 10661296	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN2009		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Bursitis	01JAN2018		Y
			Osteitis deformans	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2018		Y
			Nerve compression	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Peripheral nerve transposition	01JAN2009	31DEC2009	N
	C4591001 1066 10661299	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1066 10661300	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N
			Female sterilisation	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
	C4591001 1066 10661301	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1066 10661305	Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1066 10661307	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2018	N
	C4591001 1066 10661308	Eye disorders	Retinopathy	01JAN1996		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2007	N
		Social circumstances	Menopause	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			Mammoplasty	01JAN2009	31DEC2009	N
			Tendon operation	01JAN2018	31DEC2018	N
	C4591001 1066 10661309	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1066 10661310	Surgical and medical procedures	Pituitary tumour removal	01JAN2014	31DEC2014	N
		Investigations	Lipids increased	01JAN2017		Y
	C4591001 1066 10661312	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Investigations	Smear cervix abnormal	01JAN2017	31DEC2019	N
		Nervous system disorders	Migraine	01JUL2019		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2009	31DEC2016	N
			Anxiety	01JAN2009	31DEC2016	N
	C4591001 1066 10661315	Surgical and medical procedures	Female sterilisation	01APR2019	30APR2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1066 10661317	Immune system disorders	Seasonal allergy	01JAN2007		Y
				01SEP2015		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1066 10661321	Blood and lymphatic system disorders	Anaemia	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N
			Hepatitis C	01JAN2005	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Bipolar disorder	01JAN2000		Y
			Schizoaffective disorder	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1066 10661322	Surgical and medical procedures	Appendicectomy	01JAN1991	31DEC1991	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1066 10661323	Investigations	Blood testosterone decreased	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1066 10661324	Immune system disorders	Hypersensitivity	01JAN2009		Y
		Nervous system disorders	Migraine	01JUN2010		Y
		Psychiatric disorders	Anxiety	01FEB2009	31AUG2009	N
	C4591001 1066 10661331	Endocrine disorders	Autoimmune thyroiditis	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1066 10661332	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1991		Y
	C4591001 1066 10661333	Hepatobiliary disorders	Gallbladder disorder	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1066 10661336	Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661337	Endocrine disorders	Hyperaldosteronism	01JAN2018		Y
		Infections and infestations	Rhinitis	01JAN2019		Y
		Psychiatric disorders	Affective disorder	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661338	Congenital, familial and genetic disorders	BRCA1 gene mutation	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
			Renal cancer	01JAN1998	31DEC1998	N
			Thyroid cancer	01JAN1986	31DEC1986	N
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Mastectomy	01JAN2009	31DEC2009	N
			Nephrectomy	01JAN1998	31DEC1998	N
			Thyroidectomy	01JAN1986	31DEC1986	N
	C4591001 1066 10661340	Immune system disorders	Food allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1066 10661341	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661342	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cancer surgery	01JAN2014	31DEC2014	N
	C4591001 1066 10661344	Vascular disorders	Deep vein thrombosis	01FEB2017	28FEB2017	N
			Hypertension	01MAR2017		Y
	C4591001 1066 10661345	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
	C4591001 1066 10661346	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN1991		Y
		Infections and infestations	Urinary tract infection	01JAN1984		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1066 10661348	Immune system disorders	Hypersensitivity	01JAN1979		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
	C4591001 1066 10661355	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1066 10661358	Immune system disorders	Allergy to arthropod sting	01JAN1994		Y
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1998	31DEC1998	N
			Musculoskeletal foreign body	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Limb operation	01JAN1993	31DEC1993	N
				01JAN1998	31DEC1998	N
	C4591001 1066 10661360	Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Nervous system disorders	Essential tremor	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
	C4591001 1066 10661363	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Wrist surgery	01JAN2003	31DEC2003	N
	C4591001 1066 10661364	Immune system disorders	Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Bone operation	01JAN2018	31DEC2018	N
			Knee operation	01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
	C4591001 1066 10661366	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Varicose vein	01JAN2017		Y
	C4591001 1066 10661372	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1991	31DEC1991	N
			Femur fracture	01JAN1991	31DEC1991	N
			Hand fracture	01JAN1986	31DEC1986	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Nervous system disorders	Seizure	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Ankle operation	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fracture treatment	01JAN1986	31DEC1986	N
				01JAN1991	31DEC1991	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Lithotripsy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1066 10661379	Cardiac disorders	Atrial flutter	01JAN2018		Y
			Bundle branch block left	01JAN2014		Y
			Cardiomyopathy	01JAN2014		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1993	31DEC1993	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Renal and urinary disorders	Incontinence	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Gastrectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1066 10661386	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
			Urinary hesitation	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661388	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01DEC2011		Y
		Surgical and medical procedures	Gastrectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1990	31DEC2003	N
	C4591001 1066 10661389	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1989		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Endometrial ablation	01JAN2014	31DEC2014	N
	C4591001 1066 10661390	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Hypersensitivity	01JAN1980		Y
		Investigations	Biopsy breast	01JUN2016	30JUN2016	N
				01OCT2016	31OCT2016	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Breast mass	01JUN2016	30JUN2016	N
				01OCT2016	31OCT2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661391	Infections and infestations	Ear infection	01JAN2004	31DEC2007	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2006	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2009		Y
	C4591001 1066 10661392	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019	31DEC2020	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1066 10661393	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2013	31DEC2019	N
			Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1066 10661396	Nervous system disorders	Headache	01DEC2019		Y
		Psychiatric disorders	Anxiety	01DEC2017		Y
			Attention deficit hyperactivity disorder	01DEC2019		Y
		Skin and subcutaneous tissue disorders	Acne	01DEC2017		Y
	C4591001 1066 10661398	Gastrointestinal disorders	Salivary gland disorder	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Injury, poisoning and procedural complications	Epiphyseal fracture	01JAN2018	31DEC2018	N
			Joint injury	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Salivary gland resection	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661399	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Escherichia infection	05OCT2018	16OCT2018	N
			Kidney infection	05OCT2018	16OCT2018	N
			Tonsillitis	01JAN2004	31DEC2005	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1066 10661400	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Autism spectrum disorder	01JAN2011		Y
			Insomnia	01JAN2011		Y
	C4591001 1066 10661406	Gastrointestinal disorders	Diaphragmatic hernia	(b) (6) 2003	31DEC2005	N
		Infections and infestations	Oral herpes	01JAN2016		Y
		Surgical and medical procedures	Hernia diaphragmatic repair	01JAN2005	31DEC2005	N
	C4591001 1066 10661413	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1068 10681002	Nervous system disorders	Syncope	01SEP2018		Y
	C4591001 1068 10681003	Surgical and medical procedures	Female sterilisation	22MAY2008	22MAY2008	N
	C4591001 1068 10681010	Infections and infestations	Appendicitis	17MAY2018	17MAY2018	N
	C4591001 1068 10681012	Infections and infestations	Varicella	01JAN1980	31DEC1980	N
		Nervous system disorders	Migraine	27APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Amenorrhoea	01JAN2000		Y
		Vascular disorders	Hypotension	01SEP2019		Y
			Varicose vein	19MAY2014		Y
	C4591001 1068 10681016	Eye disorders	Punctate keratitis	01MAY2019		Y
	C4591001 1068 10681017	Psychiatric disorders	Alcohol use disorder	01DEC2009	28FEB2017	N
			Major depression	01DEC2009		Y
	C4591001 1068 10681024	Skin and subcutaneous tissue disorders	Vitiligo	01JAN1993		Y
	C4591001 1068 10681025	Surgical and medical procedures	Metabolic surgery	01JAN2011	31DEC2011	N
	C4591001 1068 10681027	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Menopause	01AUG2019		Y
	C4591001 1068 10681028	Musculoskeletal and connective tissue disorders	Neck pain	19DEC2019	19DEC2019	N
	C4591001 1068 10681031	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	31JAN2019		Y
	C4591001 1068 10681037	Investigations	Hepatic enzyme increased	15JAN2020	15AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12SEP1998	31DEC2007	N
		Social circumstances	Alcohol use	01JAN2010		Y
			Tobacco user	01JAN2010		Y
	C4591001 1068 10681042	Gastrointestinal disorders	Gastrointestinal disorder	25SEP2018	25SEP2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	White blood cell count increased	25SEP2018	23MAY2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	22APR2019		Y
		Surgical and medical procedures	Continuous positive airway pressure	22APR2019		Y
	C4591001 1068 10681046	Infections and infestations	Appendicitis	27JUL2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2018	31DEC2018	N
	C4591001 1068 10681047	Investigations	Chlamydia test positive	21AUG2020	22AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1068 10681052	Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Depression	01JAN1992	31DEC1992	N
		Skin and subcutaneous tissue disorders	Seborrhoea	01JAN2003		Y
	C4591001 1068 10681053	Congenital, familial and genetic disorders	Protein S deficiency	01JAN1994		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN2004		Y
		Nervous system disorders	Restless legs syndrome	01JAN1996		Y
	C4591001 1068 10681058	Reproductive system and breast disorders	Menorrhagia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Intrauterine contraception	08AUG2016		Y
	C4591001 1068 10681060	Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Raynaud's phenomenon	22DEC2015		Y
	C4591001 1068 10681061	Investigations	Biopsy colon	26NOV2019	26NOV2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681064	Gastrointestinal disorders	Abdominal pain lower	19SEP2019	16DEC2019	N
		General disorders and administration site conditions	Chest pain	19SEP2019	16DEC2019	N
		Infections and infestations	Herpes virus infection	21AUG2020	28AUG2020	N
		Psychiatric disorders	Stress	01JAN2018		Y
	C4591001 1068 10681066	Cardiac disorders	Atrial fibrillation	17OCT2018	12DEC2019	N
	C4591001 1068 10681071	Cardiac disorders	Palpitations	25APR2017		Y
		Gastrointestinal disorders	Abdominal hernia	06DEC2019		Y
		Infections and infestations	Acute sinusitis	06DEC2019	31DEC2019	N
			Otitis media acute	06DEC2019	31DEC2019	N
		Pregnancy, puerperium and perinatal conditions	Delivery	22JUN2018	22JUN2018	N
			Pregnancy	01SEP2017	22JUN2018	N
		Psychiatric disorders	Generalised anxiety disorder	17JUN2019		Y
	C4591001 1068 10681072	Infections and infestations	Oral herpes	01JAN1985		Y
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01FEB2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	27AUG2018	11SEP2019	N
		Surgical and medical procedures	Thyroidectomy	01FEB2013	28FEB2013	N
	C4591001 1068 10681074	Gastrointestinal disorders	Eosinophilic oesophagitis	15JAN2013		Y
		Investigations	Human papilloma virus test	15DEC2016	15DEC2016	N
		Psychiatric disorders	Depression	01AUG2018		Y
		Surgical and medical procedures	Hysterectomy	12JUN2020	12JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681076	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1068 10681080	Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	22AUG2019	26SEP2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Essential hypertension	01JAN2015		Y
	C4591001 1068 10681081	Cardiac disorders	Atrial fibrillation	23FEB2016	19APR2018	N
			Sinus node dysfunction	23FEB2016	19APR2018	N
			Supraventricular tachycardia	23FEB2016	19APR2018	N
		Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01AUG2003		Y
		Injury, poisoning and procedural complications	Joint injury	27FEB2018	28FEB2019	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	27FEB2018		Y
			Vitamin D deficiency	27FEB2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2015	23DEC2015	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2003	31AUG2003	N
		Reproductive system and breast disorders	Ectropion of cervix	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Cardiac ablation	19APR2020	20APR2020	N
			Cardiac pacemaker insertion	20APR2020	20APR2020	N
			Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1068 10681089	Renal and urinary disorders	Urinary hesitation	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681098	Immune system disorders	Food allergy	01JAN2001		Y
	C4591001 1068 10681099	Injury, poisoning and procedural complications	Joint dislocation	01JAN2006		Y
		Investigations	Diagnostic procedure	11FEB2020	11FEB2020	N
	C4591001 1068 10681100	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1068 10681102	Eye disorders	Conjunctival haemorrhage	20JUL2020	27JUL2020	N
		Immune system disorders	Hypersensitivity	01JAN1974		Y
		Infections and infestations	Tinea pedis	13MAR2018		Y
		Metabolism and nutrition disorders	Hypokalaemia	24SEP2018		Y
		Nervous system disorders	Neuropathy peripheral	04APR2019	10APR2019	N
		Psychiatric disorders	Major depression	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Haematuria	15MAY2018	30JUN2018	N
			Hypertonic bladder	01SEP2020		Y
			Micturition urgency	15MAY2018	30JUN2018	N
			Pollakiuria	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Surgical and medical procedures	Metabolic surgery	24SEP2018	24SEP2018	N
	C4591001 1068 10681106	Psychiatric disorders	Anxiety	30MAR2016		Y
			Insomnia	30MAR2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
	C4591001 1068 10681109	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1068 10681110	General disorders and administration site conditions	Fatigue	25JUL2018	08AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681112	Endocrine disorders	Hypothyroidism	01DEC2016		Y
		Immune system disorders	Hypersensitivity	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1068 10681114	Infections and infestations	Herpes simplex	01JAN2007		Y
		Surgical and medical procedures	Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1068 10681116	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	30APR2013		Y
		Social circumstances	Menopause	15JUL2019		Y
	C4591001 1068 10681117	Gastrointestinal disorders	Gastroesophageal reflux disease	22AUG2018		Y
			Oesophagitis	22AUG2018		Y
		Infections and infestations	Herpes simplex	22AUG2018		Y
	C4591001 1068 10681119	Infections and infestations	Pilonidal cyst	30DEC2017	10JAN2018	N
		Metabolism and nutrition disorders	Vitamin D deficiency	16MAY2017	08AUG2017	N
		Nervous system disorders	Dizziness	18JAN2018	31OCT2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	08MAY2017	28FEB2018	N
	C4591001 1068 10681121	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1071 10711004	Blood and lymphatic system disorders	Anaemia	27SEP2019		Y
			Antiphospholipid syndrome	19SEP2016		Y
		Gastrointestinal disorders	Diverticulum	18MAY2015		Y
			Irritable bowel syndrome	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Large intestine polyp	18MAY2015	18MAY2015	N
		Hepatobiliary disorders	Hepatic steatosis	24OCT2017		Y
			Hepatomegaly	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2013		Y
			Seasonal allergy	02JUL2014		Y
		Investigations	Colonoscopy	08MAY2015	08MAY2015	N
		Metabolism and nutrition disorders	Hyperglycaemia	12DEC2016		Y
			Hyperlipidaemia	01JAN2017		Y
			Obesity	02SEP2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Intervertebral disc protrusion	01JAN2008		Y
			Lumbar spinal stenosis	01JAN2008		Y
			Osteoarthritis	15JAN2015		Y
			Plantar fasciitis	09DEC2016		Y
		Nervous system disorders	Lumbar radiculopathy	21APR2014		Y
			Migraine without aura	01JAN1993		Y
		Psychiatric disorders	Anxiety	09DEC2016		Y
			Drug abuse	01JAN2000	05JUL2015	N
			Post-traumatic stress disorder	09DEC2016		Y
			Tobacco abuse	12MAR2018		Y
		Renal and urinary disorders	Mixed incontinence	09DEC2016		Y
			Nephrolithiasis	01JAN2015		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	10MAY2016		Y
			Menopausal symptoms	15SEP2015		Y
			Menorrhagia	01JAN2005	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rectocele	22DEC2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	22OCT2014		Y
		Surgical and medical procedures	Sleep apnoea syndrome	01JAN2015		Y
			Hysterectomy	01JAN2010	31DEC2010	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
			Spinal nerve stimulator implantation	21SEP2018	21SEP2018	N
			Urethral operation	22DEC2016	22DEC2016	N
		Vascular disorders	Deep vein thrombosis	19SEP2016	19SEP2016	N
			Hot flush	18SEP2015		Y
	C4591001 1071 10711005	Investigations	Cardiac murmur	01JAN1995		Y
	C4591001 1071 10711006	Immune system disorders	Allergy to metals	01JAN2004		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01DEC2012	31DEC2012	N
		Renal and urinary disorders	Nocturia	01JAN2002		Y
		Surgical and medical procedures	Fracture treatment	31DEC2012	31DEC2012	N
			Hysterectomy	05JUL2011	05JUL2011	N
			Limb operation	01JUN2013	30JUN2013	N
	C4591001 1071 10711008	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chronic obstructive pulmonary disease	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711018	Cardiac disorders	Cardiac failure	01DEC2018	28FEB2019	N
		Eye disorders	Eyelid ptosis	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Infections and infestations	Oral herpes	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JUL2020		Y
			Muscle spasms	01MAR2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
	C4591001 1071 10711019	Vascular disorders	Hypertension	01MAR2019		Y
		Investigations	Dehydroepiandrosterone increased	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Obsessive-compulsive disorder	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2015		Y
	C4591001 1071 10711020	General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
				01JAN2018		Y
			Osteoarthritis	01JAN2016		Y
				01JAN2018		Y
	C4591001 1071 10711021	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711022	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1071 10711026	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	17AUG2016	17AUG2016	N
	C4591001 1071 10711027	Congenital, familial and genetic disorders	Sickle cell trait	01JUN2020		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01NOV2019		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1071 10711028	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	26DEC1994	26DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711030	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Nervous system disorders	Transient ischaemic attack	05FEB2020	05FEB2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1071 10711034	Gastrointestinal disorders	Oesophageal perforation	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1071 10711036	Investigations	Weight decreased	02JUN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711037	Gastrointestinal disorders	Constipation	23MAR2018		Y
		Immune system disorders	Seasonal allergy	28MAR2017		Y
		Metabolism and nutrition disorders	Hyperglycaemia	28MAR2017		Y
			Hyperlipidaemia	28MAR2017		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1985		Y
			Insomnia	04JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
			Nocturia	01JAN2000		Y
			Stress urinary incontinence	23MAR2018		Y
		Vascular disorders	Hot flush	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711039	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1071 10711040	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
			Nephrolithiasis	01JAN2018	31DEC2018	N
			Nocturia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1071 10711041	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	13MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
				14FEB2018		Y
				17FEB2017		Y
			Joint swelling	14FEB2018		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Renal and urinary disorders	Nocturia	01JUN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Essential hypertension	04DEC2017		Y
	C4591001 1071 10711042	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	07JUN2018		Y
			Depression	18JUN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1071 10711045	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1071 10711047	Infections and infestations	Oral herpes	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	22SEP2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Intervertebral disc degeneration	01JAN2001		Y
			Intervertebral disc protrusion	01JAN2001		Y
			Spinal osteoarthritis	16MAR2018		Y
			Tendonitis	01AUG2016		Y
		Nervous system disorders	Migraine	01JAN1977		Y
			Restless legs syndrome	01JAN2019		Y
		Renal and urinary disorders	Nocturia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	15JAN2010	15JAN2010	N
		Vascular disorders	Essential hypertension	01JAN1997		Y
	C4591001 1071 10711055	Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Obesity	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
	C4591001 1071 10711056	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01OCT2019		Y
			Type 2 diabetes mellitus	01JAN1990		Y
	C4591001 1071 10711057	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1071 10711061	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
			Irritable bowel syndrome	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Rubber sensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Salpingectomy	01JAN2012	31DEC2012	N
	C4591001 1071 10711062	Psychiatric disorders	Insomnia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711065	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1071 10711079	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1999		Y
			Insomnia	01JAN2008		Y
			Obsessive-compulsive disorder	01JAN1998		Y
	C4591001 1071 10711080	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Facial neuralgia	01JAN2013		Y
			Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	12AUG2015		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	20SEP2013		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01AUG2018	31AUG2018	N
	C4591001 1071 10711081	Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2018		Y
		Nervous system disorders	Neuralgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1071 10711083	Congenital, familial and genetic disorders	Cerebral palsy	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Scoliosis	01JAN1983		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
			Insomnia	01JAN2018		Y
	C4591001 1071 10711087	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1071 10711095	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1071 10711097	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Osteoarthritis	01JAN2014		Y
			Spondylolisthesis	01JAN1966		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1071 10711098	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01AUG2019		Y
		Psychiatric disorders	Anxiety	01AUG2010		Y
			Depression	01AUG2014		Y
			Insomnia	01AUG2012		Y
		Social circumstances	Menopause	01AUG2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711100	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2005		Y
				01JAN2010		Y
			Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1992		Y
		Nervous system disorders	Restless legs syndrome	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1071 10711102	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1071 10711107	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2019		Y
	C4591001 1071 10711114	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2014		Y
			Obesity	02SEP2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Sciatica	01NOV2019		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
	C4591001 1071 10711115	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
			Obesity	01JAN2010		Y
	C4591001 1071 10711116	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
	C4591001 1071 10711118	Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1071 10711119	Infections and infestations	Oral herpes	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1071 10711124	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711125	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Allergy to vaccine	01JAN2013		Y
			Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1071 10711127	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2019		Y
			Obesity	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Joint swelling	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01MAY2018	31MAY2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1071 10711128	Gastrointestinal disorders	Crohn's disease	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1071 10711131	Immune system disorders	Drug hypersensitivity	01NOV2019		Y
				01SEP2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	11MAY2006		Y
		Surgical and medical procedures	Female sterilisation	27NOV1997	27NOV1997	N
	C4591001 1071 10711133	Immune system disorders	Drug hypersensitivity	01SEP1998		Y
	C4591001 1071 10711137	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2005		Y
			Eczema	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711138	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
	C4591001 1071 10711140	Cardiac disorders	Cardiac failure congestive	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1071 10711148	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01DEC2012	31DEC2012	N
	C4591001 1071 10711149	Cardiac disorders	Coronary artery disease	04DEC2019		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	04DEC2019		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	04DEC2019		Y
	C4591001 1071 10711150	Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1071 10711151	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
			Spinal osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Surgical and medical procedures	Salpingectomy	03OCT2015	03OCT2015	N
	C4591001 1071 10711152	Cardiac disorders	Cardiac failure	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute lymphocytic leukaemia	01JAN1995	31DEC1995	N
	C4591001 1071 10711153	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01MAR2018		Y
			Depression	01MAR2018		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1071 10711156	Infections and infestations	Oral herpes	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711159	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1071 10711160	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
			Irritable bowel syndrome	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Sinusitis	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Foot deformity	01JAN2003		Y
			Plantar fasciitis	01JAN2004		Y
			Temporomandibular joint syndrome	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1976		Y
			Rhinitis allergic	01JAN2009		Y
			Sleep apnoea syndrome	01SEP2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1976		Y
			Hidradenitis	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1071 10711161	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN1994		Y
			Bipolar disorder	01JAN2013		Y
			Depression	01JAN2001		Y
	C4591001 1071 10711164	Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711166	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1071 10711167	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2001		Y
	C4591001 1071 10711170	Infections and infestations	Body tinea	01JAN1995		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2016		Y
	C4591001 1071 10711171	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1071 10711173	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1071 10711176	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Social circumstances	Postmenopause	01MAR2020		Y
		Vascular disorders	Hot flush	01MAR2020		Y
	C4591001 1071 10711182	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1976		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
	C4591001 1071 10711183	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1071 10711189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
	C4591001 1071 10711193	Endocrine disorders	Hypothyroidism	07MAR2005		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05SEP1978		Y
	C4591001 1071 10711194	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01MAY2018		Y
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	01JAN2018		Y
	C4591001 1071 10711198	Gastrointestinal disorders	Constipation	01JAN2000		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711199	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1071 10711200	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1071 10711206	Gastrointestinal disorders	Nausea	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2010		Y
	C4591001 1071 10711208	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1071 10711209	Injury, poisoning and procedural complications	Muscle strain	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1071 10711210	Metabolism and nutrition disorders	Gout	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Osteoarthritis	01JAN2009		Y
			Spinal stenosis	01JAN2012		Y
		Renal and urinary disorders	Nocturia	01JAN2016		Y
	C4591001 1071 10711211	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Fibromyalgia	06AUG2013		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Insomnia	01JAN2007		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1071 10711212	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1071 10711215	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01MAR2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711217	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		General disorders and administration site conditions	Oedema peripheral	12APR2017		Y
		Infections and infestations	Bacterial vaginosis	07JAN2017		Y
			Genital herpes	13JAN2017		Y
		Injury, poisoning and procedural complications	Hand fracture	22SEP2020		Y
			Scar	12APR2017		Y
		Metabolism and nutrition disorders	Metabolic disorder	31JUL2018		Y
			Obesity	13JAN2017		Y
		Nervous system disorders	Hypersomnia	31JUL2018		Y
			Migraine	01JUL2018		Y
			Tension headache	23FEB2018		Y
		Psychiatric disorders	Affective disorder	07SEP2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	13JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	12APR2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
	C4591001 1071 10711218	Metabolism and nutrition disorders	Obesity	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1071 10711219	Ear and labyrinth disorders	Cerumen impaction	09APR2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	29OCT2016		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1992		Y
		Renal and urinary disorders	Nocturia	01JUN2017		Y
	C4591001 1071 10711222	Immune system disorders	Drug hypersensitivity	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01MAR2019		Y
	C4591001 1071 10711224	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1988		Y
	C4591001 1071 10711229	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
	C4591001 1071 10711231	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01FEB2000		Y
	C4591001 1071 10711232	Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2020		Y
	C4591001 1071 10711233	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1071 10711234	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Seizure	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1071 10711236	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1071 10711237	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1071 10711239	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Renal and urinary disorders	Nocturia	01MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13APR2017		Y
		Skin and subcutaneous tissue disorders	Chloasma	23JUL2018		Y
		Surgical and medical procedures	Female sterilisation	06MAY2003	06MAY2003	N
	C4591001 1071 10711241	General disorders and administration site conditions	Temperature intolerance	24OCT2014		Y
		Psychiatric disorders	Insomnia	24FEB2016		Y
		Renal and urinary disorders	Nocturia	01JAN2009		Y
		Reproductive system and breast disorders	Menopausal symptoms	27JUL2012		Y
	C4591001 1071 10711242	Infections and infestations	Oral herpes	01JAN1983		Y
	C4591001 1071 10711244	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Ulcer	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN1990		Y
			Hypercholesterolaemia	01JAN2010		Y
			Obesity	01OCT2019		Y
			Type 2 diabetes mellitus	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal stenosis	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2006		Y
			Migraine	01APR2002		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Uterine prolapse	01DEC2004	31DEC2004	N
		Social circumstances	Menopause	01DEC2004		Y
		Surgical and medical procedures	Hysterectomy	01DEC2004	31DEC2004	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1071 10711246	Metabolism and nutrition disorders	Obesity	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020		Y
		Psychiatric disorders	Bipolar disorder	01JAN2019		Y
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1071 10711247	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
		Psychiatric disorders	Bipolar disorder	01JAN2008		Y
	C4591001 1071 10711249	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711250	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1072 10721001	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1072 10721008	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1072 10721009	Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Caesarean section	14APR2011	14APR2011	N
				14NOV2009	14NOV2009	N
			Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1072 10721012	Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1072 10721013	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1072 10721023	Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1072 10721024	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Intervertebral disc degeneration	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1981		Y
		Surgical and medical procedures	Hysterectomy	01SEP2018	30SEP2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1072 10721029	Psychiatric disorders	Sleep disorder	01JAN2019		Y
	C4591001 1072 10721030	Psychiatric disorders	Affective disorder	01JAN1990		Y
			Insomnia	01SEP2013		Y
	C4591001 1072 10721031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1072 10721034	Surgical and medical procedures	Caesarean section	24APR2002	24APR2002	N
	C4591001 1072 10721035	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1072 10721040	Social circumstances	Menopause	01JAN2019		Y
	C4591001 1072 10721046	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Investigations	Progesterone decreased	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01FEB1990	28FEB1990	N
			Endometrial ablation	01JAN2011	31DEC2011	N
	C4591001 1072 10721047	Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1072 10721049	Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
	C4591001 1072 10721050	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1072 10721051	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1072 10721058	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1072 10721063	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1072 10721070	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1072 10721071	Reproductive system and breast disorders	Uterine polyp	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1072 10721074	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1072 10721077	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1072 10721084	Immune system disorders	Multiple allergies	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
	C4591001 1072 10721085	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Skin neoplasm excision	25FEB2010	25FEB2010	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1072 10721087	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005	11JUL2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1993		Y
		Surgical and medical procedures	Gastrectomy	11JUL2019	11JUL2019	N
	C4591001 1072 10721089	Metabolism and nutrition disorders	Folate deficiency	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1072 10721090	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1072 10721093	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1072 10721094	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JUL2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1072 10721099	Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1072 10721100	Psychiatric disorders	Bipolar disorder	01JAN2003		Y
			Insomnia	01JAN2018		Y
	C4591001 1073 10731006	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2018		Y
		Psychiatric disorders	Anxiety	05JAN2020		Y
	C4591001 1073 10731008	Investigations	Blood cholesterol increased	01DEC2016		Y
	C4591001 1073 10731009	Hepatobiliary disorders	Nonalcoholic fatty liver disease	15JUN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Hepatic enzyme increased	15JUN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	15NOV2019		Y
		Psychiatric disorders	Premature ejaculation	01DEC2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01DEC2019		Y
			Infertility	01DEC2019		Y
	C4591001 1073 10731012	Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1073 10731016	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Hiatus hernia	01JAN2017	31DEC2017	N
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
	C4591001 1073 10731020	Ear and labyrinth disorders	Vertigo	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1073 10731021	Surgical and medical procedures	Salpingectomy	01SEP2003	01SEP2003	N
	C4591001 1073 10731022	Immune system disorders	Seasonal allergy	01JAN1982		Y
	C4591001 1073 10731027	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN1983		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1991	31DEC1995	N
		Surgical and medical procedures	Vasectomy	24FEB2006	24FEB2006	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1073 10731029	Gastrointestinal disorders	Dyspepsia	01JAN1997		Y
		Infections and infestations	Oral herpes	01JUL1995		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	05JAN2018		Y
		Psychiatric disorders	Anxiety	05JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2012	31OCT2012	N
			Intrauterine contraception	31JUL2017		Y
		Vascular disorders	Hypertension	30MAY2017		Y
	C4591001 1073 10731032	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731034	Surgical and medical procedures	Caesarean section	15JAN2002	15JAN2002	N
				25MAY2000	25MAY2000	N
				25MAY2005	25MAY2005	N
			Cholecystectomy	09JUN2009	09JUN2009	N
			Female sterilisation	25MAY2005	25MAY2005	N
			Myomectomy	31JAN1994	31JAN1994	N
	C4591001 1073 10731036	Gastrointestinal disorders	Duodenogastric reflux	01SEP2006	30SEP2006	N
			Gastroesophageal reflux disease	01JAN1980		Y
			Hiatus hernia	01JAN2017		Y
		Immune system disorders	Milk allergy	01JAN2009		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31JAN2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
			Breast cancer	01JUL2008	31AUG2008	N
		Nervous system disorders	Migraine	01JAN1980		Y
		Surgical and medical procedures	Appendicectomy	01SEP2006	30SEP2006	N
			Breast conserving surgery	01AUG2008	31AUG2008	N
			Cholecystectomy	01SEP2006	30SEP2006	N
			Micrographic skin surgery	01JAN2008	31DEC2008	N
			Oophorectomy bilateral	01JAN2009	31JAN2009	N
			Spinal laminectomy	01JAN2016	31JAN2016	N
	C4591001 1073 10731038	Immune system disorders	Drug hypersensitivity	(b) (6) 1998		Y
	C4591001 1073 10731045	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Constipation	01JAN1996		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	(b) (6) 1973		Y
		Infections and infestations	Diverticulitis	01MAY2010	31DEC2010	N
			Kidney infection	01JAN1988	31JAN1998	N
			Sinusitis	01JAN1990		Y
		Injury, poisoning and procedural complications	Lisfranc fracture	01APR1994	01APR1994	N
		Metabolism and nutrition disorders	Hyperphagia	01JAN1996		Y
		Nervous system disorders	Migraine	05MAR2017		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN1996		Y
			Insomnia	01JAN1996		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2005	30JUN2005	N
			Urinary incontinence	29SEP1996		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012	31DEC2016	N
			Ovarian cyst	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1985		Y
			Hyperhidrosis	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN1994	31DEC1994	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Joint arthroplasty	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JAN1996		Y
	C4591001 1073 10731048	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Allergy to animal	01JAN2001		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Reaction to colouring	01JAN2001		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Urinary tract infection	15MAR2020	22MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Reproductive system and breast disorders	Polycystic ovaries	01OCT2016		Y
		Surgical and medical procedures	Ankle arthroplasty	01JUN2019	01JUN2019	N
	C4591001 1073 10731050	Endocrine disorders	Hypothyroidism	01MAR2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1073 10731056	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN1987		Y
			Seasonal allergy	01JAN1987		Y
		Infections and infestations	Herpes simplex	01JAN1977		Y
		Investigations	Human papilloma virus test positive	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2003		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
			Hernia repair	01JAN1997	31DEC1997	N
	C4591001 1073 10731057	Gastrointestinal disorders	Dyspepsia	01APR2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	10OCT2019		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2018		Y
	C4591001 1073 10731059	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1073 10731062	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1073 10731063	Gastrointestinal disorders	Pancreatitis	01MAR2011	01MAR2011	N
		Hepatobiliary disorders	Cholelithiasis	01JUL2010	01JUL2010	N
		Vascular disorders	Hot flush	01FEB2020		Y
			Hypertension	01FEB2018		Y
	C4591001 1073 10731064	Infections and infestations	Bacterial vulvovaginitis	01JAN2018	21JUL2020	N
			Herpes simplex	01JAN2017		Y
		Investigations	Human papilloma virus test positive	22JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2007	31DEC2015	N
	C4591001 1073 10731065	Surgical and medical procedures	Endometrial ablation	10JAN2017	10JAN2017	N
			Salpingectomy	20AUG2016	20AUG2016	N
	C4591001 1073 10731067	Endocrine disorders	Hypothyroidism	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	(b) (6) 1996		Y
		Infections and infestations	Cholecystitis infective	01JAN2015	31DEC2015	N
			Herpes simplex	(b) (6) 1996		Y
		Investigations	Progesterone decreased	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1073 10731068	Psychiatric disorders	Depression	15FEB2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01OCT2010		Y
	C4591001 1073 10731077	Injury, poisoning and procedural complications	Multiple fractures	01APR1993		Y
		Investigations	Blood cholesterol	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Ankle operation	01APR1993	30APR1993	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1073 10731079	Infections and infestations	Herpes simplex	13NOV2003		Y
		Investigations	Blood cholesterol increased	10JUL2017		Y
		Skin and subcutaneous tissue disorders	Eczema	13MAY2001		Y
	C4591001 1073 10731081	Eye disorders	Cataract	01FEB2011		Y
	C4591001 1073 10731083	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1999		Y
	C4591001 1073 10731085	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Hiatus hernia	01MAR2019	31MAR2019	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	26APR1996	26APR1996	N
			Gastric bypass	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1073 10731091	Reproductive system and breast disorders	Uterine prolapse	01JUN2010	30JUN2010	N
		Surgical and medical procedures	Hysterectomy	01JUN2010	30JUN2010	N
	C4591001 1073 10731101	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Panic attack	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1073 10731103	Ear and labyrinth disorders	Deafness unilateral	10SEP2016		Y
		Infections and infestations	Cellulitis	12NOV2015	12NOV2015	N
		Surgical and medical procedures	Vasectomy	25AUG2010	25AUG2010	N
	C4591001 1073 10731106	Immune system disorders	Seasonal allergy	15OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15OCT2018		Y
	C4591001 1073 10731109	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Appendicitis	08AUG2018	31DEC2018	N
			Sinusitis	01JAN2000	31DEC2000	N
			Tonsillitis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Neck pain	01JAN2015		Y
			Temporomandibular joint syndrome	01JAN2009		Y
		Psychiatric disorders	Depression	01AUG2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Generalised anxiety disorder	01AUG2008		Y
			Insomnia	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2018	31DEC2018	N
			Mole excision	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN2004	31DEC2004	N
			Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1073 10731110	Infections and infestations	Diverticulitis	01MAR2000		Y
		Surgical and medical procedures	Appendicectomy	01AUG2012	31AUG2012	N
	C4591001 1073 10731112	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2018		Y
		Psychiatric disorders	Depression	01OCT1990		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2019	31OCT2019	N
			Gastric bypass	01OCT2003	31OCT2003	N
		Vascular disorders	Hypertension	01NOV2018		Y
	C4591001 1073 10731113	Gastrointestinal disorders	Pancreatitis	01JUL2015	01JUL2015	N
		Hepatobiliary disorders	Cholelithiasis	01JUL2015	01JUL2015	N
		Infections and infestations	Sinusitis	01JAN2018	31JAN2018	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1983	31DEC1983	N
		Psychiatric disorders	Anxiety	30JUN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2003	31DEC2003	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	06JUN2009		Y
			Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1073 10731114	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Food allergy	(b) (6) 1999		Y
			Seasonal allergy	(b) (6) 1999		Y
		Infections and infestations	Sinusitis	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1073 10731116	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	10JAN2019		Y
		Infections and infestations	Diverticulitis	01SEP2019		Y
			Pneumonia	01DEC2015		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	10FEB2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Female sterilisation	01MAY1999	31MAY1999	N
			Hysterectomy	01FEB2018	28FEB2018	N
		Vascular disorders	Hypertension	10FEB2018		Y
	C4591001 1073 10731117	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Human papilloma virus test positive	01AUG2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1073 10731120	Gastrointestinal disorders	Dyspepsia	10FEB2017		Y
		Infections and infestations	Cystitis	01OCT2015	31OCT2015	N
			Staphylococcal infection	01APR2010	30APR2010	N
	C4591001 1077 10771001	Immune system disorders	Seasonal allergy	01JAN1979		Y
	C4591001 1077 10771002	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
	C4591001 1077 10771003	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1077 10771004	Gastrointestinal disorders	Diverticulum	01OCT2019		Y
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Injury, poisoning and procedural complications	Ligament rupture	01MAR2013	31MAR2013	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2013		Y
			Muscle spasms	01MAR2013		Y
	C4591001 1077 10771007	Immune system disorders	Food allergy	01AUG2019		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
	C4591001 1077 10771008	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1077 10771010	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004		Y
	C4591001 1077 10771013	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Limb mass	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2007		Y
		Nervous system disorders	Headache	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01MAY2020		Y
			Depression	01JAN2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Surgical and medical procedures	Mass excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1077 10771014	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
	C4591001 1077 10771015	Immune system disorders	Food allergy	01JAN1997		Y
			Hypersensitivity	01JAN1977		Y
	C4591001 1077 10771018	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
	C4591001 1077 10771019	Cardiac disorders	Cardiovascular disorder	01JAN1970		Y
		Gastrointestinal disorders	Inguinal hernia	01FEB2019	28FEB2019	N
			Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Allergy to chemicals	01JAN1980		Y
			Drug hypersensitivity	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1970		Y
	C4591001 1077 10771020	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Milk allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
			Mood swings	01JAN2020		Y
	C4591001 1077 10771023	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN1984		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
	C4591001 1077 10771027	Cardiac disorders	Cardiac failure congestive	03MAY2006	06MAY2006	N
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	01MAY2006	01MAY2006	N
	C4591001 1077 10771028	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
	C4591001 1077 10771029	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01FEB2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01AUG2017		Y
		Nervous system disorders	Migraine	01DEC2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01OCT2016	31OCT2016	N
	C4591001 1077 10771036	Immune system disorders	Allergy to animal	01JAN2006		Y
			Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Ear infection	01JAN2008		Y
	C4591001 1077 10771037	Infections and infestations	Appendicitis	01JAN1979	31DEC1979	N
	C4591001 1077 10771038	Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1077 10771041	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1077 10771042	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1077 10771044	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JUL2019	31AUG2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1077 10771045	Vascular disorders	Hypertension	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2007		Y
			Post-traumatic stress disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
	C4591001 1077 10771054	Vascular disorders	Hypertension	01JAN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1077 10771058	Vascular disorders	Hypertension	01JAN2018		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2013		Y
	C4591001 1077 10771061	Psychiatric disorders	Obsessive-compulsive disorder	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771067	Hepatobiliary disorders	Cholecystitis	15NOV2019	15NOV2019	N
		Psychiatric disorders	Depression	01JAN2016		Y
			Generalised anxiety disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	15NOV2019	15NOV2019	N
	C4591001 1077 10771068	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Investigations	Blood triglycerides increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1077 10771069	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1077 10771071	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Hypersensitivity	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2014		Y
			Generalised anxiety disorder	01JAN2014		Y
	C4591001 1077 10771073	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1077 10771074	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
	C4591001 1077 10771076	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Allergy to metals	01JAN2010		Y
	C4591001 1077 10771077	Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771079	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1077 10771080	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1077 10771082	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC2019		Y
	C4591001 1077 10771083	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1077 10771084	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2019	31DEC2019	N
	C4591001 1077 10771085	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1077 10771086	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771087	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
	C4591001 1077 10771096	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1077 10771097	General disorders and administration site conditions	Chronic fatigue syndrome	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1077 10771100	Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1077 10771108	Hepatobiliary disorders	Cholecystitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1077 10771114	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1077 10771118	Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771120	Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Trans-sexualism	01JAN2017		Y
		Surgical and medical procedures	Mastectomy	01JUN2019	30JUN2019	N
	C4591001 1077 10771122	Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
	C4591001 1077 10771123	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Neck pain	01DEC2005		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1077 10771124	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
	C4591001 1077 10771125	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1077 10771126	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Nervous system disorders	Idiopathic intracranial hypertension	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1077 10771128	Immune system disorders	Sarcoidosis	01JAN2015	31DEC2015	N
		Investigations	Bronchoscopy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1077 10771129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01FEB2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1077 10771131	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2005		Y
		Investigations	Biopsy breast	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999	31DEC1999	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2003	31DEC2003	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
			Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2001	31DEC2001	N
			Spinal laminectomy	01JAN1999	31DEC1999	N
	C4591001 1077 10771132	Immune system disorders	Food allergy	01JAN2009		Y
			Hypersensitivity	01JAN1997		Y
	C4591001 1077 10771133	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771134	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
			Drug hypersensitivity	01JAN2008		Y
	C4591001 1077 10771136	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1077 10771137	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Haematoma	06APR2020		Y
	C4591001 1077 10771138	Eye disorders	Iritis	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1990		Y
	C4591001 1077 10771139	Infections and infestations	Chronic sinusitis	01JAN2003	31DEC2003	N
			Herpes simplex	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Sinus operation	01JAN2003	31DEC2003	N
	C4591001 1077 10771142	Infections and infestations	Oral herpes	01JAN2003		Y
	C4591001 1077 10771150	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771152	General disorders and administration site conditions	Adverse drug reaction	01JAN1969		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JUN2020		Y
	C4591001 1077 10771156	Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1077 10771157	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1077 10771158	General disorders and administration site conditions	Adverse drug reaction	01JAN1992		Y
		Immune system disorders	Hypersensitivity	01JAN2008		Y
	C4591001 1077 10771159	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Infections and infestations	Herpes simplex	01JAN2018		Y
	C4591001 1077 10771165	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastric mucosal lesion	15DEC2019		Y
			Gastroesophageal reflux disease	15FEB2020		Y
			Large intestine polyp	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1077 10771166	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1077 10771171	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN1968		Y
			Rubber sensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01APR1995	30APR1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1077 10771183	Immune system disorders	Hypersensitivity	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1987		Y
	C4591001 1077 10771184	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01DEC2002		Y
	C4591001 1077 10771186	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1077 10771188	Ear and labyrinth disorders	Hypoacusis	01JAN1999		Y
	C4591001 1077 10771189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Umbilical hernia	01JAN2010	31DEC2010	N
		Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1077 10771190	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1077 10771192	Gastrointestinal disorders	Gastrointestinal disorder	20JUN2020		Y
	C4591001 1077 10771193	General disorders and administration site conditions	Adverse drug reaction	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1077 10771198	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
	C4591001 1077 10771200	Surgical and medical procedures	Female sterilisation	01SEP2018	30SEP2018	N
	C4591001 1077 10771201	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1077 10771202	Gastrointestinal disorders	Colitis	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771203	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2010		Y
	C4591001 1077 10771214	Immune system disorders	Allergy to plants	01JAN2000		Y
			Food allergy	01JAN2000		Y
			Hypersensitivity	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1077 10771218	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2011	31DEC2013	N
			Neck pain	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2013		Y
			Cough	01JAN2013		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2013	31DEC2013	N
	C4591001 1077 10771222	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Sinus headache	01JAN2017		Y
	C4591001 1077 10771236	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
	C4591001 1077 10771237	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1077 10771238	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771240	Immune system disorders	Allergy to animal	01JAN2014		Y
	C4591001 1077 10771242	Infections and infestations	Herpes simplex	01JAN2017		Y
	C4591001 1077 10771244	Infections and infestations	Lyme disease	01JAN2013		Y
	C4591001 1077 10771245	Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
	C4591001 1077 10771246	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1077 10771247	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Psychiatric disorders	Autism spectrum disorder	01JAN2015		Y
	C4591001 1077 10771250	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	15JUN2020		Y
			Depression	01JAN2016		Y
	C4591001 1077 10771253	Surgical and medical procedures	Pilonidal sinus repair	01JAN2005	31DEC2005	N
	C4591001 1077 10771254	Cardiac disorders	Tachycardia	01JAN2005	31DEC2008	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	22JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	16JUL2010		Y
			Depression	21FEB2012		Y
		Social circumstances	Postmenopause	01OCT2019		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1077 10771258	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1077 10771261	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Chronic sinusitis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1077 10771262	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1077 10771268	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1996	31DEC2018	N
		Psychiatric disorders	Bipolar disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis	26FEB2016		Y
		Surgical and medical procedures	Gastrectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1077 10771269	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1077 10771272	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1077 10771273	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1079 10791002	Endocrine disorders	Hypothyroidism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1079 10791003	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Infections and infestations	Bacterial vaginosis	01JAN2016	31DEC2016	N
			Herpes virus infection	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1978		Y
			Migraine	01JAN1995		Y
		Psychiatric disorders	Libido decreased	01JAN2006		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1978		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1079 10791004	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Irritable bowel syndrome	01JAN1998		Y
		Hepatobiliary disorders	Cholelithiasis	28JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1986		Y
			Insomnia	01JAN1999		Y
		Renal and urinary disorders	Hydronephrosis	28JUL2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	28JUL2020		Y
	C4591001 1079 10791008	Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1079 10791010	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	10APR2008		Y
	C4591001 1079 10791013	Investigations	Heart rate increased	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1079 10791021	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
	C4591001 1079 10791022	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2015		Y
	C4591001 1079 10791037	Reproductive system and breast disorders	Infertility	01JAN2013	31DEC2015	N
	C4591001 1079 10791039	Psychiatric disorders	Depression	01DEC2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1079 10791040	Psychiatric disorders	Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791046	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1079 10791047	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1079 10791048	Endocrine disorders	Goitre	01JAN2010	31DEC2010	N
		Eye disorders	Astigmatism	01JAN1994	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1079 10791050	Psychiatric disorders	Anxiety	01MAR2020		Y
			Insomnia	01JAN2012		Y
	C4591001 1079 10791053	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791054	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Hernia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791058	Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1079 10791059	Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Salpingectomy	01JAN2019	31DEC2019	N
	C4591001 1079 10791060	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1079 10791061	Investigations	Blood testosterone decreased	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2003		Y
			Generalised anxiety disorder	01JAN2003		Y
	C4591001 1079 10791063	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1079 10791072	Eye disorders	Keratoconus	01JAN2019		Y
	C4591001 1079 10791073	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1079 10791075	Investigations	Blood testosterone decreased	01JAN2013		Y
	C4591001 1079 10791077	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Depression	01MAY2020		Y
			Insomnia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791082	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1079 10791086	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1079 10791087	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1079 10791089	Skin and subcutaneous tissue disorders	Eczema	01JAN1969	31DEC1982	N
			Night sweats	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1079 10791090	Investigations	Blood cholesterol increased	01JAN1986		Y
	C4591001 1079 10791097	Psychiatric disorders	Insomnia	16SEP2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
	C4591001 1079 10791098	Gastrointestinal disorders	Pancreatitis chronic	01JAN2018		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006		Y
			Osteoarthritis	01MAR2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791099	Vascular disorders	Hypertension	15JUN2020		Y
	C4591001 1079 10791102	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1989		Y
			Insomnia	01JAN2008		Y
			Social anxiety disorder	01JAN2004		Y
	C4591001 1079 10791107	Cardiac disorders	Myocardial infarction	06DEC2019	06DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	06DEC2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Vascular disorders	Hypertension	06DEC2019		Y
	C4591001 1079 10791109	Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1079 10791110	Psychiatric disorders	Bipolar disorder	01JAN2020		Y
			Drug dependence	01JAN2019		Y
	C4591001 1079 10791112	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001		Y
	C4591001 1079 10791114	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791115	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791116	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1079 10791120	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791124	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791125	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2016		Y
			Sleep disorder	01JAN2012		Y
		Social circumstances	Postmenopause	01JUL2019		Y
	C4591001 1079 10791126	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1079 10791127	Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1079 10791130	Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2017		Y
	C4591001 1079 10791133	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
	C4591001 1079 10791134	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Insomnia	01JAN2007		Y
		Surgical and medical procedures	Contraceptive implant	01JAN2018		Y
	C4591001 1079 10791135	Psychiatric disorders	Anxiety	01OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV2017		Y
	C4591001 1079 10791137	Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1079 10791143	Investigations	Blood testosterone decreased	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1079 10791146	Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1079 10791147	Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
	C4591001 1079 10791153	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1079 10791154	Endocrine disorders	Hypothyroidism	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1079 10791162	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Chronic inflammatory demyelinating polyradiculoneuropathy	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1079 10791166	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1079 10791169	Hepatobiliary disorders	Cholecystitis	01DEC2015	31JAN2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN1996		Y
		Surgical and medical procedures	Benign breast lump removal	01MAR2015	31MAR2015	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1079 10791170	Psychiatric disorders	Anxiety	01SEP2019		Y
			Major depression	01SEP2019		Y
	C4591001 1079 10791172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2010	31DEC2010	N
			Sinus operation	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791174	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Hernia repair	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1079 10791175	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1999		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
			Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1079 10791176	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Glaucoma surgery	01JAN2010	31DEC2010	N
	C4591001 1079 10791177	Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1079 10791179	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1079 10791181	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2019		Y
	C4591001 1079 10791182	Immune system disorders	Drug hypersensitivity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Lyme disease	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2017		Y
	C4591001 1079 10791186	Gastrointestinal disorders	Gastroesophageal reflux disease	19AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
		Surgical and medical procedures	Appendectomy	01JAN2006	31DEC2006	N
	C4591001 1079 10791187	Psychiatric disorders	Anxiety	01JAN1982		Y
	C4591001 1079 10791192	Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1079 10791195	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Infections and infestations	Herpes simplex	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2013	31DEC2013	N
	C4591001 1079 10791197	Surgical and medical procedures	Ligament operation	01JAN2002	31DEC2002	N
	C4591001 1079 10791199	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1079 10791203	Cardiac disorders	Atrial fibrillation	01OCT2019		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1079 10791205	Surgical and medical procedures	Myomectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1079 10791206	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791211	Surgical and medical procedures	Endometriosis ablation	01JAN2012	31DEC2012	N
	C4591001 1079 10791224	Surgical and medical procedures	Wisdom teeth removal	01JAN2000	31DEC2000	N
	C4591001 1079 10791230	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
	C4591001 1079 10791232	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
			Appendicectomy	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1079 10791235	Endocrine disorders	Goitre	03SEP2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791238	Congenital, familial and genetic disorders	Cerebral palsy	01JAN2004		Y
		Eye disorders	Strabismus	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Hydrocephalus	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
		Surgical and medical procedures	Fracture treatment	01JAN2014		Y
			Spinal operation	01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N
				01JAN2014	31DEC2014	N
			Ventriculo-peritoneal shunt	01JAN2001		Y
	C4591001 1079 10791241	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1079 10791244	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1079 10791249	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791250	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Psychiatric disorders	Depression	01MAY2020		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2001		Y
	C4591001 1079 10791251	Endocrine disorders	Autoimmune thyroiditis	01JAN2007		Y
			Hypothyroidism	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood iron decreased	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2004		Y
	C4591001 1079 10791256	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Compartment syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Foot operation	01JAN2000	31DEC2000	N
			Knee operation	01JAN2000	31DEC2000	N
			Ligament operation	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2010	31DEC2010	N
			Stem cell therapy	01JAN2019	31DEC2019	N
	C4591001 1079 10791257	Immune system disorders	Food allergy	01JAN1994		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1079 10791262	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Surgical and medical procedures	Wrist surgery	01JAN2012	31DEC2012	N
	C4591001 1079 10791263	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Shoulder operation	01JAN2009	31DEC2009	N
	C4591001 1079 10791265	Injury, poisoning and procedural complications	Road traffic accident	01JAN2010	31DEC2010	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Surgical and medical procedures	Knee operation	01JAN1989	31DEC1989	N
				01JAN1991	31DEC1991	N
			Limb operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791267	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
	C4591001 1079 10791272	Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2010		Y
	C4591001 1079 10791275	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1079 10791277	Skin and subcutaneous tissue disorders	Rosacea	01JAN2008		Y
	C4591001 1079 10791288	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1079 10791289	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
	C4591001 1079 10791290	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN2018		Y
			Reaction to food additive	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Corneal transplant	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Intraocular lens implant	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791291	General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1079 10791293	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
	C4591001 1079 10791294	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1079 10791296	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1079 10791297	Metabolism and nutrition disorders	Obesity	22SEP2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1079 10791298	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1979		Y
			Iodine allergy	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2005	31DEC2005	N
			Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Foot operation	01JAN2005	31DEC2005	N
			Spinal operation	01JAN2005	31DEC2005	N
	C4591001 1079 10791300	Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1079 10791304	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
	C4591001 1079 10791305	Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1079 10791311	Investigations	Blood testosterone decreased	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2018		Y
		Surgical and medical procedures	Arteriovenous fistula operation	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1079 10791313	Investigations	Biopsy lymph gland	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1079 10791315	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
		Surgical and medical procedures	Shoulder operation	01JAN2015	31DEC2015	N
	C4591001 1079 10791316	Surgical and medical procedures	Ostectomy	01JAN2019	31DEC2019	N
	C4591001 1080 10801001	Cardiac disorders	Ventricular extrasystoles	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
	C4591001 1080 10801002	Gastrointestinal disorders	Impaired gastric emptying	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1974	31DEC1974	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Colectomy	01JAN2016	31DEC2016	N
			Intestinal operation	01JAN2018	31DEC2018	N
			Oesophagogastric fundoplasty	01JAN2014	31DEC2014	N
	C4591001 1080 10801004	Cardiac disorders	Sinus tachycardia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Impaired gastric emptying	01JAN2018		Y
		Immune system disorders	Perennial allergy	01JAN1999		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2014		Y
			Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1080 10801009	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Psychiatric disorders	Bipolar disorder	01APR2020		Y
			Depression	01JAN2018		Y
			Generalised anxiety disorder	01JAN2018		Y
			Insomnia	01JAN2018		Y
			Obsessive-compulsive disorder	01FEB2020		Y
			Panic disorder	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801010	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
	C4591001 1080 10801017	General disorders and administration site conditions	Pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Menopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1080 10801018	Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1080 10801019	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1080 10801027	General disorders and administration site conditions	Cyst	01JAN2017	30NOV2017	N
			Cyst rupture	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01NOV1998	30NOV1998	N
			Colectomy	01NOV2017	30NOV2017	N
			Hysterectomy	01DEC2019	31DEC2019	N
			Tonsillectomy	01DEC1967	31DEC1967	N
	C4591001 1080 10801032	Surgical and medical procedures	Wisdom teeth removal	01APR2020	30APR2020	N
	C4591001 1080 10801033	Immune system disorders	Seasonal allergy	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1080 10801040	Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Female sterilisation	01JAN2005	31DEC2005	N
	C4591001 1080 10801041	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Ear infection	01JAN1990	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000	31DEC2011	N
			Plantar fasciitis	01JAN2014	31DEC2016	N
		Surgical and medical procedures	Ear tube insertion	01JAN1991	31DEC1991	N
			Foot operation	01JAN2016	31DEC2016	N
			Jaw operation	01JAN2001	31DEC2001	N
			Mammoplasty	01JAN2011	31DEC2011	N
	C4591001 1080 10801042	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Surgical and medical procedures	Endometriosis ablation	01AUG2018	31AUG2018	N
			Nasal septal operation	14NOV2019	14NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801043	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Eosinophilic oesophagitis	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Post-traumatic stress disorder	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1080 10801045	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Epicondylitis	01MAY2020		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Nervous system disorders	Carotid artery dissection	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1080 10801050	Cardiac disorders	Tachycardia	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Perennial allergy	01JAN2002		Y
		Infections and infestations	Tonsillitis	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2006		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
			Tonsillectomy	01FEB2017	28FEB2017	N
	C4591001 1080 10801051	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Nausea	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2006		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2000	31DEC2006	N
			Tonsillitis	01JAN2000	31DEC2006	N
		Skin and subcutaneous tissue disorders	Rosacea	01FEB2009		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1080 10801053	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2010		Y
	C4591001 1080 10801054	Nervous system disorders	Syncope	01JAN2010	31DEC2018	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1080 10801055	Infections and infestations	Infectious mononucleosis	01OCT2019	01NOV2019	N
	C4591001 1080 10801057	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
	C4591001 1080 10801058	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801059	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2020		Y
			Neck pain	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1080 10801068	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1080 10801072	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01FEB2017	31MAY2017	N
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Cancer surgery	01MAY2017	31MAY2017	N
			Thyroidectomy	01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1080 10801078	Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1080 10801079	Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1080 10801081	Investigations	Arthroscopy	01JAN1988	31DEC1988	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801082	Endocrine disorders	Hypothyroidism	01JUL2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	07MAY2020	12JUN2020	N
	C4591001 1080 10801087	Cardiac disorders	Supraventricular tachycardia	01DEC2018		Y
	C4591001 1080 10801089	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Immune system disorders	Food allergy	01JAN2000		Y
			Milk allergy	01JAN2000		Y
			Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Wisdom teeth removal	01JAN1996	31DEC1996	N
	C4591001 1080 10801092	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1080 10801096	Gastrointestinal disorders	Gastrointestinal pain	01JAN2019		Y
			Intestinal perforation	01JAN2019	31JAN2019	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Diverticulitis	01JAN2019	31JAN2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Colostomy	01JAN2019	31JAN2019	N
			Intestinal resection	01JAN2019	31JAN2019	N
			Medical device removal	01MAR2019	31MAR2019	N
			Nasal septal operation	01JAN2008	31DEC2008	N
	C4591001 1080 10801100	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1080 10801102	Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1080 10801104	Surgical and medical procedures	Ligament operation	01JAN2006	31DEC2006	N
	C4591001 1080 10801107	Infections and infestations	Brain abscess	01JAN1988	31DEC1988	N
	C4591001 1080 10801108	Infections and infestations	Pneumonia	01JAN2009	31DEC2009	N
	C4591001 1080 10801109	Injury, poisoning and procedural complications	Foot fracture	16AUG2020		Y
	C4591001 1080 10801111	General disorders and administration site conditions	Pain	01JAN2019		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2011	31DEC2012	N
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
	C4591001 1080 10801114	Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
	C4591001 1080 10801115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Gallbladder obstruction	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN1995	31DEC2015	N
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1998	31DEC1998	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Metabolic surgery	01JAN2015	31DEC2015	N
			Wrist surgery	01JAN2014	31DEC2014	N
	C4591001 1080 10801117	Immune system disorders	Seasonal allergy	01JAN1984		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01OCT2019	31OCT2019	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01FEB2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1080 10801119	Psychiatric disorders	Anxiety	01FEB2020		Y
	C4591001 1080 10801120	Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
			Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1080 10801122	Immune system disorders	Anaphylactic reaction	01JAN1996	31DEC1996	N
		Investigations	Weight decreased	01JUL2020		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2020	31AUG2020	N
		Psychiatric disorders	Anxiety	01APR2020		Y
			Attention deficit hyperactivity disorder	01JUL2020		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2019		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01AUG2020	31AUG2020	N
			Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1080 10801131	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1080 10801132	Eye disorders	Dry eye	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN1990		Y
		Investigations	Heart rate irregular	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1080 10801135	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1080 10801136	Injury, poisoning and procedural complications	Joint injury	01JAN2019	31DEC2019	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
	C4591001 1080 10801137	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2008	31DEC2008	N
			Meniscus injury	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Ankle operation	01JAN2008	31DEC2008	N
			Meniscus operation	01JAN2006	31DEC2006	N
	C4591001 1080 10801140	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
				01JAN2011		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2019		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Knee operation	01JAN1995	31DEC1995	N
	C4591001 1080 10801141	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801142	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2009	31JAN2019	N
		Social circumstances	Postmenopause	24JUL2018		Y
		Surgical and medical procedures	Bunion operation	01JAN2019	31JAN2019	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1080 10801144	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
	C4591001 1080 10801145	Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
	C4591001 1080 10801149	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Intervertebral disc protrusion	01JAN1987		Y
	C4591001 1080 10801151	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Injury, poisoning and procedural complications	Nasal injury	01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01JAN1995		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2009	31DEC2009	N
	C4591001 1080 10801153	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Sleep disorder	01JAN2016		Y
	C4591001 1080 10801155	Infections and infestations	Oral herpes	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1080 10801159	Endocrine disorders	Hypothyroidism	01MAY2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN2015	31DEC2015	N
	C4591001 1080 10801160	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01FEB2019	28FEB2019	N
	C4591001 1080 10801162	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Hernia	01JAN1983	31DEC1983	N
			Pain	01JAN2000		Y
		Infections and infestations	Ear infection	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Compartment syndrome	01APR2004	30APR2004	N
		Nervous system disorders	Carpal tunnel syndrome	01APR2020	30APR2020	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Carpal tunnel decompression	01APR2020	30APR2020	N
			Ear tube insertion	01JAN1989	31DEC1989	N
			Hernia repair	01JAN1983	31DEC1983	N
			Limb operation	01APR2004	30APR2004	N
	C4591001 1080 10801163	General disorders and administration site conditions	Pain	01JAN2000		Y
	C4591001 1080 10801179	Surgical and medical procedures	Wisdom teeth removal	13JUL2020	13JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801180	Endocrine disorders	Hypothyroidism	01AUG1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN1994		Y
		Immune system disorders	Seasonal allergy	01MAY1976		Y
		Infections and infestations	Tonsillitis	15AUG1980	15AUG1980	N
		Psychiatric disorders	Major depression	01AUG1993		Y
		Social circumstances	Menopause	02OCT2019		Y
		Surgical and medical procedures	Tonsillectomy	15AUG1980	15AUG1980	N
	C4591001 1080 10801183	Immune system disorders	Allergy to animal	01JAN2000		Y
			Drug hypersensitivity	01JAN1985		Y
			Rubber sensitivity	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1080 10801185	Ear and labyrinth disorders	Hypoacusis	01JAN2006		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Infections and infestations	Appendicitis	29APR2005	29APR2005	N
			Gastroenteritis	16DEC1999	16DEC1999	N
			Pneumonia	01JAN1983	31DEC1983	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Hypermobility syndrome	01JAN2011		Y
			Intervertebral disc degeneration	01JAN2003		Y
			Myalgia	06AUG2020		Y
			Neck pain	01JAN2003		Y
			Pain in extremity	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2003		Y
				01JAN2006		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	12SEP2015	12SEP2015	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Insomnia	01AUG2019		Y
		Reproductive system and breast disorders	Endometriosis	09JUL2020		Y
		Surgical and medical procedures	Appendectomy	29APR2005	29APR2005	N
			Caesarean section	03APR2013	03APR2013	N
			Female sterilisation	19JAN2017	19JAN2017	N
	C4591001 1080 10801187	Infections and infestations	Diverticulitis	01JAN2018	31DEC2018	N
			Oral herpes	01JAN2005		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
				01JAN2017	31DEC2017	N
	C4591001 1080 10801192	Blood and lymphatic system disorders	Anaemia	01JAN2004		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2006		Y
		Surgical and medical procedures	Gastric bypass	01JAN2008	31DEC2008	N
			Spinal fusion surgery	01JAN2012	31JAN2012	N
	C4591001 1080 10801193	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1080 10801194	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1080 10801196	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1991	31DEC1991	N
				01JAN1997	31DEC1997	N
				01JAN2015	31DEC2015	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
		Surgical and medical procedures	Ligament operation	01JAN1991	31DEC1991	N
				01JAN1997	31DEC1997	N
				01JAN2015	31DEC2015	N
	C4591001 1080 10801197	Immune system disorders	Food allergy	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2009		Y
		Vascular disorders	Hypertension	01MAR2019		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1080 10801201	Injury, poisoning and procedural complications	Muscle rupture	01JAN2011	31DEC2012	N
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
	C4591001 1080 10801202	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Psychiatric disorders	Anxiety	25JUL2020		Y
			Depression	01JAN2017		Y
	C4591001 1080 10801205	Gastrointestinal disorders	Dental caries	14SEP2017	17SEP2017	N
		Immune system disorders	Food allergy	01JAN2017		Y
		Psychiatric disorders	Mania	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Tooth extraction	17SEP2020	17SEP2020	N
	C4591001 1080 10801212	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1080 10801214	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01OCT2018	30NOV2018	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Micrographic skin surgery	01NOV2018	30NOV2018	N
				01OCT2018	31DEC2018	N
	C4591001 1080 10801219	Eye disorders	Glaucoma	01AUG2020		Y
		Injury, poisoning and procedural complications	Foreign body in eye	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Removal of foreign body from eye	01JAN2010	31DEC2010	N
	C4591001 1080 10801221	Immune system disorders	Milk allergy	01JAN2015		Y
			Seasonal allergy	01JAN2005		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01OCT2018	31OCT2018	N
		Surgical and medical procedures	Appendicectomy	01OCT2018	31OCT2018	N
	C4591001 1081 10811001	Infections and infestations	Sinusitis	10JUL2020	24JUL2020	N
	C4591001 1081 10811006	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Drug hypersensitivity	01JAN2010		Y
			Mite allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2014		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1081 10811008	Cardiac disorders	Myocardial infarction	01DEC2009	31DEC2009	N
		Hepatobiliary disorders	Cholelithiasis	01SEP2009	01SEP2009	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01APR2020		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2009		Y
		Surgical and medical procedures	Cholecystectomy	01SEP2009	01SEP2009	N
			Coronary artery bypass	01SEP2009	01SEP2009	N
		Vascular disorders	Hypertension	01DEC2009		Y
	C4591001 1081 10811009	Infections and infestations	Pneumonia	01JAN2003	31JAN2003	N
		Respiratory, thoracic and mediastinal disorders	Pleurisy	01JAN2003	31JAN2003	N
	C4591001 1081 10811010	Immune system disorders	Drug hypersensitivity	(b) (6) 1965		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1081 10811012	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Folliculitis	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
	C4591001 1081 10811018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1969		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2009		Y
			Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811020	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1081 10811023	Eye disorders	Myopia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
			Gender dysphoria	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2008		Y
	C4591001 1081 10811025	Psychiatric disorders	Bipolar disorder	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1081 10811032	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1081 10811036	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
			Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1081 10811038	Vascular disorders	Hypertension	15JUN2020		Y
	C4591001 1081 10811042	Eye disorders	Myopia	01JAN1973	01JAN2016	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Staphylococcal infection	01MAY2019	01JUN2019	N
			Tonsillitis	01JAN1972	01JAN1972	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2000	10OCT2018	N
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	01JAN2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2003	01JAN2015	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Bipolar disorder	01JAN1999		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	01JAN2015	N
			Female sterilisation	01JAN1988	01JAN1988	N
			Finger amputation	01JUN2019	01JUN2019	N
			Gastrectomy	10OCT2018	10OCT2018	N
			Hysterectomy	01JAN2010	01JAN2010	N
			Myopia correction	01JAN2016	01JAN2016	N
			Tonsillectomy	01JAN1972	01JAN1972	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1081 10811044	Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
	C4591001 1081 10811046	Eye disorders	Presbyopia	01JAN2016		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Pneumonia	01JAN2011	31DEC2014	N
				01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Osteoarthritis	01JAN2014		Y
			Spinal osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2010		Y
			Urticaria	01JAN1989		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Transfusion	01JAN1989	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1081 10811047	Eye disorders	Retinal detachment	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Retinopexy	01JAN1998	31DEC1998	N
	C4591001 1081 10811062	Injury, poisoning and procedural complications	Tendon rupture	01NOV2019	31MAY2020	N
		Surgical and medical procedures	Tenoplasty	01NOV2019	31MAY2020	N
	C4591001 1081 10811066	Blood and lymphatic system disorders	Splenomegaly	01AUG2016	31AUG2016	N
		Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Hepatic steatosis	10NOV2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	06NOV2010	06NOV2010	N
			Hysterectomy	01NOV2014	01NOV2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1081 10811067	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1081 10811071	Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Joint dislocation	28JUN2017	28JUN2017	N
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1081 10811074	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
				01JAN2016		Y
			Rubber sensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2014	31DEC2014	N
			Hysterectomy	17SEP2019	17SEP2019	N
	C4591001 1081 10811075	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1081 10811079	Eye disorders	Myopia	01JAN2000		Y
			Presbyopia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1996	31DEC1996	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
	C4591001 1081 10811081	Eye disorders	Presbyopia	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01APR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Sinus headache	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
			Skin lesion removal	01JAN1983	31DEC1983	N
			Skin neoplasm excision	01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN1990	31DEC1990	N
	C4591001 1081 10811085	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2011		Y
	C4591001 1081 10811086	Endocrine disorders	Hypothyroidism	01NOV1988		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1081 10811087	Metabolism and nutrition disorders	Dyslipidaemia	01APR2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811089	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811092	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1081 10811094	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1081 10811095	Immune system disorders	Allergic oedema	01DEC2000		Y
			Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
	C4591001 1081 10811096	Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y
	C4591001 1081 10811104	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2017		Y
	C4591001 1081 10811105	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1081 10811106	Surgical and medical procedures	Salpingectomy	01OCT2019	31OCT2019	N
	C4591001 1081 10811108	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811118	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1081 10811119	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
	C4591001 1081 10811121	Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1081 10811126	Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811127	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2005		Y
	C4591001 1081 10811130	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811131	Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1081 10811134	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
	C4591001 1081 10811141	Psychiatric disorders	Depression	01JAN2004		Y
			Post-traumatic stress disorder	01MAY2020		Y
		Surgical and medical procedures	Salpingectomy	25NOV2018	25NOV2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811143	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1081 10811145	Surgical and medical procedures	Intrauterine contraception	01DEC2018		Y
	C4591001 1081 10811148	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1081 10811160	Surgical and medical procedures Respiratory, thoracic and mediastinal disorders	Female sterilisation Asthma	01JAN2007 01JAN1994	31DEC2007	N Y
	C4591001 1081 10811164	Endocrine disorders	Hypothyroidism	01JAN2007		Y
	C4591001 1081 10811172	Psychiatric disorders Metabolism and nutrition disorders	Depression Dyslipidaemia	01JAN2017 01APR2019		Y Y
	C4591001 1081 10811186	Vascular disorders Musculoskeletal and connective tissue disorders	Type 2 diabetes mellitus Hypertension Osteoarthritis	01APR2019 01JAN2019 01JAN1998		Y Y Y
	C4591001 1081 10811187	Reproductive system and breast disorders Social circumstances	Menorrhagia Postmenopause	01JAN2014 01JAN2013	31DEC2014	N Y
	C4591001 1081 10811187	Surgical and medical procedures	Endometrial ablation Female sterilisation	01JAN2014 01JAN1990	31DEC2014 31DEC1990	N N
	C4591001 1081 10811187	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1081 10811190	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN2017		Y
			Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1081 10811192	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2016		Y
	C4591001 1081 10811193	Gastrointestinal disorders	Inguinal hernia	01JAN2013	01JAN2013	N
		Surgical and medical procedures	Hernia repair	01JAN2013	01JAN2013	N
	C4591001 1081 10811194	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1081 10811196	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 1081 10811198	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1081 10811199	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811200	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Chronic sinusitis	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Sinus operation	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1081 10811209	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	26AUG2008	26AUG2008	N
		Social circumstances	Postmenopause	01MAR2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
		Vascular disorders	Deep vein thrombosis	26AUG2008	26AUG2008	N
	C4591001 1081 10811210	Immune system disorders	Drug hypersensitivity	01FEB2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y
	C4591001 1082 10821004	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2006	31DEC2006	N
		Infections and infestations	Adenoiditis	01JAN2013	31DEC2013	N
			Tonsillitis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Depression	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1082 10821006	Gastrointestinal disorders	Tooth impacted	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Nervous system disorders	Carpal tunnel syndrome	01DEC2019	31DEC2019	N
				01MAY2020	31MAY2020	N
		Psychiatric disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Carpal tunnel decompression	01DEC2019	31DEC2019	N
				01MAY2020	31MAY2020	N
			Endometrial ablation	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2011	31DEC2011	N
			Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1082 10821008	Eye disorders	Hypermetropia	01JAN1988		Y
			Myopia	01JAN1988		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2019	31MAR2019	N
		Nervous system disorders	Migraine	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01APR2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Mastectomy	01AUG2019	31AUG2019	N
	C4591001 1082 10821009	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1082 10821011	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
	C4591001 1082 10821013	Surgical and medical procedures	Keratomileusis	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821014	Injury, poisoning and procedural complications	Joint dislocation	01JAN2006	31DEC2006	N
			Upper limb fracture	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Elbow operation	01JAN2006	31DEC2006	N
			Rhinoplasty	01JAN2017	31DEC2017	N
	C4591001 1082 10821015	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1982	31DEC1982	N
		Eye disorders	Myopia	01DEC2018	31DEC2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Caesarean section	04DEC2018	04DEC2018	N
			Keratomileusis	01DEC2018	31DEC2018	N
			Tympanoplasty	01JUL2019	31JUL2019	N
			Myopia	01JAN1982	31DEC1982	N
	C4591001 1082 10821016	Eye disorders	Myopia	01JAN1983		Y
			Presbyopia	01JAN1983		Y
		Reproductive system and breast disorders	Premenstrual syndrome	01JAN2012		Y
	C4591001 1082 10821018	Eye disorders	Myopia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Caesarean section	24JUL2016	24JUL2016	N
			Myomectomy	01JAN2011	31DEC2011	N
	C4591001 1082 10821019	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Tendon laxity	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
			Toe operation	01JAN2014	31DEC2014	N
	C4591001 1082 10821020	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Hypermetropia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Caesarean section	23APR2020	23APR2020	N
			Uterine dilation and curettage	01JAN2000	31DEC2000	N
	C4591001 1082 10821021	Eye disorders	Myopia	01JAN1978		Y
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1974	31DEC1974	N
			Synovial cyst removal	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1974	31DEC1974	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1082 10821022	Eye disorders	Hypermetropia	01JAN1991		Y
	C4591001 1082 10821023	Eye disorders	Presbyopia	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821025	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
			Insomnia	01JAN2020		Y
	C4591001 1082 10821026	Eye disorders	Hypermetropia	01JAN2020		Y
			Myopia	01JAN1982		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1082 10821027	Congenital, familial and genetic disorders	Spina bifida	01JAN1965	31DEC1965	N
		Endocrine disorders	Goitre	01JAN2017	31DEC2017	N
			Hypothyroidism	01JAN2017		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Nervous system disorders	Hydrocephalus	01JAN1965	31DEC1965	N
			Restless legs syndrome	01JAN2010		Y
			Seizure	01JAN2003	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep deficit	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Insomnia	01APR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Medical device implantation	01JAN1965	31DEC1965	N
			Spinal fusion surgery	01JAN1965	31DEC1965	N
			Thyroidectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1082 10821028	Immune system disorders	Drug hypersensitivity	15MAR1983		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01FEB1985	01FEB1985	N
		Psychiatric disorders	Anxiety	04AUG2003		Y
			Depression	04AUG2003		Y
		Surgical and medical procedures	Caesarean section	01DEC2016	01DEC2016	N
				21JUL2009	21JUL2009	N
				25MAY2012	25MAY2012	N
			Foot operation	01FEB1985	01FEB1985	N
	C4591001 1082 10821031	Eye disorders	Hypermetropia	01JAN2016		Y
			Myopia	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Dupuytren's contracture operation	01JAN2008	31DEC2008	N
	C4591001 1082 10821034	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1999	31DEC1999	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Upper limb fracture	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Limb operation	01JAN1992	31DEC1992	N
	C4591001 1082 10821035	General disorders and administration site conditions	Xerosis	01JAN2008		Y
		Infections and infestations	Sinusitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC1995	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Sinus operation	01JAN1995	31DEC1995	N
			Uterine polypectomy	01JAN2017	31DEC2017	N
	C4591001 1082 10821036	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2011		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1082 10821037	Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821038	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Gastrointestinal disorders	Oesophageal spasm	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				01JAN2015		Y
			Food allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
	C4591001 1082 10821039	Endocrine disorders	Hypothyroidism	13JUN2001		Y
		Eye disorders	Myopia	01AUG1986		Y
		General disorders and administration site conditions	Oedema	08AUG2002		Y
		Immune system disorders	Drug hypersensitivity	07APR2001		Y
		Metabolism and nutrition disorders	Obesity	06APR2018	06APR2018	N
		Psychiatric disorders	Anxiety	08AUG2002		Y
			Insomnia	08AUG2002		Y
		Reproductive system and breast disorders	Menorrhagia	23FEB2004	23FEB2004	N
		Skin and subcutaneous tissue disorders	Psoriasis	06NOV2003	06NOV2015	N
		Surgical and medical procedures	Caesarean section	07APR2001	07APR2001	N
			Gastrectomy	06APR2018	06APR2018	N
			Hysterectomy	23JUN2013	23JUN2013	N
	C4591001 1082 10821041	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1082 10821043	Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2020		Y
		Surgical and medical procedures	Caesarean section	29AUG2015	29AUG2015	N
			Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1082 10821044	Eye disorders	Astigmatism	01JAN2008		Y
	C4591001 1082 10821045	Eye disorders	Myopia	01JAN1991		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Urinary tract infection	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2019	31DEC2019	N
			Synovial cyst	01JAN1997	31DEC1997	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	12DEC2012	12DEC2012	N
				29NOV2008	29NOV2008	N
			Lymphoid tissue operation	01JAN2002	31DEC2002	N
			Salpingectomy	01JAN2012	31DEC2012	N
			Synovial cyst removal	01JAN1997	31DEC1997	N
		Vascular disorders	Lymphoedema	01JAN2002	31DEC2002	N
	C4591001 1082 10821049	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Renal and urinary disorders	Incontinence	01JAN2006	31DEC2006	N
		Social circumstances	Menopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Urinary bladder suspension	01JAN2006	31DEC2006	N
	C4591001 1082 10821053	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
	C4591001 1082 10821054	Injury, poisoning and procedural complications	Tibia fracture	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1082 10821056	Surgical and medical procedures	Bone operation	01JAN2015	31DEC2015	N
		Eye disorders	Myopia	01SEP1979		Y
		Vascular disorders	Hypertension	01APR2006		Y
	C4591001 1082 10821060	Surgical and medical procedures	Salpingectomy	01JAN2008	31DEC2008	N
	C4591001 1082 10821064	Hepatobiliary disorders	Cholecystitis	01JAN1999	31DEC1999	N
	C4591001 1082 10821065	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1082 10821067	Infections and infestations	Adenoiditis	01JAN2009	31DEC2009	N
			Tonsillitis	01JAN2009	31DEC2009	N
		Injury, poisoning and procedural complications	Concussion	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1082 10821069	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1082 10821070	Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1991	31DEC2000	N
	C4591001 1082 10821071	Investigations	Smear cervix abnormal	01JUN2015	30JUN2015	N
		Reproductive system and breast disorders	Menorrhagia	01JUN2015	30JUN2015	N
		Surgical and medical procedures	Female sterilisation	20DEC2002	20DEC2002	N
			Hysterectomy	01JUN2015	30JUN2015	N
	C4591001 1082 10821072	Eye disorders	Myopia	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC2017	N
			Ovarian cyst	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Gastrectomy	06FEB2017	06FEB2017	N
			Hysterectomy	15MAY2017	15MAY2017	N
	C4591001 1082 10821073	Eye disorders	Presbyopia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JAN1997		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Meniscus operation	01JAN2013	31DEC2013	N
	C4591001 1082 10821077	Eye disorders	Myopia	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Nervous system disorders	Convulsive threshold lowered	01JAN1998		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2002	N
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN1992		Y
		Surgical and medical procedures	Endometriosis ablation	01JAN2002	31DEC2002	N
	C4591001 1082 10821078	Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC2006	N
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1082 10821080	Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Investigations	Blood testosterone decreased	01NOV2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
		Surgical and medical procedures	Mastectomy	01JUN2015	30JUN2015	N
			Tonsillectomy	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821081	Eye disorders	Myopia	01JAN1974		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Infections and infestations	Diverticulitis	01JAN2018	31DEC2018	N
			Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Sigmoidectomy	01JAN2018	31DEC2018	N
			Synovial cyst removal	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1082 10821082	Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1082 10821083	Psychiatric disorders	Anxiety	02APR2020		Y
	C4591001 1082 10821084	Congenital, familial and genetic disorders	Pelvic kidney	(b) (6) 1977		Y
		Eye disorders	Myopia	01JAN1984		Y
		Gastrointestinal disorders	Intestinal obstruction	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Caecopexy	01JAN2018	31DEC2018	N
	C4591001 1082 10821085	Eye disorders	Myopia	01JAN2001		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1082 10821088	Injury, poisoning and procedural complications	Tendon rupture	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05MAY2020	05MAY2020	N
		Psychiatric disorders	Depression	01FEB2020		Y
		Surgical and medical procedures	Knee arthroplasty	05MAY2020	05MAY2020	N
			Tenoplasty	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1082 10821089	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Adenoiditis	01JAN1985	31DEC1985	N
			Tonsillitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1985	31DEC1985	N
			Caesarean section	28APR2008	28APR2008	N
			Tonsillectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1082 10821090	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2005	31DEC2005	N
			Tendon rupture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Spinal operation	01JAN2005	31DEC2005	N
			Tenoplasty	01JAN2011	31DEC2011	N
	C4591001 1082 10821095	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN1995		Y
		Ear and labyrinth disorders	Ear pain	01JAN2001	31DEC2001	N
		Eye disorders	Hypermetropia	01JAN1977		Y
			Myopia	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin B12 deficiency	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2011		Y
			Intervertebral disc degeneration	01JAN2018		Y
			Osteoarthritis	01JAN2017		Y
			Osteoporosis	01JAN2014		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1988	31DEC1988	N
				01JAN1994	31DEC1994	N
		Psychiatric disorders	Depression	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1988	31DEC1988	N
				01JAN1994	31DEC1994	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Gastric bypass	01JAN2003	31DEC2003	N
			Temporomandibular joint surgery	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1082 10821100	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1999		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
			Tonsillitis	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821102	Eye disorders	Hypermetropia	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Infections and infestations	Tonsillitis	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1082 10821104	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN2016		Y
		Eye disorders	Hypermetropia	01JAN2007		Y
			Myopia	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1082 10821105	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Eye disorders	Myopia	01JAN1999		Y
			Presbyopia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1997		Y
		Surgical and medical procedures	Salpingectomy	01NOV2003	30NOV2003	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821106	Surgical and medical procedures	Abdominoplasty	17JUL2019	17JUL2019	N
	C4591001 1082 10821107	Nervous system disorders	Migraine	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	27MAR2018	27MAR2018	N
			Mammoplasty	01NOV2019	30NOV2019	N
	C4591001 1082 10821109	Eye disorders	Myopia	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1082 10821111	Hepatobiliary disorders	Cholelithiasis	01APR2009	01APR2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01APR2009	01APR2009	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1082 10821113	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Eye disorders	Corneal degeneration	01JUN2019	30JUN2019	N
			Hypermetropia	01JAN1986		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1986		Y
			Drug hypersensitivity	01JAN1987		Y
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
			Tonsillitis	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
			Corneal operation	01JUN2019	30JUN2019	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Lymphadenectomy	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine dilation and curettage	01JAN2003	31DEC2003	N
	C4591001 1082 10821115	Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2003	31DEC2003	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2003	31DEC2003	N
			Mammoplasty	01JAN1995	31DEC1995	N
			Phlebectomy	01JAN2007	31DEC2007	N
	C4591001 1082 10821116	Eye disorders	Myopia	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2018	28FEB2018	N
			Squamous cell carcinoma	01FEB2018	28FEB2018	N
		Psychiatric disorders	Depression	01APR2020		Y
		Renal and urinary disorders	Incontinence	10DEC2019	10DEC2019	N
		Reproductive system and breast disorders	Menorrhagia	10DEC2019	10DEC2019	N
		Surgical and medical procedures	Cancer surgery	01FEB2018	28FEB2018	N
			Hysterectomy	10DEC2019	10DEC2019	N
			Keratomileusis	01JAN2010	31DEC2010	N
			Skin neoplasm excision	01FEB2018	28FEB2018	N
			Tonsillectomy	01JAN1974	31DEC1974	N
			Urinary bladder suspension	10DEC2019	10DEC2019	N
		Vascular disorders	Hypertension	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821120	Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Lithotripsy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1082 10821123	Eye disorders	Myopia	01JAN1987		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Menorrhagia	01MAY2016	31MAY2016	N
		Surgical and medical procedures	Fracture treatment	01JAN2019	31DEC2019	N
			Hysterectomy	01MAY2016	31MAY2016	N
			Mammoplasty	01JAN2011	31DEC2011	N
	C4591001 1082 10821127	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Ligament operation	01JAN1989	31DEC1989	N
			Vasectomy	01JAN2010		Y
	C4591001 1082 10821129	Eye disorders	Myopia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Synovial cyst removal	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821130	Ear and labyrinth disorders	Hypoacusis	01JAN1967		Y
		Eye disorders	Myopia	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Volvulus	01JAN2017	31DEC2017	N
		General disorders and administration site conditions	Hernia	01JAN1997	31DEC1997	N
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
			Herpes simplex	01JAN1972		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Colon operation	01JAN2017	31DEC2017	N
			Hernia repair	01JAN1997	31DEC1997	N
			Keratomileusis	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1082 10821136	Cardiac disorders	Mitral valve prolapse	01JAN2005		Y
		Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1965		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1082 10821139	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2007		Y
			Tobacco abuse	01JAN2016		Y
	C4591001 1082 10821140	Congenital, familial and genetic disorders	Bicuspid pulmonary valve	01JAN1985		Y
			Neurofibromatosis	01JAN1989		Y
		Eye disorders	Myopia	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Investigations	Human papilloma virus test positive	01JAN2017	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Endometrial ablation	01JAN2009	31DEC2009	N
			Mammoplasty	01MAR2019	31MAR2019	N
	C4591001 1082 10821143	Infections and infestations	Tonsillitis	01JAN1997	31DEC1997	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Restlessness	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1082 10821145	Eye disorders	Myopia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Infections and infestations	Arthritis bacterial	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Elbow operation	01JAN2012	31DEC2012	N
			Knee operation	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
			Hypothyroidism	01JAN2015		Y
	C4591001 1082 10821148	Endocrine disorders				
		Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN2014	31DEC2014	N
			Oophorectomy	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821149	Eye disorders	Presbyopia	01JAN2020		Y
		Infections and infestations	Tonsillitis	01JAN1999	31DEC1999	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Tobacco abuse	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Renal stone removal	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal fusion surgery	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1082 10821150	Skin and subcutaneous tissue disorders	Rash	03SEP2020		Y
	C4591001 1082 10821154	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2006		Y
			Colour blindness	01JAN1987		Y
		Eye disorders	Astigmatism	01JAN1987		Y
			Strabismus	01JAN1992	31DEC1992	N
					31DEC1998	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Perfume sensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2004		Y
		Surgical and medical procedures	Eye operation	01JAN1992	31DEC1992	N
				01JAN1998	31DEC1998	N
	C4591001 1082 10821156	Eye disorders	Myopia	01JAN1988		Y
		Injury, poisoning and procedural complications	Acetabulum fracture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Hip surgery	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821158	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009	31DEC2015	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Knee operation	01JAN2019	31DEC2019	N
	C4591001 1082 10821161	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Renal and urinary disorders	Urethral stenosis	01JAN2008	31DEC2008	N
				01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Urethral repair	01JAN2008	31DEC2008	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1082 10821163	Ear and labyrinth disorders	Deafness unilateral	01JAN1999		Y
		Eye disorders	Astigmatism	01JAN2005		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN1978		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Surgical and medical procedures	Ankle operation	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lithotripsy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1082 10821168	Eye disorders	Myopia	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Myalgia	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1082 10821171	Gastrointestinal disorders	Tooth impacted	01JAN2013	31DEC2013	N
		Infections and infestations	Adenoiditis	01JAN2014	31DEC2014	N
			Tonsillitis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N
			Nasal septal operation	01JAN2014	31DEC2014	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1082 10821172	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Hypermetropia	01JAN1980		Y
		Gastrointestinal disorders	Tooth impacted	01JAN1981	31JAN1981	N
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2008	31JAN2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31JAN2007	N
			Wisdom teeth removal	01JAN1981	31JAN1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wrist surgery	01JAN2008	31JAN2008	N
	C4591001 1082 10821175	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JUN2020		Y
		Gastrointestinal disorders	Pancreatitis	01JAN2005	31DEC2005	N
		Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	23SEP2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Raynaud's phenomenon	01JAN2010		Y
	C4591001 1082 10821178	Eye disorders	Myopia	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Tooth impacted	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1989		Y
		Social circumstances	Corrective lens user	01JAN1997		Y
		Surgical and medical procedures	Female sterilisation	13SEP2016	13SEP2016	N
			Micrographic skin surgery	01JAN2020	31JAN2020	N
			Skin neoplasm excision	01JAN2020	31JAN2020	N
			Wisdom teeth removal	01JAN1997	31DEC1997	N
	C4591001 1082 10821180	Eye disorders	Myopia	01JAN2012		Y
	C4591001 1082 10821183	Gastrointestinal disorders	Tooth impacted	01JAN1988	31DEC1988	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2001	31DEC2001	N
			Wrist fracture	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Vasectomy	01FEB2006	28FEB2006	N
			Wisdom teeth removal	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821185	Surgical and medical procedures	Caesarean section	11AUG2000	11AUG2000	N
	C4591001 1082 10821186	Gastrointestinal disorders	Tooth impacted	01JAN2003	31DEC2003	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
			Wisdom teeth removal	01JAN2003	31DEC2003	N
	C4591001 1082 10821187	Endocrine disorders	Hypothyroidism	01JAN2005	31DEC2005	N
		Eye disorders	Presbyopia	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015	31DEC2015	N
			Tooth impacted	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1988	31DEC1988	N
	C4591001 1082 10821188	Eye disorders	Myopia	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Hiatus hernia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Renal and urinary disorders	Hypertonic bladder	01SEP2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2004	31DEC2004	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1082 10821194	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2009		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2016		Y
		Eye disorders	Myopia	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
			Rotator cuff syndrome	01JAN2014	31DEC2014	N
			Temporomandibular joint syndrome	01JAN2018	30SEP2018	N
		Nervous system disorders	Hypersomnia	01JAN2009		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Jaw operation	01SEP2018	30SEP2018	N
			Rotator cuff repair	01JAN2014	31DEC2014	N
			Uterine dilation and curettage	01JAN2000	31DEC2000	N
			Vision correction operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1082 10821195	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN1992		Y
			Tourette's disorder	01JAN1976		Y
		Eye disorders	Myopia	01JAN1983		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
				01JAN2010		Y
			Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insulin resistance	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Attention deficit hyperactivity disorder	01MAR2019		Y
			Depression	01JAN1993		Y
			Obsessive-compulsive disorder	01JAN1993		Y
			Panic disorder	01JAN2009		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1082 10821196	Infections and infestations	Tonsillitis	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1999	31DEC1999	N
			Fibula fracture	01JAN1999	31DEC1999	N
			Tibia fracture	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Bone operation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1082 10821197	Eye disorders	Presbyopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019	31DEC2019	N
			Trigger finger	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian neoplasm	01JAN1987	31DEC1987	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Abdominal panniculectomy	01JAN2004	31DEC2004	N
			Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
			Oophorectomy bilateral	01JAN1987	31DEC1987	N
			Skin cosmetic procedure	01JAN2004	31DEC2004	N
			Tendon sheath incision	01JAN2019	31DEC2019	N
	C4591001 1082 10821198	Infections and infestations	Diverticulitis	01JUN2020	31AUG2020	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
				01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
		Surgical and medical procedures	Meniscus operation	01JAN2018	31DEC2018	N
				01JAN2020	31JAN2020	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1082 10821199	Eye disorders	Presbyopia	01JAN2013		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2018	31DEC2018	N
	C4591001 1082 10821201	Surgical and medical procedures	Inguinal hernia repair	01JAN1996	31DEC1996	N
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y
	C4591001 1082 10821202	Cardiac disorders	Cardiac failure congestive	01JAN2017	31DEC2019	N
		Eye disorders	Presbyopia	01JAN2013		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1981	31DEC1981	N
			Tooth impacted	01JAN1983	31DEC1983	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
			Tonsillitis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Duodenal switch	01JAN2019	31DEC2019	N
			Meniscus operation	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Metabolic surgery	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1981	31DEC1981	N
			Wisdom teeth removal	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2015	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821203	Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1082 10821204	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1994	31DEC1998	N
			Gilbert's syndrome	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1994		Y
		Investigations	Arthroscopy	01JAN1998	31DEC1998	N
				01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
	C4591001 1082 10821207	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Myopia	01JAN2014		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Infections and infestations	Oral herpes	01JAN2019		Y
		Investigations	Vitamin D decreased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Haematuria	01JAN1990	31DEC2018	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Ovarian cystectomy	01JAN2002	31DEC2002	N
			Thyroidectomy	01OCT2012	31OCT2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821208	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Eye disorders	Myopia	01JAN1998	31DEC2013	N
		Surgical and medical procedures	Keratomileusis	01JAN2013	31DEC2013	N
	C4591001 1082 10821210	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Presbyopia	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
			Tonsillitis	01JAN1993	31DEC1993	N
		Reproductive system and breast disorders	Adenomyosis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1972		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2009	31DEC2009	N
			Appendicectomy	01JAN1989	31DEC1989	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2009	31DEC2009	N
			Sinus operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1082 10821211	Gastrointestinal disorders	Diarrhoea	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Chlamydial infection	01JAN2019	31DEC2019	N
			Papilloma viral infection	15SEP2020		Y
			Tonsillitis	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2019		Y
			Post-traumatic stress disorder	01JAN2019		Y
		Reproductive system and breast disorders	Varicocele	01JAN2016	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Varicocele repair	01JAN2017	31DEC2017	N
	C4591001 1082 10821212	Eye disorders	Myopia	01JAN1993		Y
		Infections and infestations	Tonsillitis	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1082 10821215	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01NOV2013	01NOV2013	N
				15MAR2011	15MAY2011	N
			Large intestinal polypectomy	01FEB2017	28FEB2017	N
			Mammoplasty	01JAN2020	01JAN2020	N
			Salpingectomy	01JAN2013	31DEC2013	N
	C4591001 1082 10821216	Eye disorders	Myopia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015		Y
			Intervertebral disc degeneration	01JAN2005		Y
			Rotator cuff syndrome	01JAN2005	31DEC2015	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1996	31DEC2007	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Shoulder arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1082 10821217	Endocrine disorders	Goitre	01JAN2012	31DEC2012	N
			Hypothyroidism	01JAN2012		Y
		Eye disorders	Myopia	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Tonsillitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Endometrial ablation	01MAY2020	31MAY2020	N
			Mammoplasty	01JAN1999	31DEC1999	N
			Rhinoplasty	01JAN2008	31DEC2008	N
			Salpingectomy	01JAN2011	31DEC2011	N
			Thyroidectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1082 10821218	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN2008	31DEC2008	N
			Ligament rupture	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Knee operation	01JAN2008	31DEC2008	N
				01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821220	Gastrointestinal disorders	Tooth impacted	01JAN1996	31DEC1996	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1996	31DEC1996	N
	C4591001 1082 10821221	Eye disorders	Myopia	01JAN1983		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2003	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	16OCT2020		Y
		Surgical and medical procedures	Endometriosis ablation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1082 10821224	Congenital, familial and genetic disorders	Cryptorchism	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1083 10831001	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1083 10831002	Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Psychiatric disorders	Panic attack	01JAN2019		Y
	C4591001 1083 10831004	Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2015		Y
		Psychiatric disorders	Alcoholism	01JAN1980	17OCT2019	N
			Anxiety	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2007		Y
		Social circumstances	Menopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831005	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1083 10831006	Gastrointestinal disorders	Dyspepsia	01JAN2017	31DEC2017	N
			Gastrooesophageal reflux disease	01JAN2017	31DEC2017	N
			Mouth ulceration	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Nervous system disorders	Headache	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Social circumstances	Ex-tobacco user	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Female sterilisation	25AUG2017	25AUG2017	N
	C4591001 1083 10831007	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2006		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Genital herpes	01JAN2005		Y
			Oral herpes	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2016		Y
	C4591001 1083 10831009	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	01MAY2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermal cyst	01FEB2020		Y
		Surgical and medical procedures	Hysterectomy	01MAY2017	01MAY2017	N
	C4591001 1083 10831011	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1083 10831013	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUN2020		Y
	C4591001 1083 10831015	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2018		Y
			Hiatus hernia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2002		Y
	C4591001 1083 10831017	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1996		Y
	C4591001 1083 10831018	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005		Y
		Vascular disorders	Hot flush	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831020	Gastrointestinal disorders	Inguinal hernia	01JAN2002	31DEC2002	N
	C4591001 1083 10831025	Immune system disorders	Food allergy	01JAN2000		Y
			Rubber sensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2016		Y
	C4591001 1083 10831026	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1083 10831029	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Allergy to plants	01JAN2013		Y
		Infections and infestations	Chronic sinusitis	01JAN1990	31DEC2011	N
			Tonsillitis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2002	31DEC2003	N
			Headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2003	31DEC2003	N
			Sinuplasty	01JAN2011	31DEC2011	N
	C4591001 1083 10831032	Immune system disorders	Food allergy	01JAN2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Obesity	01JAN1996		Y
			Type 1 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Post-traumatic stress disorder	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1083 10831033	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2020		Y
	C4591001 1083 10831034	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1083 10831040	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831043	Metabolism and nutrition disorders	Obesity	01JAN1985		Y
	C4591001 1083 10831044	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1994		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831045	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Post procedural sepsis	01DEC2018	31DEC2018	N
			Septic shock	01DEC2018	31DEC2018	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
		Surgical and medical procedures	Gastric banding	01JAN2010	31DEC2010	N
			Gastric operation	30NOV2018	30NOV2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Thrombosis	01JAN2018	31DEC2018	N
	C4591001 1083 10831046	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Food allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
	C4591001 1083 10831047	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Hepatitis A	01JAN1992	31DEC1992	N
			Herpes simplex	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831052	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1083 10831054	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2020	14FEB2020	N
			Rhinitis allergic	01JAN1983		Y
		Surgical and medical procedures	Nasal septal operation	14FEB2020	14FEB2020	N
	C4591001 1083 10831055	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Alcoholism	01JAN2001	31DEC2014	N
			Depression	01JAN2008	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1083 10831057	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Diverticulitis	01AUG2019		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1083 10831060	Gastrointestinal disorders	Abdominal pain upper	03AUG2020		Y
			Umbilical hernia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2013	31DEC2013	N
				01MAR2018	31MAR2018	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
		Surgical and medical procedures	Tenoplasty	01JAN2013	31DEC2013	N
				01MAR2018	31MAR2018	N
	C4591001 1083 10831061	Reproductive system and breast disorders	Polycystic ovaries	01AUG2019	23OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	23OCT2019	23OCT2019	N
	C4591001 1083 10831062	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Generalised anxiety disorder	01JAN2015		Y
			Insomnia	01JAN2015		Y
	C4591001 1083 10831065	Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2001		Y
	C4591001 1083 10831067	Immune system disorders	Seasonal allergy	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1083 10831068	Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005		Y
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1083 10831069	Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Gastrectomy	01JAN2013	31DEC2013	N
	C4591001 1083 10831070	Immune system disorders	Food allergy	01JAN2002		Y
		Nervous system disorders	Headache	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1994		Y
	C4591001 1083 10831074	Infections and infestations	Gastroenteritis	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01DEC2018		Y
	C4591001 1083 10831078	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831081	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01MAR2017	31MAR2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1083 10831082	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1083 10831083	Eye disorders	Lacrimal disorder	01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Lacrimal gland operation	01JAN2018	31DEC2018	N
	C4591001 1083 10831084	Injury, poisoning and procedural complications	Epicondylitis	01JAN2019		Y
	C4591001 1083 10831086	Injury, poisoning and procedural complications	Joint dislocation	01JAN2018	19JUN2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Joint dislocation reduction	10JUL2017	10JUL2017	N
	C4591001 1083 10831091	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JUL2019	31JUL2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	20OCT2019		Y
		Social circumstances	Menopause	01MAY2020		Y
		Surgical and medical procedures	Ligament operation	01JUL2019	31JUL2019	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1083 10831093	Renal and urinary disorders	Nephrolithiasis	01JAN2020	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1083 10831094	Psychiatric disorders	Insomnia	01JAN2011		Y
			Obsessive-compulsive disorder	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1083 10831098	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Surgical and medical procedures	Caesarean section	01DEC2018		Y
	C4591001 1083 10831099	Metabolism and nutrition disorders	Lactose intolerance	01JAN2003		Y
	C4591001 1083 10831101	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1083 10831102	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1083 10831105	Skin and subcutaneous tissue disorders	Acne	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831106	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1083 10831112	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Panic attack	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
			Eczema	01JAN2005		Y
	C4591001 1083 10831113	Gastrointestinal disorders	Peritoneal cyst	01NOV2018	09NOV2019	N
		Surgical and medical procedures	Cyst removal	09NOV2018	09NOV2018	N
	C4591001 1083 10831118	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1989		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2017	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cervicectomy	01JAN2010	31DEC2010	N
	C4591001 1083 10831119	Gastrointestinal disorders	Dyspepsia	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831122	Ear and labyrinth disorders	Hypoacusis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Eustachian tube operation	01JAN1990	31DEC1990	N
			Renal stone removal	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1083 10831124	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1083 10831127	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1083 10831128	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Genital herpes	01JAN1992		Y
		Injury, poisoning and procedural complications	Radius fracture	01MAY2017	31MAY2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Bipolar II disorder	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Rhinitis allergic	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01AUG2015	31DEC2020	N
				17MAY2020		Y
	C4591001 1083 10831130	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
	C4591001 1083 10831132	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1083 10831133	Immune system disorders	Allergy to animal	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1083 10831136	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1083 10831139	Immune system disorders	Seasonal allergy	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831140	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
	C4591001 1083 10831141	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1083 10831142	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Psychiatric disorders	Panic attack	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1083 10831143	Eye disorders	Cataract	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
	C4591001 1083 10831145	Infections and infestations	Tonsillitis	01JAN2019	31JAN2020	N
		Nervous system disorders	Headache	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Social circumstances	Electronic cigarette user	01JAN2015		Y
			Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2020	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01JAN2020	31JAN2020	N
	C4591001 1083 10831148	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1083 10831152	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Allergy to metals	01JAN2006		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Bronchitis	01MAR2020	31MAR2020	N
			Herpes simplex	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1999		Y
		Surgical and medical procedures	Sesamoidectomy	01JUL2019	31JUL2019	N
	C4591001 1083 10831153	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1083 10831154	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1083 10831160	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1083 10831161	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Obesity	01MAY2020		Y
	C4591001 1083 10831162	Gastrointestinal disorders	Abdominal pain upper	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN1993		Y
		Nervous system disorders	Headache	01JAN2005	31DEC2005	N
			Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2003		Y
	C4591001 1083 10831163	Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
	C4591001 1083 10831164	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN1983		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
	C4591001 1083 10831166	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	27JUL2018	27JUL2018	N
	C4591001 1083 10831169	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Intervertebral disc protrusion	01JAN2008	31DEC2009	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Gastrectomy	01JUL2019		Y
			Intervertebral disc operation	01FEB2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831170	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2002		Y
		Immune system disorders	Allergy to surgical sutures	01JAN1976		Y
			Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Headache	01JAN1993		Y
			Migraine	01JAN1993		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1083 10831171	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1083 10831174	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1083 10831178	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1083 10831179	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Reaction to food additive	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Arthropod bite	01JAN2005	31DEC2005	N
			Lower limb fracture	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Knee operation	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wound treatment	01JAN2005	31JAN2005	N
	C4591001 1083 10831181	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Infections and infestations	Urinary tract infection	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2018		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2019	31DEC2019	N
			Hypertonic bladder	01JUL2020		Y
		Surgical and medical procedures	Urinary bladder suspension	01JAN2019	31DEC2019	N
	C4591001 1083 10831183	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Investigations	Precancerous cells present	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
			Osteoarthritis	01JAN1997		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2004	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1083 10831185	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1083 10831186	Surgical and medical procedures	Hysterectomy	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Oesophagitis	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN1997		Y
				01JAN2013		Y
			Seasonal allergy	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal hamartoma	01JAN2010		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2020	31JAN2020	N
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1083 10831187	Surgical and medical procedures	Uterine polypectomy	01JAN2020	31JAN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1083 10831188	Endocrine disorders	Hypogonadism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831191	Gastrointestinal disorders	Dyspepsia	01SEP2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1083 10831194	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1083 10831197	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1083 10831198	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Vaginal infection	01JUN2020		Y
		Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1083 10831201	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2003		Y
		Surgical and medical procedures	Mole excision	01MAR2020	31MAR2020	N
	C4591001 1083 10831203	Gastrointestinal disorders	Dyspepsia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN2002		Y
		Surgical and medical procedures	Vasectomy	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1083 10831205	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1083 10831207	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Nervous system disorders	Headache	01JAN1989		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01MAY2020		Y
	C4591001 1083 10831210	Investigations	Blood testosterone decreased	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1083 10831212	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Panic attack	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Perioral dermatitis	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014		Y
	C4591001 1083 10831214	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1986		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2007	31JAN2007	N
		Social circumstances	Menopause	01JAN2017		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1083 10831219	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1083 10831221	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
	C4591001 1083 10831222	Cardiac disorders	Supraventricular tachycardia	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
			Irritable bowel syndrome	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1083 10831223	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1083 10831227	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831232	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1968		Y
		Infections and infestations	Herpes simplex	01JAN2018		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1979		Y
	C4591001 1083 10831235	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Bipolar I disorder	01JAN2000		Y
			Insomnia	01JAN2000		Y
	C4591001 1083 10831240	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
		Social circumstances	Ex-tobacco user	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Fracture treatment	01JAN2017	31DEC2017	N
	C4591001 1083 10831241	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Panic attack	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1083 10831244	Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831245	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1083 10831247	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1083 10831249	Congenital, familial and genetic disorders	Naevus flammeus	(b) (6) 1982		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2014		Y
			Temporomandibular joint syndrome	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Surgical and medical procedures	Temporomandibular joint surgery	01JAN2016	31DEC2016	N
	C4591001 1083 10831250	Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
	C4591001 1083 10831252	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1083 10831253	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1083 10831254	Immune system disorders	Drug hypersensitivity	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831255	Gastrointestinal disorders	Dental caries	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Tooth infection	03SEP2020	11SEP2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JUN2018	31DEC2018	N
	C4591001 1083 10831256	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2011		Y
		Surgical and medical procedures	Liposuction	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1083 10831259	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
			Obesity	01JAN1998		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1083 10831262	Congenital, familial and genetic disorders	Cerebral palsy	01JAN1983		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2014		Y
			Food allergy	01JAN1999		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010		Y
			Mycotic allergy	01JAN1983		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
		Surgical and medical procedures	Caesarean section	26JUL2018	26JUL2018	N
	C4591001 1083 10831264	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
	C4591001 1083 10831265	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
	C4591001 1083 10831266	Immune system disorders	Food allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Rhinitis allergic	01JAN1980		Y
	C4591001 1083 10831267	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1083 10831268	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831270	Immune system disorders	Food allergy	01JAN2004		Y
			Rubber sensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	04APR2020		Y
			Depression	04APR2020		Y
			Insomnia	04APR2020		Y
			Panic attack	04APR2020		Y
	C4591001 1083 10831271	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019		Y
	C4591001 1083 10831272	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1083 10831273	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Umbilical hernia repair	21SEP2020	21SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831276	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993		Y
			Dermatitis contact	01JAN2001		Y
	C4591001 1083 10831278	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2020	31JAN2020	N
				17OCT2017	17OCT2017	N
			Intra-uterine contraceptive device insertion	01FEB2020		Y
			Uterine dilation and curettage	01JAN2019	31DEC2019	N
	C4591001 1083 10831279	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1083 10831281	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Headache	01JAN1979		Y
		Social circumstances	Menopause	01APR2017		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1083 10831282	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2018		Y
			Rhinitis allergic	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831284	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Mouth ulceration	01JAN1975		Y
		Immune system disorders	Food allergy	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Postmenopause	01APR2019		Y
	C4591001 1084 10841001	Immune system disorders	Drug hypersensitivity	01FEB1989		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Tonsillitis	01MAR1990	31MAR1990	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Foot deformity	01MAR2009	31MAR2009	N
			Scoliosis	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	01MAR2009	31MAR2009	N
			Tonsillectomy	01MAR1990	31MAR1990	N
	C4591001 1084 10841003	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1084 10841004	Eye disorders	Visual acuity reduced	01JAN1991	31DEC2010	N
	C4591001 1084 10841008	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Otitis media	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Ear tube insertion	01JAN1985	31DEC1985	N
	C4591001 1084 10841009	Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Removal of foreign body	01JAN2008	31DEC2008	N
	C4591001 1084 10841012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Iodine allergy	01JAN2012		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	19MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1084 10841013	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2002		Y
	C4591001 1084 10841014	Eye disorders	Visual acuity reduced	01JAN2003		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Contact lens therapy	01JAN2019	31JAN2019	N
	C4591001 1084 10841015	Eye disorders	Visual acuity reduced	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Headache	01APR2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hernia repair	01JAN2006	31DEC2006	N
	C4591001 1084 10841016	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1084 10841017	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
	C4591001 1084 10841018	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2013		Y
		Infections and infestations	Genital herpes	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
		Reproductive system and breast disorders	Breast swelling	01JAN2005	31DEC2005	N
			Erectile dysfunction	01MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Adenoidectomy	01JAN1986	31DEC1986	N
			Benign breast lump removal	01JAN2005	31DEC2005	N
			Spinal nerve stimulator implantation	01JAN2019	31DEC2019	N
	C4591001 1084 10841023	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Rubber sensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1982		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2015	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1084 10841029	Eye disorders	Visual acuity reduced	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Investigations	Endoscopy	01JAN2016	31DEC2016	N
	C4591001 1084 10841031	Eye disorders	Myopia	01NOV2018		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01NOV2019		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
			Hyperhidrosis	01MAY2020		Y
		Surgical and medical procedures	Contraceptive implant	01NOV2018		Y
			Synovial cyst removal	01JAN2009	31DEC2009	N
	C4591001 1084 10841033	Immune system disorders	Drug hypersensitivity	(b) (6) 1985		Y
			Hypersensitivity	01JAN1991		Y
		Infections and infestations	Appendicitis	24MAY2019	24MAY2019	N
		Surgical and medical procedures	Appendicectomy	24MAY2019	24MAY2019	N
	C4591001 1084 10841035	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to plants	01JAN2010		Y
			Mycotic allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01APR2019		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1084 10841036	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Nervous system disorders	Headache	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN2005	31DEC2007	N
				01JAN2015	31DEC2017	N
			Depression	01JAN2005	31DEC2007	N
				01JAN2015	31DEC2017	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1084 10841038	Eye disorders	Myopia	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841041	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Human papilloma virus test positive	01JAN1992	31DEC1992	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Reproductive system and breast disorders	Premenstrual syndrome	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
			Sinus congestion	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
			Cervix cryotherapy	01JAN1992	31DEC1992	N
	C4591001 1084 10841042	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012		Y
	C4591001 1084 10841044	Cardiac disorders	Palpitations	01JAN2018		Y
		Eye disorders	Visual acuity reduced	01JAN2004		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01MAR2008	31MAR2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
			Bipolar I disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01MAR2008	31MAR2008	N
	C4591001 1084 10841047	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1084 10841054	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Investigations	Cardiac murmur	01JAN1985		Y
			Hepatic enzyme increased	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JUL2019	31DEC2019	N
			Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	26JUN2006	26JUN2006	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Bunion operation	01DEC2019	31DEC2019	N
				01JUL2019	31DEC2019	N
			Nasal septal operation	26JUN2020	26JUN2020	N
			Thyroidectomy	01OCT2006	31OCT2006	N
	C4591001 1084 10841055	Gastrointestinal disorders	Constipation	01JAN1996		Y
		Infections and infestations	Tuberculosis	01MAY2016	31MAY2016	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2004	31DEC2006	N
		Psychiatric disorders	Insomnia	01AUG2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841056	Eye disorders	Visual acuity reduced	01JAN1997		Y
		Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1084 10841057	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Tonsillitis	01JAN2002	31DEC2002	N
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	12FEB1992	12FEB1992	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1084 10841058	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1084 10841059	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Infections and infestations	Herpes virus infection	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1084 10841060	Gastrointestinal disorders	Diverticulum	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988	31DEC1998	N
			Rhinitis allergic	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841061	Ear and labyrinth disorders	Meniere's disease	01JAN1998		Y
			Vertigo	01JAN1998	31DEC2019	N
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2000	31DEC2000	N
		Hepatobiliary disorders	Cholecystitis	01JAN2004	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1977	31DEC1977	N
			Wrist fracture	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1998	31DEC1998	N
				01JAN2004	31DEC2004	N
		Nervous system disorders	Headache	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1998	31DEC1998	N
		Skin and subcutaneous tissue disorders	Peau d'orange	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Skin neoplasm excision	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1992	31DEC1992	N
			Uterine dilation and curettage	01JAN1998	31DEC1998	N
	C4591001 1084 10841062	Eye disorders	Visual acuity reduced	01JAN2002		Y
		Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Bipolar disorder	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2020		Y
	C4591001 1084 10841064	Eye disorders	Retinal tear	01JAN2013	31DEC2013	N
			Visual acuity reduced	01JAN1990	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1987	31DEC1987	N
			Tonsillar hypertrophy	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Adenoidectomy	01JAN1987	31DEC1987	N
			Keratomileusis	01JAN2014	31DEC2014	N
			Retinal operation	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1084 10841066	Eye disorders	Visual acuity reduced	01JAN2002		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1994	31DEC1994	N
			Radius fracture	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
			Sinus congestion	01JAN1992		Y
	C4591001 1084 10841068	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1084 10841069	Eye disorders	Visual acuity reduced	01JAN2011		Y
	C4591001 1084 10841071	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1084 10841073	Eye disorders	Visual acuity reduced	01JAN1992		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Depression	01SEP2016		Y
			Insomnia	01JAN2016		Y
	C4591001 1084 10841076	Eye disorders	Visual acuity reduced	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Allergy to animal	01JAN1986		Y
				01JAN1995		Y
			Allergy to plants	01JAN1975		Y
			Drug hypersensitivity	01JAN1998		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2012	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1997		Y	
			Spinal osteoarthritis	01JAN2002		Y	
			Spinal stenosis	01JAN2017		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N	
		Reproductive system and breast disorders	Ovarian cyst	01JAN2010	31DEC2010	N	
		Surgical and medical procedures	Bone debridement	01JAN2002	31DEC2002	N	
			Hysterectomy	01JAN2010	31DEC2010	N	
			Spinal fusion surgery	01JAN2002	31DEC2002	N	
				01JAN2011	31DEC2011	N	
				Spinal operation	01JAN2006	31DEC2006	N
				01JAN2012	31DEC2012	N	
			Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2018		Y	
	C4591001 1084 10841079	Eye disorders	Visual acuity reduced	01JAN1984		Y	
		Injury, poisoning and procedural complications	Radius fracture	01JAN1991	31DEC1992	N	
			Wrist fracture	01JAN1980	31DEC1980	N	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ganglioneuroblastoma	01JAN1977	31DEC1977	N	
		Psychiatric disorders	Bipolar II disorder	01JAN2000		Y	
			Depression	01JAN2000	31DEC2010	N	
			Insomnia	01JAN2020		Y	
		Renal and urinary disorders	Nephrolithiasis	01JAN2020	31JAN2020	N	
		Reproductive system and breast disorders	Prostatitis	03AUG2020		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1084 10841081	Eye disorders	Visual acuity reduced	01JAN2005		Y
		Gastrointestinal disorders	Abdominal hernia	01MAY2019	31MAY2019	N
			Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes zoster	01DEC2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Abdominal hernia repair	01MAY2019	31MAY2019	N
	C4591001 1084 10841082	Eye disorders	Visual acuity reduced	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1084 10841083	Eye disorders	Visual acuity reduced	01JAN2012		Y
		Hepatobiliary disorders	Hepatic cirrhosis	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	31JUL2020		Y
		Psychiatric disorders	Insomnia	01JAN1997		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2002		Y
	C4591001 1084 10841084	Nervous system disorders	Headache	01JAN1999		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Menorrhagia	01JAN2011		Y
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1084 10841085	Eye disorders	Visual acuity reduced	01JAN1991		Y
		Gastrointestinal disorders	Constipation	01JAN2010	31DEC2018	N
			Haemorrhoids	01JAN2018	31DEC2018	N
		Infections and infestations	Bronchitis	01MAR2020	31MAR2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01DEC2017		Y
			Sinus congestion	01DEC2017		Y
	C4591001 1084 10841087	Vascular disorders	Hypertension	01JAN2011		Y
		Eye disorders	Visual acuity reduced	01JAN1999		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Intervertebral disc protrusion	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985	31DEC1986	N
		Skin and subcutaneous tissue disorders	Dermal cyst	28DEC2019	28DEC2019	N
		Surgical and medical procedures	Limb operation	28DEC2019	28DEC2019	N
			Spinal operation	09AUG2019	09AUG2019	N
	C4591001 1084 10841089	Eye disorders	Visual acuity reduced	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841091	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019	31DEC2019	N
	C4591001 1084 10841092	Eye disorders	Visual acuity reduced	01JAN2019		Y
	C4591001 1084 10841095	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
			Traumatic renal injury	01JAN1981	31DEC1981	N
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	10JUN2005	10JUN2005	N
			Ligament operation	01JAN2011	31DEC2011	N
	C4591001 1084 10841097	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Sternal fracture	01JAN2001	31DEC2001	N
	C4591001 1084 10841098	Eye disorders	Visual acuity reduced	01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	09AUG2017	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2013	09AUG2017	N
		Surgical and medical procedures	Hysterectomy	09AUG2017	09AUG2017	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841099	Ear and labyrinth disorders	Deafness unilateral	01JAN1985		Y
			Ear disorder	01JAN1985		Y
		Eye disorders	Visual acuity reduced	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2003	24JUN2020	N
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
	C4591001 1084 10841100	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2011		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1991	31DEC1991	N
			Asthma	01JAN1981		Y
			Tonsillar hypertrophy	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Adenoidectomy	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1991	31DEC1991	N
			Vasectomy	01APR2020	30APR2020	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1084 10841101	Eye disorders	Myopia	01DEC2019		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2010	31DEC2010	N
			Wrist fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841102	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of lung	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1084 10841104	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1084 10841107	Eye disorders	Visual acuity reduced	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Haemorrhoids	01JAN2010		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Traumatic lung injury	01JAN1985	31DEC1985	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1996		Y
			Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
	C4591001 1084 10841111	Eye disorders	Visual acuity reduced	01JAN1982		Y
	C4591001 1084 10841113	Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN1999	31DEC1999	N
	C4591001 1084 10841114	Injury, poisoning and procedural complications	Ligament rupture	01JAN1985	31DEC1985	N
				01JAN1988	31DEC1988	N
				01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
	C4591001 1084 10841115	Eye disorders	Visual acuity reduced	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1990		Y
			Tonsillitis	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Foot deformity	01JAN2015	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973	31DEC1981	N
			Bronchitis chronic	01JAN1989	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1084 10841117	Eye disorders	Myopia	01JAN2006		Y
		Infections and infestations	Appendicitis	01MAR2019	31MAR2019	N
		Injury, poisoning and procedural complications	Fibula fracture	01APR2018	30APR2018	N
		Surgical and medical procedures	Appendectomy	01MAR2019	31MAR2019	N
	C4591001 1084 10841118	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Eye disorders	Visual acuity reduced	01JAN1999		Y
		Immune system disorders	Hypersensitivity	01JAN2013		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Shoulder operation	01JAN2017	31DEC2017	N
	C4591001 1084 10841119	Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1084 10841120	Eye disorders	Visual acuity reduced	01JAN1991		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Solar lentigo	01JAN2015	30JUN2020	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Muscle operation	01JAN2019	31DEC2019	N
			Shoulder operation	01JAN2019	31DEC2019	N
	C4591001 1084 10841121	Eye disorders	Visual acuity reduced	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Premature ejaculation	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Nasal operation	01JAN2000	31DEC2000	N
	C4591001 1084 10841122	Eye disorders	Visual acuity reduced	01JAN1984		Y
		Immune system disorders	Seasonal allergy	01MAR2020		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015		Y
		Surgical and medical procedures	Tenoplasty	01JAN2012	31DEC2012	N
	C4591001 1084 10841123	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Chronic sinusitis	01JAN2015		Y
			Staphylococcal infection	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1995		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Oophorectomy bilateral	01JAN2011	31DEC2011	N
			Sinus operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1084 10841129	Eye disorders	Myopia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
	C4591001 1084 10841136	Eye disorders	Visual acuity reduced	01JAN1990		Y
		Gastrointestinal disorders	Crohn's disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fistula	01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	02JUN2008	02JUN2008	N
				09DEC2010	09DEC2010	N
			Fistula repair	01JAN2016	31DEC2016	N
	C4591001 1084 10841137	Eye disorders	Visual acuity reduced	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
			Endometriosis	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993		Y
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841138	Endocrine disorders	Hypothyroidism	01SEP2019		Y
	C4591001 1084 10841141	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN2000		Y
		Hepatobiliary disorders	Biliary tract disorder	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tinea pedis	01JAN1980		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2004	31DEC2004	N
		Investigations	Colonoscopy	01JAN2013	31DEC2013	N
				01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Prostatitis	01OCT2017	31OCT2017	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
			Dry skin	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1084 10841146	Ear and labyrinth disorders	Tinnitus	01JAN2006		Y
		Eye disorders	Visual acuity reduced	01MAY1996		Y
		Hepatobiliary disorders	Biliary colic	01NOV2017	30NOV2017	N
		Surgical and medical procedures	Cholecystectomy	01NOV2017	31DEC2017	N
	C4591001 1084 10841148	Immune system disorders	Hypersensitivity	01JAN2010		Y
	C4591001 1084 10841154	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Transfusion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1084 10841155	Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1084 10841156	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Social circumstances	Postmenopause	01SEP2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084 10841159	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Visual acuity reduced	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2004	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1084 10841163	Eye disorders	Visual acuity reduced	01JAN2005		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01MAY2019		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
			Snoring	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1977	31DEC1977	N
			Uvulopalatopharyngoplasty	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1084 10841164	Eye disorders	Visual acuity reduced	01JAN1996		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1084 10841170	Eye disorders	Visual acuity reduced	01JAN1986		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01JAN2005		Y
			Neuralgia	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1995	31DEC1995	N
			Hernia repair	01JAN2015	31DEC2015	N
			Spinal operation	01JAN2009	31DEC2009	N
			Strabismus correction	01JAN1983	31DEC1994	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1084 10841181	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Acquired oesophageal web	01JAN2014		Y
			Anal fissure	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1994		Y
		Investigations	Colonoscopy	01JUN2016	30JUN2016	N
		Surgical and medical procedures	Lipoma excision	01AUG2017	31AUG2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1084 10841182	Eye disorders	Visual acuity reduced	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2005		Y
			Seasonal allergy	01JAN1979		Y
		Infections and infestations	Pneumonia	01JUN2018	31JUL2018	N
		Investigations	Colonoscopy	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1991	31DEC1992	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2018		Y
		Social circumstances	Postmenopause	01AUG2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
			Ovarian cystectomy	01JAN1992	31DEC1992	N
				01JUL2018	31JUL2018	N
	C4591001 1084 10841185	Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1084 10841186	Eye disorders	Astigmatism	01JAN2003		Y
			Visual acuity reduced	01JAN1989		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2009		Y
		Hepatobiliary disorders	Cholelithiasis	01OCT2018	31OCT2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1992		Y
		Nervous system disorders	Headache	01JAN1994		Y
		Reproductive system and breast disorders	Endometriosis	01DEC2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
			Nasal septum deviation	01JAN2016	31MAY2017	N
		Surgical and medical procedures	Cholecystectomy	01OCT2018	31OCT2018	N
			Endometrial ablation	01DEC2011	31DEC2011	N
			Rhinoplasty	01MAY2017	31MAY2017	N
	C4591001 1084 10841187	Eye disorders	Visual acuity reduced	01JAN1998		Y
		Infections and infestations	Urinary tract infection	01JAN2015		Y
		Injury, poisoning and procedural complications	Scar	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Psychiatric disorders	Insomnia	01JAN2004		Y
	C4591001 1084 10841188	Skin and subcutaneous tissue disorders	Acne	01JAN2003		Y
		Eye disorders	Visual acuity reduced	01JAN2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01NOV2016	30NOV2016	N
		Nervous system disorders	Migraine	01JAN1987		Y
		Skin and subcutaneous tissue disorders	Rosacea	01AUG2020		Y
		Surgical and medical procedures	Knee operation	01NOV2016	30NOV2016	N
			Nephrectomy	01JUL2019	31JUL2019	N
	C4591001 1084 10841189	Eye disorders	Visual acuity reduced	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841197	Eye disorders	Visual acuity reduced	01JAN1996		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1991	31DEC1991	N
		Psychiatric disorders	Depression	01JAN2016	31DEC2018	N
			Post-traumatic stress disorder	01JAN1991		Y
		Reproductive system and breast disorders	Polycystic ovaries	01DEC2019		Y
		Surgical and medical procedures	Fracture treatment	01JAN1991	31DEC1991	N
	C4591001 1084 10841199	Metabolism and nutrition disorders	Obesity	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Metabolic surgery	01NOV2019	30NOV2019	N
	C4591001 1084 10841200	Eye disorders	Visual acuity reduced	01JAN1997		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01SEP2019		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2011		Y
		Social circumstances	Postmenopause	01NOV2018		Y
	C4591001 1084 10841201	Injury, poisoning and procedural complications	Bladder injury	01JAN2009	31DEC2009	N
			Gastrointestinal injury	01JAN2009	31DEC2009	N
			Head injury	01JAN2009	31DEC2009	N
			Limb injury	01JAN2009	31DEC2009	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Bladder repair	01JAN2009	31DEC2009	N
			Cranial operation	01JAN2009	31DEC2009	N
			Gastric operation	01JAN2009	31DEC2009	N
			Limb operation	01JAN2009	31DEC2009	N
			Vascular disorders	Hypertension	14JUN2013	
	C4591001 1084 10841208	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Onychomycosis	01JUL2020		Y
			Otitis media	01JAN1991	31DEC1991	N
			Nervous system disorders	Migraine	01JAN2004	
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1991	31DEC1991	N
			Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1084 10841209		Eye disorders	Myopia	01JAN2013	
		Hepatobiliary disorders	Gallbladder oedema	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Gastrectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1084 10841214		Eye disorders	Visual acuity reduced	01JAN2002	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
	C4591001 1084 10841215	Eye disorders	Myopia	01JAN1987		Y
	C4591001 1084 10841220	Eye disorders	Visual acuity reduced	01JAN1986		Y
		Infections and infestations	Appendicitis perforated	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Small intestinal resection	01JAN1994	31DEC1994	N
	C4591001 1084 10841222	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1084 10841223	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN1998		Y
		Infections and infestations	Rhinitis	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Keratomeleusis	01JAN2002	31DEC2002	N
			Rotator cuff repair	01JAN1995	31DEC1995	N
	C4591001 1084 10841228	Eye disorders	Visual acuity reduced	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN2007	31DEC2007	N
	C4591001 1084 10841234	Eye disorders	Visual acuity reduced	01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 1 diabetes mellitus	04MAR1989		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2020		Y
		Surgical and medical procedures	Strabismus correction	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1084 10841241	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Staphylococcal infection	25JUN2020	15JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01NOV2019	30NOV2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Gastrectomy	01SEP2016	30SEP2016	N
			Tonsillectomy	01NOV2019	30NOV2019	N
	C4591001 1084 10841249	Eye disorders	Visual acuity reduced	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Tonsillitis	01JAN1977	31DEC1977	N
		Psychiatric disorders	Depression	01JAN1996		Y
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Keratomileusis	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841251	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Allergy to plants	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Myringotomy	01JAN1976	31DEC1976	N
			Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1084 10841254	Eye disorders	Visual acuity reduced	01JAN1975		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2002	31DEC2002	N
		Investigations	Aspiration joint	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Joint swelling	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Azoospermia	01JAN2001		Y
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1084 10841255	Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Eye disorders	Visual acuity reduced	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1084 10841259	General disorders and administration site conditions	Pain	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841262	Immune system disorders	Allergy to plants	01JAN1995		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841267	Endocrine disorders	Hyperthyroidism	01JAN2005	31DEC2006	N
		Eye disorders	Visual acuity reduced	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Pharyngitis	01JAN1975	31DEC1975	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2015	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
			Hysterectomy	01DEC2015	31DEC2015	N
			Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1084 10841268	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Visual acuity reduced	01JAN1979		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2016	31DEC2016	N
			Thyroid neoplasm	01JAN2003	31DEC2003	N
		Reproductive system and breast disorders	Adenomyosis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1974	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2013	31DEC2013	N
			Nasal septal operation	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neurectomy	01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1084 10841269	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN1995		Y
			Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1984	31DEC1984	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Nasal septum deviation	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Abdominoplasty	01JAN2004	31DEC2004	N
			Bunion operation	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2007	31DEC2007	N
			Nasal septal operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1084 10841270	Congenital, familial and genetic disorders	Spina bifida occulta	(b) (6) 1991		Y
		Eye disorders	Visual acuity reduced	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2011		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841272	Infections and infestations	Pharyngitis	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1084 10841273	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1084 10841274	Cardiac disorders	Mitral valve prolapse	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1084 10841275	Eye disorders	Visual acuity reduced	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Herpes simplex	01JAN2013		Y
			Tonsillitis	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Breast cyst	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Breast cyst excision	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1084 10841279	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2005	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Bipolar disorder	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Pharyngeal cyst	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac operation	01JAN2010	31DEC2010	N
			Pharyngeal operation	01JAN1994	31DEC1994	N
	C4591001 1084 10841280	Surgical and medical procedures	Ankle operation	02APR2020	02APR2020	N
			Open reduction of fracture	02APR2020	02APR2020	N
	C4591001 1084 10841281	Eye disorders	Visual acuity reduced	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Eustachian tube operation	01JAN2018	31DEC2018	N
			Knee operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1084 10841283	Hepatobiliary disorders	Hepatic steatosis	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Infections and infestations	Septic arthritis staphylococcal	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Surgical and medical procedures	Elbow operation	01JAN2004	31DEC2004	N
	C4591001 1084 10841286	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN1991		Y
			Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2009		Y
		Surgical and medical procedures	Gastrectomy	01MAR2016	31MAR2016	N
	C4591001 1084 10841287	Injury, poisoning and procedural complications	Ligament sprain	13JUL2020		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1084 10841288	Eye disorders	Hypermetropia	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2017		Y
	C4591001 1084 10841290	Immune system disorders	Hypersensitivity	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1084 10841291	Eye disorders	Visual acuity reduced	01JAN1999		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Infections and infestations	Onychomycosis	29MAY2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N
	C4591001 1084 10841292	Eye disorders	Visual acuity reduced	01JAN1980		Y
	C4591001 1084 10841294	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
	C4591001 1084 10841301	Nervous system disorders	Headache	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	13AUG2012	13AUG2012	N
			Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1084 10841303	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2017	N
			Sleep apnoea syndrome	01DEC2019		Y
		Surgical and medical procedures	Nasal septal operation	01DEC2017	31DEC2017	N
	C4591001 1084 10841306	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
	C4591001 1084	Eye disorders	Female sterilisation	01JAN2008	31DEC2008	N
	10841307		Visual acuity reduced	01JAN1985		Y
		General disorders and administration site conditions	Oedema peripheral	26AUG2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Fracture treatment	01JAN1992	31DEC1992	N
			Gastric banding	01JAN2000	31DEC2000	N
			Hospitalisation	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1084	Skin and subcutaneous tissue disorders	Rosacea	01JAN2007		Y
	10841308					
	C4591001 1084	Eye disorders	Visual acuity reduced	01JAN1999		Y
	10841309					
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN1989	31DEC1992	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084	Eye disorders	Visual acuity reduced	01JAN1971		Y
	10841311					
		Gastrointestinal disorders	Hiatus hernia	01JAN2012	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1974		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
			Depression	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hot flush	01JAN2013		Y
	C4591001 1084 10841312	Infections and infestations	Bronchitis	01JAN1972	31DEC1972	N
			Pneumonia	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1084 10841315	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2013	31DEC2013	N
		Infections and infestations	Tonsillitis	01JAN1984	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Haematuria	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1084 10841316	Surgical and medical procedures	Tonsillectomy	01JAN1984	31DEC1984	N
	C4591001 1084 10841317	Immune system disorders	Seasonal allergy	01JAN2016		Y
		General disorders and administration site conditions	Hernia	01JAN1998	31DEC1998	N
			Inflammation	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1084 10841318	Surgical and medical procedures	Hernia repair	01JAN1998	31DEC1998	N
		Endocrine disorders	Hypothyroidism	01SEP2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Varicocele	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Varicocele repair	01JAN2004	31DEC2004	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1084 10841321	Eye disorders	Visual acuity reduced	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Foreign body	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal stenosis	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Removal of foreign body	01JAN2001	31DEC2001	N
			Vasectomy	01JAN2005	31DEC2005	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841322	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2009	N
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
			Gastrectomy	01JAN2009	31DEC2009	N
	C4591001 1084 10841324	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1084 10841328	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1084 10841330	Infections and infestations	Staphylococcal infection	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2005	31DEC2006	N
	C4591001 1084 10841333	Eye disorders	Cataract	01JUL2020		Y
			Visual acuity reduced	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Amnesia	01OCT2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2008		Y
	C4591001 1084 10841334	Eye disorders	Entropion	01JAN1978	31DEC1981	N
			Visual acuity reduced	01JAN2010	31DEC2011	N
		Investigations	Human papilloma virus test positive	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Genital lesion	01JAN2001		Y
		Surgical and medical procedures	Blepharoplasty	01JAN1981	31DEC1981	N
			Botulinum toxin injection	01MAY2020	31MAY2020	N
			Keratomileusis	01JAN2017	31DEC2017	N
			Lesion excision	01JAN2001	31DEC2001	N
	C4591001 1084 10841338	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Mycotic allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1984		Y
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1084 10841339	Cardiac disorders	Mitral valve prolapse	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1992	31DEC1992	N
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2020		Y
		Social circumstances	Postmenopause	01SEP2018		Y
		Surgical and medical procedures	Bunion operation	01JAN1992	31DEC1992	N
	C4591001 1084 10841342	Infections and infestations	Staphylococcal infection	01JUN2019	01JUN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1084 10841344	General disorders and administration site conditions	Pain	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1084 10841346	Blood and lymphatic system disorders	Anaemia	01JAN2007	31DEC2007	N
		Eye disorders	Myopia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2014		Y
			Vitamin D deficiency	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01APR2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1992	31DEC1992	N
			Pre-eclampsia	01JAN2015	31JAN2015	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
				01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2015	31JAN2015	N
			Ovarian cystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841348	Cardiac disorders	Mitral valve incompetence	01JAN2015		Y
		Eye disorders	Visual acuity reduced	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Cyclosporidium infection	01JUL2020	31AUG2020	N
		Nervous system disorders	Migraine	01JAN1999		Y
	C4591001 1084 10841350	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1084 10841351	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2007		Y
		Psychiatric disorders	Post-traumatic stress disorder	01AUG2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1084 10841352	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anogenital warts	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Papilloma excision	01JAN2015	31DEC2015	N
	C4591001 1084 10841353	Injury, poisoning and procedural complications	Hand fracture	01JAN2004	31DEC2004	N
			Lumbar vertebral fracture	01AUG2014	31AUG2014	N
		Investigations	Colonoscopy	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2002		Y
			Osteoarthritis	01JAN2017	31DEC2017	N
			Trigger finger	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01SEP2017	30SEP2017	N
			Headache	01JAN1990		Y
			Migraine	01JAN1984		Y
			Restless legs syndrome	01JAN2010	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Bone operation	01JAN2004	31DEC2004	N
			Carpal tunnel decompression	01SEP2017	30SEP2017	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Spinal fracture treatment	01AUG2014	31AUG2014	N
			Tendon sheath incision	01JAN2017	31DEC2017	N
	C4591001 1084 10841355	Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1988	31DEC2014	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2006		Y
			Rosacea	01JAN2012		Y
		Surgical and medical procedures	Keratomileusis	01JAN2014	31DEC2014	N
			Transfusion	01JAN2014	31DEC2014	N
	C4591001 1084 10841356	Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cyst removal	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2013	31DEC2013	N
	C4591001 1084 10841358	Immune system disorders	Seasonal allergy	01JAN2020		Y
	C4591001 1084 10841359	Eye disorders	Visual acuity reduced	01JAN1972		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Investigations	Arthroscopy	01JAN2013	31DEC2013	N
			Biopsy prostate	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JUN2020	30JUN2020	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
	C4591001 1084 10841365	Eye disorders	Visual acuity reduced	01JUN2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1974	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		N
			Seasonal allergy	01JAN2009		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010		Y
			Eye laser surgery	01JAN2009	31DEC2009	N
	C4591001 1084 10841371	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841373	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Vitamin D deficiency	01FEB2020		Y
		Surgical and medical procedures	Influenza immunisation	08AUG2020	08AUG2020	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084 10841374	Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1084 10841375	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Rhinitis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841376	Endocrine disorders	Hypogonadism male	01JAN2010		Y
		Eye disorders	Eyelid ptosis	01JAN1989	31DEC2005	N
			Visual acuity reduced	01JAN2005	31DEC2005	N
			Visual acuity reduced	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Immune system disorders	Hypersensitivity	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eyelid haemangioma	01JAN1987		Y
			Lymphangioma	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Depression	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Parotidectomy	01JAN2017	31DEC2017	N
			Ptosis repair	01JAN1989	31DEC1989	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
	C4591001 1084 10841378	Metabolism and nutrition disorders	Obesity	01JAN1992		Y
			Type 2 diabetes mellitus	01JAN2000	31DEC2007	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y
		Surgical and medical procedures	Gastric bypass	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841381	Eye disorders	Astigmatism	01JAN1985		Y
			Dry eye	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Visual acuity reduced	01JAN1985	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2015	N
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
			Refeeding syndrome	01FEB2020		Y
		Nervous system disorders	Sciatica	01JAN2019		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
			Skin lesion removal	01JAN2013	31DEC2013	N
	C4591001 1084 10841382	Eye disorders	Visual acuity reduced	01JAN2004	31MAY2019	N
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Surgical and medical procedures	Keratomileusis	01JAN2019	31DEC2019	N
	C4591001 1084 10841384	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1983	31DEC1983	N
		Nervous system disorders	Epilepsy	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1084 10841385	Endocrine disorders	Hypoparathyroidism	01JAN1984		Y
		Eye disorders	Pterygium	01JAN2018		Y
			Visual acuity reduced	01JAN1984		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Haemorrhoid operation	01JAN2016	31DEC2016	N
	C4591001 1084 10841386	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypovitaminosis	01SEP2019		Y
		Vascular disorders	Hypertension	01SEP2000		Y
	C4591001 1084 10841388	Eye disorders	Visual acuity reduced	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1984	31DEC1984	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2010	31DEC2010	N
			Knee operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841390	Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	06AUG1992	06AUG1992	N
				21JAN1990	21JAN1990	N
	C4591001 1084 10841391	Eye disorders	Visual acuity reduced	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Enchondromatosis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Chondrectomy	01JAN2018	31DEC2018	N
	C4591001 1084 10841393	Eye disorders	Visual acuity reduced	01JUL2019		Y
	C4591001 1084 10841394	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Visual acuity reduced	01JAN2005	31DEC2017	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2017	31DEC2017	N
			Hernia repair	01JAN2018	31DEC2018	N
	C4591001 1084 10841396	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Headache	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Oligospermia	01JAN2017		Y
	C4591001 1084 10841402	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841404	Eye disorders	Visual acuity reduced	01JAN2017		Y
	C4591001 1084 10841404	Eye disorders	Visual acuity reduced	01JAN1986		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1999		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2013	31DEC2016	N
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1084 10841405	Ear and labyrinth disorders	Ear disorder	01JUN2020	30JUN2020	N
		Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y
			Costochondritis	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1084 10841407	Cardiac disorders	Tachycardia	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Visual acuity reduced	01JAN2002		Y
		Immune system disorders	Allergy to animal	01JAN2019		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1084 10841409	Eye disorders	Visual acuity reduced	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003	31DEC2009	N
	C4591001 1084 10841410	Immune system disorders	Allergy to animal	01JAN2003		Y
			Seasonal allergy	01JAN2003		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Nervous system disorders	Epilepsy	01JAN2016		Y
			Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1084 10841413	Eye disorders	Visual acuity reduced	01JAN2009		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841416	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1084 10841417	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Bacterial vaginosis	12AUG2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1084 10841418	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1084 10841420	Congenital, familial and genetic disorders	Factor VIII deficiency	(b) (6) 1988		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1084 10841422	Ear and labyrinth disorders	Deafness bilateral	01JAN2008		Y
		Eye disorders	Visual acuity reduced	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1982		Y
			Seasonal allergy	01DEC1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Nervous system disorders	Sciatica	01APR2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1084 10841423	Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Bacterial vaginosis	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2014	31DEC2016	N
	C4591001 1084 10841425	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Nervous system disorders	Restless legs syndrome	01JAN2011		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2007		Y
	C4591001 1084 10841426	Cardiac disorders	Mitral valve prolapse	01JAN2007		Y
		Endocrine disorders	Thyroid mass	01JAN2003	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Scleroderma	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Mammoplasty	01JAN2000		Y
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1084 10841428	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841429	Vascular disorders	Hypertension	01JAN2013		Y
		Endocrine disorders	Goitre	01JAN2014		Y
		Eye disorders	Myopia	01SEP2018		Y
		Immune system disorders	Food allergy	01JAN1996		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Endodontic procedure	27JUL2020	27JUL2020	N
			Liposuction	01SEP2018	30SEP2018	N
	C4591001 1084 10841431	Eye disorders	Visual acuity reduced	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Infections and infestations	Bronchitis	17DEC2015	24DEC2015	N
			Herpes simplex	01JAN2018		Y
			Otitis media	01JAN2012	31DEC2012	N
			Pelvic inflammatory disease	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2004		Y
			Bursitis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
			Insomnia	01JAN1999		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ear tube insertion	01JAN2012	31DEC2012	N
	C4591001 1084 10841433	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
	C4591001 1084 10841434	Eye disorders	Visual acuity reduced	01JAN1991	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1995	31DEC1995	N
			Wrist fracture	01JAN1998	31DEC1998	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Surgical and medical procedures	Fracture treatment	01JAN1998	31DEC1998	N
			Keratomileusis	01JAN2013	31DEC2013	N
			Photorefractive keratectomy	01JAN2014	31DEC2014	N
	C4591001 1084 10841435	Eye disorders	Myopia	01JAN1989		Y
		Immune system disorders	Allergy to animal	01JAN2004		Y
			Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1084 10841436	Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1084 10841437	Ear and labyrinth disorders	Tinnitus	01JAN2005		Y
		Eye disorders	Visual acuity reduced	01JAN1988		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus injury	01JAN2010	31DEC2010	N
			Skin laceration	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Chondroplasty	01JAN2011	31DEC2011	N
			Fracture treatment	01JAN1992	31DEC1992	N
			Meniscus operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1084 10841438	Ear and labyrinth disorders	Deafness unilateral	01JAN2012		Y
			Tinnitus	01JAN1983		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Visual acuity reduced	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1084 10841439	Surgical and medical procedures	Tympanoplasty	01JAN2010	31DEC2010	N
		Hepatobiliary disorders	Cholecystitis	01JAN1993	31DEC1993	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2004	31DEC2004	N
			Ovarian cyst	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN1993	31DEC1993	N
			Endometrial ablation	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Oophorectomy	01JAN2016	31DEC2016	N
	C4591001 1084 10841441	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01MAY2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nasal septal operation	01JAN2014		Y
			Skin neoplasm excision	01MAY2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841442	Ear and labyrinth disorders	Deafness	01JAN2003		Y
			Tinnitus	01JAN2003		Y
		Eye disorders	Myopia	01JAN1986		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2004		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997	31DEC2017	N
			Compartment syndrome	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
			Insomnia	01SEP2020		Y
			Post-traumatic stress disorder	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Fasciotomy	01JAN2003	31DEC2003	N
			High frequency ablation	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1084 10841448	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Myopia	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1084 10841449	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2013	N
		Eye disorders	Visual acuity reduced	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2015	31DEC2015	N
			Gastroesophageal reflux disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Fibromyalgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Bipolar disorder	01JAN2012		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
			Post-traumatic stress disorder	01JAN2012		Y
		Reproductive system and breast disorders	Bartholin's cyst	01JAN1999	31DEC1999	N
			Endometrial hyperplasia	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1983	31DEC2005	N
		Surgical and medical procedures	Bartholin's cyst removal	01JAN1999	31DEC1999	N
			Caesarean section	01JAN1989	31DEC1989	N
				01JAN1993	31DEC1993	N
				01JAN1997	31DEC1997	N
				01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN1998	31DEC1998	N
			Gastric bypass	01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemostasis	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Intervertebral disc operation	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841450	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Laparoscopy	01MAY2019	31MAY2019	N
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Reproductive system and breast disorders	Endometriosis	01DEC2018		Y
	C4591001 1084 10841452	Eye disorders	Visual acuity reduced	01JAN2003	31DEC2015	N
		Immune system disorders	Allergy to animal	25SEP2003		Y
			Seasonal allergy	01SEP2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Keratomileusis	01MAY2015	31MAY2015	N
			Shoulder operation	01NOV2008	31DEC2008	N
	C4591001 1084 10841454	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2019	N
		Endocrine disorders	Thyroid mass	01JAN2015	31DEC2016	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1994		Y
				01JAN2004		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01DEC2018	31JAN2019	N
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN1996	31DEC1998	N
		Surgical and medical procedures	Ankle operation	01JAN1998	31DEC1998	N
			Elbow operation	01JAN2019	31DEC2019	N
			Thyroidectomy	01JAN2016	31DEC2016	N
	C4591001 1084 10841456	Eye disorders	Visual acuity reduced	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2019		Y
			Vitamin D deficiency	01OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2012	N
		Nervous system disorders	Headache	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1084 10841457	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Abdominoplasty	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841458	Renal and urinary disorders	Ureteric stenosis	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Ureteric operation	01JAN1998	31DEC1998	N
	C4591001 1084 10841461	Eye disorders	Visual acuity reduced	01JAN1998		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2019	N
			Hepatic steatosis	01JAN2018		Y
		Immune system disorders	Allergy to animal	01JAN1989		Y
			Food allergy	01JAN1989		Y
				01JAN2001		Y
			Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Attention deficit hyperactivity disorder	01JAN1986		Y
			Depression	01JAN1997		Y
			Insomnia	01JAN1989	31DEC2020	N
			Post-traumatic stress disorder	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1984		Y
	C4591001 1084 10841462	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01FEB2020	29FEB2020	N
			Eczema	01JAN2018		Y
		Surgical and medical procedures	Spinal operation	01FEB2020	29FEB2020	N
	C4591001 1084 10841464	Eye disorders	Glaucoma	01JAN2005		Y
			Visual acuity reduced	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Infections and infestations	Hepatitis B	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Periarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Surgical and medical procedures	Jaw operation	01JAN2018	31DEC2018	N
			Vascular operation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841465	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1084 10841466	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1997	N
		Immune system disorders	Allergy to animal	01JAN1995		Y
		Investigations	Laparoscopy	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Endometriosis	01JAN2005		Y
			Polycystic ovaries	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Ovarian cystectomy	01JAN2012	31DEC2012	N
	C4591001 1084 10841468	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Visual acuity reduced	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Diverticulitis	01JAN2015		Y
			Oral herpes	01JAN1980		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Hernia repair	01JAN1998	31DEC1998	N
			Lipoma excision	01JAN2008	31DEC2008	N
			Lipoma excision	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN2018	31DEC2018	N
			Ankle fracture	01APR2019	31MAY2019	N
	C4591001 1084 10841469	Injury, poisoning and procedural complications				
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
			Insomnia	01MAR2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841474	Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
			Face lift	01JAN2015	31DEC2015	N
			Hernia repair	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1084 10841479	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1084 10841480	Eye disorders	Visual acuity reduced	01JAN1987		Y
		Gastrointestinal disorders	Abdominal hernia	01SEP2019	31OCT2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Tendon rupture	01MAR2006	31MAR2006	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1991		Y
		Nervous system disorders	Headache	01JAN1991		Y
		Surgical and medical procedures	Abdominal hernia repair	01SEP2019	31OCT2019	N
			Tenoplasty	01MAR2006	31MAR2006	N
	C4591001 1084 10841481	Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Appendectomy	01JAN2001	31DEC2001	N
	C4591001 1084 10841484	Ear and labyrinth disorders	Deafness unilateral	01JAN2000	31DEC2000	N
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1983		Y
		Investigations	Heart rate irregular	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Psychiatric disorders	Insomnia	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cochlea implant	01JAN2000	31DEC2000	N
			Implantable cardiac monitor insertion	01JAN2020	31JAN2020	N
			Limb operation	01JAN1983	31DEC1983	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1084 10841486	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841488	General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Fracture treatment	01JAN1998	31DEC1998	N
	C4591001 1084 10841489	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Os trigonum syndrome	(b) (6) 1967	31DEC2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Ankle operation	01JAN2006	31DEC2006	N
			Caesarean section	20DEC1993	20DEC1993	N
				22DEC1995	22DEC1995	N
				25SEP1989	25SEP1989	N
			Female sterilisation	22DEC1995	22DEC1995	N
			Lithotripsy	01JAN2017	31DEC2017	N
		Vascular disorders	Hot flush	01JUN2019		Y
	C4591001 1084 10841492	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2017		Y
		Surgical and medical procedures	Eye operation	01JAN2015	31DEC2015	N
	C4591001 1084 10841493	Ear and labyrinth disorders	Tinnitus	01JAN1998		Y
		Eye disorders	Glaucoma	01JAN2016		Y
			Myopia	01JAN2016		Y
		Immune system disorders	Mycotic allergy	01JAN1985		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC1999	N
		Investigations	Arthroscopy	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000	31DEC2000	N
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2019		Y
			Parkinson's disease	01JAN2019		Y
			Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Spinal operation	15APR2019	15APR2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841494	Eye disorders	Visual acuity reduced	01JAN1999		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2002	31DEC2002	N
		Skin and subcutaneous tissue disorders	Alopecia	15JUN2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
			Hair transplant	18AUG2020	18AUG2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia repair	01JAN2001	31DEC2001	N
	C4591001 1084 10841495	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Nasal septum deviation	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	31DEC2019	N
	C4591001 1084 10841496	Eye disorders	Myopia	01JAN2019		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Tenoplasty	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841499	Eye disorders	Myopia	01JAN1991		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Hepatic steatosis	01AUG2020		Y
		Immune system disorders	Allergy to animal	01JAN1987		Y
			Food allergy	01JAN1987		Y
			Milk allergy	01JAN1987		Y
		Nervous system disorders	Headache	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01AUG2020	31AUG2020	N
			Renal cyst	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1084 10841500	Gastrointestinal disorders	Umbilical hernia	01JAN2005	31DEC2007	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
			Tonsillitis	01JAN1990	31DEC1991	N
		Nervous system disorders	Headache	01JAN2012		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Surgical and medical procedures	Appendectomy	01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN2003	31DEC2003	N
			Hernia repair	01JAN2007	31DEC2007	N
			Mammoplasty	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1084 10841502	Ear and labyrinth disorders	Vertigo	01JAN2016	31DEC2016	N
		Eye disorders	Myopia	01JAN1986		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Food allergy	01JAN1988		Y
				01JAN1990		Y
		Infections and infestations	Sinusitis	01JAN2013	31DEC2015	N
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1987		Y
		Surgical and medical procedures	Sinuplasty	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015	31DEC2015	N
	C4591001 1084 10841503	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1084 10841506	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2009		Y
	C4591001 1084 10841509	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1975	31DEC2004	N
			Visual acuity reduced	01JAN2019		Y
		Gastrointestinal disorders	Intestinal obstruction	01JAN2019	31DEC2019	N
		General disorders and administration site conditions	Oedema	01JAN2008		Y
		Hepatobiliary disorders	Gallbladder oedema	01JAN2019	31DEC2019	N
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019		Y
			Hysterectomy	01JAN2007		Y
			Intestinal operation	01JAN2019		Y
			Keratomileusis	01JAN2004		Y
	C4591001 1084 10841511	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084 10841512	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Immune system disorders	Allergy to plants	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015	31DEC2016	N
	C4591001 1084 10841513	Cardiac disorders	Coronary artery disease	01JAN1998		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Back pain	01JAN2017	31DEC2019	N
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
			Tendonitis	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1983	31DEC1983	N
			Sleep apnoea syndrome	01JAN2014	31DEC2017	N
		Surgical and medical procedures	Adenoidectomy	01JAN1983	31DEC1983	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			High frequency ablation	01JAN2019	31DEC2019	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841514	Eye disorders	Visual acuity reduced	01OCT2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JUL2006	31OCT2006	N
		Metabolism and nutrition disorders	Obesity	01OCT2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid neoplasm	01MAR1991	30APR1991	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01FEB2016		Y
		Surgical and medical procedures	Gastrectomy	01OCT2015	31OCT2015	N
			Thyroidectomy	01MAR1991	31MAR1991	N
			Wrist surgery	01JUL2006	31JUL2006	N
	C4591001 1084 10841517	Eye disorders	Visual acuity reduced	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001	31DEC2005	N
	C4591001 1084 10841518	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Investigations	Colonoscopy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2015	31DEC2017	N
		Surgical and medical procedures	Tonsillectomy	01JAN1988	31DEC1988	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1084 10841519	Immune system disorders	Allergy to animal	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1084 10841520	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841521	Immune system disorders	Allergy to animal	01JAN1996		Y
			Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN1991		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1084 10841522	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Surgical and medical procedures	Hernia repair	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1084 10841526	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Umbilical hernia	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Intervertebral disc injury	08SEP2000	08SEP2000	N
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Spinal operation	01JAN2014	31DEC2014	N
			Pain	08SEP2000	08SEP2000	N
	C4591001 1084 10841530	General disorders and administration site conditions		01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1084 10841532	Ear and labyrinth disorders	Motion sickness	01JAN2015		Y
		Eye disorders	Visual acuity reduced	01JAN1992	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2008	31DEC2008	N
				01JAN2013	31DEC2013	N
			Uterine dilation and curettage	01JAN2012	31DEC2012	N
	C4591001 1084 10841533	Infections and infestations	Adenoiditis	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN2014	31DEC2014	N
			Radius fracture	01JAN2018	31DEC2018	N
	C4591001 1084 10841535	Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Ear infection	01OCT2003	31MAY2004	N
	C4591001 1084 10841536	Surgical and medical procedures	Ear tube insertion	01MAY2004	31MAY2004	N
		Eye disorders	Visual acuity reduced	01JAN2017		Y
		Immune system disorders	Allergy to animal	01JAN2007		Y
			Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2014	31DEC2014	N
			Hand fracture	01JAN2014	31DEC2014	N
			Limb fracture	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2019		Y
			Major depression	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Varicocele	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Shoulder operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2008	31DEC2008	N
			Varicocele repair	01JAN2019	31DEC2019	N
	C4591001 1084 10841537	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1084 10841538	Immune system disorders	Seasonal allergy	01JAN2009		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Kidney infection	01AUG2010		Y
			Tonsillitis	01JAN2004	30NOV2006	N
			Urinary tract infection	01SEP2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1084 10841539	Eye disorders	Visual acuity reduced	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01MAR2011		Y
		Investigations	Arthroscopy	30JUN2020	30JUN2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2004	31DEC2005	N
				01JAN2005	31DEC2006	N
	C4591001 1084 10841540	Nervous system disorders	Headache	01JAN2016		Y
	C4591001 1085 10851003	Immune system disorders	Seasonal allergy	01APR2011		Y
		Psychiatric disorders	Anxiety	01DEC2015		Y
			Insomnia	01MAY2020		Y
	C4591001 1085 10851004	Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1085 10851013	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01JUL2018	31JUL2018	N
		Surgical and medical procedures	Hysterectomy	01JUL2018	31JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851015	Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1085 10851016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin D deficiency	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1085 10851018	Cardiac disorders	Left ventricular hypertrophy	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851019	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1085 10851022	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1085 10851026	Nervous system disorders	Glossopharyngeal neuralgia	01OCT2017		Y
	C4591001 1085 10851027	Immune system disorders	Seasonal allergy	01MAR2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851029	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851032	Immune system disorders	Seasonal allergy	01APR2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01AUG2002	31AUG2002	N
				01MAR2000	31MAR2000	N
				01NOV1998	30NOV1998	N
		Social circumstances	Postmenopause	01JUN2019		Y
	C4591001 1085 10851033	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1085 10851047	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1085 10851048	Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
	C4591001 1085 10851049	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01JAN1998	31DEC2014	N
		Surgical and medical procedures	Cholesteatoma removal	01JAN2014	31DEC2014	N
			Cochlea implant	01MAY2018		Y
	C4591001 1085 10851050	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01SEP2018	30SEP2018	N
		Surgical and medical procedures	Intervertebral disc operation	01SEP2018	30SEP2018	N
	C4591001 1085 10851058	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1085 10851062	Ear and labyrinth disorders	Vertigo	01JAN2019		Y
	C4591001 1085 10851063	Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1085 10851068	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2010		Y
	C4591001 1085 10851075	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851079	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1997		Y
	C4591001 1085 10851081	Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
	C4591001 1085 10851090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
			Rhinitis allergic	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1988		Y
	C4591001 1085 10851098	Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01AUG2020		Y
	C4591001 1085 10851104	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1085 10851109	Immune system disorders	Seasonal allergy	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851110	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01DEC2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1085 10851112	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN1980		Y
			Bipolar disorder	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1085 10851114	Immune system disorders	Seasonal allergy	01JAN2001		Y
	C4591001 1085 10851124	Reproductive system and breast disorders	Endometriosis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1085 10851125	Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1085 10851127	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Vitamin B complex deficiency	01JAN2010		Y
			Vitamin D deficiency	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851128	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1085 10851132	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1085 10851136	Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
	C4591001 1085 10851137	Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1085 10851140	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1085 10851141	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851142	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1085 10851143	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851153	Psychiatric disorders	Anxiety	01JAN2015		Y
			Bipolar disorder	01JAN2013		Y
			Insomnia	01JAN2015		Y
	C4591001 1085 10851158	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1085 10851159	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1085 10851163	Investigations	Blood oestrogen increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Torticollis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1999		Y
	C4591001 1085 10851164	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
	C4591001 1085 10851165	Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1085 10851170	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1085 10851178	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851179	Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2019		Y
	C4591001 1085 10851180	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1085 10851189	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851193	Infections and infestations	Chronic sinusitis	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1085 10851196	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1085 10851200	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1085 10851203	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2019		Y
		Renal and urinary disorders	Nephropathy	01JAN2010		Y
	C4591001 1085 10851210	Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
	C4591001 1085 10851211	Gastrointestinal disorders	Bile acid malabsorption	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1085 10851212	Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1085 10851217	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851219	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2019	N
	C4591001 1085 10851221	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1085 10851231	Injury, poisoning and procedural complications	Burns second degree	28AUG2020		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1085 10851237	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1085 10851239	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2012		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1085 10851240	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851242	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1085 10851248	Psychiatric disorders	Anxiety	01JAN1997		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Insomnia	01JAN1997		Y
	C4591001 1085 10851249	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851252	Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1985		Y
	C4591001 1085 10851253	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851256	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1085 10851259	Infections and infestations	Onychomycosis	01JAN2019		Y
	C4591001 1085 10851264	Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1085 10851265	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Psychiatric disorders	Depression	01JAN2006		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1085 10851270	Nervous system disorders	Neuropathy peripheral	01FEB2020		Y
	C4591001 1085 10851280	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1085 10851281	Psychiatric disorders	Depression	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01AUG2020		Y
	C4591001 1085 10851283	Immune system disorders	Seasonal allergy	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
			Mastectomy	01JAN2011	31DEC2011	N
	C4591001 1085 10851284	Reproductive system and breast disorders	Polycystic ovaries	13AUG2020		Y
	C4591001 1085 10851286	Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Infections and infestations	Hepatitis C	01JAN2015	30JUN2017	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1085 10851287	Endocrine disorders	Hyperthyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2010		Y
	C4591001 1085 10851290	Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2020		Y
	C4591001 1085 10851291	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Tonsillectomy	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851294	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1085 10851296	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1085 10851298	Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 1085 10851299	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1085 10851300	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1085 10851302	Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1085 10851304	Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1085 10851305	Cardiac disorders	Arrhythmia	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Seizure	01JAN1991		Y
			Anxiety	01JAN1991		Y
			Depression	01JAN1991		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01FEB2020		Y
	C4591001 1085 10851307	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
	C4591001 1085 10851309	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Oral herpes	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01AUG2016	31AUG2016	N
	C4591001 1085 10851310	Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y
	C4591001 1085 10851312	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y
		Surgical and medical procedures	Large intestinal polypectomy	01APR2020	30APR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1085 10851314	Immune system disorders	Seasonal allergy	01FEB2000		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
	C4591001 1085 10851316	Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1085 10851320	Gastrointestinal disorders	Appendicitis noninfective	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Intestinal resection	01JAN2002	31DEC2002	N
	C4591001 1085 10851323	Infections and infestations	Herpes simplex	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
	C4591001 1085 10851325	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851327	Nervous system disorders	Migraine	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1085 10851328	Immune system disorders	Seasonal allergy	01JAN1989		Y
	C4591001 1085 10851330	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1085 10851332	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1085 10851337	Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2012		Y
	C4591001 1085 10851339	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851341	Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2008		Y
	C4591001 1085 10851342	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1085 10851343	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1085 10851346	Investigations	Cardiac murmur	(b) (6) 1990		Y
	C4591001 1085 10851349	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1085 10851352	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1085 10851354	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01JAN2014		Y
		Eye disorders	Pterygium	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1085 10851355	Surgical and medical procedures	Intrauterine contraception	01JUL2020		Y
	C4591001 1085 10851356	Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JUN2019	30JUN2019	N
			Umbilical hernia repair	01MAR2020	30JUN2020	N
	C4591001 1085 10851357	Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Intrauterine contraception	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851358	Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1085 10851361	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1085 10851366	Gastrointestinal disorders	Bile acid malabsorption	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Functional endoscopic sinus surgery	01JAN1999	31DEC2008	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Nasal septal operation	01JAN1999	31DEC2008	N
	C4591001 1085 10851367	Endocrine disorders	Hypogonadism	01AUG2020		Y
	C4591001 1085 10851368	Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
	C4591001 1085 10851369	Surgical and medical procedures	Intrauterine contraception	01JAN2017		Y
	C4591001 1085 10851371	Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Contraceptive implant	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851372	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851373	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1085 10851374	Psychiatric disorders	Depression	01SEP2020		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y
	C4591001 1085 10851375	Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
			Depression	01APR2020		Y
	C4591001 1087 10871007	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Oral herpes	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1087 10871010	Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1087 10871020	Gastrointestinal disorders	Dyspepsia	01SEP2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871021	Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01MAY2019		Y
	C4591001 1087 10871028	Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871035	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1087 10871041	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1087 10871042	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006		Y
	C4591001 1087 10871045	Immune system disorders	Food allergy	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1087 10871052	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1087 10871053	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Food allergy	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871059	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
	C4591001 1087 10871062	Psychiatric disorders	Anxiety	01DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1087 10871064	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1087 10871065	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1087 10871066	Infections and infestations	Herpes simplex	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871067	Nervous system disorders	Sciatica	01JAN2018		Y
	C4591001 1087 10871068	Immune system disorders	Seasonal allergy	01JAN1978		Y
	C4591001 1087 10871074	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1087 10871076	Blood and lymphatic system disorders	Anaemia	01JAN2013		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Food allergy	01JAN1992		Y
	C4591001 1087 10871078	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1087 10871083	Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871084	Immune system disorders	Food allergy	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1970		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871085	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1087 10871086	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012	01JAN2020	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1087 10871087	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Onychomycosis	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1087 10871088	Investigations	Blood testosterone decreased	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1087 10871089	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1087 10871092	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2019		Y
	C4591001 1087 10871094	Injury, poisoning and procedural complications	Fall	15AUG2020	15AUG2020	N
	C4591001 1087 10871102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2018		Y
			Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1087 10871103	Investigations	Blood testosterone decreased	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
			Post-traumatic stress disorder	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871107	Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1087 10871108	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
	C4591001 1087 10871109	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Post-traumatic pain	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1990		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
	C4591001 1087 10871110	Endocrine disorders	Hypothyroidism	01JAN2009		Y
	C4591001 1087 10871111	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN1995		Y
	C4591001 1087 10871114	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN1994		Y
	C4591001 1087 10871119	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Rubber sensitivity	01JAN2009		Y
			Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871120	Vascular disorders	Hypertension	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Tension headache	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
	C4591001 1087 10871135	Gastrointestinal disorders	Constipation	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1087 10871138	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
	C4591001 1087 10871148	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
	C4591001 1087 10871149	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Dehydration	01JUL2020	31JUL2020	N
			Hypokalaemia	01JUL2020		Y
			Obesity	01JAN1992		Y
			Type 2 diabetes mellitus	01JUN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
			Insomnia	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1087 10871151	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01MAR2020		Y
	C4591001 1087 10871152	Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1087 10871153	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN2003		Y
			Food allergy	01JAN2013		Y
	C4591001 1087 10871160	Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JUN2020		Y
		Psychiatric disorders	Depression	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871166	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1992		Y
				01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1087 10871171	Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1087 10871172	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Essential tremor	01JAN1994		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871179	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871180	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871181	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
			Food allergy	01JAN1970		Y
			Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1087 10871182	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1087 10871186	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871189	Gastrointestinal disorders	Constipation	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1087 10871191	Skin and subcutaneous tissue disorders	Alopecia	01JAN1998		Y
	C4591001 1087 10871194	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
	C4591001 1087 10871195	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1087 10871196	Social circumstances	Postmenopause	01SEP2018		Y
	C4591001 1087 10871201	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
	C4591001 1087 10871205	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1087 10871212	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871214	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2005		Y
	C4591001 1087 10871215	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1087 10871225	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1087 10871230	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Hydrocephalus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1087 10871231	Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
			Depression	01JAN2010		Y
			Insomnia	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1087 10871235	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1087 10871241	Psychiatric disorders	Anxiety	01JAN2014		Y
			Post-traumatic stress disorder	01JAN2014		Y
	C4591001 1087 10871243	Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2017		Y
	C4591001 1087 10871244	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Immune system disorders	Perennial allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1087 10871247	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871248	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1087 10871252	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JUN2019		Y
	C4591001 1087 10871265	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy	01JAN2008	31DEC2008	N
	C4591001 1087 10871276	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871279	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
	C4591001 1087 10871285	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1087 10871296	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871297	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1087 10871299	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1087 10871301	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
		Nervous system disorders	Neuralgia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1087 10871308	Metabolism and nutrition disorders	Obesity	01JAN2010		Y	
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005	31DEC2005	N	
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N	
			Oophorectomy	01JAN2005	31DEC2005	N	
			Salpingectomy	01JAN2005	31DEC2005	N	
	C4591001 1087 10871310	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y	
	C4591001 1087 10871314	Immune system disorders	Drug hypersensitivity	01JAN2002		Y	
			Food allergy	01JAN1999		Y	
			Seasonal allergy	01JAN1996		Y	
			Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1087 10871316	Immune system disorders	Drug hypersensitivity	01JAN1993		Y	
			Reaction to colouring	01JAN1993		Y	
			Seasonal allergy	01JAN2012		Y	
			Infections and infestations	Herpes simplex	01JAN2016		Y
			Psychiatric disorders	Insomnia	01JAN2015		Y
			Reproductive system and breast disorders	Polycystic ovaries	01APR2000		Y
	C4591001 1087 10871325	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y	
	C4591001 1087 10871330	Psychiatric disorders	Insomnia	01JAN2005		Y	
	C4591001 1087 10871332	Social circumstances	Postmenopause	01JAN2017		Y	



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871336	Hepatobiliary disorders	Cholelithiasis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01DEC2004	31DEC2004	N
	C4591001 1087 10871338	Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
	C4591001 1087 10871342	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871343	Injury, poisoning and procedural complications	Muscle strain	01AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1087 10871348	Renal and urinary disorders	Nephropathy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Salpingectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871355	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1087 10871356	Immune system disorders	Food allergy	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1087 10871357	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1087 10871360	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
	C4591001 1087 10871361	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Perennial allergy	01JAN1985		Y
		Infections and infestations	Vulvovaginal mycotic infection	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1087 10871363	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1087 10871372	Surgical and medical procedures	Intrauterine contraception	01MAR2017		Y
	C4591001 1087 10871377	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871378	Nervous system disorders	Carpal tunnel syndrome	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871387	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1087 10871389	Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1087 10871391	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1087 10871393	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
	C4591001 1087 10871394	Psychiatric disorders	Anxiety	01JAN2001		Y
	C4591001 1087 10871398	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1087 10871399	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1087 10871401	Psychiatric disorders	Anxiety	01NOV2019		Y
		Surgical and medical procedures	Oophorectomy bilateral	01MAR2020	31MAR2020	N
			Salpingectomy	01MAR2020	31MAR2020	N
	C4591001 1087 10871404	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Iodine allergy	01JAN2013		Y
	C4591001 1087 10871412	Immune system disorders	Perennial allergy	01JAN1992		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2015		Y
			Insomnia	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871414	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1087 10871415	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1087 10871420	Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1087 10871426	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Vitamin B12 deficiency	01JAN2012		Y
			Vitamin D deficiency	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871427	Musculoskeletal and connective tissue disorders	Myalgia	01JUN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1087 10871435	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1975		Y
		Social circumstances	Postmenopause	01JUN2019		Y
		Vascular disorders	Hot flush	01DEC2019		Y
	C4591001 1087 10871443	Gastrointestinal disorders	Impaired gastric emptying	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
	C4591001 1087 10871454	Investigations	Blood oestrogen increased	01JUL2020		Y
	C4591001 1087 10871457	Immune system disorders	Food allergy	01JAN1981		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1995		Y
	C4591001 1087 10871468	Injury, poisoning and procedural complications	Joint injury	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1087 10871471	Gastrointestinal disorders	Nausea	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Oral herpes	01JAN2015		Y
			Tinea pedis	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1977		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2019		Y
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1087 10871473	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1087 10871474	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1087 10871480	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871484	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1087 10871486	Psychiatric disorders	Anxiety	01AUG2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2005		Y
	C4591001 1087 10871487	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Social circumstances	Woman of childbearing potential	01JAN1983		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
	C4591001 1087 10871490	Infections and infestations	Bacterial vaginosis	09SEP2020	16SEP2020	N
		Psychiatric disorders	Anxiety	11SEP2020		Y
	C4591001 1087 10871491	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1087 10871493	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1087 10871494	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1087 10871499	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1980		Y
			Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1087 10871504	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Rubber sensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871506	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Urinary tract infection	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1087 10871513	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Infections and infestations	Rhinitis	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1087 10871520	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1990		Y
				01JAN2013		Y
		Nervous system disorders	Epilepsy	01JAN2013		Y
			Nerve compression	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1087 10871525	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
	C4591001 1087 10871527	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1087 10871530	Gastrointestinal disorders	Umbilical hernia	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1993		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1993	31DEC1993	N
	C4591001 1087 10871535	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996		Y
	C4591001 1087 10871541	Metabolism and nutrition disorders	Hypocholesterolaemia	01MAR2020		Y
			Obesity	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN1989		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1996	31DEC2006	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1087 10871546	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1087 10871550	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01MAY2020		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1087 10871551	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01MAR2020		Y
	C4591001 1087 10871552	Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1087 10871553	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1087 10871554	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871555	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Nervous system disorders	Cerebrovascular accident	02JUN2020	02JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1087 10871557	Immune system disorders	Food allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
	C4591001 1087 10871558	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871563	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Bacterial allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1087 10871568	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01APR1991		Y
	C4591001 1087 10871571	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Polyneuropathy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Post-traumatic stress disorder	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871572	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
	C4591001 1087 10871573	Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871576	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1087 10871579	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Investigations	Blood triglycerides increased	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1087 10871581	Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1087 10871582	Gastrointestinal disorders	Umbilical hernia	01JAN1982	31DEC1982	N
		Immune system disorders	Food allergy	01JAN1977		Y
			Perennial allergy	01JAN2005		Y
		Investigations	Arthroscopy	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2018	31JAN2018	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN1982	31DEC1982	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1087 10871583	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871584	Congenital, familial and genetic disorders	Dysmorphism	01JAN1965	31DEC1982	N
		Infections and infestations	Chronic tonsillitis	01JAN1969	31DEC1970	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Binge eating	01JAN2000		Y
			Depression	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1970	31DEC1970	N
			Jaw operation	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1087 10871586	Cardiac disorders	Coronary artery disease	25SEP2013		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Obesity	01JAN2000		Y
		Renal and urinary disorders	Urethral stenosis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Stent placement	25SEP2013	25SEP2013	N
			Tonsillectomy	01JAN1975	31DEC1975	N
			Urethral repair	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1087 10871588	Immune system disorders	Food allergy	01FEB2020		Y
	C4591001 1087 10871593	Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2010	31DEC2010	N
	C4591001 1087 10871594	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc degeneration	01JAN2010	01AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Spinal fusion surgery	01AUG2020	31AUG2020	N
	C4591001 1087 10871595	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Spinal operation	01JAN2010	31DEC2010	N
	C4591001 1087 10871596	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
			Gastric bypass	01JAN2013	31DEC2013	N
	C4591001 1087 10871597	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1087 10871599	Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2020		Y
	C4591001 1087 10871601	Infections and infestations	Urinary tract infection	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881005	Psychiatric disorders	Alcoholism	01JUN2018	31JUL2018	N
	C4591001 1088 10881009	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Pancreatitis acute	01JAN2011	31DEC2011	N
		Nervous system disorders	Headache	01JAN1984		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1088 10881011	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1088 10881012	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881016	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2011		Y
	C4591001 1088 10881017	Immune system disorders	Drug hypersensitivity	01MAR2018		Y
			Multiple allergies	01MAR2019		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Insomnia	01JAN2010		Y
			Mania	01APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Psychotic disorder	01APR2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1088 10881019	Psychiatric disorders	Dependence	01JAN2016		Y
	C4591001 1088 10881021	Reproductive system and breast disorders	Adenomyosis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1088 10881024	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2009		Y
		Nervous system disorders	Disturbance in attention	01JAN2013		Y
			Migraine	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Post-traumatic stress disorder	01JAN2012	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Rhinitis perennial	01JAN1987		Y
	C4591001 1088 10881025	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881030	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1088 10881033	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Epilepsy	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1088 10881036	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881037	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881038	Psychiatric disorders	Anxiety	01JUL2020		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
			Insomnia	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1985		Y
	C4591001 1088 10881039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2012	31DEC2016	N
	C4591001 1088 10881040	Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
	C4591001 1088 10881044	Infections and infestations	Oral herpes	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1088 10881045	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
		Social circumstances	Menopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01JAN2016		Y
			Hypertension	01JAN2015		Y
	C4591001 1088 10881050	Cardiac disorders	Myocardial infarction	07JUN2019	07JUN2019	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JUN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1088 10881053	Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1088 10881054	Infections and infestations	Paronychia	14AUG2020		Y
	C4591001 1088 10881059	Immune system disorders	Hypersensitivity	01JAN1996		Y
		Investigations	Blood potassium decreased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1088 10881060	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Vascular disorders	Hypertension	01DEC2015		Y
	C4591001 1088 10881064	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881065	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1088 10881067	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Depression	01JUL2020		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1088 10881074	Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1088 10881077	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1088 10881079	Investigations	Blood testosterone decreased	01JAN1985		Y
	C4591001 1088 10881080	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1999		Y
	C4591001 1088 10881081	Psychiatric disorders	Stress	01OCT2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31JAN1996	N
	C4591001 1088 10881082	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1088 10881084	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881087	Endocrine disorders	Basedow's disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Back pain	01JAN2005		Y
	C4591001 1088 10881094	Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
	C4591001 1088 10881095	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
			Stress	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1088 10881098	Ear and labyrinth disorders	Motion sickness	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1983		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar II disorder	01JAN2016		Y
			Depression	01JAN1993		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Menopause	01JUL2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881100	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1088 10881101	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1088 10881102	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1088 10881103	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Intervertebral disc degeneration	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1088 10881107	Eye disorders	Dry eye	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Investigations	Human papilloma virus test positive	01JAN2009	31DEC2016	N
		Psychiatric disorders	Affective disorder	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Salpingectomy	01JAN2006	31DEC2006	N
			Vaginal operation	01JAN2009	31DEC2009	N
			Vulvectomy	01JAN2012	31DEC2012	N
	C4591001 1088 10881109	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881111	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2006	31DEC2006	N
	C4591001 1088 10881112	Gastrointestinal disorders	Colitis ulcerative	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1088 10881114	Infections and infestations	Herpes zoster	01JAN1988		Y
		Social circumstances	Menopause	01JAN2009		Y
	C4591001 1088 10881116	Metabolism and nutrition disorders	Gout	01JAN2003		Y
			Hypercholesterolaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1088 10881117	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1088 10881123	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2007		Y
	C4591001 1088 10881128	Cardiac disorders	Tachycardia	01JAN2003		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Autism spectrum disorder	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2002		Y
			Insomnia	01JAN2014		Y
	C4591001 1088 10881130	Musculoskeletal and connective tissue disorders	Spinal deformity	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2004		Y
	C4591001 1088 10881137	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2010		Y
	C4591001 1088 10881143	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1088 10881151	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1980		Y
			Back pain	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881153	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Immune system disorders	Multiple allergies	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Bipolar disorder	01JAN2012		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1088 10881158	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1088 10881159	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01SEP2019	30SEP2019	N
		Vascular disorders	Hypertension	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881160	Endocrine disorders	Hyperthyroidism	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Nausea	01JAN2000		Y
		Nervous system disorders	Dizziness	01JAN2000		Y
			Migraine	01JAN2000		Y
			Seizure	01JAN2011		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1088 10881162	Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
			Depression	01JAN2015		Y
	C4591001 1088 10881166	Endocrine disorders	Hyperthyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Multiple allergies	01JAN1972		Y
		Vascular disorders	Hypertension	01JUL2018		Y
	C4591001 1088 10881169	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2016	N
	C4591001 1088 10881171	Blood and lymphatic system disorders	Coagulopathy	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Oedema	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2000		Y
			Insomnia	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881176	Psychiatric disorders	Anxiety	01JAN1998		Y
	C4591001 1088 10881177	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1088 10881180	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
	C4591001 1088 10881185	Reproductive system and breast disorders	Menstruation irregular	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1088 10881187	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
		Infections and infestations	Oral herpes	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1968		Y
			Osteopenia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Vascular disorders	Deep vein thrombosis	01DEC2012	31DEC2012	N
	C4591001 1088 10881192	Psychiatric disorders	Anxiety	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881194	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
	C4591001 1088 10881196	Cardiac disorders	Ventricular extrasystoles	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1986		Y
	C4591001 1088 10881197	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2006		Y
	C4591001 1088 10881200	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1088 10881201	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1088 10881213	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2020		Y
	C4591001 1088 10881214	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis perennial	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1088 10881217	Immune system disorders	Multiple allergies	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881218	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01APR2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
	C4591001 1088 10881220	Nervous system disorders	Headache	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1088 10881222	Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1088 10881224	Psychiatric disorders	Anxiety	01OCT2019		Y
	C4591001 1088 10881225	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1088 10881232	Injury, poisoning and procedural complications	Tibia fracture	01APR2020	30APR2020	N
		Psychiatric disorders	Insomnia	01JUL2020		Y
	C4591001 1088 10881233	Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Insomnia	01JAN2015		Y
	C4591001 1088 10881235	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1088 10881238	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1088 10881239	Psychiatric disorders	Affective disorder	01JAN2003		Y
			Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2003		Y
			Insomnia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2015		Y
	C4591001 1088 10881245	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1088 10881246	Surgical and medical procedures	Shoulder operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1088 10881248	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1088 10881251	Cardiac disorders	Tachycardia	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Oedema	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1088 10881254	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2008	N
		Psychiatric disorders	Depression	01AUG2020		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1088 10881255	Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Seborrhoea	01JAN1995		Y
	C4591001 1088 10881256	Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1088 10881258	Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2017		Y
	C4591001 1088 10881259	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
			Intervertebral disc degeneration	01JAN2014		Y
			Plantar fasciitis	01JAN2014		Y
			Spinal stenosis	01JAN2014		Y
		Nervous system disorders	Amnesia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01APR2020		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Embolism	01JAN2008		Y
			Hypertension	01JAN2017		Y
	C4591001 1089 10891011	Eye disorders	Amblyopia	01JAN1976	31DEC1976	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Nasal septal operation	01JAN1988	31DEC1988	N
			Strabismus correction	01JAN1976	31DEC1976	N
			Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1089 10891013	Eye disorders	Blindness unilateral	01JAN2015		Y
	C4591001 1089 10891015	Endocrine disorders	Hypothyroidism	01MAY2019		Y
		Immune system disorders	Allergy to chemicals	01JAN2001		Y
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01SEP2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01SEP2018		Y
			Insomnia	01SEP2018		Y
		Surgical and medical procedures	Limb operation	01JAN2010	31DEC2010	N
	C4591001 1089 10891020	Cardiac disorders	Arrhythmia	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1089 10891022	Endocrine disorders	Thyroid mass	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Surgical and medical procedures	Thyroid nodule removal	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891025	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Tonsillitis	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Ankle operation	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1089 10891027	Cardiac disorders	Angina pectoris	01JAN2013		Y
		Endocrine disorders	Thyroid disorder	01JAN2016		Y
		Gastrointestinal disorders	Abdominal distension	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2016		Y
			Impaired gastric emptying	01JAN2019		Y
			Nausea	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Fungal infection	01JAN2010		Y
			Genital herpes simplex	01JAN2016		Y
			Tonsillitis	01JAN1980	31DEC1980	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2003		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Restless legs syndrome	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1998		Y
		Surgical and medical procedures	Bladder repair	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Knee operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1089 10891049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Colectomy	01JAN2010	31DEC2010	N
	C4591001 1089 10891050	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1089 10891054	Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
	C4591001 1089 10891055	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
	C4591001 1089 10891056	General disorders and administration site conditions	Cyst	01JAN2000	31DEC2003	N
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2013		Y
			Food allergy	01JAN2002		Y
		Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Bone cyst	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Bone cyst excision	01JAN2008	31DEC2008	N
			Caesarean section	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Limb operation	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891057	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Knee operation	01JAN1985	31DEC1995	N
				01JAN1988	31DEC1988	N
				01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
	C4591001 1089 10891058	Cardiac disorders	Salpingectomy	01JAN2004	31DEC2004	N
			Angina pectoris	01JAN2016		Y
			Arrhythmia	06NOV2018	06NOV2018	N
			Myocardial infarction	10JUN2013	10JUN2013	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	17OCT2018	17OCT2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				25JUL1989	25JUL1989	N
			Cardiac pacemaker insertion	06NOV2018		Y
			Cholecystectomy	01JAN1995	31DEC1995	N
			Coronary arterial stent insertion	10JUN2018	10JUN2018	N
		Vascular disorders	Hot flush	01JAN2003		Y
	C4591001 1089 10891059	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Bunion operation	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891061	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1089 10891062	Eye disorders	Eye irritation	01JUL2020		Y
		Hepatobiliary disorders	Gallbladder hypofunction	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Ovarian operation	01JAN2005	31DEC2005	N
	C4591001 1089 10891064	Infections and infestations	Appendicitis	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Knee operation	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
				01JAN2016	31DEC2016	N
					31DEC2019	N
			Spinal fusion surgery	01JAN2009	31DEC2009	N
			Wrist surgery	01JAN2008	31DEC2008	N
			Cholelithiasis	01JAN1973	31DEC1973	N
	C4591001 1089 10891065	Hepatobiliary disorders				
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Skin ulcer	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Cholecystectomy	01JAN1973	31DEC1973	N
	C4591001 1089 10891067	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
			Colonoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1089 10891070	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Adenoiditis	01JAN1977	31DEC1977	N
			Tonsillitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1977	31DEC1977	N
			Caesarean section	01MAR2007	31MAR2007	N
			Nasal septal operation	01JUL2007	31JUL2007	N
			Tonsillectomy	01MAR2018	31MAR2018	N
			Hypertension	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1089 10891072	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Gastric bypass	01JAN2007	31DEC2007	N
	C4591001 1089 10891074	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1089 10891077	Cardiac disorders	Bundle branch block left	01MAR2019		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2004		Y
			Gastroesophageal reflux disease	01JAN2017		Y
			Irritable bowel syndrome	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2006		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01FEB2016	29FEB2016	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Osteoarthritis	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2008		Y
		Social circumstances	Postmenopause	01JUN2017		Y
	C4591001 1089 10891078	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1089 10891080	Surgical and medical procedures	Caesarean section	12FEB2007	12FEB2007	N
				12MAR2012	12MAR2012	N
	C4591001 1089 10891082	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1089 10891084	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891091	Injury, poisoning and procedural complications	Joint dislocation	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Hip surgery	01JAN1984	31DEC1984	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1089 10891097	Gastrointestinal disorders	Inguinal hernia	01JAN1987	31DEC1987	N
			Umbilical hernia	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neuropathy peripheral	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN1987	31DEC1987	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1089 10891100	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteoporosis	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013	31DEC2013	N
			Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2019	19FEB2020	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Rhinoplasty	19FEB2020	19FEB2020	N
	C4591001 1089 10891101	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Pneumonia	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Chest tube insertion	01JAN2018	31DEC2018	N
	C4591001 1089 10891103	Investigations	Blood testosterone decreased	01JAN2019		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1089 10891105	Immune system disorders	Allergy to arthropod sting	01JAN1978		Y
			Drug hypersensitivity	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Intervertebral disc degeneration	01JAN2000		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Shoulder operation	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2018	31DEC2018	N
	C4591001 1089 10891106	Injury, poisoning and procedural complications	Tendon rupture	01AUG2015	31AUG2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Surgical and medical procedures	Limb operation	01AUG2015	31AUG2015	N
		Vascular disorders	Hypertension	01APR2016		Y
	C4591001 1089 10891107	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN2016	31DEC2016	N
	C4591001 1089 10891111	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Knee operation	01JAN2003	31DEC2003	N
			Ligament operation	01JAN2003	31DEC2003	N
	C4591001 1089 10891113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1089 10891115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
			Herpes simplex	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1089 10891116	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2008		Y
		Infections and infestations	Herpes simplex	01JAN2001		Y
		Investigations	Human papilloma virus test positive	01JAN2001	31DEC2014	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2001	31DEC2014	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1997		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Loop electrosurgical excision procedure	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2006	31DEC2006	N
			Wisdom teeth removal	01JAN2014	31DEC2014	N
			Drug hypersensitivity	01JAN2003	31DEC2003	N
	C4591001 1089 10891120	Immune system disorders		01JAN1997		Y
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2001		Y
		Surgical and medical procedures	Bone operation	01JAN2001		Y
	C4591001 1089 10891123	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1089 10891130	Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1089 10891131	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1985	31DEC1985	N
				01JAN2011	31DEC2011	N
		Nervous system disorders	Sinus headache	01JAN1985		Y
		Surgical and medical procedures	Female sterilisation	01OCT2001	31OCT2001	N
	C4591001 1089 10891132	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Abdominal operation	01JAN1983	31DEC1983	N
			Appendicectomy	01JAN2000	31DEC2000	N
			Limb operation	01JAN2003	31DEC2003	N
	C4591001 1089 10891134	Hepatobiliary disorders	Gallbladder hypofunction	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1089 10891135	Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
	C4591001 1089 10891138	Congenital, familial and genetic disorders	Cerebrovascular arteriovenous malformation	01JAN1980	31DEC1980	N
				01JAN1994	31DEC1994	N
		Ear and labyrinth disorders	Deafness	01JAN2013		Y
		Infections and infestations	Hepatitis C	01JAN2005	31DEC2005	N
		Nervous system disorders	Peroneal nerve palsy	01JAN1980		Y
			Transient ischaemic attack	01JAN1980	31DEC1980	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Brain operation	01JAN1980	31DEC1980	N
				01JAN1994	31DEC1994	N
			Ovarian cystectomy	01JAN2002	31DEC2002	N
	C4591001 1089 10891139	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2015		Y
			Iodine allergy	01JAN2002		Y
			Rubber sensitivity	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2006	31DEC2006	N
			Uterine dilation and curettage	01JAN2005	31DEC2005	N
	C4591001 1089 10891140	Gastrointestinal disorders	Constipation	01JAN2017		Y
		General disorders and administration site conditions	Oedema	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Osteoarthritis	01JAN2000		Y
			Bipolar disorder	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Postmenopause	01JUL2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
			Uterine dilation and curettage	01JAN1990	31DEC1990	N
	C4591001 1089 10891141	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
	C4591001 1089 10891147	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1089 10891151	Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Female sterilisation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891152	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Peripheral nerve injury	01JAN1997	31DEC1997	N
			Scar	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Surgical and medical procedures	Foot operation	01JAN1995	31DEC1995	N
				01JAN1997	31DEC1997	N
	C4591001 1089 10891155	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
	C4591001 1089 10891156	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2017		Y
	C4591001 1089 10891162	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2001	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
			Bipolar disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1994	31DEC1994	N
			Asthma	01JAN1992		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1994	31DEC1994	N
			Chest wall operation	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb operation	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1996	31DEC1996	N
			Wisdom teeth removal	01JAN2004	31DEC2004	N
	C4591001 1089 10891165	Infections and infestations	Ear infection	01JAN2001	31DEC2001	N
			Tonsillitis	01JAN2000	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Adenoidectomy	01JAN2001	31DEC2001	N
			Ear tube insertion	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1089 10891166	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1089 10891168	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Irritable bowel syndrome	01JAN2010		Y
			Nausea	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989	31DEC2007	N
			Rotator cuff syndrome	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN1989	31DEC1989	N
				01JAN2007	31DEC2007	N
			Nasal operation	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891173	Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1089 10891176	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
	C4591001 1089 10891179	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Nervous system disorders	Seizure	01JAN2009		Y
	C4591001 1089 10891180	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01JAN1993	31DEC1993	N
			Epilepsy	01JAN1992		Y
			Hydrocephalus	01JAN1987		Y
			Migraine	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Medical device implantation	01JAN1987	31DEC1987	N
				01JAN2000	31DEC2000	N
				01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891181	Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
	C4591001 1089 10891182	Surgical and medical procedures	Shoulder operation	01JAN2014	31DEC2014	N
		Cardiac disorders	Atrial fibrillation			Y
		Congenital, familial and genetic disorders	Cryptorchism			N
			Pectus excavatum			Y
		Immune system disorders	Drug hypersensitivity			Y
			Food allergy			Y
		Injury, poisoning and procedural complications	Hand fracture	12AUG2020	24AUG2020	N
		Investigations	Biopsy lymph gland			N
		Musculoskeletal and connective tissue disorders	Arthritis			Y
		Nervous system disorders	Cerebrovascular accident			N
			Seizure			Y
		Psychiatric disorders	Borderline personality disorder	01JAN2014		Y
			Post-traumatic stress disorder			Y
			Schizophrenia	03NOV2017		Y
			Substance abuse	17AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma			Y
			Chronic obstructive pulmonary disease	17DEC2014		Y
		Skin and subcutaneous tissue disorders	Rash	27JUL2020		Y
		Surgical and medical procedures	Abdominal operation			N
			Hernia repair			N
			Testes exploration			N
		Vascular disorders	Hypertension			Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891183	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
	C4591001 1089 10891185	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1983	31DEC1983	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC1999	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
			Cholecystectomy	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891192	Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
	C4591001 1089 10891193	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2009	31DEC2009	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1089 10891194	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Rubber sensitivity	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1089 10891196	Injury, poisoning and procedural complications	Limb injury	01JAN1988	31DEC1988	N
			Lower limb fracture	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Limb operation	01JAN1988	31DEC1988	N
			Tenoplasty	01JAN1988	31DEC1988	N
	C4591001 1089 10891199	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2008		Y
			Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour	01JAN2018		Y
		Surgical and medical procedures	Spinal operation	01JAN2019	31JAN2019	N
			Wisdom teeth removal	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1089 10891200	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Infections and infestations	Skin infection	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Plantar fasciitis	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Surgical and medical procedures	Abscess drainage	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1089 10891201	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN1972	31DEC1976	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2019		Y
			Seasonal allergy	01JAN1976		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Hernia repair	01JAN1976	31DEC1976	N
			Laparoscopic surgery	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1089 10891204	Immune system disorders	Food allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2015		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891205	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
				01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
			Endodontic procedure	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2014	31DEC2014	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1089 10891206	Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1089 10891207	Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1089 10891209	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891212	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1089 10891213	Immune system disorders	Allergy to arthropod sting	01JAN1990		Y
			Food allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1089 10891215	Injury, poisoning and procedural complications	Clavicle fracture	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Bone operation	01JAN1986	31DEC1986	N
	C4591001 1089 10891220	Gastrointestinal disorders	Abdominal hernia	01JAN2011	31DEC2011	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2007		Y
			Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2019		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Knee operation	01JAN2010	31DEC2010	N
	C4591001 1089 10891221	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2001		Y
		Surgical and medical procedures	Neck surgery	01JAN2001	31DEC2001	N
	C4591001 1089 10891225	Injury, poisoning and procedural complications	Ligament rupture	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Lithotripsy	01JAN2018	31DEC2018	N
	C4591001 1089 10891226	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1988		Y
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
	C4591001 1089 10891228	Gastrointestinal disorders	Umbilical hernia	01JAN1978	31DEC1978	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2012		Y
				01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia repair	01JAN1978	31DEC1978	N
	C4591001 1089 10891230	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Nasal operation	01JAN2000	31DEC2000	N
	C4591001 1089 10891231	Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1089 10891232	Hepatobiliary disorders	Gallbladder hypofunction	01JAN1990	31DEC1990	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Psychiatric disorders	Substance dependence	01JAN2016		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1970		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1089 10891233	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Infections and infestations	Adenoiditis	01JAN1996	31DEC1996	N
			Tonsillitis	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Adenoidectomy	01JAN1996	31DEC1996	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1996	31DEC1996	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891234	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
			Limb operation	01JAN2006	31DEC2006	N
	C4591001 1089 10891235	Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
			Substance dependence	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
	C4591001 1089 10891238	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Knee operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1089 10891239	Hepatobiliary disorders	Cholecystitis	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Abdominal operation	01JAN2001	31DEC2001	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Cranial operation	01JAN2001	31DEC2001	N
	C4591001 1089 10891241	Surgical and medical procedures	Limb operation	01JAN2002	31DEC2002	N
			Spinal operation	01JAN2002	31DEC2002	N
	C4591001 1089 10891246	Gastrointestinal disorders	Inguinal hernia	01JAN2018		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus injury	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005	31DEC2012	N
		Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
			Limb operation	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2004	31DEC2004	N
			Ankle fracture	01JAN2014	31DEC2014	N
	C4591001 1089 10891253	Injury, poisoning and procedural complications		01JAN1998	31DEC1998	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Ankle operation	01JAN1998	31DEC1998	N
			Hip surgery	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891261	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2004	31DEC2004	N
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
			Tonsillitis	01JAN1971	31DEC1971	N
		Injury, poisoning and procedural complications	Foot fracture	29AUG2020		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2001	31DEC2001	N
				01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2017		Y
		Social circumstances	Postmenopause	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
			Rotator cuff repair	01JAN2001	31DEC2001	N
				01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1971	31DEC1971	N
			Umbilical hernia repair	01JAN2004	31DEC2004	N
	C4591001 1089 10891268	Cardiac disorders	Angina pectoris	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Limb operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891271	Endocrine disorders	Hyperthyroidism	01JAN1986		Y
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1089 10891272	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2016	31DEC2016	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1089 10891273	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	C4591001 1089 10891275	Eye disorders	Myopia	01JAN1980	31DEC2001	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN2001	31DEC2001	N
	C4591001 1089 10891277	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
	C4591001 1089 10891278	Hepatobiliary disorders	Gallbladder hypofunction	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1089 10891280	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
	C4591001 1089 10891285	Eye disorders	Dry eye	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1089 10891287	Infections and infestations	Appendicitis	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Obsessive-compulsive disorder	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891289	Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	31DEC1990	N
	C4591001 1089 10891291	Injury, poisoning and procedural complications	Ligament rupture	01JAN1994	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN1994	31DEC1994	N
			Wrist surgery	01JAN2012	31DEC2012	N
	C4591001 1089 10891293	Investigations	Blood cholesterol increased	01JAN2015		Y
			Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Pain in jaw	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Ankle operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891296	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		General disorders and administration site conditions	Oedema	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01APR2020	30APR2020	N
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
			Tonsillitis	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Cholecystectomy	01APR2020	30APR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891299	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1984		Y
		Infections and infestations	Adenoiditis	01JAN1998	31DEC1998	N
			Appendicitis	01JAN1995	31DEC1995	N
			Tonsillitis	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1089 10891306	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2016	31DEC2016	N
	C4591001 1089 10891310	Surgical and medical procedures	Jaw operation	01JAN2002	31DEC2002	N
			Limb operation	01JAN2006	31DEC2006	N
	C4591001 1089 10891315	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Tinea pedis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1089 10891318	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2001		Y
	C4591001 1089 10891330	Hepatobiliary disorders	Cholelithiasis	01JUN2019	30JUN2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891334	Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
	C4591001 1089 10891335	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1089 10891336	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Thermal burn	01JAN2007	31DEC2007	N
		Nervous system disorders	Neuropathy peripheral	01JAN2020		Y
	C4591001 1089 10891337	Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1089 10891339	Injury, poisoning and procedural complications	Skeletal injury	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Bone operation	01JAN2009	31DEC2009	N
	C4591001 1089 10891342	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1975		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
				01JAN2005	31DEC2005	N
			Knee operation	01JAN2010	31DEC2010	N
	C4591001 1089 10891346	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Investigations	Cardiac murmur	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1089 10891347	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
	C4591001 1089 10891348	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1985		Y
		Surgical and medical procedures	Neck surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891349	Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1089 10891350	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1980		Y
		Injury, poisoning and procedural complications	Spinal column injury	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Chest tube insertion	01JAN2000	31DEC2000	N
	C4591001 1089 10891352	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Infections and infestations	Oral herpes	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901001	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1090 10901002	Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1980		Y
	C4591001 1090 10901005	Immune system disorders	Reaction to colouring	01JAN1980		Y
			Seasonal allergy	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1994		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1090 10901006	Immune system disorders	Seasonal allergy	01DEC2003		Y
		Nervous system disorders	Headache	31DEC2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hot flush	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901007	Gastrointestinal disorders	Haemorrhoids	01NOV2017		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
	C4591001 1090 10901008	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1993	31DEC1993	N
	C4591001 1090 10901012	Surgical and medical procedures	Blood donation	01JAN2010	29FEB2020	N
	C4591001 1090 10901015	Blood and lymphatic system disorders	Anaemia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Bipolar II disorder	01JAN2014		Y
			Depression	01JAN2007		Y
	C4591001 1090 10901016	Injury, poisoning and procedural complications	Lower limb fracture	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01DEC1979		Y
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1090 10901021	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Social circumstances	Blood donor	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901022	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1090 10901023	Endocrine disorders	Hypothyroidism	01FEB2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
	C4591001 1090 10901029	Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1090 10901031	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1090 10901034	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety disorder	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Depression	01JAN2013		Y
			Insomnia	01JAN2013		Y
	C4591001 1090 10901035	Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1090 10901037	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Blood donation	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	01MAR2010	31MAR2010	N
				23APR2012	23APR2012	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1090 10901038	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1999	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
		Surgical and medical procedures	Hip surgery	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
	C4591001 1090 10901039	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Surgical and medical procedures	Blood donation	01MAY2020	31MAY2020	N
			Caesarean section	21APR2000	21APR2000	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1090 10901043	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Chlamydial infection	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Major depression	01JAN2018		Y
	C4591001 1090 10901044	Blood and lymphatic system disorders	Anaemia	01JAN2008	31DEC2010	N
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2018		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Nervous system disorders	Idiopathic intracranial hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Contraceptive implant	01JAN2019		Y
			Tonsillectomy	01JAN2013	31DEC2013	N
			Tooth extraction	01JAN2014	31DEC2014	N
	C4591001 1090 10901045	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Procedural pneumothorax	01JAN2011	31DEC2011	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	01APR2019	N
		Surgical and medical procedures	Renal stone removal	01APR2019	01APR2019	N
				01JAN2011	31DEC2011	N
	C4591001 1090 10901046	Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
	C4591001 1090 10901050	Immune system disorders	Allergy to animal	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1995		Y
			Eczema	01JAN1995		Y
	C4591001 1090 10901051	Gastrointestinal disorders	Umbilical hernia	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar disorder	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Fracture treatment	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JUL2018	31JUL2018	N
	C4591001 1090 10901052	Immune system disorders	Seasonal allergy	01JUN2018		Y
		Psychiatric disorders	Anxiety	01MAR2012	31JAN2014	N
			Depression	01FEB2012	31JAN2014	N
	C4591001 1090 10901058	Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Blood donation	01JAN2020	31DEC2020	N
			Ligament operation	01JAN2010	31DEC2010	N
	C4591001 1090 10901061	Immune system disorders	Drug hypersensitivity	31DEC1989		Y
			Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Migraine	01DEC1995		Y
	C4591001 1090 10901065	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1993		Y
		Infections and infestations	Herpes simplex	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2016	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1090 10901068	Surgical and medical procedures	Cholelithotomy	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN2005	31DEC2005	N
	C4591001 1090 10901070	Gastrointestinal disorders	Constipation	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Surgical and medical procedures	Lipoma excision	01JUL2018	31JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1090 10901072	Endocrine disorders	Autoimmune thyroiditis	01NOV2014	30NOV2014	N	
					01JAN1985		Y
			Immune system disorders	Food allergy	01JAN1997		Y
						01JAN1970	
			Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
							01JAN2000
			Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy			N
			Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
							01JAN1975
			Skin and subcutaneous tissue disorders	Rosacea			Y
			Social circumstances	Menopause	01JUN2019		Y
			Surgical and medical procedures	Blood donation	01MAY2020	31MAY2020	N
							01JAN2020
			Vascular disorders	Hot flush	01JAN2019	29FEB2020	N
	C4591001 1090 10901073	Immune system disorders	Seasonal allergy	01MAR2020		Y	
							01DEC2003
			Nervous system disorders	Tension headache			N
			Reproductive system and breast disorders	Ovarian cyst	01JAN1999	31DEC1999	N
							01JAN2018
		Social circumstances	Postmenopause			Y	
		Surgical and medical procedures	Oophorectomy	01JAN1999	31DEC1999	N	
	C4591001 1090 10901074	Immune system disorders	Seasonal allergy	01JAN2006		Y	
							01JAN2015
			Injury, poisoning and procedural complications	Meniscus injury			N
			Investigations	Blood cholesterol increased	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cyst removal	01DEC1997	31DEC1997	N
			Urethrectomy	01JAN1990	31DEC1990	N
	C4591001 1090 10901076	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
	C4591001 1090 10901079	Immune system disorders	Food allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1994		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Rhinitis allergic	01JAN2014		Y
	C4591001 1090 10901081	Surgical and medical procedures	Scoliosis surgery	01JAN1995	31DEC1995	N
		Congenital, familial and genetic disorders	Cryptorchism	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
	C4591001 1090 10901086	Injury, poisoning and procedural complications	Ligament rupture	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1090 10901088	Nervous system disorders	Cluster headache	01JAN2005		Y
			Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983		Y
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
	C4591001 1090 10901090	Psychiatric disorders	Anxiety	01DEC2012		Y
			Bipolar disorder	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Hiatus hernia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1090 10901095	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hyperlipidaemia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Social circumstances	Blood donor	01JAN1998		Y
		Surgical and medical procedures	Chondroplasty	01JAN2000		Y
			Ligament operation	01JAN2000	31DEC2000	N
	C4591001 1090 10901096	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1090 10901099	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Rectocele	01MAY2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Urinary bladder suspension	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901101	Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1090 10901103	Ear and labyrinth disorders	Eustachian tube dysfunction	01MAY2020		Y
		Immune system disorders	Allergy to chemicals	01JAN1988		Y
			Seasonal allergy	01MAY2020		Y
		Infections and infestations	Oral herpes	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1090 10901104	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Night sweats	01JAN2018		Y
			Psoriasis	01JAN2008		Y
	C4591001 1090 10901105	Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN1993		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
			Pain in extremity	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
	C4591001 1090 10901106	Cardiac disorders	Cardiac failure congestive	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypogonadism	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Gastric ulcer	01JAN2017		Y
		Infections and infestations	Oral herpes	01JAN1994		Y
		Injury, poisoning and procedural complications	Brachial plexus injury	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
			Back pain	01JAN2013		Y
		Psychiatric disorders	Bipolar disorder	01JAN2016		Y
			Depression	01JAN1994		Y
			Insomnia	01JAN1995		Y
			Panic disorder	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Nasal congestion	01MAR2020		Y
			Pulmonary hypertension	01JAN2013		Y
			Rhinitis allergic	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Cardiac operation	01MAR2013	31DEC2013	N
			Carpal tunnel decompression	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Gastric bypass	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N
			Spinal operation	01JAN2013	31DEC2013	N
			Tenotomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901109	Eye disorders	Glaucoma	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2015		Y
			Food allergy	01JAN2016		Y
		Infections and infestations	Diverticulitis	01JAN2014	31DEC2014	N
		Investigations	Heart rate irregular	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Gluten sensitivity	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
	C4591001 1090 10901114	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1090 10901115	Gastrointestinal disorders	Constipation	01JAN2009		Y
			Gastroesophageal reflux disease	01JAN1989		Y
			Inguinal hernia	01JAN1983	31DEC1983	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
	C4591001 1090 10901116	Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1090 10901125	Gastrointestinal disorders	Diarrhoea	01DEC2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Rubber sensitivity	01JAN2007		Y
		Infections and infestations	Fungal infection	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Diabetic ketoacidosis	01JAN2001	31JAN2001	N
			Type 1 diabetes mellitus	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN1988		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Gastric bypass	01DEC2017	31DEC2017	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Ovarian cystectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1090 10901131	Immune system disorders	Drug hypersensitivity	01DEC1976		Y
			Multiple allergies	01JAN1976		Y
		Injury, poisoning and procedural complications	Muscle strain	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1090 10901132	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Nervous system disorders	Tension headache	01JAN2003		Y
	C4591001 1090 10901133	Surgical and medical procedures	Cyst removal	01JAN2007	31DEC2007	N
		Infections and infestations	Herpes simplex	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	12JUL2014	12JUL2014	N
				17JUL2017	17JUL2017	N
	C4591001 1090 10901135	Endocrine disorders	Female sterilisation	01JAN2017	31DEC2017	N
			Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2015		Y
			Rubber sensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2015	31DEC2015	N
		Investigations	Hepatic enzyme increased	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
			Osteoarthritis	01JAN2002		Y
			Spinal osteoarthritis	01DEC2002		Y
		Nervous system disorders	Vestibular migraine	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Rhinitis allergic	01JAN1966		Y
			Cholecystectomy	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Knee operation	01JAN2002	31DEC2002	N
			Rocky mountain spotted fever	01MAY2020	31MAY2020	N
	C4591001 1090 10901136	Infections and infestations	Rocky mountain spotted fever	01MAY2020	31MAY2020	N
		Investigations	Human papilloma virus test positive	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
	C4591001 1090 10901139	Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
			Rhinitis allergic	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
	C4591001 1090 10901140	Immune system disorders	Dust allergy	01JAN1990		Y
			Food allergy	01JAN1990		Y
			Rubber sensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1996		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2003		Y
			Polycystic ovaries	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Rhinitis allergic	01JAN1985		Y
			Rhinitis allergic	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
		Surgical and medical procedures	Ligament operation	01JAN2003	31DEC2003	N
			Meniscus operation	01JAN2016	31DEC2016	N
	C4591001 1090 10901147	Surgical and medical procedures	Mitral valve replacement	08AUG2017	08AUG2017	N
	C4591001 1090 10901154	Immune system disorders	Drug hypersensitivity	01JAN1994	31DEC1994	N
		Nervous system disorders	Anosmia	01JAN2013		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001	31DEC2001	N
				01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Keratomileusis	01JAN2018	31JAN2018	N
	C4591001 1090 10901156	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Allergy to arthropod sting	10JUL2016		Y
			Drug hypersensitivity	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intervertebral disc operation	01APR2005	30APR2005	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1090 10901160	Infections and infestations	Streptococcal infection	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1090 10901161	Surgical and medical procedures	Tonsillectomy	01JAN1981	31DEC1981	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1090 10901163	Investigations	Blood cholesterol increased	01JAN2014		Y
			Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990	31DEC2016	N
			Type 2 diabetes mellitus	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016	31DEC2016	N
	C4591001 1090 10901167	Surgical and medical procedures	Metabolic surgery	01DEC2016	31DEC2016	N
		Infections and infestations	Streptococcal infection	01JAN2011	31DEC2011	N
		Psychiatric disorders	Perinatal depression	01JAN2014	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901169	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Infections and infestations	Herpes simplex	01JAN1996		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN2005	31DEC2005	N
		Vascular disorders	Hot flush	01JAN2018		Y
			Hypertension	01JAN2019		Y
	C4591001 1090 10901172	Psychiatric disorders	Anxiety	06APR2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
	C4591001 1090 10901174	Eye disorders	Iritis	01MAR2015	31AUG2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1985	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1090 10901177	Blood and lymphatic system disorders	Anaemia	01APR2020		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2002	02SEP2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
			Rhinitis allergic	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901178	Investigations	Blood cholesterol increased	01JAN2017		Y
		Nervous system disorders	Tension headache	01JAN2010		Y
		Psychiatric disorders	Depression	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
	C4591001 1090 10901185	Surgical and medical procedures	Skin lesion removal	01APR2000	30APR2000	N
	C4591001 1090 10901187	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1982		Y
		Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Hernia repair	01JAN2009	31DEC2009	N
	C4591001 1090 10901193	Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1090 10901197	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Petit mal epilepsy	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1090 10901200	Immune system disorders	Allergy to animal	01JAN1989		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01AUG2016	31AUG2016	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1090 10901201	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Dyspepsia	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Food allergy	01JAN2002		Y
			Milk allergy	01JUN2020		Y
		Infections and infestations	Tinea versicolour	01JAN2011	31DEC2016	N
		Metabolism and nutrition disorders	Gluten sensitivity	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1090 10901206	Social circumstances	Postmenopause	01MAY2019		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1090 10901210	Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Knee operation	01JAN2015	31DEC2015	N
	C4591001 1090 10901212	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Hepatobiliary disorders	Biliary colic	01JAN2020	31JAN2020	N
		Investigations	Lipids increased	01JAN2015		Y
			Liver function test increased	01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Endometrial ablation	01SEP2008	30SEP2008	N
			Hip surgery	01DEC2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1090 10901216	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1090 10901220	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1992		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1969		Y
		Social circumstances	Postmenopause	01MAR2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1969	31DEC1969	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1090 10901226	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Psychiatric disorders	Anxiety	01MAR2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1090 10901239	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
			Insomnia	01JAN2019		Y
			Perinatal depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1090 10901244	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1973		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
		Vascular disorders	Fibromuscular dysplasia	01JAN2016		Y
			Hot flush	01JAN2019		Y
	C4591001 1090 10901245	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1090 10901251	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
	C4591001 1090 10901253	Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2005	31MAY2020	N
		Psychiatric disorders	Depression	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2002		Y
		Surgical and medical procedures	Foot operation	01JAN2002	31DEC2002	N
			Neck surgery	01JAN2003	31DEC2003	N
			Shoulder operation	01JAN2003	31DEC2003	N
			Toe amputation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901256	Congenital, familial and genetic disorders	Syringomyelia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
			Rhinitis allergic	01JAN1986		Y
	C4591001 1090 10901260	Investigations	Blood cholesterol increased	01JUN2020		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1090 10901262	Infections and infestations	Sinusitis	01JAN1993		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1090 10901264	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Allergy to plants	01JAN2013		Y
			Food allergy	01JAN2013		Y
			Milk allergy	01JAN2013		Y
		Infections and infestations	Pneumonia	01JAN2019	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
			Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
		Surgical and medical procedures	Knee operation	01JAN1998		Y
			Spinal fusion surgery	01JAN2012		Y
	C4591001 1090 10901266	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1987	30NOV2018	N
		Surgical and medical procedures	Knee arthroplasty	01NOV2018	30NOV2018	N
	C4591001 1090 10901267	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Rhinitis allergic	01JAN1980		Y
	C4591001 1090 10901268	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Essential thrombocythaemia	01JAN2004		Y
		Nervous system disorders	Cluster headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
			Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1090 10901269	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
			Oral herpes	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	15AUG2016	15AUG2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901270	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1090 10901271	Psychiatric disorders	Depression	01JAN1994	31DEC2013	N
		Surgical and medical procedures	Metabolic surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1090 10901277	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Tension headache	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1976	31DEC1976	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2007	31JAN2007	N
			Tonsillectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1090 10901278	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Nervous system disorders	Shift work disorder	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1090 10901281	Nervous system disorders	Migraine	01JAN2000		Y
			Visual field defect	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2010	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2010	N
			Rhinitis allergic	01JAN2002		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2004	31DEC2004	N
			Bone lesion excision	01JAN2018	31DEC2018	N
	C4591001 1090 10901283	Psychiatric disorders	Anxiety disorder	01JAN2014		Y
		Surgical and medical procedures	Meniscus removal	01JAN2016	31DEC2016	N
	C4591001 1090 10901288	Eye disorders	Glaucoma	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Bipolar disorder	01JAN2012		Y
			Insomnia	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1090 10901289	Investigations	Blood cholesterol increased	01JAN2002	31DEC2017	N
		Nervous system disorders	Migraine	01JAN1980		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
			Spinal fusion surgery	01DEC2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1090 10901290	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1090 10901291	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Pilonidal sinus repair	01JAN2003	31DEC2003	N
			Sinus operation	01JAN1991	31DEC1991	N
	C4591001 1090 10901294	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Surgical and medical procedures	Female sterilisation	01DEC2016	31DEC2016	N
			Keratomileusis	01JAN1998	31DEC1998	N
			Tonsillectomy	01APR2012	30APR2012	N
	C4591001 1090 10901295	Nervous system disorders	Cerebrovascular accident	01JAN2017	31JAN2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Arterial therapeutic procedure	01JAN2017	31JAN2017	N
			Stent placement	01JAN2017	31JAN2017	N
	C4591001 1090 10901304	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Social circumstances	Postmenopause	01APR2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901312	Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1090 10901314	Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Dyspepsia	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2001		Y
			Drug hypersensitivity	01JAN2008		Y
			Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Dairy intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2008		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Wisdom teeth removal	01DEC2016	31DEC2016	N
	C4591001 1090 10901315	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2015	N
	C4591001 1090 10901316	Infections and infestations	Herpes virus infection	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Nerve compression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Tonsillectomy	01DEC1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1090 10901318	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1990		Y
		Immune system disorders	Allergy to animal	01JAN1973		Y
			Allergy to arthropod sting	01JAN1973		Y
			Contrast media allergy	01JAN2000		Y
			Drug hypersensitivity	01DEC2000		Y
			Dust allergy	01JAN1973		Y
		Infections and infestations	Urinary tract infection	01JAN2000	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01OCT2013	31OCT2013	N
			Rhinitis allergic	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Deep vein thrombosis	01MAR2011	31MAR2011	N
			Hot flush	01JAN2018		Y
			Hypertension	01JAN2011		Y
	C4591001 1090 10901319	Investigations	Blood cholesterol increased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1991		Y
	C4591001 1090 10901320	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901321	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2004	31DEC2004	N
	C4591001 1090 10901323	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Rhinitis allergic	01JAN1990		Y
	C4591001 1090 10901325	Immune system disorders	Drug hypersensitivity	01AUG2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAY2012		Y
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
	C4591001 1090 10901326	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01DEC2005	31DEC2005	N
	C4591001 1090 10901328	Immune system disorders	Food allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1090 10901329	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1090 10901330	Endocrine disorders	Hypothyroidism	01JUL2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diarrhoea	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Lacrimal duct procedure	01JAN2013		Y
			Ligament operation	01JAN2017	31DEC2017	N
	C4591001 1090 10901334	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	01JAN1989		Y
	C4591001 1090 10901335	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
			Hiatus hernia	01JAN2012		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2019	N
			Bronchitis chronic	01JAN1970		Y
			Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970		Y
			Hidradenitis	01JAN2018		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1988	31DEC1988	N
		Vascular disorders	Hot flush	01JAN2018		Y
			Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901336	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Infections and infestations	Diverticulitis	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Gastrectomy	01JAN2014	31DEC2014	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1090 10901339	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1090 10901343	Immune system disorders	Allergy to arthropod sting	01JUN2020		Y
		Injury, poisoning and procedural complications	Limb injury	01MAR2018	31MAR2018	N
		Nervous system disorders	Migraine	01JAN2015		Y
			Tension headache	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Limb operation	01MAR2018	31MAR2018	N
	C4591001 1090 10901346	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1090 10901348	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901349	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2012	N
		Investigations	Blood cholesterol increased	01SEP2000		Y
		Surgical and medical procedures	Hernia repair	01SEP2012	30SEP2012	N
			Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1090 10901355	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Ligament operation	01JAN1994	31DEC1994	N
			Nasal septal operation	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1984	31DEC1984	N
	C4591001 1090 10901356	Injury, poisoning and procedural complications	Peripheral nerve injury	11JUN2011		Y
		Metabolism and nutrition disorders	Obesity	01DEC1990		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2015		Y
	C4591001 1090 10901357	Investigations	Blood cholesterol increased	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN1992	31DEC2002	N
			Prostate cancer	01DEC2018	31DEC2018	N
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1090 10901358	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2002		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1993		Y
		Investigations	Cardiac murmur	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1993		Y
		Surgical and medical procedures	Vasectomy	01JUN2020	30JUN2020	N
	C4591001 1090 10901360	Hepatobiliary disorders	Cholelithiasis	01JUN2002	30JUN2002	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1090 10901362	Investigations	Blood cholesterol increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901363	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Rhinitis allergic	01JAN1996		Y
		Surgical and medical procedures	Abdominal hernia repair	15NOV2019	15NOV2019	N
	C4591001 1090 10901365	Ear and labyrinth disorders	Meniere's disease	01JAN2017		Y
		Endocrine disorders	Hyperthyroidism	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1981		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901366	Immune system disorders	Allergy to arthropod sting	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN1988		Y
		Nervous system disorders	Post herpetic neuralgia	01JAN2015		Y
			Seizure	01JAN1988	31DEC1989	N
		Surgical and medical procedures	Appendectomy	01JAN2001	31DEC2001	N
	C4591001 1090 10901367	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Investigations	Laparoscopy	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC1998	N
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1090 10901369	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1090 10901370	Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1090 10901371	Skin and subcutaneous tissue disorders	Eczema	01JUL2020		Y
	C4591001 1090 10901372	Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
	C4591001 1090 10901373	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013		Y
		Nervous system disorders	Tension headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1090 10901374	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01MAY2017		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1995		Y
		Surgical and medical procedures	Fracture treatment	01JUL2018	31JUL2018	N
				01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1090 10901375	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
			Spinal osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1981		Y
			Actinic keratosis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901377	Immune system disorders	Allergy to animal	01JAN2004		Y
			Food allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901378	Surgical and medical procedures	Vasectomy	01MAY2018		Y
		Vascular disorders	Hypertension	01JAN2007	31DEC2015	N
	C4591001 1090 10901379	Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Rhinitis allergic	Rhinitis allergic	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2017	31DEC2017	N
	C4591001 1090 10901380	Immune system disorders	Allergy to animal	01JAN1987		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
		Rhinitis allergic	Rhinitis allergic	01JAN1987		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1090 10901382	Investigations	Blood cholesterol increased	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Guttate psoriasis	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901383	Immune system disorders	Milk allergy	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Menopause	01MAR2020		Y
		Vascular disorders	Hot flush	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901384	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1994		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1981	31DEC1983	N
	C4591001 1090 10901386	Social circumstances	Postmenopause	01JUN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Knee operation	01JAN1986	31DEC1986	N
	C4591001 1090 10901387	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC2013		Y
		Surgical and medical procedures	Female sterilisation	01DEC2007	31DEC2007	N
			Gastric bypass	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901391	Immune system disorders	Food allergy	01NOV2019		Y
			Rubber sensitivity	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1992	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2020		Y
		Surgical and medical procedures	Myomectomy	01JAN2004		Y
		Vascular disorders	Hot flush	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901392	Nervous system disorders	Migraine	01NOV2011		Y
	C4591001 1090 10901393	Infections and infestations	Fungal skin infection	01AUG2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2010		Y
		Psychiatric disorders	Post-traumatic stress disorder	01SEP2010		Y
	C4591001 1090 10901394	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Mite allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1090 10901395	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Lymphadenectomy	01JAN2020		Y
	C4591001 1090 10901397	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Investigations	Blood cholesterol increased	01DEC2016		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1998	31DEC2019	N
		Surgical and medical procedures	Lithotripsy	30JUL2019		Y
	C4591001 1090 10901398	Immune system disorders	Drug hypersensitivity	(b) (6) 1969		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee arthroplasty	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901399	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Psychiatric disorders	Anxiety disorder	01JAN2002		Y
	C4591001 1090 10901400	Surgical and medical procedures	Appendectomy	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Helicobacter infection	01JAN1989	31DEC1989	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901401	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Investigations	Blood cholesterol increased	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1090 10901402	Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hot flush	01MAY2020		Y
			Hypertension	01MAR2018		Y
	C4591001 1090 10901407	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Nervous system disorders	Tension headache	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
	C4591001 1090 10901408	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901410	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	(b) (6) 1982		Y
	C4591001 1090 10901413	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety disorder	01JAN2005		Y
			Bipolar II disorder	01JAN2016		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1090 10901416	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1090 10901418	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Food allergy	01JAN1979		Y
		Infections and infestations	Appendicitis	01SEP2019	30SEP2019	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01SEP2019	30SEP2019	N
			Female sterilisation	01MAR2009	31MAR2009	N
			Knee operation	01JUL1987	31JUL1987	N
			Urinary bladder suspension	01JUN1999	30JUN1999	N
		Vascular disorders	Hot flush	01JAN1995		Y
	C4591001 1090 10901419	Ear and labyrinth disorders	Tinnitus	13OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Diarrhoea	01JAN2000		Y
		General disorders and administration site conditions	Pain	13OCT2019		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN1995		Y
			Mite allergy	01JAN1980		Y
			Mycotic allergy	01JAN1980		Y
		Investigations	Human papilloma virus test positive	01AUG2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	13OCT2019		Y
			Exostosis	01JAN2014	31MAY2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2015		Y
			Depression	01NOV2019	31MAR2020	N
			Insomnia	01AUG2017		Y
			Panic disorder	01OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2017		Y
			Rhinitis allergic	01OCT1985		Y
		Surgical and medical procedures	Endometrial ablation	01OCT2008	31OCT2008	N
			Female sterilisation	01SEP1997	30SEP1997	N
			Shoulder operation	01MAY2014	31MAY2014	N
			Sinus operation	01FEB2009	28FEB2009	N
			Thyroidectomy	01MAY2019	31MAY2019	N
			Tonsillectomy	01OCT1981	31OCT1981	N
	C4591001 1090 10901422	Investigations	Blood cholesterol increased	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901423	Nervous system disorders	Neuropathy peripheral	30NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Spinal laminectomy	30DEC2019	30DEC2019	N
			Turbinectomy	(b) (6) 1983	31MAY2010	N
	C4591001 1090 10901424	Infections and infestations	Lyme disease	01JAN2002	31DEC2002	N
		Psychiatric disorders	Insomnia	01OCT2012	31MAY2014	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012	31MAR2016	N
		Surgical and medical procedures	Ear tube insertion	01MAY1995	31MAY1996	N
			Shoulder operation	01DEC2014	31DEC2014	N
	C4591001 1090 10901426	Cardiac disorders	Angina pectoris	01JAN2015		Y
			Cardiac failure congestive	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2006	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2011		Y
		Psychiatric disorders	Irritability	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901427	Injury, poisoning and procedural complications	Joint dislocation	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN1992	31DEC1992	N
	C4591001 1090 10901429	Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1090 10901431	Nervous system disorders	Tension headache	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1090 10901432	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
	C4591001 1090 10901437	Gastrointestinal disorders	Dyspepsia	01JAN2001		Y
			Gastroesophageal reflux disease	01JAN2001		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
	C4591001 1090 10901440	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1090 10901441	Ear and labyrinth disorders	Tinnitus	01JAN2008		Y
		Immune system disorders	Allergy to animal	01JAN1977		Y
			Allergy to arthropod sting	01JAN1977		Y
			Seasonal allergy	01JAN1977		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1991	31DEC1991	N
				01JAN2008	31DEC2008	N
		Nervous system disorders	Muscle contractions involuntary	01JAN2018		Y
			Neuropathy peripheral	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901443	Psychiatric disorders	Anxiety disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2013	31JUL2013	N
	C4591001 1090 10901451	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2010		Y
	C4591001 1090 10901452	Immune system disorders	Mite allergy	01JAN1980		Y
			Mycotic allergy	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1983	31DEC1983	N
			Skin laceration	01JAN1983	31DEC1983	N
		Investigations	Cardiac murmur	01JAN1980	31DEC1990	N
		Surgical and medical procedures	Myomectomy	01JAN2013	31DEC2013	N
			Surgery	01JAN1983	31DEC1983	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1090 10901457	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1090 10901461	Blood and lymphatic system disorders	Anaemia	01JAN2006	30JUN2018	N
		Immune system disorders	Rubber sensitivity	01JAN1967		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1987	31JUL2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1090 10901463	Psychiatric disorders	Depression	01JAN2003		Y
	C4591001 1090 10901464	Investigations	Human papilloma virus test positive	01JAN2017	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2012		Y
			Eczema	01JAN1992		Y
	C4591001 1090 10901465	Infections and infestations	Pilonidal cyst	01SEP2007	30NOV2016	N
		Investigations	Blood cholesterol increased	23MAY2019		Y
			Human papilloma virus test positive	01SEP2005	31OCT2008	N
		Vascular disorders	Hypertension	23MAY2019		Y
	C4591001 1090 10901470	Gastrointestinal disorders	Diarrhoea	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	22JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY1999		Y
		Nervous system disorders	Headache	01JUL2020		Y
			Neuropathy peripheral	01MAY1999		Y
		Psychiatric disorders	Depression	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2001		Y
		Surgical and medical procedures	Bunion operation	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1982	31DEC1982	N
	C4591001 1090 10901473	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Tonsillitis	01JAN1984		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Blood testosterone decreased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01NOV2000	30NOV2000	N
		Psychiatric disorders	Seasonal affective disorder	01JAN2002		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1090 10901474	Infections and infestations	Appendicitis	01JAN2014	31JAN2014	N
		Investigations	Blood cholesterol increased	01MAR2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Surgical and medical procedures	Appendectomy	01JAN2014	31JAN2014	N
	C4591001 1090 10901476	Investigations	Blood cholesterol increased	09SEP2020		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1090 10901477	Infections and infestations	Ear infection	01JAN1984	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	04MAR2020	06MAR2020	N
	C4591001 1090 10901479	Surgical and medical procedures	Myringotomy	01JAN1984	31DEC1984	N
	C4591001 1090 10901480	Psychiatric disorders	Anxiety disorder	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Inguinal hernia		01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	31DEC1990	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1090 10901481	Immune system disorders	Food allergy	01JAN1989		Y
		Nervous system disorders	Tension headache	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1090 10901482	Blood and lymphatic system disorders	Anaemia	01JAN1992		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2008		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901484	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Hiatus hernia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
			Tonsillitis	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
	C4591001 1090 10901489	Gastrointestinal disorders	Dyspepsia	01JAN1998		Y
	C4591001 1090 10901491	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
			Insomnia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1090 10901496	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2012	31DEC2012	N
	C4591001 1090 10901497	Immune system disorders	Allergy to animal	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Contrast media allergy	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Renal and urinary disorders	Renal cyst	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Surgical and medical procedures	Renal surgery	01JAN2017	31DEC2017	N
			Turbinectomy	01JAN1992	31DEC1992	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1996	31DEC1996	N
			Vasectomy reversal	01JAN2001	31DEC2006	N
	C4591001 1090 10901498	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1998		Y
			Tension headache	01JAN1998		Y
		Psychiatric disorders	Anxiety disorder	01JAN1992		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
			Urethral stent insertion	01JAN2018	31DEC2018	N
	C4591001 1090 10901502	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN1993		Y
			Food allergy	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
	C4591001 1090 10901503	Surgical and medical procedures	Tonsillectomy	01JUN2020	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1090 10901507	Gastrointestinal disorders	Constipation	01JAN2007		Y
			Irritable bowel syndrome	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
	C4591001 1090 10901508	Immune system disorders	Drug hypersensitivity	15MAY2020	18MAY2020	N
			Rubber sensitivity	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Fibromyalgia	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2004		Y
			Ovarian cyst	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Rhinitis allergic	01JAN2009		Y
		Surgical and medical procedures	Fracture treatment	11NOV2019		Y
			Ovarian cystectomy	15MAY2020	15MAY2020	N
			Strabismus correction	01JAN1993	31DEC1993	N
				01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901509	Investigations	Blood testosterone decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Plica syndrome	01OCT2008	31OCT2008	N
		Surgical and medical procedures	Knee operation	01OCT2008	31OCT2008	N
			Shoulder operation	01OCT2013	31OCT2013	N
	C4591001 1090 10901510	Gastrointestinal disorders	Dyspepsia	01JAN2003		Y
		Immune system disorders	Food allergy	01JAN1973		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1090 10901513	Blood and lymphatic system disorders	Anaemia	01JAN2007	31DEC2007	N
		Cardiac disorders	Angina pectoris	01JAN2017	31DEC2017	N
			Tachycardia	01JAN2017	31DEC2017	N
		Endocrine disorders	Hyperthyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Injury, poisoning and procedural complications	Traumatic lung injury	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01JAN2007		Y
			Depression	01JAN1984		Y
			Post-traumatic stress disorder	01JAN2007		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2019		Y
			Nasal septum deviation	01JAN2019	31DEC2019	N
			Pneumothorax	01JAN2007	31DEC2007	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN1972		Y
		Surgical and medical procedures	Chest tube insertion	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Nasal septal operation	01JAN2019	31DEC2019	N
	C4591001 1090 10901516	Gastrointestinal disorders	Constipation	01JAN1991		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1971		Y
		Psychiatric disorders	Anxiety disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	(b) (6) 1971		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1971		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hot flush	01JAN2012		Y
			Hypertension	01JAN2012		Y
	C4591001 1090 10901517	Endocrine disorders	Hypothyroidism	01JAN1997		Y
	C4591001 1090 10901518	Immune system disorders	Drug hypersensitivity	01OCT2009		Y
			Seasonal allergy	01OCT2008		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01MAR2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01AUG2011		Y
	C4591001 1090 10901520	Nervous system disorders	Amnesia	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
			Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1090 10901524	Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01MAY2020	31MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
			Upper-airway cough syndrome	01JAN1990		Y
	C4591001 1090 10901526	Investigations	Blood cholesterol increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2006		Y
		Social circumstances	Blood donor	01SEP2020	30SEP2020	N
		Surgical and medical procedures	Fracture treatment	01SEP1986	30SEP1986	N
			Vasectomy	01MAR2007	31MAR2007	N
	C4591001 1090 10901527	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1090 10901528	Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
			Gastric ulcer	01JAN2008	31DEC2010	N
		Immune system disorders	Seasonal allergy	(b) (6) 1967		Y
		Infections and infestations	Myringitis	(b) (6) 1967		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	(b) (6) 1967		Y
		Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Turbinectomy	01JAN1999	31DEC1999	N
	C4591001 1090 10901529	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN1997		Y
				06JUL2020		Y
		Infections and infestations	Gastrointestinal infection	01JAN2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2018		Y
	C4591001 1090 10901530	Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Gastric bypass	01OCT2018	31OCT2018	N
	C4591001 1090 10901535	Immune system disorders	Drug hypersensitivity	01JUL2011		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2003	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
				01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
			Caesarean section	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1090 10901536	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood iron decreased	01JUL2020		Y
			Blood testosterone decreased	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D decreased	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1090 10901537	General disorders and administration site conditions	Hernia	(b) (6) 1974	31DEC1975	N
		Immune system disorders	Drug hypersensitivity	(b) (6) 1974		Y
			Seasonal allergy	(b) (6) 1974		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1984	31DEC1984	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1090 10901538	Gastrointestinal disorders	Abdominal hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Animal scratch	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2017		Y
			Rosacea	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901539	Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
		Infections and infestations	Sinusitis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JUN2019	31AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Rhinitis allergic	01JAN2000		Y
			Sinus polyp	01JAN1998	31DEC1998	N
				01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N
			Surgical and medical procedures	Sinus operation	01JAN1998	31DEC1998
				01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N
	C4591001 1090 10901540	Investigations	Serum ferritin decreased	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2019	31DEC2019	N
			Ear tube insertion	01JAN2001	31DEC2001	N
			Limb operation	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1090 10901543	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990	31DEC2002	N
		Surgical and medical procedures	Ligament operation	01JUN2020	30JUN2020	N
	C4591001 1090 10901544	Cardiac disorders	Mitral valve prolapse	01JAN2011		Y
		Gastrointestinal disorders	Constipation	01JAN2007		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diarrhoea	01JAN2007		Y
			Dyspepsia	01JAN2007		Y
		Immune system disorders	Rubber sensitivity	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
		Surgical and medical procedures	Mole excision	01JAN2009	31DEC2009	N
	C4591001 1090 10901546	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2020	15SEP2020	N
	C4591001 1090 10901547	Immune system disorders	Seasonal allergy	(b) (6) 1967		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Nervous system disorders	Ischaemic stroke	01JUL2015	31JUL2015	N
		Psychiatric disorders	Anxiety	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1090 10901548	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2003		Y
			Post-traumatic stress disorder	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1977		Y
			Upper-airway cough syndrome	01JAN1977		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JUN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1090 10901550	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1090 10901551	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1090 10901557	Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2020		Y
			Depression	01JAN2008		Y
			Postpartum anxiety	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
			Asthma exercise induced	01JAN1984		Y
			Rhinitis allergic	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1997		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1090 10901558	Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1090 10901559	Gastrointestinal disorders	Pelvic floor dysfunction	01JAN2016		Y
		Investigations	Pelvic laparoscopy	04AUG2020	31DEC2020	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2017		Y
	C4591001 1090	Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	10901565	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Social circumstances	Blood donor	01JAN1991		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Uterine dilation and curettage	01JAN2016	31DEC2016	N
	C4591001 1090	Immune system disorders	Wisdom teeth removal	01JAN1990	31DEC1990	N
	10901566		Allergy to plants	01JAN2010		Y
			Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1990		Y
		Investigations	Human papilloma virus test positive	01JAN1998	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN1989		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1091	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
	10911005	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		General disorders and administration site conditions	Hernia	01JAN1992	31DEC1992	N
		Immune system disorders	Contrast media allergy	01JAN2012		Y
			Drug hypersensitivity	01JAN1967		Y
				01JAN2005		Y
			Perennial allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2019		Y
			Obesity	30JUL2020		Y
			Vitamin B complex deficiency	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2009	31DEC2011	N
			Uterine cyst	01JAN2009	31DEC2011	N
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
				01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N
			Hernia repair	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Oophorectomy bilateral	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1091 10911008	Eye disorders	Cataract	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Seasonal allergy	01JAN1974		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2006	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Surgical and medical procedures	Shoulder operation	01JAN2009		Y
	C4591001 1091 10911011	Endocrine disorders	Hypothyroidism	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2012		Y
	C4591001 1091 10911013	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911014	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Allergy to animal	01JAN2019		Y
			Mite allergy	01JAN2019		Y
			Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2016	31DEC2017	N
			Ligament rupture	01JAN1997	31DEC1997	N
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
			Tendonitis	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Surgical and medical procedures	Gastric banding	01JAN2017	31DEC2017	N
			Ligament operation	01JAN1997	31DEC1997	N
			Nasal septal operation	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Tendon operation	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911015	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1091 10911017	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1091 10911019	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2011		Y
		Investigations	Cardiac murmur	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1091 10911022	Gastrointestinal disorders	Inguinal hernia	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1977	31DEC1977	N
	C4591001 1091 10911025	Infections and infestations	Pertussis	01JAN1989	31DEC1989	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2012	31DEC2012	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1091 10911027	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Thyroidectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hot flush	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911032	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1091 10911037	Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
	C4591001 1091 10911038	Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
	C4591001 1091 10911039	Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JUL2019		Y
	C4591001 1091 10911042	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Psychiatric disorders	Anxiety	01MAY2018		Y
			Depression	01MAY2018		Y
			Obsessive-compulsive disorder	01MAY2018		Y
	C4591001 1091 10911043	Metabolism and nutrition disorders	Obesity	01JAN2001	31DEC2009	N
		Nervous system disorders	Migraine	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Metabolic surgery	01JAN2009	31DEC2009	N
		Vascular disorders	Hot flush	01JAN2018		Y
			Hypertension	01JAN2002		Y
	C4591001 1091 10911046	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Dystonia	01SEP2018		Y
		Vascular disorders	Deep vein thrombosis	01MAR2020	30JUN2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911051	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JUL2020		Y
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1091 10911053	Nervous system disorders	Migraine	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010		Y
	C4591001 1091 10911054	Immune system disorders	Seasonal allergy	01JAN1999		Y
	C4591001 1091 10911057	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2004	31DEC2004	N
		Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1091 10911058	Immune system disorders	Food allergy	01JAN2009		Y
			Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
	C4591001 1091 10911061	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2011	31DEC2011	N
	C4591001 1091 10911062	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Ovarian cystectomy	01JAN2016	31DEC2016	N
	C4591001 1091 10911065	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
				01JAN1995		Y
		Infections and infestations	Scarlet fever	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1091 10911066	Surgical and medical procedures	Meniscus operation	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
			Osteoarthritis	01JAN2018		Y
			Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1091 10911067	General disorders and administration site conditions	Pain	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2007		Y
	C4591001 1091 10911069	Nervous system disorders	Headache	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Investigations	Coagulation factor V level	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019		Y
			Arthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	10FEB2005	10FEB2005	N
			Knee arthroplasty	01DEC2019	31DEC2019	N
			Meniscus operation	01SEP2019	30SEP2019	N
	C4591001 1091 10911070	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Injury, poisoning and procedural complications	Stress fracture	01JAN2012	31DEC2012	N
	C4591001 1091 10911075	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1091 10911077	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
	C4591001 1091 10911078	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2016		Y
			Anxiety	01JAN2019		Y
			Insomnia	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2011		Y
			Eczema	01JAN2013		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1091 10911079	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN1985	31DEC1995	N
		Ear and labyrinth disorders	Deafness	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1091 10911082	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN1981		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Toe amputation	01MAY2018	31MAY2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1091 10911083	Nervous system disorders	Headache	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1091 10911085	Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2020		Y
	C4591001 1091 10911087	Nervous system disorders	Headache	01JAN2018		Y
		Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 1091 10911088	Immune system disorders	Hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911090	Immune system disorders	Seasonal allergy	01JAN1974		Y
	C4591001 1091 10911091	Congenital, familial and genetic disorders	Thalassaemia alpha	(b) (6) 1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1091 10911093	Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1091 10911095	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2019		Y
	C4591001 1091 10911096	Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1091 10911098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01OCT2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2018		Y
	C4591001 1091 10911099	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2002	31DEC2002	N
		Investigations	Arthroscopy	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1091 10911104	Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2018	31JUL2018	N
			Female sterilisation	06APR2011	06APR2011	N
			Gastric bypass	01JAN2019	31DEC2019	N
	C4591001 1091 10911106	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2020		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
	C4591001 1091 10911107	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Sciatica	01JAN1995		Y
	C4591001 1091 10911108	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2008	N
		Surgical and medical procedures	Bone operation	01JAN2012	31DEC2012	N
			Bunion operation	01JAN2008	31DEC2008	N
	C4591001 1091 10911111	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911113	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2015	31DEC2015	N
		Investigations	Human papilloma virus test positive	01JAN2005		Y
		Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
	C4591001 1091 10911116	Endocrine disorders	Hyperthyroidism	01JAN2000	31DEC2010	N
		Gastrointestinal disorders	Pancreatitis	01JAN1994	31DEC1994	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
	C4591001 1091 10911118	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01MAY2020	31MAY2020	N
	C4591001 1091 10911119	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
			Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1091 10911120	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
	C4591001 1091 10911121	Ear and labyrinth disorders	Vertigo	01JAN2008		Y
		Endocrine disorders	Basedow's disease	01JAN2010	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb injury	01AUG2019	31AUG2019	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Rotator cuff repair	01AUG2019	31DEC2019	N
			Tenonectomy	01AUG2019	31AUG2019	N
			Thyroidectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911122	General disorders and administration site conditions	Cyst	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JUL2019		Y
		Surgical and medical procedures	Foot operation	01JAN2014	31DEC2014	N
	C4591001 1091 10911123	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911125	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Ear infection	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2010	31DEC2010	N
			Tympanoplasty	01JAN2010	31DEC2010	N
	C4591001 1091 10911130	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2008	31DEC2008	N
			Tendonitis	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Keratomileusis	01JAN2004	31DEC2004	N
			Platelet rich plasma therapy	12AUG2020	12AUG2020	N
			Shoulder operation	01JAN2008	31DEC2008	N
	C4591001 1091 10911132	Gastrointestinal disorders	Colitis ulcerative	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01OCT2018		Y
	C4591001 1091 10911133	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y
			Spinal stenosis	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1091 10911134	Nervous system disorders	Headache	01JAN1973		Y
	C4591001 1091 10911137	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01SEP2019		Y
	C4591001 1091 10911138	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1091 10911139	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
	C4591001 1091 10911140	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
	C4591001 1091 10911142	Nervous system disorders	Migraine	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2019	31DEC2019	N
			Tendon rupture	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Chondroplasty	01JAN2019	31DEC2019	N
			Tendon operation	01JAN2019	31DEC2019	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1091 10911143	Congenital, familial and genetic disorders	Micrognathia	01JAN2010	31DEC2010	N
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Orthognathic surgery	01JAN2000	31DEC2000	N
	C4591001 1091 10911144	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015	28FEB2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1091 10911145	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Finger repair operation	01JAN2014	31DEC2014	N
	C4591001 1091 10911149	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
	C4591001 1091 10911150	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	30JUN2018	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2018	31JAN2018	N
	C4591001 1091 10911151	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1091 10911152	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
	C4591001 1091 10911156	Hepatobiliary disorders	Hepatic cirrhosis	01JAN2016		Y
	C4591001 1091 10911157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Hiatus hernia	01JAN2020		Y
			Impaired gastric emptying	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1091 10911160	Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2005		Y
	C4591001 1091 10911162	Immune system disorders	Mycotic allergy	01JAN1978		Y
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911164	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2005		Y
	C4591001 1091 10911165	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
	C4591001 1091 10911169	Nervous system disorders	Headache	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1997		Y
	C4591001 1091 10911172	Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1091 10911174	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
	C4591001 1091 10911175	Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2005		Y
	C4591001 1091 10911176	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
				01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN1989		Y
		Surgical and medical procedures	Skin lesion removal	01JAN2009	31DEC2009	N
	C4591001 1091 10911177	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911179	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
	C4591001 1091 10911182	Eye disorders	Amblyopia	01JAN1968	31DEC1978	N
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1978		Y
		Surgical and medical procedures	Eye muscle operation	01JAN1978	31DEC1978	N
	C4591001 1091 10911183	Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01DEC2019	31DEC2019	N
		Surgical and medical procedures	Haemangioma removal	01DEC2019	31DEC2019	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N
			Ligament operation	01JAN2011	31DEC2011	N
	C4591001 1091 10911185	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1091 10911186	Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1999	31DEC1999	N
				01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
			Bunion operation	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2009	31DEC2009	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1091 10911189	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
	C4591001 1091 10911192	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
	C4591001 1091 10911197	Congenital, familial and genetic disorders	Oesophageal cyst	01JAN2008	31DEC2008	N
		General disorders and administration site conditions	Chest pain	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Depression	01OCT2019		Y
		Surgical and medical procedures	Oesophageal lesion excision	01JAN2008	31DEC2008	N
		Vascular disorders	Deep vein thrombosis	01JAN2017	31DEC2017	N
	C4591001 1091 10911198	Injury, poisoning and procedural complications	Tendon rupture	01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Tendon pain	01JAN2020		Y
		Surgical and medical procedures	Tenoplasty	01JAN2020	31JAN2020	N
	C4591001 1091 10911200	Immune system disorders	Seasonal allergy	01JAN1993		Y
	C4591001 1091 10911203	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Meningioma surgery	01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
	C4591001 1091 10911206	Infections and infestations	Sinusitis	01JAN2010		Y
	C4591001 1091 10911207	Immune system disorders	Seasonal allergy	01FEB2020		Y
	C4591001 1091 10911210	Cardiac disorders	Myocardial infarction	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2009		Y
	C4591001 1091 10911215	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP1987		Y
	C4591001 1091 10911218	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1091 10911219	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Surgical and medical procedures	Bone operation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1091 10911220	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911221	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Surgical and medical procedures	Dental prosthesis placement	26AUG2020	26AUG2020	N
	C4591001 1091 10911223	Congenital, familial and genetic disorders	Olfacto genital dysplasia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Orchidopexy	01JAN2004		Y
	C4591001 1091 10911229	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1091 10911232	Nervous system disorders	Headache	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Perinatal depression	01JUL2001	31DEC2001	N
		Surgical and medical procedures	Caesarean section	01JUN2001	01JUN2001	N
				25MAY1999	25MAY1999	N
	C4591001 1091 10911233	Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1091 10911236	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Investigations	Laparoscopy	01JAN2000	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
		Nervous system disorders	Migraine	01JAN1988		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1999		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911237	Eye disorders	Strabismus	01JAN2001	31DEC2001	N
		Nervous system disorders	Headache	01JAN2005		Y
		Surgical and medical procedures	Strabismus correction	01JAN2001	31DEC2001	N
	C4591001 1091 10911238	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1091 10911239	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
	C4591001 1091 10911240	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1091 10911241	Eye disorders	Glaucoma	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911245	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000		Y
	C4591001 1091 10911246	Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
		Investigations	Cardiac murmur	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	01JAN2020		Y
	C4591001 1091 10911250	Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1091 10911252	Ear and labyrinth disorders	Motion sickness	01JAN2006		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Hepatic enzyme increased	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2009		Y
			Seizure	01JAN1999	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Post-traumatic stress disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2015		Y
	C4591001 1091 10911255	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
	C4591001 1091 10911256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Injury, poisoning and procedural complications	Muscle strain	04SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1091 10911257	Infections and infestations	Oral herpes	01JAN2013		Y
	C4591001 1091 10911261	Congenital, familial and genetic disorders	Protein S deficiency	01JAN2000		Y
		Reproductive system and breast disorders	Premenstrual syndrome	01JAN2017		Y
	C4591001 1091 10911270	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
			Cold urticaria	01JAN2014		Y
	C4591001 1091 10911271	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Conjunctivitis allergic	30JUN2020		Y
	C4591001 1091 10911276	Nervous system disorders	Headache	01JAN2005		Y
			Migraine	01JAN2005		Y
	C4591001 1091 10911277	Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1091 10911279	Injury, poisoning and procedural complications	Spinal cord injury	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2008	31JAN2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Deep vein thrombosis	01JAN2017	31DEC2017	N
	C4591001 1091 10911281	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1091 10911283	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1979		Y
		Skin and subcutaneous tissue disorders	Lichen planus	01JUN2000		Y
	C4591001 1091 10911284	Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Organ donor	01JAN2019	31JAN2019	N
	C4591001 1091 10911286	Skin and subcutaneous tissue disorders	Acne	01JAN1989		Y
	C4591001 1091 10911288	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Joint effusion	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1991	31DEC1991	N
			Appendicectomy	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2002	31DEC2002	N
	C4591001 1091 10911289	Nervous system disorders	Headache	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1091 10911290	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1091 10911291	Surgical and medical procedures	Salpingectomy	01SEP2019	30SEP2019	N
		Musculoskeletal and connective tissue disorders	Metatarsalgia	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1091 10911293	Congenital, familial and genetic disorders	Methylenetetrahydrofolate reductase gene mutation	01JAN2010	(b) (6) 1972	Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1997		Y
	C4591001 1091 10911297	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
			Depression	01DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
	C4591001 1091 10911298	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
	C4591001 1091 10911300	Injury, poisoning and procedural complications	Jaw fracture	01JAN1992	31DEC1992	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2011	N
			Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2011	31DEC2011	N
			Endometrial ablation	01DEC2019	31DEC2019	N
			Fracture treatment	01JAN1992	31DEC1992	N
			Mammoplasty	01DEC2018	31DEC2018	N
	C4591001 1091 10911301	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1091 10911302	Ear and labyrinth disorders	Deafness bilateral	01JUL2016		Y
		Immune system disorders	Anaphylactic reaction	01JAN2007		Y
		Injury, poisoning and procedural complications	Accident	03JAN2020	03JAN2020	N
			Concussion	01JUL2016	31JUL2016	N
			Peripheral nerve injury	03JAN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	31AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911304	Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y
		Eye disorders	Myopia	01JAN1980	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2007		Y
			Seasonal allergy	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01AUG2020		Y
		Nervous system disorders	Headache	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1091 10911306	Cardiac disorders	Atrial fibrillation	01JAN2009	31DEC2012	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31AUG2019	N
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
			Cardiac ablation	01JAN2012	31DEC2012	N
			Hernia repair	01JAN2018	31DEC2018	N
			Intervertebral disc operation	01AUG2019	31AUG2019	N
	C4591001 1091 10911309	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2006	31DEC2007	N
		Psychiatric disorders	Libido decreased	01JAN2015		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1091 10911310	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastritis	01JUN2020		Y
			Gastroesophageal reflux disease	01JUN2020		Y
			Irritable bowel syndrome	01JAN2000		Y
		Investigations	Blood prolactin increased	01JAN2012	31DEC2019	N
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1091 10911313	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Anxiety	01APR2018		Y
	C4591001 1091 10911315	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
	C4591001 1091 10911319	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1980		Y
	C4591001 1091 10911321	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Spinal compression fracture	01JUL2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Psychiatric disorders	Anxiety	01SEP2019		Y
			Attention deficit hyperactivity disorder	01JAN1991		Y
			Depression	01JAN2011		Y
			Post-traumatic stress disorder	01SEP2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
	C4591001 1091 10911322	Congenital, familial and genetic disorders	Micrognathia	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Orthognathic surgery	01JAN2015	31DEC2015	N
	C4591001 1091 10911325	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1091 10911327	Ear and labyrinth disorders	Tinnitus	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2007	31DEC2007	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007	31DEC2007	N
			Migraine	01JAN1996		Y
		Psychiatric disorders	Libido decreased	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2007	31DEC2007	N
			Synovial cyst removal	01JAN2007	31DEC2007	N
	C4591001 1091 10911328	Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2002	31DEC2002	N
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2002	31DEC2002	N
	C4591001 1091 10911331	Investigations	Cardiac murmur	01JAN2005		Y
	C4591001 1091 10911333	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911334	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1091 10911336	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Rubber sensitivity	01JAN2012		Y
			Seasonal allergy	01JUN2019		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2008		Y
	C4591001 1091 10911338	Gastrointestinal disorders	Tooth impacted	01JAN1997	31DEC1997	N
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
			Herpes simplex	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sweat gland tumour	01JAN2017	30SEP2017	N
		Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1996	31DEC1996	N
			Wisdom teeth removal	01JAN1997	31DEC1997	N
	C4591001 1091 10911339	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1091 10911340	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Vasectomy	01JAN2017	31DEC2017	N
			Anxiety	01AUG2019		Y
	C4591001 1091 10911341	Psychiatric disorders				
	C4591001 1091 10911342	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1091 10911343	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Infections and infestations	Hepatitis C	01JAN2020	31MAY2020	N
			Tonsillitis	01JAN1984	31DEC1986	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y
			Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Drug abuse	01JAN1987	04APR2014	N
		Social circumstances	Tobacco user	01JAN1994		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1091 10911344	Nervous system disorders	Headache	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Autism spectrum disorder	01JAN2015		Y
			Insomnia	01JAN2019		Y
	C4591001 1091 10911348	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2012		Y
	C4591001 1091 10911350	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
			Attention deficit hyperactivity disorder	01JAN1986		Y
			Depression	01NOV2019		Y
	C4591001 1091 10911352	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
	C4591001 1091 10911353	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Sciatica	01FEB2020		Y
	C4591001 1091 10911355	Cardiac disorders	Palpitations	01APR2020		Y
		Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
	C4591001 1091 10911356	Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1995		Y
	C4591001 1091 10911358	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Polyarthriti	01JAN2000		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1091 10911361	Cardiac disorders	Mitral valve prolapse	01JAN1981		Y
		Eye disorders	Blindness unilateral	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Haemorrhoids	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN2000		Y
		Injury, poisoning and procedural complications	Eye injury	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN1994	31DEC1994	N
	C4591001 1091 10911362	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1091 10911363	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1091 10911366	Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911371	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1091 10911372	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
	C4591001 1091 10911373	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Hepatitis C	01MAY2004	30NOV2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2004		Y
			Intervertebral disc degeneration	01JUL2004	30SEP2004	N
		Nervous system disorders	Migraine	01SEP2017		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Spinal fusion surgery	01SEP2004	30SEP2004	N
		Vascular disorders	Hypertension	01MAY2005		Y
	C4591001 1091 10911375	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1091 10911376	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1091 10911378	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
		Vascular disorders	Deep vein thrombosis	01JAN2018	31DEC2018	N
	C4591001 1091 10911379	Endocrine disorders	Autoimmune thyroiditis	01JAN2011		Y
	C4591001 1091 10911380	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01AUG2019		Y
	C4591001 1091 10911381	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1091 10911382	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2018		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911383	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
	C4591001 1091 10911384	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1091 10911385	Surgical and medical procedures	Meniscus operation	03JAN2020	03JAN2020	N
	C4591001 1091 10911386	Injury, poisoning and procedural complications	Ligament rupture	01AUG2020	30SEP2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Rhinitis allergic	01FEB2005		Y
		Surgical and medical procedures	Ligament operation	01JAN2020	31DEC2020	N
	C4591001 1091 10911387	Immune system disorders	Food allergy	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	05AUG2020		Y
		Reproductive system and breast disorders	Menorrhagia	01AUG2013		Y
	C4591001 1091 10911389	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2017		Y
	C4591001 1091 10911392	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1091 10911393	Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1091 10911398	Psychiatric disorders	Anxiety	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1092 10921002	Eye disorders	Myopia	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2018	01OCT2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1092 10921003	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1092 10921008	Eye disorders	Myopia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014	31DEC2014	N
		Nervous system disorders	Brain injury	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
			Spinal laminectomy	01JAN2014	31DEC2014	N
	C4591001 1092 10921020	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921024	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
	C4591001 1092 10921027	Ear and labyrinth disorders	Tinnitus	01JAN2011		Y
		Eye disorders	Myopia	01JAN2004		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
			Hyperinsulinaemia	01JAN2004		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN1995		Y
			Rosacea	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1092 10921029	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
	C4591001 1092 10921033	Eye disorders	Myopia	01JAN2014		Y
			Presbyopia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2016		Y
			Rubber sensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2014		Y
	C4591001 1092 10921035	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2014	31DEC2014	N
	C4591001 1092 10921036	Eye disorders	Myopia	01JAN1996	30JUN2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01MAY2020		Y
		Infections and infestations	Tonsillitis	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Keratomileusis	01JUN2020	31DEC2020	N
			Tonsillectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1092 10921042	Immune system disorders	Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Obesity	01FEB2020		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921045	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
	C4591001 1092 10921053	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1092 10921055	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1092 10921056	Eye disorders	Presbyopia	01AUG2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Renal and urinary disorders	Incontinence	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1092 10921064	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921065	Cardiac disorders	Ventricular extrasystoles	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2009	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Mastectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921066	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1092 10921075	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1092 10921081	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921082	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1092 10921083	Immune system disorders	Seasonal allergy	01JAN2006		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1092 10921084	Ear and labyrinth disorders	Tinnitus	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1092 10921091	Immune system disorders	Sarcoidosis	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1092 10921098	Congenital, familial and genetic disorders	Cornelia de Lange syndrome	(b) (6) 1998		Y
		Nervous system disorders	Migraine	(b) (6) 1998		Y
	C4591001 1092 10921106	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2017		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1092 10921109	Metabolism and nutrition disorders	Obesity	01JAN1996	31DEC2014	N
		Surgical and medical procedures	Gastric bypass	01JAN2014	31DEC2014	N
	C4591001 1092 10921112	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1092 10921113	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1092 10921118	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1092 10921125	Immune system disorders	Rubber sensitivity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Osteoporosis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1092 10921127	Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2016		Y
	C4591001 1092 10921128	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921130	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
			Post-traumatic stress disorder	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1092 10921131	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Obesity	01JAN1987		Y
		Social circumstances	Postmenopause	01FEB2019		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1092 10921132	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1092 10921139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
	C4591001 1092 10921143	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1092 10921144	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1092 10921153	Cardiac disorders	Mitral valve prolapse	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921157	Nervous system disorders	Headache	01JAN2008		Y
	C4591001 1092 10921161	Eye disorders	Retinal detachment	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
	C4591001 1092 10921162	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1092 10921168	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1092 10921175	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUL2020		Y
		Psychiatric disorders	Depression	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Social circumstances	Menopause	01DEC2019		Y
		Surgical and medical procedures	Rotator cuff repair	19AUG2020	19AUG2020	N
	C4591001 1092 10921177	Endocrine disorders	Hypothyroidism	19FEB2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1092 10921179	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1092 10921181	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1092 10921183	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
	C4591001 1092 10921184	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921186	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1092 10921188	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1092 10921189	Metabolism and nutrition disorders	Obesity	05FEB2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
			Hirsutism	19JUN2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1092 10921197	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1092 10921198	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2019		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921200	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921201	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Hiatus hernia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
	C4591001 1092 10921208	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1092 10921209	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1092 10921210	Endocrine disorders	Hypogonadism	01JAN2018		Y
	C4591001 1092 10921211	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1092 10921219	Gastrointestinal disorders	Pancreatitis	06DEC1969	06DEC1969	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	13JUN2019	13JUN2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921227	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1092 10921229	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1985		Y
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1092 10921237	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Osteoarthritis	01JAN1991		Y
				01JAN2018		Y
			Osteochondritis	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1092 10921239	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1976		Y
	C4591001 1092 10921245	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Presbyopia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921246	Eye disorders	Dry eye	01JAN2020		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1092 10921248	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1092 10921249	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921260	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2007		Y
		Reproductive system and breast disorders	Ovarian cyst	08JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1092 10921272	Metabolism and nutrition disorders	Obesity	27OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1092 10921274	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1092 10921276	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1093 10931001	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931002	Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1093 10931003	Immune system disorders	Food allergy	01JAN1986		Y
			Rubber sensitivity	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1995		Y
	C4591001 1093 10931006	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1093 10931007	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1093 10931009	Endocrine disorders	Hyperthyroidism	01SEP2018	31DEC2018	N
			Hypothyroidism	01DEC2018		Y
		Surgical and medical procedures	Thyroidectomy	01DEC2018	31DEC2018	N
	C4591001 1093 10931011	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1093 10931013	Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931017	Psychiatric disorders	Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1093 10931018	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931019	Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
		Immune system disorders	Allergy to plants	01JAN2000		Y
	C4591001 1093 10931020		Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Immune system disorders	Dust allergy	01JAN2015		Y
	C4591001 1093 10931022	Injury, poisoning and procedural complications	Ligament rupture	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Ligament operation	01JAN2017	31DEC2017	N
	C4591001 1093 10931027	Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1093 10931028	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1093 10931030	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1093 10931031	Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hot flush	01JAN2011		Y
	C4591001 1093 10931031	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1093 10931032	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1093 10931033	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1093 10931039	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
			Chronic obstructive pulmonary disease	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1093 10931041	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
		Nervous system disorders	Tension headache	01JAN2019		Y
	C4591001 1093 10931042	Gastrointestinal disorders	Diverticulum	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hypercholesterolaemia	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1093 10931043	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1093 10931049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1093 10931052	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
	C4591001 1093 10931053	Surgical and medical procedures	Female sterilisation	01MAR2019	31MAR2019	N
	C4591001 1093 10931055	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2013		Y
	C4591001 1093 10931063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1093 10931066	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1093 10931067	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1093 10931068	Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1093 10931070	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1093 10931071	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1093 10931073	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1093 10931074	Surgical and medical procedures	Depression Female sterilisation	01JAN2019 01JAN2017	31DEC2017	Y N
	C4591001 1093 10931078	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Vitamin B12 deficiency	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1093 10931084	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017		Y
	C4591001 1093 10931085	Immune system disorders	Mycotic allergy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010	31DEC2010	N
	C4591001 1093 10931087	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931088	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Food allergy	01JAN2018		Y
			Milk allergy	01JAN2018		Y
	C4591001 1093 10931089	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1093 10931090	Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931091	Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1093 10931093	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1093 10931095	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN2017		Y
	C4591001 1093 10931096	Cardiac disorders	Arrhythmia	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y
	C4591001 1093 10931098	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1093 10931099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Bipolar disorder	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1093 10931100	Immune system disorders	Food allergy	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1093 10931103	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01MAY2020	30JUN2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1093 10931111	Gastrointestinal disorders	Oesophagitis	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1093 10931113	Immune system disorders	Allergy to metals	01JAN2001		Y
			Rubber sensitivity	01JAN1999		Y
		Infections and infestations	Herpes simplex	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1999		Y
	C4591001 1093 10931115	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1093 10931117	Infections and infestations	Herpes simplex	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1093 10931121	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31OCT2018	N
		Surgical and medical procedures	Hysterectomy	01OCT2018	31OCT2018	N
	C4591001 1093 10931123	Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1093 10931124	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Lipoprotein (a) increased	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Renal and urinary disorders	Urinary retention	01JAN2018		Y
	C4591001 1093 10931126	Psychiatric disorders	Depression	01JAN2019		Y
		Renal and urinary disorders	Micturition urgency	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931131	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2018		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2006		Y
	C4591001 1093 10931132	Reproductive system and breast disorders	Menorrhagia	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01MAR2009	31MAR2009	N
	C4591001 1093 10931133	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1093 10931134	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2019		Y
	C4591001 1093 10931136	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1093 10931137	General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1093 10931138	Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1093 10931145	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y
	C4591001 1093 10931146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1093 10931147	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	11OCT2019	22OCT2019	N
		Nervous system disorders	Headache	01OCT2019		Y
		Surgical and medical procedures	Thyroidectomy	22OCT2019	22OCT2019	N
	C4591001 1093 10931149	Social circumstances	Ex-tobacco user	20AUG2020		Y
	C4591001 1093 10931150	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
	C4591001 1093 10931152	Endocrine disorders	Hypothyroidism	01JAN2014		Y
			Thyroid mass	01JAN2014	31JUL2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Surgical and medical procedures	Thyroidectomy	01JUL2014	31JUL2014	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Raynaud's phenomenon	01JAN2017		Y
	C4591001 1093 10931155	General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2010		Y
			Drug abuse	01JAN2016		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN2013	31DEC2013	N
	C4591001 1093 10931158	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Heart rate increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2017		Y
	C4591001 1093 10931168	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1093 10931169	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes zoster	10AUG2020	21SEP2020	N
	C4591001 1093 10931177	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1093 10931178	Immune system disorders	Drug hypersensitivity	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2005	31DEC2005	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Surgical and medical procedures	Orchidectomy	01JAN2005	31DEC2005	N
	C4591001 1093 10931179	Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
	C4591001 1093 10931180	Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1093 10931183	Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1093 10931185	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Dry eye	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Hypokalaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Narcolepsy	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1093 10931186	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1093 10931188	Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1093 10931194	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y
	C4591001 1093 10931195	Surgical and medical procedures	Mammoplasty	01MAR2019	31MAR2019	N
	C4591001 1093 10931196	Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
	C4591001 1093 10931197	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1093 10931199	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Psychiatric disorders	Anxiety	23OCT1998		Y
			Depression	01JAN1998		Y
			Schizophrenia	01JAN1998		Y
	C4591001 1093 10931200	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1093 10931201	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN2015	31DEC2015	N
			Intraocular lens implant	01JAN2016	31DEC2016	N
			Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1093 10931202	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Salpingectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931203	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1093 10931204	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1093 10931205	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
	C4591001 1093 10931210	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1093 10931211	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1093 10931214	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1093 10931215	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1992		Y
	C4591001 1093 10931217	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
	C4591001 1093 10931218	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931219	Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
	C4591001 1093 10931222	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Seasonal allergy	01MAR2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2004	N
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2017	31DEC2017	N
			Abdominal panniculectomy	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Gastric banding	01JAN2004	31DEC2004	N
	C4591001 1093 10931223	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Arthritis	01JAN2018		Y
	C4591001 1093 10931224	Immune system disorders	Seasonal allergy	01SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1093 10931226	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1094 10941004	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2019		Y
			Vitamin D deficiency	28MAY2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01APR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Abdominoplasty	01JUN2007	31DEC2007	N
			Liposuction	01JUN2007	30JUN2007	N
			Mammoplasty	01JUN2007	31DEC2007	N
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1094 10941010	Endocrine disorders	Hyperthyroidism	01MAY2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2007		Y
			Vitamin D deficiency	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1991	31DEC1991	N
			Nephrostomy	01JAN1982	31DEC1982	N
			Venous reconstruction	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1094 10941016	Ear and labyrinth disorders	Vertigo	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01DEC2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2018		Y
			Hyperlipidaemia	01JUN2018		Y
			Vitamin D deficiency	01JUN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
			Polyarthritits	01MAY2019		Y
		Psychiatric disorders	Anxiety	01AUG2019		Y
		Social circumstances	Postmenopause	01MAR2019		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2005	31DEC2005	N
			Intervertebral disc operation	04JUN2019	04JUN2019	N
			Spinal laminectomy	04JUN2019	04JUN2019	N
	C4591001 1094 10941017	Cardiac disorders	Coronary artery disease	01JAN2015		Y
			Myocardial infarction	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Bone abscess	01OCT2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Ankle operation	01JAN2008	31DEC2008	N
			Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Coronary artery bypass	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1094 10941025	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
			Cardiac failure congestive	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Duodenal ulcer	01JAN2019		Y
			Inguinal hernia	01JAN2019	31DEC2019	N
			Oesophageal ulcer	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019		Y
			Hepatic cirrhosis	01JUN2019		Y
		Immune system disorders	Seasonal allergy	01JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JUN2019		Y
		Renal and urinary disorders	End stage renal disease	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Arteriosclerosis	01JAN2019		Y
			Peripheral arterial occlusive disease	01JAN2019		Y
	C4591001 1094 10941030	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1094 10941031	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Surgical and medical procedures	Ankle operation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1094 10941040	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JUL1977	31JUL1977	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Nervous system disorders	Diabetic neuropathy	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Microalbuminuria	01OCT2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01DEC2016		Y
	C4591001 1094 10941043	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
	C4591001 1094 10941048	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941055	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01APR2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1094 10941066	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2011		Y
		Social circumstances	Postmenopause	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUL2011		Y
	C4591001 1094 10941070	Gastrointestinal disorders	Dyspepsia	01APR2020		Y
			Gastroesophageal reflux disease	01APR2020		Y
	C4591001 1094 10941075	Metabolism and nutrition disorders	Vitamin D deficiency	06AUG2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Autism spectrum disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Adenoidectomy	01JAN2003	31DEC2003	N
	C4591001 1094 10941076	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2005		Y
			Autism spectrum disorder	01JAN2005		Y
	C4591001 1094 10941077	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Inflammatory bowel disease	01JAN1983		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Infections and infestations	Appendicitis	01DEC2004	31DEC2004	N
		Metabolism and nutrition disorders	Vitamin D deficiency	06AUG2020		Y
		Skin and subcutaneous tissue disorders	Rash	06AUG2020		Y
		Surgical and medical procedures	Appendicectomy	01DEC2004	31DEC2004	N
			Caesarean section	03AUG1999	03AUG1999	N
			Thrombectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Deep vein thrombosis	01JAN2017		Y
	C4591001 1094 10941082	Gastrointestinal disorders	Abdominal hernia	01JAN1993	31DEC1993	N
				01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Vitamin D deficiency	20AUG2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1993	31DEC1993	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000	31DEC2000	N
	C4591001 1094 10941084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01MAY2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	16JUL2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
			Osteoarthritis	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1995		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2019	31MAR2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01FEB2020		Y
		Surgical and medical procedures	Knee arthroplasty	01JUN2020		Y
			Knee operation	01FEB2010	28FEB2010	N
			Shoulder operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1995	31DEC1995	N
	C4591001 1094 10941087	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
		Social circumstances	Postmenopause	01MAR2020		Y
		Surgical and medical procedures	Caesarean section	01JAN2016		Y
	C4591001 1094 10941091	Metabolism and nutrition disorders	Hypercholesterolaemia	14APR1987	14APR1987	N
			Type 2 diabetes mellitus	01APR2019		Y
			Vitamin D deficiency	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	04AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2020		Y
		Surgical and medical procedures	Knee operation	01JAN2015		Y
				01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941095	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Vitamin D deficiency	01OCT2019		Y
		Nervous system disorders	Neuropathy peripheral	01OCT2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JUN2020		Y
		Surgical and medical procedures	Foot amputation	01JAN2016	31DEC2016	N
			Toe amputation	01JAN2016	31DEC2016	N
			Vascular graft	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Peripheral vascular disorder	01JAN2016		Y
	C4591001 1094 10941098	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01MAY2019		Y
		Immune system disorders	Drug hypersensitivity	02SEP2020		Y
		Metabolism and nutrition disorders	Hypercalcaemia	01JUN2020		Y
			Hyperlipidaemia	01DEC2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin D deficiency	01APR2019		Y
		Psychiatric disorders	Anxiety	01APR2019		Y
			Bipolar disorder	01APR2019		Y
			Depression	01APR2019		Y
			Insomnia	01APR2019		Y
			Schizophrenia	01APR2019		Y
		Renal and urinary disorders	Microalbuminuria	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JUN2020	02SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1094 10941100	Vascular disorders	Hypertension	01JAN2019		Y	
		Cardiac disorders	Coronary artery disease	01JAN2017		Y	
				Myocardial infarction	04JAN2019	04JAN2019	N
					14AUG2017	14AUG2017	N
			Endocrine disorders	Hypogonadism	01JUN2018		Y
			Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
				Umbilical hernia	01DEC1999	31DEC1999	N
			Infections and infestations	Tonsillitis	01JAN1978	31DEC1978	N
			Injury, poisoning and procedural complications	Clavicle fracture	01JAN1985	31DEC1985	N
			Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
				Hyperkalaemia	01JAN2020		Y
				Type 2 diabetes mellitus	01JAN2014		Y
				Vitamin D deficiency	01JUN2018		Y
			Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
				Bipolar disorder	01JAN2008		Y
				Depression	01JAN2008		Y
			Renal and urinary disorders	Chronic kidney disease	01FEB2018		Y
			Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2019		Y
				Erectile dysfunction	01JAN2018		Y
			Surgical and medical procedures	Coronary arterial stent insertion	01AUG2017	31AUG2017	N
				01JAN2019	31JAN2019	N	
			Tonsillectomy	01JAN1978	31DEC1978	N	
			Umbilical hernia repair	01DEC1999	31DEC1999	N	
	C4591001 1094 10941104	Vascular disorders	Hypertension	01JAN2018		Y	
		Immune system disorders	Seasonal allergy	01JAN1991		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1996	31DEC2019	N
	C4591001 1094 10941107	Surgical and medical procedures	Nasal septal operation	01DEC2019	31DEC2019	N
		Eye disorders	Blindness unilateral	01JAN2010		Y
			Glaucoma	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
			Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Insomnia	01APR2019		Y
	C4591001 1094 10941108	Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N
	C4591001 1094 10941109	Gastrointestinal disorders	Dyspepsia	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2018		Y
		Psychiatric disorders	Depression	01JAN2004		Y
			Insomnia	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1094 10941117	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Helicobacter infection	01JUN2020	30JUN2020	N
			Onychomycosis	01JUN2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01OCT2019		Y
		Nervous system disorders	Hypoaesthesia	16JUN2020		Y
			Migraine	01JAN2015	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941124	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Vitamin B12 deficiency	01JUN2019		Y
			Vitamin D deficiency	01JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Talipes correction	(b) (6) 1991	(b) (6) 1991	N
	C4591001 1094 10941129	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Axillary lymphadenectomy	17DEC2019	17DEC2019	N
			Intrauterine contraception	01JUL2020		Y
	C4591001 1094 10941131	Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JUN2020		Y
		Social circumstances	Postmenopause	01MAR2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
			Ovarian cystectomy	01JAN1996	31DEC1996	N
			Ovarian cystectomy	01JAN2006	31DEC2006	N
	C4591001 1094 10941132	Metabolism and nutrition disorders	Vitamin D deficiency	01MAY2020		Y
		Vascular disorders	White coat hypertension	01JUN2020		Y
	C4591001 1094 10941137	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine leiomyoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Migraine	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
		Surgical and medical procedures	Caesarean section	01NOV2000	30NOV2000	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Ovarian neoplasm surgery	01JAN2001	31DEC2001	N
			Rib excision	01JAN2003	31DEC2003	N
	C4591001 1094 10941143	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941144	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941150	Blood and lymphatic system disorders	Anaemia	01JUN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2011		Y
			Type 2 diabetes mellitus	01MAR2011		Y
			Vitamin B12 deficiency	01JAN2020		Y
			Vitamin D deficiency	01JAN2020		Y
		Nervous system disorders	Transient ischaemic attack	01JUN2010	30JUN2010	N
		Renal and urinary disorders	Chronic kidney disease	01AUG2018		Y
			Microalbuminuria	01MAR2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01NOV2010		Y
	C4591001 1094 10941153	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1094 10941155	Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1094 10941156	Eye disorders	Strabismus	(b) (6) 2000	31AUG2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01APR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Surgical and medical procedures	Strabismus correction	01AUG2018	31AUG2018	N
	C4591001 1094 10941163	Blood and lymphatic system disorders	Anaemia	01JAN1997		Y
		Gastrointestinal disorders	Constipation	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
			Onychomycosis	01OCT2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Vitamin D deficiency	01OCT2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01AUG2013		Y
		Psychiatric disorders	Insomnia	01MAY2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2012	31DEC2012	N
			Uterine cyst	01JAN2018	31DEC2018	N
			Uterine haemorrhage	01JAN2015	31DEC2018	N
		Surgical and medical procedures	Appendectomy	01JAN1994	31DEC1994	N
			Caesarean section	01JAN1984	31DEC1984	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ovarian cystectomy	01JAN2012	31DEC2012	N
			Uterine cystectomy	01JAN2018	31DEC2018	N
	C4591001 1094 10941166	Infections and infestations	Appendicitis	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Carotid artery stenosis	01NOV2019		Y
			Diabetic neuropathy	01FEB2019		Y
		Renal and urinary disorders	Microalbuminuria	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	13JAN2020	13JAN2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1094 10941167	Surgical and medical procedures	Varicose vein operation	01JAN2006	31DEC2006	N
		Vascular disorders	Varicose vein	01JAN1998	31DEC2006	N
	C4591001 1094 10941169	Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2020		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
	C4591001 1094 10941176	Metabolism and nutrition disorders	Obesity	09OCT2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Amnesia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Nicotine dependence	09OCT2000		Y
		Surgical and medical procedures	Mammoplasty	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941179	Metabolism and nutrition disorders	Hyperuricaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1094 10941181	Endocrine disorders	Hypothyroidism	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2018		Y
		Nervous system disorders	Epilepsy	01NOV2018		Y
		Psychiatric disorders	Depression	01MAR2020		Y
			Insomnia	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2019		Y
	C4591001 1094 10941182	Metabolism and nutrition disorders	Vitamin D deficiency	01OCT2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1094 10941186	Psychiatric disorders	Anxiety	01JAN2004		Y
			Bipolar disorder	01JAN2004		Y
			Depression	01JAN2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1094 10941188	Gastrointestinal disorders	Intestinal obstruction	01JAN2007	31DEC2007	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31JUL2020	N
		Psychiatric disorders	Insomnia	01APR2020		Y
		Surgical and medical procedures	Hysterectomy	01JUL2020	31JUL2020	N
	C4591001 1094 10941189	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
	C4591001 1094 10941192	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2019		Y
	C4591001 1095 10951001	Infections and infestations	Otitis media	01JAN1996	31DEC1997	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2001		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1996	31DEC1997	N
	C4591001 1095 10951002	Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
	C4591001 1095 10951005	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1095 10951006	Infections and infestations	Candida infection	01APR2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1095 10951007	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1990	01JAN1990	N
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	01JAN1990	N
			Vasectomy	01JAN2003	01JAN2003	N
	C4591001 1095 10951008	Nervous system disorders	Migraine	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1095 10951009	Social circumstances	Postmenopause	01NOV2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Subdural haematoma	03APR2006	05APR2006	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1994	15MAY2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015	30APR2020	N
		Surgical and medical procedures	Hysterectomy	15MAY2018	15MAY2018	N
			Sinus operation	01APR2020	30APR2020	N
	C4591001 1095 10951011	Infections and infestations	Appendicitis	01JAN1986	01JAN1986	N
		Surgical and medical procedures	Appendicectomy	01JAN1986	01JAN1986	N
	C4591001 1095 10951014	Gastrointestinal disorders	Irritable bowel syndrome	15JUL2019		Y
		Psychiatric disorders	Anxiety	15JUL2018		Y
	C4591001 1095 10951018	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
	C4591001 1095 10951021	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01FEB2019	30APR2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2008		Y
		Surgical and medical procedures	Renal stone removal	01JAN2016	31DEC2016	N
			Thyroidectomy	01APR2019	30APR2019	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1095 10951022	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2016		Y
		Psychiatric disorders	Depression	01MAR2019		Y
		Reproductive system and breast disorders	Endometrial disorder	01JAN2015	11SEP2019	N
		Surgical and medical procedures	Hysterectomy	11SEP2019	11SEP2019	N
	C4591001 1095 10951023	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Diverticulum	01DEC2018		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1998	31DEC1998	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1095 10951024	Immune system disorders	Seasonal allergy	01JUN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01MAY2006	31MAY2006	N
		Surgical and medical procedures	Ligament operation	01MAY2006	31MAY2006	N
	C4591001 1095 10951025	Reproductive system and breast disorders	Menorrhagia	01JAN2018	18DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	09NOV2015	09NOV2015	N
			Hysterectomy	01DEC2018	31DEC2018	N
	C4591001 1095 10951026	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1095 10951028	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1095 10951029	Hepatobiliary disorders	Cholelithiasis	03DEC2003	03DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	03DEC2003	03DEC2003	N
	C4591001 1095 10951030	Gastrointestinal disorders	Haemorrhoids	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2017		Y
	C4591001 1095 10951031	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1095 10951033	Nervous system disorders	Headache	15JUN1988		Y
		Renal and urinary disorders	Hypertonic bladder	15JAN2011		Y
		Skin and subcutaneous tissue disorders	Alopecia	15FEB2011		Y
		Surgical and medical procedures	Vasectomy	15OCT2004	15OCT2004	N
	C4591001 1095 10951034	Infections and infestations	Appendicitis	04JUL2018	04JUL2018	N
		Surgical and medical procedures	Appendicectomy	04JUL2018	04JUL2018	N
			Salpingectomy	10SEP2018	10SEP2018	N
	C4591001 1095 10951036	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951038	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1095 10951039	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Onychomycosis	15JAN2010		Y
		Psychiatric disorders	Anxiety	15MAR1995		Y
			Attention deficit hyperactivity disorder	15JAN2015		Y
	C4591001 1095 10951040	Infections and infestations	Tonsillitis	15MAY1999	15MAY1999	N
		Surgical and medical procedures	Tonsillectomy	15MAY1999	15MAY1999	N
		Vascular disorders	Hot flush	01JUN2020		Y
	C4591001 1095 10951042	Skin and subcutaneous tissue disorders	Alopecia	01JAN2020		Y
	C4591001 1095 10951044	Blood and lymphatic system disorders	Anaemia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2019		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01DEC2017		Y
		Reproductive system and breast disorders	Fallopian tube cyst	01SEP2016	30SEP2016	N
		Surgical and medical procedures	Salpingectomy	01SEP2016	30SEP2016	N
	C4591001 1095 10951045	Immune system disorders	Seasonal allergy	01JUL1988		Y
		Nervous system disorders	Migraine	01JUL2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL1988		Y
			Depression	01JUL1988		Y
			Insomnia	01JUL1988		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951046	Immune system disorders	Seasonal allergy	15MAR2013		Y
		Nervous system disorders	Migraine	15OCT2019		Y
	C4591001 1095 10951047	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
	C4591001 1095 10951055	Psychiatric disorders	Attention deficit hyperactivity disorder	15JUL2018		Y
	C4591001 1095 10951057	Endocrine disorders	Basedow's disease	01OCT2018	30APR2019	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1095 10951058	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1095 10951059	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975	31DEC2005	N
			Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1095 10951060	Immune system disorders	Seasonal allergy	01FEB2019		Y
	C4591001 1095 10951061	Immune system disorders	Seasonal allergy	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951062	Infections and infestations	Tonsillitis	20JUL2004	20JUL2004	N
		Surgical and medical procedures	Adenoidectomy	01MAR1989	31MAR1989	N
			Tonsillectomy	20JUL2004	20JUL2004	N
	C4591001 1095 10951066	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1095 10951069	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1095 10951070	Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Post-traumatic stress disorder	01JAN2008		Y
		Surgical and medical procedures	Meniscus operation	01JAN2013	31DEC2013	N
	C4591001 1095 10951073	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1095 10951074	Blood and lymphatic system disorders	Coagulopathy	01AUG2019		Y
		Cardiac disorders	Mitral valve prolapse	01JAN2006		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Investigations	Smear cervix abnormal	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	26MAR2020	26MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Loop electrosurgical excision procedure	01JAN2016	31DEC2016	N
	C4591001 1095 10951076	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01DEC2010	31DEC2010	N
	C4591001 1095 10951083	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1095 10951084	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1095 10951087	Immune system disorders	Drug hypersensitivity	(b) (6) 1969		Y
			Seasonal allergy	01JAN1969		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2019	31DEC2019	N
				01NOV2017	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2017		Y
			Plantar fasciitis	01JAN1993		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1989		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1095 10951089	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2006		Y
	C4591001 1095 10951090	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2018		Y
	C4591001 1095 10951091	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Infections and infestations	Genital herpes simplex	01SEP1996		Y
			Herpes simplex	01JAN2004		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2018		Y
		Nervous system disorders	Headache	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1095 10951092	Endocrine disorders	Basedow's disease	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1095 10951093	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1095 10951094	Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1095 10951095	Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
	C4591001 1095 10951112	Blood and lymphatic system disorders	Lymphadenopathy	19AUG2020		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1980		Y
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2005		Y
	C4591001 1095 10951114	Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1095 10951116	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015	31OCT2017	N
		Immune system disorders	Hypersensitivity	01MAR2016		Y
		Infections and infestations	Herpes simplex	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Temporomandibular joint syndrome	05JAN1987	01JAN1991	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Bipolar disorder	01JAN1992		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2013	01JAN2013	N
			Female sterilisation	01JAN1995	01JAN1995	N
			Hysterectomy	01APR2015	30APR2015	N
			Temporomandibular joint surgery	01JAN1991	01JAN1991	N
	C4591001 1095 10951119	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JUL2020		Y
	C4591001 1095 10951121	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951124	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951128	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1988		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1095 10951129	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
	C4591001 1095 10951132	Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1095 10951138	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Headache	01JUN2020		Y
		Psychiatric disorders	Insomnia	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01MAY2020		Y
	C4591001 1095 10951141	Eye disorders	Cataract	01JUN2020	12AUG2020	N
		Immune system disorders	Hypersensitivity	01JAN2019		Y
		Infections and infestations	Osteomyelitis	01JAN2017	31DEC2019	N
		Injury, poisoning and procedural complications	Procedural pain	01DEC2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	05JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2014		Y
			Pruritus	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	12AUG2020	12AUG2020	N
			Toe amputation	01JAN2017	31DEC2019	N
		Vascular disorders	Deep vein thrombosis	01JAN2015		Y
			Hypertension	01JAN2014		Y
	C4591001 1095 10951142	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1095 10951143	Cardiac disorders	Myocardial infarction	26DEC2017	26DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2017		Y
		Vascular disorders	Hypertension	01DEC2017		Y
	C4591001 1095 10951144	Nervous system disorders	Migraine	01JAN1988		Y
		Reproductive system and breast disorders	Polycystic ovaries	30JUN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Surgical and medical procedures	Gastric bypass	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1095 10951147	Immune system disorders	Seasonal allergy	01JAN1989		Y
	C4591001 1095 10951149	Injury, poisoning and procedural complications	Meniscus injury	01FEB2020		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951150	Infections and infestations	Skin infection	01JUN2020		Y
					18SEP2020	N
		Psychiatric disorders	Sleep disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1095 10951152	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Ligament operation	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1095 10951153	Gastrointestinal disorders	Coeliac disease	01JAN2011		Y
			Gastrooesophageal reflux disease	01JAN1987		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2012		Y
	C4591001 1095 10951154	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Anaphylactic reaction	01JAN2012		Y
			Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Social circumstances	Postmenopause	01MAY2019		Y
	C4591001 1095 10951155	Investigations	Blood testosterone decreased	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951156	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2003	31MAY2003	N
		Surgical and medical procedures	Pituitary tumour removal	01JAN2018		Y
	C4591001 1095 10951159	Immune system disorders	Seasonal allergy	01MAY2003	31MAY2003	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2000		Y
	C4591001 1095 10951160	Immune system disorders	Seasonal allergy	01JUL2020	04SEP2020	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1985		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1999	31DEC1999	N
	C4591001 1095 10951163	Cardiac disorders	Supraventricular tachycardia	01JAN1999	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JUL2019	01JUL2019	N
		Surgical and medical procedures	Sinus operation	01JAN1985		Y
		Vascular disorders	Hypertension	01JUL2019	01JUL2019	N
	C4591001 1095 10951166	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003		Y
	C4591001 1095 10951168	Psychiatric disorders	Depression	01JAN2007	31DEC2007	N
				01MAY2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951169	Psychiatric disorders	Anxiety	01AUG2010		Y
			Bipolar disorder	01AUG2010		Y
	C4591001 1095 10951170	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1095 10951171	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2013	31DEC2013	N
	C4591001 1095 10951172	Investigations	Blood testosterone decreased	01JAN2018		Y
			Cardiac murmur	01JAN2013		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	10NOV2019	10NOV2019	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1095 10951173	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1095 10951174	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2017	31DEC2018	N
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Shoulder operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1095 10951176	Immune system disorders	Seasonal allergy	01OCT2018		Y
	C4591001 1095 10951177	Gastrointestinal disorders	Dyspepsia	01APR2020		Y
	C4591001 1095 10951178	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1095 10951182	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN1995		Y
	C4591001 1095 10951183	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1095 10951184	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1095 10951185	Immune system disorders	Hypersensitivity	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1095 10951188	Immune system disorders	Seasonal allergy	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951191	Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1095 10951194	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN2015		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1095 10951196	Gastrointestinal disorders	Umbilical hernia	01JAN2004	31DEC2005	N
		Injury, poisoning and procedural complications	Limb traumatic amputation	01JAN1987	31DEC1987	N
		Investigations	Blood testosterone decreased	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2005	31DEC2005	N
	C4591001 1095 10951197	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Pyelonephritis	01APR2017	30APR2017	N
		Investigations	Epstein-Barr virus test positive	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2020		Y
			Intervertebral disc degeneration	01JAN2013		Y
			Spinal stenosis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1993		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	01JAN2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1994		Y
		Surgical and medical procedures	Cyst removal	01JAN2016	31JAN2016	N
	C4591001 1095 10951198	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Appendicectomy	01JAN1991	31DEC1991	N
	C4591001 1095 10951199	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Psychiatric disorders	Depression	01JAN1993		Y
	C4591001 1095 10951201	Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
	C4591001 1095 10951202	Immune system disorders	Seasonal allergy	01APR2000		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	01MAY2019		Y
	C4591001 1095 10951203	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1095 10951207	Immune system disorders	Food allergy	01JAN2016		Y
	C4591001 1095 10951208	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Amenorrhoea	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1095 10951215	Immune system disorders	Mycotic allergy	01JAN2010		Y
	C4591001 1095 10951217	Musculoskeletal and connective tissue disorders	Scoliosis	01JUN2006	07DEC2011	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1998	01JAN2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	01JAN2019	N
			Scoliosis surgery	01JAN2011	01JAN2011	N
			Tonsillectomy	01JAN2000	01JAN2000	N
	C4591001 1095 10951218	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Hypersensitivity	01JAN1992		Y
		Injury, poisoning and procedural complications	Ligament sprain	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Costochondritis	01JAN2011		Y
			Fibromyalgia	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1095 10951222	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	14MAY2000	14MAY2000	N
	C4591001 1095 10951223	Psychiatric disorders	Anxiety	01JUL2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951225	Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1095 10951231	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1999		Y
	C4591001 1095 10951233	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
		Nervous system disorders	Headache	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2011		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
	C4591001 1095 10951236	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JAN2001	31DEC2002	N
	C4591001 1095 10951241	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1095 10951243	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1095 10951244	Immune system disorders	Rubber sensitivity	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
	C4591001 1095 10951245	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	22MAY2020		Y
	C4591001 1095 10951248	Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2019	31DEC2019	N
	C4591001 1095 10951250	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1095 10951251	Hepatobiliary disorders	Cholestasis	01JAN1997	31DEC1997	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Infectious mononucleosis	01MAY2020	30JUN2020	N
		Nervous system disorders	Headache	01JAN1996		Y
			Migraine	01JAN1996		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997		Y
	C4591001 1095 10951253	Immune system disorders	Seasonal allergy	28SEP2016		Y
	C4591001 1095 10951254	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1095 10951255	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Ligament sprain	04JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1095 10951257	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1095 10951259	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1095 10951260	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1095 10951262	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y
	C4591001 1095 10951266	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN2003		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Investigations	Cardiac murmur	01JAN1982		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
	C4591001 1095 10951267	Psychiatric disorders	Anxiety	01JUN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2016		Y
	C4591001 1095 10951270	Vascular disorders	Hypertension	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1095 10951271	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
		Psychiatric disorders	Tobacco abuse	01JAN2010		Y
	C4591001 1095 10951274	Immune system disorders	Seasonal allergy	01JAN2007		Y
	C4591001 1095 10951277	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2000	31DEC2000	N
		Investigations	Blood testosterone decreased	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1095 10951278	Gastrointestinal disorders	Gastrointestinal pain	21AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2020		Y
			Depression	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951280	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2019		Y
	C4591001 1095 10951281	Gastrointestinal disorders	Large intestine polyp	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01SEP2018	30NOV2018	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01NOV2018	30NOV2018	N
			Large intestinal polypectomy	01JAN2014	31DEC2014	N
	C4591001 1095 10951282	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1095 10951283	Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
			Endometrial ablation	01JAN2014	31DEC2014	N
	C4591001 1095 10951285	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1095 10951286	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1095 10951288	Cardiac disorders	Supraventricular tachycardia	01JAN1994	31DEC2003	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31OCT2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2003	31DEC2003	N
			Cholecystectomy	01OCT2013	31OCT2013	N
	C4591001 1095 10951291	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1095 10951292	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1095 10951294	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1095 10951295	Hepatobiliary disorders	Cholecystitis	01FEB2018	28FEB2018	N
			Cholelithiasis	01FEB2018	28FEB2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Nasal septum deviation	01NOV2018	30NOV2018	N
		Surgical and medical procedures	Cholecystectomy	01FEB2018	28FEB2018	N
			Nasal septal operation	01NOV2018	30NOV2018	N
	C4591001 1095 10951296	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Pregnancy, puerperium and perinatal conditions	Intrapartum haemorrhage	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1095 10951298	Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
	C4591001 1095 10951301	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Glaucoma	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1095 10951304	Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Gastric bypass	01JAN2011	31DEC2011	N
			Hysterectomy	01JUN2011	30JUN2011	N
	C4591001 1095 10951306	Injury, poisoning and procedural complications	Epicondylitis	01JAN2015		Y
			Tendon rupture	02OCT2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2003	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1095 10951307	Nervous system disorders	Headache	01JAN2001		Y
	C4591001 1095 10951308	Psychiatric disorders	Depression	01DEC2016		Y
	C4591001 1095 10951309	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
	C4591001 1095 10951311	Ear and labyrinth disorders	Hypoacusis	(b) (6) 2003		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Renal and urinary disorders	Nephrotic syndrome	01JAN2007	31DEC2007	N
	C4591001 1095 10951312	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1095 10951313	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1095 10951314	Nervous system disorders	Epilepsy	01JAN2012		Y
	C4591001 1095 10951315	Nervous system disorders	Headache	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1095 10951316	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2019		Y
	C4591001 1095 10951317	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951319	Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1096 10961007	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Tenoplasty	01JAN2004	31DEC2004	N
	C4591001 1096 10961012	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1096 10961013	General disorders and administration site conditions	Perforated ulcer	01MAR1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN1999		Y
		Psychiatric disorders	Depression	01FEB2019		Y
		Surgical and medical procedures	Therapeutic procedure	01MAR1999	31DEC1999	N
			Thrombectomy	01JUN2019	30JUN2019	N
		Vascular disorders	Deep vein thrombosis	01JUN2019	30JUN2019	N
			Hypertension	01JAN1999		Y
	C4591001 1096 10961018	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Calcium deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Thyroidectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961022	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	25JUN2019	25JUN2019	N
	C4591001 1096 10961023	Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	13AUG2020		Y
		Infections and infestations	Gastrointestinal infection	13AUG2020	23AUG2020	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
	C4591001 1096 10961026	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1096 10961027	Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
		Psychiatric disorders	Depression	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2004	31DEC2004	N
	C4591001 1096 10961029	Gastrointestinal disorders	Abdominal hernia	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2018	31DEC2018	N
		Vascular disorders	Varicose vein	01JAN1990		Y
	C4591001 1096 10961030	Skin and subcutaneous tissue disorders	Rash	01APR2020	30APR2020	N
	C4591001 1096 10961031	Immune system disorders	Allergy to animal	01JAN2000		Y
		Infections and infestations	Mastitis	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004	31DEC2008	N
		Surgical and medical procedures	Breast operation	01OCT2016	31OCT2016	N
			Caesarean section	08JUN2016	08JUN2016	N
	C4591001 1096 10961032	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
	C4591001 1096 10961036	Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Bipolar disorder	01JAN2004		Y
			Depression	01JAN2004		Y
	C4591001 1096 10961049	Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1096 10961052	Hepatobiliary disorders	Gallbladder disorder	01JAN1995	31DEC1995	N
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Meniscus operation	01JAN2017	31DEC2017	N
	C4591001 1096 10961053	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1096 10961057	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961059	Nervous system disorders	Headache	01JAN2000		Y
			Restless legs syndrome	01JAN2016		Y
	C4591001 1096 10961060	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Spinal laminectomy	01JAN1999	31DEC1999	N
	C4591001 1096 10961061	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
	C4591001 1096 10961062	Endocrine disorders	Androgen deficiency	01JAN2017		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2002	31DEC2002	N
		Injury, poisoning and procedural complications	Road traffic accident	01AUG2019	31AUG2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2019		Y
			Intervertebral disc protrusion	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2002		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Spinal fusion surgery	01FEB2020	29FEB2020	N
			Tonsillectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1096 10961063	Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961064	Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1096 10961067	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1096 10961072	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1096 10961074	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1096 10961075	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Bronchitis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1096 10961076	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1096 10961077	Congenital, familial and genetic disorders	Marfan's syndrome	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Jaw cyst	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Functional endoscopic sinus surgery	01MAY2013	31MAY2013	N
			Jaw operation	01JAN2019	31DEC2019	N
			Rhinoplasty	01MAY2013	31MAY2013	N
	C4591001 1096 10961078	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1096 10961083	Injury, poisoning and procedural complications	Lower limb fracture	01MAR2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1096 10961085	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		General disorders and administration site conditions	Fatigue	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
			Piriformis syndrome	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961087	Hepatobiliary disorders	Hepatitis	01JAN1974	31DEC1974	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Hepatitis B test negative	01JAN2010	31DEC2010	N
			Hepatitis C test negative	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1096 10961088	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rash	14AUG2020	28AUG2020	N
	C4591001 1096 10961089	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2008		Y
	C4591001 1096 10961090	Surgical and medical procedures	Caesarean section	02OCT2002	02OCT2002	N
				08JUN2005	08JUN2005	N
				24AUG2001	24AUG2001	N
				29OCT2013	29OCT2013	N
			Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1096 10961093	Infections and infestations	Syphilis	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961096	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1096 10961097	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1096 10961098	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1096 10961099	Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1096 10961100	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2019	08JUN2020	N
		Psychiatric disorders	Anxiety disorder	01JAN2003		Y
			Attention deficit hyperactivity disorder	01JAN2003		Y
			Bipolar disorder	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
			Gastrectomy	08JUN2020	08JUN2020	N
			Wisdom teeth removal	01JAN2009	31DEC2009	N
	C4591001 1096 10961101	General disorders and administration site conditions	Oedema peripheral	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1978		Y
		Nervous system disorders	Migraine	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
	C4591001 1096 10961102	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
		Reproductive system and breast disorders	Premenstrual syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1096 10961103	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1096 10961105	Surgical and medical procedures	Female sterilisation	10AUG2012	10AUG2012	N
	C4591001 1096 10961109	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1096 10961110	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1096 10961111	Nervous system disorders	Headache	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961112	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1096 10961114	Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01MAY2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Gastrectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1096 10961115	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2010	31DEC2010	N
			Abdominal pain	01JAN2015		Y
			Intussusception	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01FEB2020		Y
		Nervous system disorders	Epilepsy	01JAN2011		Y
			Migraine	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1096 10961122	Injury, poisoning and procedural complications	Skin laceration	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Skin graft	01JAN2012	31DEC2012	N
	C4591001 1096 10961125	Social circumstances	Postmenopause	01FEB2019		Y
	C4591001 1096 10961130	Infections and infestations	Diverticulitis	01NOV2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012	25AUG2020	N
		Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1096 10961137	Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 1987	31DEC1992	N
			Congenital heart valve disorder	(b) (6) 1987	31DEC1992	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Surgical and medical procedures	Cardiac operation	01JAN1992	31DEC1992	N
			Gastrectomy	09JUL2020	09JUL2020	N
			Ligament operation	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
	C4591001 1096 10961139	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1096 10961140	Immune system disorders	Seasonal allergy	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961141	Gastrointestinal disorders	Flatulence	25AUG2020	09SEP2020	N
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1096 10961142	Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				08NOV1996	08NOV1996	N
				09DEC2019	09DEC2019	N
				16FEB2001	16FEB2001	N
	C4591001 1096 10961145	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1096 10961147	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1992	31DEC1993	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01AUG1999	01AUG1999	N
				24JAN2008	24JAN2008	N
			Spinal fusion surgery	01JAN1993	31DEC1993	N
	C4591001 1096 10961148	Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01APR2018		Y
	C4591001 1096 10961150	Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01MAR2020	31MAR2020	N
			Gastrectomy	10JUL2019	10JUL2019	N
	C4591001 1096 10961151	Endocrine disorders	Hypothyroidism	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01FEB2020	30SEP2020	N
			Tibia fracture	01FEB2020	30SEP2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1096 10961154	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1999		Y
	C4591001 1096 10961158	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint injury	23AUG2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2001	31DEC2005	N
		Surgical and medical procedures	Hair transplant	01JAN2005	31DEC2005	N
	C4591001 1096 10961168	Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1096 10961169	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1096 10961172	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2018		Y
	C4591001 1096 10961173	Injury, poisoning and procedural complications	Joint dislocation	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Wrist surgery	01JAN2004	31DEC2004	N
	C4591001 1096 10961175	Endocrine disorders	Hypothyroidism	01JAN1997		Y
	C4591001 1096 10961176	Injury, poisoning and procedural complications	Jaw fracture	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Jaw operation	01JAN2018	31DEC2018	N
	C4591001 1096 10961177	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Bipolar disorder	01JAN1998		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Caesarean section	17OCT2006	17OCT2006	N
				20MAR2005	20MAR2005	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1096 10961178	Infections and infestations	Herpes simplex	01DEC2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011	31DEC2013	N
				01JAN2014		Y
		Nervous system disorders	Headache	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008	31DEC2009	N
		Surgical and medical procedures	Caesarean section	14JUL2014	14JUL2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				24JUL2019	24JUL2019	N
			Gastric bypass	01JAN2013	31DEC2013	N
	C4591001 1096 10961179	Psychiatric disorders	Anxiety	01JAN2013		Y
			Bipolar disorder	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1096 10961180	Gastrointestinal disorders	Periodontal disease	01JAN2020		Y
		General disorders and administration site conditions	Pain	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Tooth abscess	01JAN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
			Depression	01JAN2006		Y
	C4591001 1096 10961185	Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1096 10961186	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Head injury	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2002		Y
		Social circumstances	Postmenopause	01JUN2019		Y
		Surgical and medical procedures	Gallbladder operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961187	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
	C4591001 1096 10961195	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1096 10961197	Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
	C4591001 1096 10961199	Metabolism and nutrition disorders	Gout	01JAN1989		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1981		Y
	C4591001 1096 10961200	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Renal and urinary disorders	IgA nephropathy	01JAN2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
	C4591001 1096 10961205	Injury, poisoning and procedural complications	Ligament rupture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N
	C4591001 1096 10961206	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2012	31DEC2012	N
			Sterilisation reversal	01JAN2018	31DEC2018	N
	C4591001 1096 10961207	Immune system disorders	Allergy to animal	01JAN1980		Y
			Seasonal allergy	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
			Obesity	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2016		Y
			Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JUL2019		Y
		Surgical and medical procedures	Female sterilisation	02MAY1991	02MAY1991	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961208	Infections and infestations	Herpes simplex	01JAN2010		Y
			Syphilis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Neck injury	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Vertebroplasty	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1096 10961209	Psychiatric disorders	Depression	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Caesarean section	12AUG2017	12AUG2017	N
	C4591001 1096 10961210	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1096 10961211	Psychiatric disorders	Depression	01JAN1999		Y
	C4591001 1096 10961213	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1096 10961214	Infections and infestations	Epididymitis	01MAR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Testicular pain	01JUL2020		Y
	C4591001 1096 10961215	Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Post herpetic neuralgia	01JAN2019		Y
			Sciatica	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	02JUL1999	02JUL1999	N
			Gastrectomy	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961217	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1096 10961218	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1096 10961219	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
			Chronic sinusitis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Ankle operation	01JAN2016	31DEC2016	N
			Appendicectomy	01JAN2014	31DEC2014	N
			Sinus operation	01JAN2018	31DEC2018	N
			Osteoma	01JAN2018	31DEC2018	N
	C4591001 1096 10961220	Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N
	C4591001 1096 10961222	Musculoskeletal and connective tissue disorders	Knee deformity	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN2018	31DEC2018	N
	C4591001 1096 10961223	Reproductive system and breast disorders	Menorrhagia	01JAN2017	30SEP2020	N
			Metrorrhagia	01JAN2017	30SEP2020	N
	C4591001 1096 10961225	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN1986		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1096 10961226	Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1096 10961227	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN1999		Y
		Investigations	Hepatic enzyme increased	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Surgical and medical procedures	Mammoplasty	01JAN2016	31DEC2016	N



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1096 10961229	Infections and infestations	Dengue fever	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN1996	31DEC1996	N
		Pregnancy, puerperium and perinatal conditions	Stillbirth	01MAR2020		Y
				01JAN1998	31DEC1998	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
				01JAN1996	31DEC1996	N
	C4591001 1096 10961230	Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
			Drug hypersensitivity	01JAN1993		Y
		Nervous system disorders	Headache	01JAN2001		Y
	C4591001 1096 10961231	General disorders and administration site conditions	Vaccination site swelling	01JAN2010	31DEC2010	N
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	24AUG2010	24AUG2010	N
	C4591001 1096 10961236	Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
			Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1096 10961238	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Social circumstances	Postmenopause	01JUL2019		Y
	C4591001 1096 10961239	Gastrointestinal disorders	Hiatus hernia	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hernia hiatus repair	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961240	Congenital, familial and genetic disorders	Fallot's tetralogy	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Cardiac operation	01JAN1994	31DEC1994	N
	C4591001 1096 10961242	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1096 10961243	Metabolism and nutrition disorders	Obesity	01JAN2005	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Abdominoplasty	01JAN2013	31DEC2013	N
			Caesarean section	01JAN1994	31DEC1994	N
				01JAN2005	31DEC2005	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Gastrectomy	01JAN2012	31DEC2012	N
	C4591001 1096 10961244	Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1096 10961245	Infections and infestations	Arthritis bacterial	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2013		Y
	C4591001 1096 10961246	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995	31DEC1995	N
	C4591001 1096 10961249	Infections and infestations	Hepatitis A	01JAN1989	31DEC1989	N
	C4591001 1096 10961251	Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Nervous system disorders	Epilepsy	01JAN2015		Y
		Surgical and medical procedures	Ankle operation	01JAN2012	31DEC2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961254	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	31OCT2019	31OCT2019	N
	C4591001 1096 10961255	Eye disorders	Blindness unilateral	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011		Y
		Nervous system disorders	Brain injury	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Attention deficit hyperactivity disorder	01JAN2004		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1998		Y
		Surgical and medical procedures	Brain operation	01JAN2000	31DEC2000	N
	C4591001 1096 10961256	Infections and infestations	Urinary tract infection	03SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2010		Y
	C4591001 1096 10961257	Investigations	Blood testosterone decreased	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018		Y
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
	C4591001 1096 10961258	Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961261	Psychiatric disorders	Anxiety	01DEC2018		Y
	C4591001 1096 10961262	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Breast prosthesis removal	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2004	31DEC2004	N
				01JAN2018	31DEC2018	N
	C4591001 1096 10961265	Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2001	31DEC2001	N
			Lower limb fracture	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Appendectomy	01JAN2006	31DEC2006	N
			Ligament operation	01JAN2006	31DEC2006	N
			Shoulder operation	01JAN2001	31DEC2001	N
	C4591001 1096 10961266	Skin and subcutaneous tissue disorders	Rosacea	01JUN2020		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1096 10961267	Injury, poisoning and procedural complications	Lower limb fracture	04JUL2020	06JUL2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	04JUL2020		Y
		Surgical and medical procedures	Knee operation	06JUL2020	06JUL2020	N
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961268	Immune system disorders	Seasonal allergy	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1096 10961271	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	15SEP2010	15SEP2010	N
				24NOV2008	24NOV2008	N
	C4591001 1096 10961275	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
	C4591001 1096 10961276	Gastrointestinal disorders	Constipation	01JAN2018	31DEC2018	N
		General disorders and administration site conditions	Localised oedema	01JAN2018		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2016		Y
		Injury, poisoning and procedural complications	Respiratory fume inhalation disorder	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Renal and urinary disorders	Renal cyst	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Chronic respiratory failure	01JAN2018		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1096 10961277	Musculoskeletal and connective tissue disorders	Musculoskeletal pain	01MAR2020		Y
			Plantar fasciitis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1096 10961278	Gastrointestinal disorders	Dyspepsia	24AUG2020	24AUG2020	N
		Immune system disorders	Iodine allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Lithotripsy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961279	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
	C4591001 1096 10961280	Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1096 10961284	Metabolism and nutrition disorders	Obesity	01JAN1983		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1096 10961288	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961289	Hepatobiliary disorders	Gallbladder disorder	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Obesity	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Hernia hiatus repair	01JAN2001		Y
	C4591001 1096 10961291	Nervous system disorders	Migraine	01JAN2005		Y
	C4591001 1096 10961293	Immune system disorders	Drug hypersensitivity	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1989	31DEC1989	N
			Splenic rupture	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Arthralgia	07SEP2020		Y
			Back pain	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Splenectomy	01JAN1989	31DEC1989	N
	C4591001 1096 10961299	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Adenoiditis	01JAN1995	31DEC1995	N
				01JAN1996	31DEC1998	N
			Ear infection	01JAN1993	31DEC2003	N
			Tonsillitis	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1988		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
			Caesarean section	11FEB2016	11FEB2016	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1096 10961301	Injury, poisoning and procedural complications	Ligament rupture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1998	31DEC1998	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1096 10961303	General disorders and administration site conditions	Injection site erythema	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2020		Y
	C4591001 1096 10961305	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1998	31DEC1998	N
			Iliotibial band syndrome	01JUN2020	30JUN2020	N
			Tendon rupture	02FEB2016	02FEB2016	N
		Investigations	Arthroscopy	01DEC2019	31DEC2019	N
				01NOV2019	30NOV2019	N
			Hysteroscopy	01JUL2008	01JUL2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2010	07FEB2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006	31DEC2006	N
			Cerebrospinal fluid leakage	09OCT2015	09OCT2015	N
			Neuralgia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01OCT2004	01OCT2004	N
				03JUN2005	03JUN2005	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Social circumstances	Menopause	01JAN2020		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bursa removal	01JUL2020	31JUL2020	N
			Carpal tunnel decompression	01JAN2007	31DEC2007	N
			Facet joint block	29APR2003	29APR2003	N
			Injection	03APR2015	03APR2015	N
			Intervertebral disc operation	01JAN2007	31DEC2007	N
				19JUL2016	19JUL2016	N
			Keratomileusis	02APR2012	02APR2012	N
			Nerve block	01MAY2019	31MAY2019	N
				19DEC2016	19DEC2016	N
			Neurectomy	07FEB2012	07FEB2012	N
			Rhinoplasty	01JAN1998	31DEC1998	N
			Rotator cuff repair	03APR2019	03APR2019	N
			Sinus operation	20AUG2020	20AUG2020	N
			Tendon operation	02FEB2016	02FEB2016	N
			Therapeutic nerve ablation	14MAY2003	14MAY2003	N
	C4591001 1096 10961306	Eye disorders	Dry eye	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1096 10961307	Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Cardiac disorders	Coronary artery disease	04JUL2008		Y
		Gastrointestinal disorders	Gastric ulcer	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Injury, poisoning and procedural complications	Neck injury	01AUG2016	31AUG2016	N
			Tendon rupture	01NOV2007	30NOV2007	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2008		Y
			Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Back pain	01JAN2016		Y
			Exostosis	01JAN2007	30NOV2007	N
				01JAN2015		Y
			Intervertebral disc protrusion	01AUG2016		Y
			Neck pain	01AUG2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	04JUL2008	04JUL2008	N
			Tenoplasty	01NOV2007	30NOV2007	N
		Vascular disorders	Hypertension	01JUL2008		Y
	C4591001 1096 10961313	Gastrointestinal disorders	Flatulence	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1096 10961317	Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1096 10961318	Metabolism and nutrition disorders	Obesity	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Alopecia areata	01JAN2015		Y
	C4591001 1096 10961319	Gastrointestinal disorders	Salivary gland cyst	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAY2018	31DEC2018	N
			Parotidectomy	01JAN2015	31DEC2015	N
	C4591001 1096 10961321	Gastrointestinal disorders	Hiatus hernia	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01MAR2019		Y
			Depression	01APR2020		Y
			Suicidal ideation	05SEP2020		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2004	31DEC2004	N
	C4591001 1096 10961322	Renal and urinary disorders	Hypertonic bladder	01JUN2020		Y
	C4591001 1096 10961328	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1985		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1096 10961330	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017	31DEC2017	N
				01MAR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018	31DEC2018	N
	C4591001 1096 10961331	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1096 10961335	Investigations	Hormone level abnormal	01AUG2019	31AUG2019	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
			Post-traumatic stress disorder	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01AUG2019	31AUG2019	N
	C4591001 1096 10961336	Eye disorders	Retinal detachment	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Depression	01MAR2019		Y
		Surgical and medical procedures	Eye operation	01JAN2013	31DEC2013	N
	C4591001 1096 10961340	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Social circumstances	Postmenopause	01JUN2019		Y
	C4591001 1096 10961341	Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1096 10961342	Musculoskeletal and connective tissue disorders	Myalgia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2012	31DEC2012	N
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Cancer surgery	01JAN2012	31DEC2012	N
	C4591001 1096 10961343	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Intestinal prolapse	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma benign	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Bladder prolapse	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Bladder repair	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2018	31DEC2018	N
			Intestinal operation	01JAN2018	31DEC2018	N
			Oophorectomy	01JAN2010	31DEC2010	N
	C4591001 1096 10961344	Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1096 10961345	Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1981		Y
	C4591001 1096 10961348	Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1096 10961350	Infections and infestations	Appendicitis	01SEP2019	31DEC2019	N
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Calcium deficiency	01JAN1981		Y
			Hypertriglyceridaemia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01SEP2019	30SEP2019	N
			Spinal laminectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1096 10961351	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Cough	28AUG2020	04SEP2020	N
			Respiratory tract congestion	28AUG2020	10SEP2020	N
	C4591001 1096 10961358	Musculoskeletal and connective tissue disorders	Myalgia	16SEP2020		Y
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	01AUG2020	31AUG2020	N
		Surgical and medical procedures	Precancerous lesion excision	01AUG2020	31AUG2020	N
	C4591001 1096 10961359	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1096 10961360	Endocrine disorders	Androgen deficiency	01OCT2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01MAY2019		Y
	C4591001 1096 10961362	Injury, poisoning and procedural complications	Ligament rupture	01SEP1996	31JUL1997	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JUL1997	31JUL1997	N
			Mammoplasty	01JAN2014	31DEC2014	N
	C4591001 1096 10961366	Vascular disorders	Hypertension	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961367	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961370	Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
	C4591001 1096 10961372	Injury, poisoning and procedural complications	Back injury	01JUL2019	31JUL2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2019		Y
			Intervertebral disc protrusion	01JUL2019	30JUN2020	N
		Surgical and medical procedures	Physiotherapy	01JUN2020		Y
			Spinal laminectomy	01JUN2020	30JUN2020	N
	C4591001 1096 10961373	Immune system disorders	Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN2018		Y
	C4591001 1096 10961374	Metabolism and nutrition disorders	Obesity	01AUG2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
			Salpingectomy	01JAN2018	31DEC2018	N
	C4591001 1096 10961375	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1096 10961376	Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	02APR2012	02APR2012	N
				18JAN2016	18JAN2016	N
				26APR2014	26APR2014	N
	C4591001 1096 10961378	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1096 10961379	Metabolism and nutrition disorders	Obesity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Back pain	14JUN2020		Y
		Surgical and medical procedures	Caesarean section	01FEB1989	01FEB1989	N
				06DEC1991	06DEC1991	N
				28MAY1993	28MAY1993	N
			Female sterilisation	01JAN1994	31DEC1994	N
	C4591001 1096 10961382	Cardiac disorders	Tachycardia	01JAN1995		Y
		Congenital, familial and genetic disorders	Tuberous sclerosis complex	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Milk allergy	01JAN2010		Y
			Mite allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y
			Staphylococcal skin infection	01MAR2019	31MAR2019	N
				01SEP2019	30SEP2019	N
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1096 10961385	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Ear infection	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Ear tube insertion	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961387	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1096 10961388	Gastrointestinal disorders	Nausea	11SEP2020	13SEP2020	N
			Vomiting	11SEP2020	13SEP2020	N
		Infections and infestations	Gastroenteritis viral	11SEP2020	13SEP2020	N
		Injury, poisoning and procedural complications	Joint injury	01JUN2018	30JUN2018	N
		Surgical and medical procedures	Ligament operation	01JUN2018	30JUN2018	N
			Osteotomy	01JUN2018	30JUN2018	N
	C4591001 1096 10961390	Infections and infestations	Tonsillitis	01JAN2010	30JUN2019	N
		Surgical and medical procedures	Tonsillectomy	01JUN2019	30JUN2019	N
	C4591001 1096 10961392	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Bipolar disorder	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1096 10961393	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1097 10971007	Skin and subcutaneous tissue disorders	Neurodermatitis	29MAY2018	29JUN2018	N
	C4591001 1097 10971018	Surgical and medical procedures	Hysterectomy	01DEC2019	31DEC2019	N
	C4591001 1097 10971041	Gastrointestinal disorders	Gastroesophageal reflux disease	25APR2018		Y
		Psychiatric disorders	Depression	25APR2018		Y
		Surgical and medical procedures	Salpingectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Essential hypertension	25APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1097 10971081	Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1097 10971096	Reproductive system and breast disorders	Polycystic ovaries	01JUL2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1097 10971119	Metabolism and nutrition disorders	Type 2 diabetes mellitus	31MAR2020		Y
	C4591001 1098 10981004	Surgical and medical procedures	Salpingectomy	01JAN2013	31DEC2013	N
	C4591001 1098 10981006	Investigations	Blood cholesterol increased	11AUG2020		Y
		Vascular disorders	Hypertension	27SEP2019		Y
	C4591001 1098 10981014	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1098 10981015	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N
	C4591001 1098 10981018	Vascular disorders	Hypertension	06JUN2017		Y
	C4591001 1098 10981023	Metabolism and nutrition disorders	Type 2 diabetes mellitus	03SEP2019		Y
		Surgical and medical procedures	Salpingectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	13SEP2019		Y
	C4591001 1098 10981025	Psychiatric disorders	Anxiety	01FEB2000		Y
			Attention deficit hyperactivity disorder	15AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981031	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
	C4591001 1098 10981032	Surgical and medical procedures	Salpingectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1098 10981035	Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN1987		Y
		Social circumstances	Corrective lens user	01JAN1987		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1098 10981043	Metabolism and nutrition disorders	Hyperlipidaemia	11FEB2019		Y
			Type 2 diabetes mellitus	11FEB2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	16SEP2019		Y
	C4591001 1098 10981048	Metabolism and nutrition disorders	Type 2 diabetes mellitus	15DEC2019		Y
	C4591001 1098 10981052	Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1098 10981054	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1098 10981055	Psychiatric disorders	Attention deficit hyperactivity disorder	27AUG2011		Y
	C4591001 1098 10981056	Nervous system disorders	Neuralgia	22MAR2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1098 10981057	Metabolism and nutrition disorders	Hyperlipidaemia	22JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981060	Metabolism and nutrition disorders	Hyperlipidaemia	03JUN2020		Y
	C4591001 1098 10981064	Metabolism and nutrition disorders	Hyperlipidaemia	27AUG2013		Y
			Type 2 diabetes mellitus	11AUG2013		Y
		Surgical and medical procedures	Female sterilisation	01MAR1996	01MAR1996	N
		Vascular disorders	Hypertension	27AUG2013		Y
	C4591001 1098 10981065	Gastrointestinal disorders	Umbilical hernia	01JAN2012		Y
	C4591001 1098 10981067	Metabolism and nutrition disorders	Hyperlipidaemia	13JAN2013		Y
			Type 2 diabetes mellitus	25NOV2012		Y
		Surgical and medical procedures	Female sterilisation	01AUG2005	01AUG2005	N
		Vascular disorders	Hypertension	28NOV2012		Y
	C4591001 1098 10981068	Eye disorders	Hypermetropia	01JAN2001		Y
		Social circumstances	Corrective lens user	01JAN2001		Y
	C4591001 1098 10981069	Gastrointestinal disorders	Gastrooesophageal reflux disease	02SEP2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	12DEC2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	12DEC2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1098 10981073	Congenital, familial and genetic disorders	Hepato-lenticular degeneration	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1985	01JAN1985	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1985	01JAN1985	N
	C4591001 1098 10981074	Blood and lymphatic system disorders	Thrombocytopenia	22JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	13FEB2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	13FEB2019		Y
	C4591001 1098 10981075	Endocrine disorders	Hypothyroidism	20MAR2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	06SEP2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22APR2017		Y
		Vascular disorders	Hypertension	22APR2017		Y
	C4591001 1098 10981079	Eye disorders	Myopia	01JAN1988		Y
		Injury, poisoning and procedural complications	Skull fracture	01JAN1988	31DEC1988	N
		Social circumstances	Corrective lens user	01JAN1988		Y
		Surgical and medical procedures	Female sterilisation	01JAN2019	31DEC2019	N
			Splenectomy	01JAN1988	31DEC1988	N
	C4591001 1098 10981085	Eye disorders	Myopia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
	C4591001 1098 10981086	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1098 10981089	Endocrine disorders	Hypothyroidism	15JAN2015		Y
	C4591001 1098 10981091	Gastrointestinal disorders	Gastrooesophageal reflux disease	03APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	14JUN2013		Y
		Vascular disorders	Hypertension	14JUN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981095	Endocrine disorders	Hypothyroidism	19MAY2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12FEB2016		Y
	C4591001 1098 10981096	Reproductive system and breast disorders	Polycystic ovaries	09MAY2018		Y
		Vascular disorders	Hypertension	15MAY2019		Y
	C4591001 1098 10981097	Metabolism and nutrition disorders	Hypertriglyceridaemia	22JAN2013		Y
			Type 2 diabetes mellitus	22JAN2013		Y
	C4591001 1098 10981100	Surgical and medical procedures	Hysterectomy	24NOV2019	24NOV2019	N
	C4591001 1098 10981101	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2014		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1098 10981103	Metabolism and nutrition disorders	Gout	01JAN2012		Y
			Hyperlipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1098 10981106	Infections and infestations	Oral infection	01JUL2020	04SEP2020	N
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
	C4591001 1098 10981117	Social circumstances	Postmenopause	01SEP2018		Y
	C4591001 1098 10981120	Endocrine disorders	Hypothyroidism	25JUL2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	25JUL2016		Y
			Type 2 diabetes mellitus	12JUN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981121	Immune system disorders	Seasonal allergy	01JUN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1098 10981122	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JUL2012		Y
	C4591001 1098 10981125	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1098 10981129	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN1990		Y
	C4591001 1098 10981132	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1098 10981134	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1098 10981137	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Pneumonia	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01MAR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1098 10981141	Surgical and medical procedures	Hysterectomy	01APR2012	30APR2012	N
	C4591001 1098 10981144	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1992		Y
		Surgical and medical procedures	Salpingectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1098 10981145	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1098 10981147	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
	C4591001 1098 10981151	General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1098 10981152	Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Migraine	01JAN2018		Y
	C4591001 1098 10981153	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y
	C4591001 1098 10981155	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Infections and infestations	Hepatitis C	01JAN1991		Y
	C4591001 1098 10981156	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981160	Surgical and medical procedures	Female sterilisation	17SEP2015	17SEP2015	N
	C4591001 1098 10981161	Immune system disorders	Dust allergy	01JAN1994		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
			Post-traumatic stress disorder	01JAN2006		Y
	C4591001 1098 10981166	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1098 10981168†	Investigations	HIV test positive	01MAY2016		Y
	C4591001 1098 10981169†	Investigations	HIV test positive	01FEB2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31OCT2005	N
	C4591001 1098 10981170	Immune system disorders	Seasonal allergy	01JAN1986		Y
	C4591001 1098 10981176	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1098 10981177	Immune system disorders	Allergy to animal	01JAN2001		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Infectious mononucleosis	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01SEP2020		Y
			Depression	01SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1098 10981181	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2010		Y
	C4591001 1098 10981183	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1987		Y
	C4591001 1098 10981185	Immune system disorders	Allergy to animal	01JAN1979		Y
			Seasonal allergy	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1098 10981187	Immune system disorders	Allergy to animal	01JAN2010		Y
	C4591001 1098 10981188	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1098 10981189	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1098 10981191	Immune system disorders	Dust allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1098 10981194	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1978		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981196	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1098 10981198	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1098 10981199	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Infections and infestations	Herpes simplex	01SEP2019		Y
	C4591001 1098 10981200	Nervous system disorders	Epilepsy	01JAN2002		Y
	C4591001 1098 10981205	Immune system disorders	Allergy to plants	01JAN1971		Y
			Dust allergy	01JAN1971		Y
			Seasonal allergy	01JAN1971		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN1971		Y
	C4591001 1098 10981207	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
	C4591001 1098 10981210	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1098 10981216	Endocrine disorders	Hypogonadism male	01JAN2017		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1098 10981217	Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2015		Y
	C4591001 1098 10981219	Surgical and medical procedures	Vasectomy	01FEB2013	01FEB2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981224	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1098 10981226	Immune system disorders	Food allergy	01JAN2001		Y
			Hypersensitivity	01JAN2001		Y
			Rubber sensitivity	01JAN2001		Y
			Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Surgical and medical procedures	Keratomileusis	01OCT2017	31OCT2017	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1098 10981229	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Diverticulitis	01JAN2017		Y
		Investigations	Blood oestrogen decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1976		Y
			Insomnia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1098 10981230	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1098 10981232	Immune system disorders	Seasonal allergy	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981234	Psychiatric disorders	Post-traumatic stress disorder	01JAN2019		Y
	C4591001 1098 10981235	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1098 10981236	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1098 10981241	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1098 10981252	Reproductive system and breast disorders	Polycystic ovaries	01JUL2020		Y
	C4591001 1098 10981253	Immune system disorders	Food allergy	01JAN1995		Y
				01JAN2009		Y
	C4591001 1098 10981254	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2005	31DEC2005	N
		Psychiatric disorders	Bipolar disorder	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Adenoidectomy	01JAN2005	31DEC2005	N
			Circumcision	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1098 10981259	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1098 10981260	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1101 11011001	Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Fibromyalgia	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Rhinitis allergic	01JAN2008		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterosalpingo-oophorectomy	01JAN2007	31DEC2007	N
			Ligament operation	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1101 11011004	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1101 11011005	Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1101 11011007	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1101 11011010	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1101 11011012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1991		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1101 11011013	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
			Rhinitis allergic	01JAN2010		Y
	C4591001 1101 11011015	Gastrointestinal disorders	Haemorrhoids	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Urinary tract infection	01JUL2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Depression	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1101 11011016	Ear and labyrinth disorders	Deafness unilateral	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1101 11011020	Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
			Irritable bowel syndrome	01JAN1993		Y
		General disorders and administration site conditions	Pain	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Blood glucose increased	01JUN2020		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
			Obesity	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Fibromyalgia	01JAN1993		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1980		Y
			Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1967		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1101 11011021	Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
		Nervous system disorders	Headache	01JAN1977		Y
			Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
			Sinus congestion	01JAN2002		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1101 11011022	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1101 11011024	Blood and lymphatic system disorders	Anaemia	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Urinary tract infection	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1101 11011028	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1101 11011029	Gastrointestinal disorders	Volvulus	01JAN2020	31JAN2020	N
		Immune system disorders	Food allergy	01APR2020		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Muscle tightness	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011030	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1101 11011033	Infections and infestations	Bronchitis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Rhinitis allergic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1101 11011038	Immune system disorders	Food allergy	01JAN2011		Y
	C4591001 1101 11011039	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1101 11011040	Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1101 11011041	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1101 11011044	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1101 11011045	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
			Sinus congestion	01JAN1992		Y
			Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1101 11011048	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1101 11011052	Immune system disorders	Mycotic allergy	01JAN2015		Y
		Infections and infestations	Bronchitis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2013		Y
	C4591001 1101 11011056	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1101 11011058	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1101 11011059	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01OCT2018		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAY1990		Y
			Sleep apnoea syndrome	01DEC2019		Y
	C4591001 1101 11011060	Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
	C4591001 1101 11011061	Gastrointestinal disorders	Haemorrhoids	01JAN2008		Y
		Immune system disorders	Allergy to animal	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nephrectomy	01JAN2005	31DEC2005	N
	C4591001 1101 11011062	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1101 11011065	Ear and labyrinth disorders	Meniere's disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN1988		Y
	C4591001 1101 11011069	Musculoskeletal and connective tissue disorders	Back pain	20JUN2014		Y
		Skin and subcutaneous tissue disorders	Acne	20JUL2020		Y
	C4591001 1101 11011071	Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Immune system disorders	Mycotic allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1101 11011072	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Mycotic allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015		Y
		Vascular disorders	Peripheral artery thrombosis	01JAN2009		Y
			Subclavian artery aneurysm	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011073	Gastrointestinal disorders	Constipation	01JAN2000		Y
			Diarrhoea	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1101 11011075	Gastrointestinal disorders	Haemorrhoids	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1101 11011076	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2002		Y
			Haemorrhoids	01JAN2001		Y
		General disorders and administration site conditions	Fatigue	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN2018		Y
		Infections and infestations	Bronchitis	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1982		Y
			Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	30APR2020		Y
			Depression	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011080	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1101 11011085	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1101 11011087	Eye disorders	Visual acuity reduced	01JAN1972		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2018		Y
			Diverticulum	01JAN2018		Y
			Gastric ulcer	01JAN2005		Y
			Haemorrhoids	01JAN2000		Y
			Irritable bowel syndrome	01JAN2012		Y
		General disorders and administration site conditions	Pain	01JAN1995		Y
		Infections and infestations	Hepatitis C	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2016		Y
			Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
			Emphysema	01JAN2014		Y
			Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal fusion surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
			Raynaud's phenomenon	01JAN2017		Y
	C4591001 1101 11011088	Skin and subcutaneous tissue disorders	Acne	01SEP2017		Y
	C4591001 1101 11011090	Nervous system disorders	Epilepsy	01JAN2005		Y
			Migraine	01JAN1995		Y
		Psychiatric disorders	Depression	01FEB2016		Y
	C4591001 1101 11011091	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
	C4591001 1101 11011094	Blood and lymphatic system disorders	Anaemia	01FEB2020		Y
		Eye disorders	Visual acuity reduced	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1101 11011096	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
	C4591001 1101 11011097	Gastrointestinal disorders	Diarrhoea	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Nervous system disorders	Headache	01JAN2020		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
	C4591001 1101 11011100	Skin and subcutaneous tissue disorders	Acne	01AUG2016		Y
	C4591001 1101 11011101	Metabolism and nutrition disorders	Lactose intolerance	01JAN2009		Y
	C4591001 1101 11011105	Psychiatric disorders	Anxiety	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
			Eczema	01JAN2000		Y
	C4591001 1101 11011106	Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
	C4591001 1101 11011107	Gastrointestinal disorders	Gastric ulcer	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Bipolar disorder	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1101 11011108	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1101 11011110	Immune system disorders	Food allergy	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011115	Immune system disorders	Food allergy	01JAN1989		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1101 11011118	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1107 11071003	Eye disorders	Pupils unequal	01JAN1996		Y
			Retinal detachment	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Bone lesion excision	01JAN2000	31DEC2000	N
	C4591001 1107 11071006	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
	C4591001 1107 11071012	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1107 11071018	Metabolism and nutrition disorders	Central obesity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	03AUG2020		Y
	C4591001 1107 11071019	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2018		Y
	C4591001 1107 11071020	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Nervous system disorders	Migraine	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1107 11071022	Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1107 11071025	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1107 11071026	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1107 11071027	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Renal stone removal	01JAN2020	31JAN2020	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1107 11071028	Immune system disorders	Seasonal allergy	(b) (6) 1967		Y
	C4591001 1107 11071031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Irritable bowel syndrome	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Neurectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Raynaud's phenomenon	01JAN2007		Y
	C4591001 1107 11071032	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
	C4591001 1107 11071033	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1107 11071039	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2015		Y
		Endocrine disorders	Hypogonadism	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1107 11071046	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1107 11071052	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2020		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Oophorectomy bilateral	01JAN2014	31DEC2014	N
	C4591001 1107 11071054	Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1107 11071055	Nervous system disorders	Headache	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1107 11071056	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
	C4591001 1107 11071057	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	11DEC2000	11DEC2000	N
	C4591001 1107 11071059	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1107 11071063	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2000		Y
	C4591001 1107 11071065	Injury, poisoning and procedural complications	Ankle fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
	C4591001 1107 11071067	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Eye disorders	Extraocular muscle paresis	01JAN2001		Y
			Eye movement disorder	01JAN2001		Y
		Investigations	Blood testosterone decreased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071069	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Gastrectomy	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071070	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01JAN2005		Y
	C4591001 1107 11071071	Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31MAR2020	N
		Psychiatric disorders	Anxiety	01MAR2017		Y
			Depression	01MAR2017		Y
		Surgical and medical procedures	Ligament operation	01MAR2020	31MAR2020	N
	C4591001 1107 11071074	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Vascular disorders	Varicose vein	01JAN2018		Y
	C4591001 1107 11071083	Immune system disorders	Hypersensitivity	01JAN1997		Y
		Injury, poisoning and procedural complications	Arthropod bite	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1107 11071086	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071087	Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1107 11071089	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Overweight	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1107 11071098	Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2001	31DEC2001	N
		Nervous system disorders	Neuropathy peripheral	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1994		Y
		Surgical and medical procedures	Meniscus operation	01JAN2001	31DEC2001	N
	C4591001 1107 11071102	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Overweight	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
			Vasectomy	09MAY2012	09MAY2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1107 11071104	Metabolism and nutrition disorders	Overweight	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2014	N
	C4591001 1107 11071105	Surgical and medical procedures Investigations	Endometrial ablation Blood cholesterol increased	01JAN2014 01JAN2010	31DEC2014	N Y
	C4591001 1107 11071106	Metabolism and nutrition disorders Surgical and medical procedures Endocrine disorders	Overweight Vasectomy Hypothyroidism	01JAN2004 01JAN2009 01JAN2010	31DEC2009	Y N Y
		Injury, poisoning and procedural complications Investigations	Wrist fracture Blood cholesterol increased	01JAN2016 01JAN2014	31DEC2016	N Y
		Metabolism and nutrition disorders Psychiatric disorders Surgical and medical procedures	Overweight Anxiety Female sterilisation	01JAN2014 01JAN2014 01JAN2004	31DEC2004	Y Y N
	C4591001 1107 11071110	Vascular disorders Psychiatric disorders	Hypertension Depression	01JAN2014 01JAN2010		Y Y
	C4591001 1107 11071111	Vascular disorders Nervous system disorders	Hypertension Headache	01JAN2007 01JAN2000		Y Y
	C4591001 1107 11071112	Renal and urinary disorders Immune system disorders	Nephrolithiasis Drug hypersensitivity	01JAN2018 01JAN1989		Y Y
	C4591001 1107 11071114	Psychiatric disorders Gastrointestinal disorders Immune system disorders	Anxiety Depression Gastroesophageal reflux disease Drug hypersensitivity	01JAN1976 01JAN1976 01JAN2015 01JAN1980		Y Y Y Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
	C4591001 1107 11071118	Injury, poisoning and procedural complications	Humerus fracture	01DEC1999	31DEC1999	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Limb deformity	(b) (6) 1977		Y
		Psychiatric disorders	Anxiety	01OCT2017		Y
			Depression	01OCT2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1992	31OCT2016	N
		Surgical and medical procedures	Endometrial ablation	01OCT2016	31OCT2016	N
			Fracture treatment	01DEC1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1107 11071122	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1107 11071124	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1107 11071126	Psychiatric disorders	Anxiety	01JAN2000		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1107 11071129	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Oophorectomy	01JAN2014	31DEC2014	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1107 11071130	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1107 11071134	Hepatobiliary disorders	Cholelithiasis	01AUG2017	31AUG2017	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1964		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2017	30NOV2017	N
	C4591001 1107 11071136	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1107 11071138	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1107 11071139	Surgical and medical procedures	Female sterilisation	01FEB2014	28FEB2014	N
	C4591001 1107 11071144	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Psychiatric disorders	Alcoholism	01JAN2001		Y
			Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1107 11071146	Immune system disorders	Drug hypersensitivity	01JAN1975		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
		Infections and infestations	Oral herpes	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1107 11071151	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2010		Y
	C4591001 1107 11071154	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1107 11071155	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1107 11071156	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
	C4591001 1107 11071157	Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1107 11071160	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1107 11071162	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 1969		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Infections and infestations	Appendicitis	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Overweight	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC2009	N
		Surgical and medical procedures	Appendectomy	01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1107 11071163	Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1107 11071164	Metabolism and nutrition disorders	Overweight	01JAN2014		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
			Premenstrual dysphoric disorder	01MAY2020		Y
	C4591001 1107 11071165	Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	(b) (6) 1975		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1107 11071168	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1107 11071171	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Overweight	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
	C4591001 1107 11071174	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
			Insomnia	01JAN2009		Y
	C4591001 1107 11071178	Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1107 11071179	Metabolism and nutrition disorders	Overweight	01JAN2005		Y
	C4591001 1107 11071180	Psychiatric disorders	Anxiety	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2009		Y
		Surgical and medical procedures	Oophorectomy	01JAN2009	31DEC2009	N
	C4591001 1107 11071181	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2013		Y
		Surgical and medical procedures	Endometrial ablation	28AUG2013	28AUG2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071184	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2010		Y
	C4591001 1107 11071190	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1107 11071193	Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1107 11071195	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Rubber sensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1983	31DEC2007	N
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			Gastric bypass	01JAN2010	31DEC2010	N
	C4591001 1107 11071200	Metabolism and nutrition disorders	Overweight	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1107 11071203	Gastrointestinal disorders	Dental caries	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2001		Y
			Back pain	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1107 11071211	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1107 11071213	Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2007		Y
	C4591001 1107 11071215	Cardiac disorders	Coronary artery disease	01JAN2019		Y
			Myocardial infarction	06DEC2019	06DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	06DEC2019	06DEC2019	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1109 11091001	Hepatobiliary disorders	Cholecystitis	01JAN2015	31JAN2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	01JAN2015	N
	C4591001 1109 11091002	Immune system disorders	Drug hypersensitivity	01NOV1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
	C4591001 1109 11091003	Immune system disorders	Allergy to arthropod sting	01JAN1967		Y
	C4591001 1109 11091006	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1990	31JAN1990	N
		Infections and infestations	Appendicitis	01JAN1990	01JAN1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Back pain	01JAN2000		Y
			Neck pain	01JAN2005		Y
		Nervous system disorders	Cerebrovascular accident	09JAN2014	09JAN2014	N
			Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	01JAN1990	N
			Cholecystectomy	01JAN1990	31JAN1990	N
			Female sterilisation	01JAN1993	01JAN1993	N
	C4591001 1109 11091007	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2005	01JAN2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1975		Y
		Infections and infestations	Sinusitis	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1975	31JAN2019	N
			Neck pain	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	01JAN2005	N
		Vascular disorders	Hot flush	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1109 11091010	Nervous system disorders	Migraine	01JAN1992		Y	
		Reproductive system and breast disorders	Premenstrual syndrome	01MAY2020		Y	
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1992		Y	
		Surgical and medical procedures	Adenoidectomy	01JAN2000	31JAN2000	N	
			Caesarean section	01JAN2015	01JAN2015	N	
			Tonsillectomy	01JAN2000	31JAN2000	N	
	C4591001 1109 11091011	Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y	
			Intervertebral disc protrusion	01JAN2002		Y	
	C4591001 1109 11091013	Immune system disorders	Drug hypersensitivity	01JAN1990		Y	
			Seasonal allergy	01JAN1990		Y	
			Psychiatric disorders	Anxiety	01JAN2018		Y
			Surgical and medical procedures	Vasectomy	01JAN2009	31JAN2009	N
			Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1109 11091014	Immune system disorders	Seasonal allergy	01JAN2017		Y	
	C4591001 1109 11091015	Ear and labyrinth disorders	Meniere's disease	01JAN2002		Y	
	C4591001 1109 11091016	Infections and infestations	Appendicitis	01JAN1984	01JAN1984	N	
		Nervous system disorders	Migraine	01JAN1995		Y	
		Social circumstances	Tobacco user	01JAN1998	02JAN2018	N	
		Surgical and medical procedures	Appendicectomy	01JAN1984	01JAN1984	N	
			Mammoplasty	23APR2008	23APR2008	N	
	C4591001 1109 11091017	Immune system disorders	Seasonal allergy	01JAN1990		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	01APR2020	01APR2020	N
			Endoscopy	01JAN2015	01JAN2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1969		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000		Y
	C4591001 1109 11091018	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1109 11091019	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091020	Infections and infestations	Appendicitis	28JUN2013	28JUN2013	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	28JUN2013	28JUN2013	N
	C4591001 1109 11091021	Gastrointestinal disorders	Constipation	01JAN1999		Y
				01JAN2005		Y
			Haemorrhoids	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JUL1968		Y
		Injury, poisoning and procedural complications	Back injury	01JAN1998	01JAN1998	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y
			Fibromyalgia	05JAN2003		Y
			Intervertebral disc protrusion	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Muscle spasms	01JAN1998		Y
		Nervous system disorders	Cluster headache	01JAN2009	01JAN2020	N
			Migraine	01JAN1980	01JAN2020	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN1990		Y
			Insomnia	01JAN1995		Y
			Panic attack	01JAN2002		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1992	01JAN1992	N
		Skin and subcutaneous tissue disorders	Eczema	01MAY2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN1992	01JAN1992	N
			Spinal fusion surgery	01JAN2000	01JAN2000	N
			Spinal operation	01JAN1989	01JAN1989	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1109 11091022	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1998		Y
		Immune system disorders	Allergy to animal	01JAN1988		Y
			Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1988		Y
			Back pain	01JAN1998		Y
			Neck pain	01JAN1988		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Insomnia	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2004		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1989	01JAN1989	N
			Cholecystectomy	01JAN1998	01JAN1998	N
	C4591001 1109 11091023	Endocrine disorders	Hypogonadism	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2009		Y
		Nervous system disorders	Cerebrovascular accident	05JAN2011	05JAN2011	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
		Renal and urinary disorders	Nocturia	05JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1982	01JAN1982	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091024	Infections and infestations	Appendicitis	01AUG2011	01AUG2011	N
		Surgical and medical procedures	Appendicectomy	01AUG2011	01AUG2011	N
			Limb operation	01JAN2004	01JAN2004	N
			Vasectomy	01JAN2007		Y
	C4591001 1109 11091030	Metabolism and nutrition disorders	Hypercholesterolaemia	(b) (6) 1994		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Splenectomy	01JAN2015	01JAN2015	N
	C4591001 1109 11091033	Investigations	Colonoscopy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1109 11091041	Endocrine disorders	Hypogonadism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Large intestine polyp	01JAN2013		Y
		Infections and infestations	Hepatitis A	01JAN1981		Y
		Investigations	Colonoscopy	01JAN2013	31JAN2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1995		Y
			Back pain	01JAN1980		Y
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1974		Y
		Surgical and medical procedures	Vasectomy	01JAN1998		Y
	C4591001 1109 11091046	Surgical and medical procedures	Oral surgery	01JAN2016	31JAN2016	N
	C4591001 1109 11091047	Nervous system disorders	Migraine	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091048	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1979		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Angioplasty	01JAN2020		Y
			Coronary arterial stent insertion	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091052	Infections and infestations	Sinusitis	31JAN2019		Y
	C4591001 1109 11091054	Gastrointestinal disorders	Colitis	01JUL1975	01JUL1975	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Intestinal resection	01JUL1975	01JUL1975	N
			Neck surgery	01JAN2015	31JAN2015	N
	C4591001 1109 11091055	Immune system disorders	Seasonal allergy	01MAY2005		Y
		Investigations	Colonoscopy	01JAN2018	31JAN2018	N
			Endoscopy	01JAN2018	31JAN2018	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2012		Y
		Nervous system disorders	Sinus headache	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y
		Surgical and medical procedures	Female sterilisation	01DEC2018	31DEC2018	N
			Limb operation	01JAN2000	31JAN2000	N
	C4591001 1109 11091056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
				01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Skin laceration	30JUL2004	30JUL2004	N
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	30JUL2004		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2004		Y
		Surgical and medical procedures	Wound closure	30JUL2004	30JUL2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091057	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1969		Y
		Social circumstances	Postmenopause	28MAR2018		Y
	C4591001 1109 11091058	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31JAN2019	N
			Hernia repair	01JAN2000	31JAN2000	N
	C4591001 1109 11091060	Psychiatric disorders	Bipolar disorder	01JAN2006		Y
	C4591001 1109 11091062	Metabolism and nutrition disorders	Type 2 diabetes mellitus	13JUN2013		Y
		Psychiatric disorders	Anxiety	13JUN2017		Y
			Depression	13JUN2017		Y
			Insomnia	13JUN2017		Y
		Vascular disorders	Hypertension	13JUN2013	13JUN2013	N
	C4591001 1109 11091063	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	26JUL2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31JAN2004	N
	C4591001 1109 11091066	Gastrointestinal disorders	Constipation	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2000	31JAN2017	N
			Insomnia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091067	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091070	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1109 11091071	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1109 11091075	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
	C4591001 1109 11091077	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1109 11091078	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091078	Psychiatric disorders	Anxiety	01JAN2008		Y
	C4591001 1109 11091080	Surgical and medical procedures	Female sterilisation	01JAN1995	31JAN1995	N
	C4591001 1109 11091082	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1977		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31JAN2005	N
	C4591001 1109 11091083	Investigations	Arthroscopy	01JAN2000	31JAN2000	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1109 11091086	Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Infections and infestations	Pneumonia	08APR2019	30APR2019	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2008		Y
			Perinatal depression	01JAN2008	31DEC2010	N
		Surgical and medical procedures	Abscess drainage	08APR2019	08APR2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast prosthesis removal	01JAN2010	01JAN2010	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Fracture treatment	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2000	01JAN2000	N
	C4591001 1109 11091092	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1109 11091098	Gastrointestinal disorders	Constipation	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1109 11091099	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1109 11091100	Psychiatric disorders	Nicotine dependence	01JAN2019		Y
	C4591001 1109 11091102	Renal and urinary disorders	Nephrolithiasis	01MAY2019	01MAY2019	N
		Surgical and medical procedures	Vasectomy	01JAN2009	01JAN2009	N
	C4591001 1109 11091105	Hepatobiliary disorders	Cholecystitis	01JAN1996	31JAN1996	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31JAN1996	N
			Gastric bypass	01JAN2017		Y
			Nasal operation	01JAN1980	31JAN1980	N
	C4591001 1109 11091106	Surgical and medical procedures	Vasectomy	10JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091108	General disorders and administration site conditions	Polyp	01JAN2019	31JAN2019	N
		Investigations	Arthroscopy	01JAN1985	31JAN1985	N
			Colonoscopy	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091109	Infections and infestations	Staphylococcal infection	01JAN2010	31JAN2010	N
	C4591001 1109 11091110	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1109 11091112	Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN2010	31JAN2010	N
	C4591001 1109 11091115	Cardiac disorders	Tachycardia	01JAN1998		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010		Y
		Investigations	Endoscopy	01JAN2002	31JAN2002	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01DEC2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Eye operation	01JAN1995	31JAN1995	N
			Knee operation	01JAN1986	31JAN1986	N
			Renal stone removal	01DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091117	Infections and infestations	Sinusitis	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091122	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Surgical and medical procedures	Renal stone removal	01JAN2019	31JAN2019	N
			Vasectomy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091126	Surgical and medical procedures	Wrist surgery	01JAN1998	31JAN1998	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091127	Surgical and medical procedures	Breast conserving surgery	01JAN2019	31JAN2019	N
			Caesarean section	01JAN1990	31JAN1999	N
				01JAN2002	31JAN2002	N
				01JAN2004	31JAN2004	N
	C4591001 1109 11091132	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Cluster headache	01JAN2018		Y
			Migraine	28JAN2018		Y
			Narcolepsy	04JUN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091134	Immune system disorders	Food allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y
			Intervertebral disc protrusion	01JAN2016		Y
				01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Bipolar I disorder	01JAN1996		Y
			Bipolar disorder	01JAN1996		Y
		Surgical and medical procedures	Gastric bypass	01JAN2015	01JAN2015	N
	C4591001 1109 11091136	Immune system disorders	Seasonal allergy	01JAN1991		Y
	C4591001 1109 11091147	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2016	31JAN2016	N
			Liposuction	08JUL2019	08JUL2019	N
			Mammoplasty	01JAN2002	31JAN2002	N
	C4591001 1109 11091148	Gastrointestinal disorders	Constipation	01JAN2007		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
		Surgical and medical procedures	Limb operation	01JAN2000	31JAN2000	N
	C4591001 1109 11091158	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1109 11091159	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1109 11091160	Eye disorders	Blindness unilateral	(b) (6) 1979		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1109 11091176	Immune system disorders	Seasonal allergy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091178	Nervous system disorders	Migraine	01JAN1985		Y
		Surgical and medical procedures	Foot operation	01JAN2008	01JAN2008	N
			Knee operation	01JAN2018	01JAN2018	N
	C4591001 1109 11091180	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	01JAN2000	01JAN2000	N
	C4591001 1109 11091183	Cardiac disorders	Arrhythmia	01JAN2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1989		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	01JAN2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1980		Y
			Seasonal allergy	01JAN1973		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	01JAN2007	N
	C4591001 1109 11091184	Endocrine disorders	Hypogonadism	01JUL2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Gastric operation	01JAN2016	01JAN2016	N
			Skin neoplasm excision	01JAN2016	01JAN2016	N
			Vasectomy	01JAN2014	01JAN2014	N
	C4591001 1109 11091185	Cardiac disorders	Atrial fibrillation	01JAN1967		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091186	Immune system disorders	Rubber sensitivity	01JAN1979		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1109 11091190	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091197	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Rubber sensitivity	01JAN1999		Y
			Seasonal allergy	01JUN2019		Y
		Infections and infestations	Oral herpes	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018		Y
			Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Tympanoplasty	01JAN2018	31DEC2018	N
				01OCT2019	31OCT2019	N
	C4591001 1109 11091199	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Iron deficiency	01JAN2019		Y
	C4591001 1109 11091204	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Keratomileusis	01JAN2015	31DEC2015	N
			Otoplasty	01JAN2013	01JAN2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091205	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Genital herpes	01JAN2012		Y
	C4591001 1109 11091211	Immune system disorders	Food allergy	01JAN1990		Y
			Iodine allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01SEP2001	01SEP2001	N
	C4591001 1109 11091214	Immune system disorders	Hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1109 11091215	Hepatobiliary disorders	Cholecystitis	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
	C4591001 1109 11091216	Investigations	Arthroscopy	01JAN1987	31DEC1987	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2017	31DEC2017	N
	C4591001 1109 11091219	Gastrointestinal disorders	Colitis	01JAN2014		Y
		Psychiatric disorders	Bipolar disorder	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Post-traumatic stress disorder	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1109 11091221	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2015		Y
			Haemorrhoids	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Osteoarthritis	01JAN2018		Y
				01OCT2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1998		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2004		Y
		Surgical and medical procedures	Surgery	01JAN1989	31DEC1989	N
	C4591001 1109 11091223	Psychiatric disorders	Depression	01JAN1990		Y
	C4591001 1109 11091226	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1109 11091228	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1984		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	01JAN2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091230	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Migraine	01JUN2014		Y
			Tension headache	01JAN1990		Y
	C4591001 1109 11091232	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1109 11091234	Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1994		Y
	C4591001 1109 11091236	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
			Spinal osteoarthritis	01JAN2018		Y
	C4591001 1109 11091238	Congenital, familial and genetic disorders	Arnold-Chiari malformation	30JUN2006		Y
	C4591001 1109 11091245	Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010	31DEC2014	N
	C4591001 1109 11091246	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Tension headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1992		Y
	C4591001 1109 11091249	Surgical and medical procedures	Appendectomy	01JAN1982	01JAN1982	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091250	Infections and infestations	Sinusitis	01JAN2004		Y
		Nervous system disorders	Cluster headache	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Social circumstances	Ex-tobacco user	01JAN2000	01JAN2000	N
		Surgical and medical procedures	Appendicectomy	01JAN1996	01JAN1996	N
			Caesarean section	01JAN2006	01JAN2006	N
			Tonsillectomy	01JAN1981	01JAN1981	N
	C4591001 1109 11091251	Surgical and medical procedures	Foot operation	01JAN2014	31DEC2014	N
	C4591001 1109 11091252	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1109 11091256	Ear and labyrinth disorders	Deafness	(b) (6) 1967		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1109 11091258	Infections and infestations	Appendicitis	01JAN1976	01JAN1976	N
		Nervous system disorders	Migraine	01JAN1991		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
			Nocturia	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1976	01JAN1976	N
	C4591001 1109 11091260	Infections and infestations	Herpes simplex	01JAN1995		Y
	C4591001 1109 11091261	Gastrointestinal disorders	Dyspepsia	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1109 11091267	Injury, poisoning and procedural complications	Meniscus injury	01JAN1995	01JAN1995	N
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1995		Y
	C4591001 1109 11091275	Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091278	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091288	Musculoskeletal and connective tissue disorders	Neck pain	01DEC2019		Y
		Nervous system disorders	Brain injury	01DEC2019	01DEC2019	N
	C4591001 1109 11091303	Social circumstances	Postmenopause	09JUL2012		Y
		Surgical and medical procedures	Hysterectomy	09JUL2012	09JUL2012	N
	C4591001 1109 11091304	Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091308	Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091309	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1109 11091311	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
	C4591001 1109 11091314	Endocrine disorders	Hypothyroidism	20AUG2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
	C4591001 1109 11091315	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1109 11091316	Nervous system disorders	Narcolepsy	01JAN2003		Y
	C4591001 1109 11091319	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1109 11091324	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1109 11091326	Immune system disorders	Seasonal allergy	01JAN1998		Y
	C4591001 1109 11091329	Surgical and medical procedures	Female sterilisation	01JAN2003		Y
	C4591001 1109 11091331	Endocrine disorders	Hypothyroidism	01JAN2001	31DEC2001	N
	C4591001 1109 11091332	Surgical and medical procedures	Knee operation	01JAN2005		Y
	C4591001 1109 11091333	Congenital, familial and genetic disorders	Congenital multiplex arthrogryposis	01JAN2017	31DEC2017	N
				(b) (6) 1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Limb operation	01JAN2010	31DEC2010	N
	C4591001 1109 11091335	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
	C4591001 1109 11091337	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1109 11091338	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
			Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN2007		Y
	C4591001 1109 11091340	Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
		Endocrine disorders	Hypogonadism	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2008		Y
		General disorders and administration site conditions	Chronic fatigue syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Nervous system disorders	Cluster headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Sleep disorder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091343	Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Social circumstances	Menopause	15JAN2020		Y
	C4591001 1109 11091349	Gastrointestinal disorders	Colitis ulcerative	01JAN1991		Y
	C4591001 1109 11091350	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1109 11091353	Psychiatric disorders Gastrointestinal disorders	Obsessive-compulsive disorder Gastroesophageal reflux disease	01JAN2017 01JAN2019		Y Y
	C4591001 1109 11091355	Psychiatric disorders	Depression	01JAN1990		Y
	C4591001 1109 11091362	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1109 11091375	Social circumstances	Menopause	01APR2019		Y
	C4591001 1109 11091378	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Nerve injury	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091382	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Haemorrhoids	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01MAY2014	31MAY2014	N
			Knee arthroplasty	01SEP2017	30SEP2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091392	Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1109 11091395	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1109 11091396	Social circumstances	Postmenopause	01APR2019		Y
	C4591001 1109 11091397	Infections and infestations	Herpes simplex	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091403	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Bipolar disorder	01JAN1998		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091412	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1109 11091414	Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091415	Cardiac disorders	Tachycardia	01JAN2015		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2017		Y
		Gastrointestinal disorders	Crohn's disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Vitamin B complex deficiency	01JUN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1109 11091416	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1109 11091418	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01JUN2018		Y
	C4591001 1109 11091419	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1109 11091422	Infections and infestations	Herpes simplex	01JAN1983		Y
		Nervous system disorders	Migraine	01JAN1982		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2016	01JAN2016	N
			Female sterilisation	01JAN2002	01JAN2002	N
	C4591001 1109 11091424	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
	C4591001 1109 11091425	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1109 11091427	Metabolism and nutrition disorders	Gout	01JAN2017		Y
	C4591001 1109 11091432	Nervous system disorders	Migraine	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2003		Y
	C4591001 1109 11091434	Surgical and medical procedures	Intra-uterine contraceptive device insertion	30APR2020	30APR2020	N
	C4591001 1109 11091435	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1109 11091439	Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1109 11091440	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1109 11091444	Nervous system disorders	Cerebrovascular accident	01JAN2013	31DEC2013	N
	C4591001 1109 11091448	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008		Y
			Rubber sensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Hemiplegic migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1109 11091450	Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1109 11091453	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091455	Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091457	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Alcohol abuse	01JAN2017	31DEC2019	N
			Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
			Drug abuse	01JAN2017	31DEC2019	N
	C4591001 1109 11091459	Infections and infestations	Chronic sinusitis	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Neck pain	01JAN1986		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1109 11091465	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
	C4591001 1109 11091468	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1109 11091472	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091473	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1109 11091476	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1109 11091477	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
	C4591001 1109 11091479	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091484	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
	C4591001 1109 11091485	Immune system disorders	Hypersensitivity	01JAN1990		Y
	C4591001 1109 11091488	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			Hysterectomy	22MAR2019	22MAR2019	N
	C4591001 1109 11091489	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1109 11091492	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1109 11091495	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Food allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
	C4591001 1109 11091496	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
	C4591001 1109 11091497	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
			Insomnia	01JAN1998		Y
	C4591001 1109 11091499	Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Social circumstances	Postmenopause	01AUG2014		Y
	C4591001 1109 11091502	Surgical and medical procedures	Hysterectomy	01AUG2014	31AUG2014	N
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 1 diabetes mellitus	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091506	Immune system disorders	Iodine allergy	01JAN1999		Y
	C4591001 1109 11091507	Immune system disorders	Allergy to animal	01JAN1980		Y
	C4591001 1109 11091513	Vascular disorders	Seasonal allergy Hypertension	01JAN2018 01JAN1995		Y Y
	C4591001 1109 11091514	Immune system disorders	Hypersensitivity	01JAN2005		Y
	C4591001 1109 11091517	Surgical and medical procedures	Appendectomy	01MAY2020	31MAY2020	N
	C4591001 1109 11091517	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
	C4591001 1109 11091518	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1109 11091518	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
	C4591001 1109 11091518	Nervous system disorders	Cerebrovascular accident	01JAN2011	31DEC2011	N
	C4591001 1109 11091518	Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1109 11091518	Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1109 11091518	Endocrine disorders	Hypogonadism	01JAN2018		Y
	C4591001 1109 11091518	Metabolism and nutrition disorders	Glucose tolerance impaired	04MAY2020		Y
	C4591001 1109 11091518	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
	C4591001 1109 11091518	Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2005		Y
	C4591001 1109 11091518	Psychiatric disorders	Post-traumatic stress disorder	01JAN1999		Y
	C4591001 1109 11091518	Surgical and medical procedures	Spinal operation	01JAN2018	31DEC2018	N
	C4591001 1109 11091520	Respiratory, thoracic and mediastinal disorders	Vasectomy Asthma	01JAN2005 01JAN1986	01JAN1996	Y N
	C4591001 1109 11091521	Metabolism and nutrition disorders	Hyperlipidaemia	15SEP2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	15SEP2001		Y
		Vascular disorders	Hypertension	15SEP2010		Y
	C4591001 1109 11091522	Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	01JAN2008		Y
	C4591001 1109 11091526	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1109 11091528	Immune system disorders	Food allergy	01JAN1995		Y
	C4591001 1109 11091529	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Sarcoidosis	01JAN2014		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hot flush	01JAN2003		Y
	C4591001 1109 11091530	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1109 11091531	Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091532	Psychiatric disorders	Post-traumatic stress disorder	01JAN2015		Y
	C4591001 1109 11091534	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
	C4591001 1109 11091539	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1109 11091541	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091545	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Myomectomy	01FEB2017	28FEB2017	N
	C4591001 1109 11091547	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2015	N
	C4591001 1109 11091554	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
	C4591001 1110 11101001	Psychiatric disorders	Anxiety	01OCT2017		Y
			Insomnia	01FEB2020		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Salpingostomy	01JAN2013	31DEC2013	N
	C4591001 1110 11101002	Cardiac disorders	Tachycardia	01JAN1982		Y
	C4591001 1110 11101013	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
	C4591001 1110 11101020	Congenital, familial and genetic disorders	Neurofibromatosis	(b) (6) 1979		Y
		Nervous system disorders	Migraine	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Post-traumatic stress disorder	01JAN1985		Y
	C4591001 1110 11101022	Reproductive system and breast disorders	Endometriosis	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01NOV2018		Y
		Surgical and medical procedures	Hysterectomy	01NOV2018	30NOV2018	N
	C4591001 1110 11101033	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Social circumstances	Ex-tobacco user	01AUG2019		Y
			Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	11SEP2001	11SEP2001	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1110 11101034	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101035	Psychiatric disorders	Anxiety	12MAY2018		Y
	C4591001 1110 11101037	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1999		Y
			Androgenetic alopecia	01JAN2006		Y
	C4591001 1110 11101044	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101050	Psychiatric disorders	Attention deficit hyperactivity disorder	(b) (6) 1973		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101058	Surgical and medical procedures	Female sterilisation	11JAN2004	11JAN2004	N
	C4591001 1110 11101059	Nervous system disorders	Neuropathy peripheral	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101069	Psychiatric disorders	Anxiety	01JAN2015		Y
			Bipolar disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1110 11101076	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01NOV2016		Y
	C4591001 1110 11101077	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1110 11101078	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1110 11101080	Social circumstances	Postmenopause	01APR2018		Y
	C4591001 1110 11101082	Psychiatric disorders	Anxiety	01JAN1994		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1110 11101083	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101085	Surgical and medical procedures	Fracture treatment	01JAN2015	31JAN2015	N
	C4591001 1110 11101086	Surgical and medical procedures	Female sterilisation	02FEB2004	02FEB2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101091	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1110 11101092	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Essential tremor	01JAN1983		Y
	C4591001 1110 11101099	Injury, poisoning and procedural complications	Cartilage injury	25AUG2019	25OCT2019	N
			Limb injury	25AUG2019	31DEC2019	N
			Road traffic accident	25AUG2019	25AUG2019	N
		Nervous system disorders	Migraine	24MAR2020		Y
			Neuropathy peripheral	25AUG2019		Y
		Surgical and medical procedures	Hip surgery	25OCT2019	25OCT2019	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1110 11101102	Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2019		Y
			Major depression	01MAR2020		Y
	C4591001 1110 11101111	Gastrointestinal disorders	Anal fistula	01JAN2005	31DEC2005	N
			Haemorrhoids	01JAN1998		Y
		Hepatobiliary disorders	Hepatic steatosis	01FEB2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Post-traumatic stress disorder	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Surgical and medical procedures	Rectal fistula repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101116	Psychiatric disorders	Insomnia	01JAN2004		Y
	C4591001 1110 11101117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Immune system disorders	Dust allergy	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101125	Injury, poisoning and procedural complications	Ankle fracture	01APR2018	30APR2018	N
		Nervous system disorders	Migraine	01JAN1988		Y
		Renal and urinary disorders	Nephrolithiasis	01JUL2015	31JUL2015	N
		Surgical and medical procedures	Ankle operation	05MAY2018	05MAY2018	N
			Lithotripsy	01JUL2015	31JUL2015	N
	C4591001 1110 11101126	Endocrine disorders	Hypothyroidism	01JAN2006		Y
	C4591001 1110 11101131	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1110 11101139	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1110 11101141	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1110 11101148	Infections and infestations	Chronic sinusitis	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1110 11101149	Gastrointestinal disorders	Umbilical hernia	01JAN1999	31DEC2000	N
		Injury, poisoning and procedural complications	Incisional hernia	01DEC2015	29FEB2016	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2009	31MAY2012	N
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Intervertebral disc operation	01FEB2016	29FEB2016	N
				01MAY2012	31MAY2012	N
			Umbilical hernia repair	01DEC2000	31DEC2000	N
	C4591001 1110 11101151	Surgical and medical procedures	Caesarean section	22FEB2012	22FEB2012	N
				26FEB2014	26FEB2014	N
	C4591001 1110 11101154	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101155	Surgical and medical procedures	Caesarean section	05MAR2008	05MAR2008	N
	C4591001 1110 11101156	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	C4591001 1110 11101158	Surgical and medical procedures	Female sterilisation	01OCT2006	31OCT2006	N
	C4591001 1110 11101162	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2019		Y
	C4591001 1110 11101163	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
	C4591001 1110 11101167	Cardiac disorders	Atrioventricular block complete	01AUG2012	30JUN2015	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01AUG2012	31AUG2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cardiac pacemaker removal	01JUN2015	30JUN2015	N
	C4591001 1110 11101175	Psychiatric disorders	Depression	01FEB2020		Y
	C4591001 1110 11101180	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Salpingectomy	03JUL2006	03JUL2006	N
	C4591001 1110 11101182	Psychiatric disorders	Major depression	23MAR2010		Y
		Surgical and medical procedures	Female sterilisation	24DEC1989	24DEC1989	N
	C4591001 1110 11101183	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1110 11101186	Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
			Cholecystectomy	01JAN2011	31DEC2011	N
	C4591001 1110 11101187	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01NOV2019	30NOV2019	N
	C4591001 1110 11101189	General disorders and administration site conditions	Cyst	01JAN2009	31DEC2009	N
		Infections and infestations	Tonsillitis	01JAN1997	31DEC1997	N
		Nervous system disorders	Tension headache	14JUL2020		Y
		Psychiatric disorders	Anxiety	11JUL2018		Y
			Attention deficit hyperactivity disorder	31JUL2013		Y
			Depression	31JUL2013		Y
			Insomnia	15FEB2016	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Foot operation	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1110 11101194	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2010		Y
		Vascular disorders	Hypertension	01MAY2010		Y
	C4591001 1110 11101196	Gastrointestinal disorders	Intestinal strangulation	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2015	31DEC2015	N
			Foot fracture	01JAN2015	31JAN2015	N
			Humerus fracture	01JAN2015	31JAN2015	N
			Lower limb fracture	01JAN2015	31JAN2015	N
			Road traffic accident	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01APR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31JAN2010	N
		Surgical and medical procedures	Arthrodesis	01JAN2015	31JAN2015	N
			Gastrectomy	01JUN2008	30JUN2008	N
			Hysterectomy	01JAN2010	31JAN2010	N
			Intestinal resection	01JAN2012	31DEC2012	N
			Open reduction of fracture	01JAN2015	31JAN2015	N
	C4591001 1110 11101198	Infections and infestations	Localised infection	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Limb operation	01JAN1971	31DEC1971	N
	C4591001 1110 11101200	Gastrointestinal disorders	Inguinal hernia	01JAN1970	31DEC1970	N
	C4591001 1110 11101203	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101211	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1110 11101213	Injury, poisoning and procedural complications	Fibula fracture	01FEB2018	03MAY2018	N
		Surgical and medical procedures	Caesarean section	09NOV2002	09NOV2002	N
				23NOV2000	23NOV2000	N
			Fracture treatment	03MAY2018	03MAY2018	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101214	Endocrine disorders	Hypothyroidism	16JUL2020		Y
		Infections and infestations	Rhinitis	01JAN2005		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	16JUL2020		Y
	C4591001 1110 11101217	Surgical and medical procedures	Caesarean section	15JUN2010	15JUN2010	N
			Female sterilisation	15JUN2010	15JUN2010	N
	C4591001 1110 11101219	Surgical and medical procedures	Caesarean section	03NOV2003	03NOV2003	N
	C4591001 1110 11101223	Infections and infestations	Paronychia	01JAN1991	31DEC1991	N
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
			Precancerous cells present	01JAN2002	31DEC2002	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Bipolar disorder	01JAN2001		Y
			Insomnia	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
			Loop electrosurgical excision procedure	01JAN2002	31DEC2002	N
			Nail operation	01JAN1991	31DEC1991	N
	C4591001 1110 11101226	Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2018		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1110 11101227	Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1110 11101229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Surgical and medical procedures	Salpingectomy	12JAN2013	12JAN2013	N
	C4591001 1110 11101231	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Trigeminal neuralgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Mammoplasty	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
	C4591001 1110 11101236	Gastrointestinal disorders	Peptic ulcer	01FEB2017	07AUG2020	N
		Immune system disorders	Rubber sensitivity	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
			Sleep disorder	01JAN2014		Y
	C4591001 1110 11101238	Hepatobiliary disorders	Cholelithiasis	01NOV2012	30NOV2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01MAY2019	31MAY2019	N
		Surgical and medical procedures	Cholecystectomy	01NOV2012	30NOV2012	N
			Hysterectomy	01OCT2019	31OCT2019	N
			Mammoplasty	01SEP2004	30SEP2004	N
			Nasal septal operation	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01MAY2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101242	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1110 11101243	Immune system disorders	Hypersensitivity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2016		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JUL2020	31JUL2020	N
				01SEP2009	30SEP2009	N
	C4591001 1110 11101247	Injury, poisoning and procedural complications	Ankle fracture	01JAN2014	31DEC2014	N
		Psychiatric disorders	Schizophrenia	01JAN1994		Y
		Surgical and medical procedures	Ankle operation	01JAN2014	31DEC2014	N
	C4591001 1110 11101250	Psychiatric disorders	Bipolar disorder	01JAN1986		Y
	C4591001 1110 11101261	Infections and infestations	Tonsillitis	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Tonsillectomy	01JAN1986	31DEC1986	N
	C4591001 1110 11101264	Infections and infestations	Urinary tract infection	13SEP2020	15SEP2020	N
	C4591001 1110 11101268	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1110 11101269	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2014	20MAR2014	N
		Surgical and medical procedures	Radical prostatectomy	20MAR2014	20MAR2014	N
	C4591001 1110 11101271	Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Caesarean section	07JUL2010	07JUL2010	N
				09NOV2018	09NOV2018	N
			Salpingectomy	09NOV2018	09NOV2018	N
	C4591001 1110 11101274	Injury, poisoning and procedural complications	Humerus fracture	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Internal fixation of fracture	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1110 11101275	Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2013		Y
	C4591001 1110 11101278	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1110 11101283	Endocrine disorders	Hypothyroidism	01FEB2000		Y
	C4591001 1110 11101287	Injury, poisoning and procedural complications	Skin laceration	20SEP2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
	C4591001 1110 11101290	Injury, poisoning and procedural complications	Hand fracture	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Open reduction of fracture	01FEB2020	29FEB2020	N
	C4591001 1110 11101292	Infections and infestations	Diverticulitis	01SEP2010	31MAY2013	N
		Surgical and medical procedures	Sigmoidectomy	01MAY2013	31MAY2013	N
	C4591001 1110 11101293	Surgical and medical procedures	Caesarean section	27SEP2010	27SEP2010	N
	C4591001 1110 11101298	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Surgical and medical procedures	Gastric bypass	01DEC2009	31DEC2009	N
	C4591001 1110 11101300	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1110 11101314	Endocrine disorders	Hyperthyroidism	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	10DEC2010	10DEC2018	N
		Surgical and medical procedures	Hysterectomy	10DEC2018	10DEC2018	N
			Salpingectomy	10SEP2018	10DEC2018	N
	C4591001 1110 11101316	Infections and infestations	Rhinitis	01JAN2006		Y
	C4591001 1110 11101317	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101319	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
	C4591001 1110 11101320	Psychiatric disorders	Anxiety disorder	01JAN2010		Y
			Major depression	01JAN2010		Y
	C4591001 1110 11101321	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1110 11101323	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	14JAN1995	31JAN2013	N
		Skin and subcutaneous tissue disorders	Dermatitis	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2013	31JAN2013	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1110 11101325	Hepatobiliary disorders	Cholecystitis	01DEC2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Injury, poisoning and procedural complications	Ankle fracture	01DEC2014	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01DEC2017	31DEC2017	N
			Fracture treatment	01DEC2014	31DEC2014	N
			Mammoplasty	18FEB2020	18FEB2020	N
	C4591001 1110 11101326	Infections and infestations	Chronic tonsillitis	01JAN1980	31DEC1981	N
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1981	31DEC1981	N
	C4591001 1110 11101327	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN1997		Y
			Schizophrenia	01JAN1997		Y
	C4591001 1110 11101333	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1110 11101338	Immune system disorders	Allergy to animal	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1110 11101341	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Post-traumatic stress disorder	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1110 11101342	Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2007	31DEC2007	N
			Appendicectomy	01JAN1984	31DEC1984	N
	C4591001 1110 11101343	Injury, poisoning and procedural complications	Nerve injury	01NOV2019	30NOV2019	N
		Surgical and medical procedures	Caesarean section	10JUN2014	10JUN2014	N
				12JUL2018	12JUL2018	N
				22MAY2011	22MAY2011	N
			Endodontic procedure	01NOV2019	30NOV2019	N
	C4591001 1110 11101345	Musculoskeletal and connective tissue disorders	Trigger finger	23APR2020		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	10FEB2020		Y
		Surgical and medical procedures	Caesarean section	02JAN1988	02JAN1988	N
				04SEP2007	04SEP2007	N
			Hysterectomy	20AUG2017	20AUG2017	N
	C4591001 1110 11101346	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1110 11101347	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1110 11101348	Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN2012	31DEC2012	N
			Salpingectomy	01JAN2012	31DEC2012	N
	C4591001 1110 11101349	Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2010	31DEC2010	N
			Knee operation	01JAN2013	31DEC2013	N
	C4591001 1110 11101350	Surgical and medical procedures	Caesarean section	15SEP2001	15SEP2001	N
				20SEP1996	20SEP1996	N
				30SEP1995	30SEP1995	N
			Hysterectomy	04APR2004	04APR2004	N
	C4591001 1110 11101352	Immune system disorders	Seasonal allergy	01JAN1966		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2005		Y
	C4591001 1110 11101356	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Psychiatric disorders	Major depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1110 11101361	Surgical and medical procedures	Mammoplasty	01JAN1999	31DEC1999	N
	C4591001 1110 11101365	Infections and infestations	Appendicitis	01JAN2018	31JAN2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2018	31JAN2018	N
	C4591001 1110 11101372	Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101375	Psychiatric disorders	Insomnia	01JAN2020		Y
			Major depression	01OCT1999		Y
	C4591001 1110 11101379	Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2019		Y
	C4591001 1111 11111001	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1111 11111009	Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2012		Y
		Vascular disorders	Thrombosis	01JAN2017		Y
	C4591001 1111 11111012	Cardiac disorders	Tachycardia	01JAN2018		Y
		Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Fibromyalgia	01JAN2012		Y
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Amnesia	01JAN2011		Y
			Carpal tunnel syndrome	01JAN2014		Y
			Headache	01JAN2010		Y
			Migraine	01JAN2016		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
			Rash	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Nasal operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1985	31DEC1985	N
			Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1111 11111018	Gastrointestinal disorders	Constipation	01JAN2004	31DEC2004	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Psoriasis	01JAN2010		Y
	C4591001 1111 11111022	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Overweight	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2016		Y
			Migraine	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2020		Y
	C4591001 1111 11111023	Eye disorders	Hypermetropia	01JAN1998		Y
			Myopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1111 11111024	Eye disorders	Myopia	01JAN1984		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2002	31DEC2002	N
			Upper limb fracture	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1111 11111029	Infections and infestations	Onychomycosis	01JAN2012		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1111 11111040	Eye disorders	Myopia	01JAN1970		Y
			Strabismus	01JAN1970	31DEC1984	N
		Gastrointestinal disorders	Dyspepsia	01JAN1999	31DEC2006	N
		Immune system disorders	Allergy to animal	01JAN1977		Y
			Drug hypersensitivity	01JAN1971		Y
			Reaction to colouring	01JAN1973		Y
		Infections and infestations	Device related infection	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diverticulitis	01JAN1999		Y
		Metabolism and nutrition disorders	Overweight	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31MAY2008	N
		Nervous system disorders	Headache	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1971		Y
		Social circumstances	Postmenopause	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
			Caesarean section	01JAN1990	31DEC1990	N
				01JAN1996	31DEC1996	N
				01JAN1999	31DEC1999	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Mammoplasty	01JAN2014	31DEC2014	N
			Maxillofacial operation	01JAN2016	31DEC2017	N
				01JAN2017	31DEC2017	N
			Myomectomy	01JAN2008	31MAY2008	N
			Osteotomy	01JAN2016	31DEC2017	N
				01JAN2017	31DEC2017	N
			Strabismus correction	01JAN1978	31DEC1978	N
				01JAN1980	31DEC1980	N
				01JAN1982	31DEC1982	N
				01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1111 11111048	Eye disorders	Myopia	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Salpingectomy	10MAR2020	10MAR2020	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1111 11111050	Infections and infestations	Urinary tract infection	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1111 11111051	Eye disorders	Myopia	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1111 11111052	Eye disorders	Presbyopia	01JAN2003		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
			Hip arthroplasty	01MAY2020	31DEC2020	N
	C4591001 1111 11111053	Eye disorders	Myopia	01JAN2009		Y
		Investigations	Heart rate irregular	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1111 11111054	Infections and infestations	Urinary tract infection	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Skeletal injury	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1111 11111057	Eye disorders	Myopia	01NOV1994		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
	C4591001 1111 11111060	Ear and labyrinth disorders	Tinnitus	01JAN1990		Y
			Vertigo	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Reproductive system and breast disorders	Prostatitis	01JUN2020	30JUN2020	N
		Surgical and medical procedures	Spinal laminectomy	01JAN2017	31DEC2017	N
	C4591001 1111 11111061	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Diverticulum	12MAY2020		Y
			Dyspepsia	01DEC2019		Y
			Gastroesophageal reflux disease	01AUG2019		Y
			Hiatus hernia	12MAY2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1995		Y
	C4591001 1111 11111064	Eye disorders	Hypermetropia	01JAN2002	31DEC2002	N
			Myopia	01JAN2002	31DEC2002	N
		Gastrointestinal disorders	Crohn's disease	01JAN2016	31JAN2020	N
			Irritable bowel syndrome	01JAN2015		Y
		Infections and infestations	Nasopharyngitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Overweight	01JAN2010		Y
			Vitamin D deficiency	20JUN2020		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2016		Y
		Reproductive system and breast disorders	Genital rash	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1998	31DEC1998	N
			Bladder repair	01JAN2005	31DEC2005	N
	C4591001 1111 11111068	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
	C4591001 1111 11111069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2011	N
	C4591001 1111 11111072	Ear and labyrinth disorders	Deafness	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1998		Y
		Gastrointestinal disorders	Diarrhoea	01JAN1985		Y
			Dyspepsia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN2004		Y
			Vitamin B12 deficiency	01MAR2020		Y
			Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1994		Y
			Sciatica	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Insomnia	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Eczema	01JAN2004		Y
			Rosacea	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Inguinal hernia repair	01JAN1985	31DEC1985	N
	C4591001 1111 11111078	Eye disorders	Hypermetropia	01JAN2019		Y
			Myopia	01JAN1977		Y
		Hepatobiliary disorders	Cholelithiasis	01JUN2000	30JUN2000	N
		Nervous system disorders	Migraine	01JAN1982		Y
		Surgical and medical procedures	Cholelithotomy	01JUN2000	30JUN2000	N
	C4591001 1111 11111079	Eye disorders	Myopia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1111 11111081	Ear and labyrinth disorders	Vertigo	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1987		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1111 11111082	Eye disorders	Myopia	01JAN2011		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1997	31DEC1997	N
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1111 11111083	Eye disorders	Myopia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1111 11111086	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 1974		Y
		Skin and subcutaneous tissue disorders	Ingrown hair	01MAY2020	31MAY2020	N
	C4591001 1111 11111087	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111089	Eye disorders	Hypermetropia	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC2016	N
		Reproductive system and breast disorders	Endometriosis	01JAN1976	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1111 11111090	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1996		Y
			Gastroesophageal reflux disease	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Muscle spasms	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1111 11111097	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Eye disorders	Visual impairment	01JAN2012		Y
		Gastrointestinal disorders	Diverticulum	01JAN2012		Y
			Gastroesophageal reflux disease	01JAN1998		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2010	N
			Head injury	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
			Prostatomegaly	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1111 11111099	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2009		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN1983	31DEC1983	N
			Tibia fracture	01JAN1983	31DEC1983	N
		Investigations	Smear cervix abnormal	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1111 11111101	Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
				01JAN2010		Y
	C4591001 1111 11111104	Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1111 11111105	Infections and infestations	Staphylococcal infection	01JAN2015		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
	C4591001 1111 11111113	Eye disorders	Myopia	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1111 11111115	Metabolism and nutrition disorders	Overweight	01JAN2013		Y
	C4591001 1111 11111121	Eye disorders	Hypermetropia	01JAN1984		Y
		Nervous system disorders	Hydrocephalus	01JAN1982	31DEC1995	N
			Migraine	01JAN1982		Y
			Tremor	01JAN1982		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
			Ventriculo-peritoneal shunt	01JAN1982	31DEC1995	N
	C4591001 1111 11111130	Eye disorders	Hypermetropia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1987		Y
			Libido decreased	01JAN2012		Y
	C4591001 1111 11111132	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111138	Cardiac disorders	Tachycardia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2015	30SEP2016	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1111 11111139	Eye disorders	Myopia	01JAN1983		Y
		Investigations	Cardiac murmur	05DEC2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1987		Y
	C4591001 1111 11111142	Eye disorders	Hypermetropia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Investigations	Blood triglycerides increased	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
			Vitamin B12 deficiency	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1992	31DEC1992	N
			Uterine leiomyoma	01JAN2007	31DEC2007	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1111 11111143	Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015	31DEC2018	N
			Synovial cyst	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Attention deficit hyperactivity disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
			Dandruff	01JAN2015		Y
	C4591001 1111 11111144	Congenital, familial and genetic disorders	Thalassaemia	01JAN1998		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2004		Y
		Infections and infestations	Hepatitis A	01NOV2019	30NOV2019	N
	C4591001 1111 11111145	Eye disorders	Astigmatism	01JAN1999		Y
		Infections and infestations	Herpes zoster	01JAN2007	31DEC2007	N
			Meningitis viral	01JAN1993	31DEC1993	N
			Scarlet fever	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Overweight	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neurilemmoma benign	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2011	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2006	31DEC2006	N
	C4591001 1111 11111146	Vascular disorders	Hypertension	01JAN2012		Y
		Eye disorders	Hypermetropia	01JAN2017		Y
		Investigations	Blood potassium decreased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian fibroma	01JAN1998	31DEC1998	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
			Blepharoplasty	01JAN2017	31DEC2017	N
			Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1111 11111148	Endocrine disorders	Hypothyroidism	01DEC2009		Y
	C4591001 1111 11111151	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Fungal skin infection	01JAN2015		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1983		Y
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
	C4591001 1111 11111155	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1111 11111156	Investigations	Blood triglycerides increased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01DEC2017	31DEC2017	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1111 11111159	Cardiac disorders	Myocardial infarction	01JAN2016	31DEC2016	N
		Congenital, familial and genetic disorders	Congenital hydronephrosis	01JAN1966		Y
		Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Diarrhoea	01MAR2020		Y
			Diverticulum	01JAN2015		Y
			Gastroesophageal reflux disease	01MAR2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1111 11111166	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1111 11111169	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
			Dyspepsia	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ewing's sarcoma	01JAN2013	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2013		Y
			Libido decreased	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Pulmonary fibrosis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2012	31DEC2012	N
		Eye disorders	Myopia	01JAN1984		Y
	C4591001 1111 11111170	Gastrointestinal disorders	Dyspepsia	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
			Overweight	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1111 11111172	Eye disorders	Hypermetropia	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1111 11111176	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Sinus headache	01JAN2000		Y
	C4591001 1111 11111177	Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2013	31DEC2013	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
	C4591001 1111 11111179	Eye disorders	Hypermetropia	01JAN1996		Y
		Metabolism and nutrition disorders	Overweight	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
	C4591001 1111 11111180	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
	C4591001 1111 11111184	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Eye disorders	Hypermetropia	01JAN1983		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Muscle spasms	01JAN2017		Y
			Osteoarthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JUL2020	31JUL2020	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN1986		Y
			Bipolar disorder	01JAN1986		Y
			Depression	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
			Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
				01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1111 11111188	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2009		Y
	C4591001 1111 11111189	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1111 11111191	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2018	N
		Eye disorders	Glaucoma	01JAN2010		Y
			Myopia	01JAN1980		Y
		Injury, poisoning and procedural complications	Skeletal injury	03APR2020	04APR2020	N
		Investigations	Heart rate irregular	01JAN1990	31DEC1999	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2006	31DEC2019	N
	C4591001 1111 11111192	Gastrointestinal disorders	Hiatus hernia	01JAN1970	31DEC2001	N
		Infections and infestations	Herpes zoster	01JAN2007		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990		Y
			Squamous cell carcinoma	01JAN1990	31DEC1990	N
		Nervous system disorders	Headache	01JAN2016		Y
			Idiopathic intracranial hypertension	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rash	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111200	Ear and labyrinth disorders	Deafness	01JAN2014		Y
		Eye disorders	Myopia	01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Hypertriglyceridaemia	01JAN2017		Y
			Overweight	01JAN1980		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1111 11111203	Hepatobiliary disorders	Hepatic steatosis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2016		Y
		Nervous system disorders	Arachnoid cyst	01MAY2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1112 11121004	Cardiac disorders	Extrasystoles	01AUG2014		Y
		Eye disorders	Strabismus	(b) (6) 1976		Y
		Immune system disorders	Rubber sensitivity	01JAN1978		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1112 11121006	Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
	C4591001 1112 11121008	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1112 11121009	Metabolism and nutrition disorders	Obesity	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1112 11121013	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1112 11121014	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Herpes simplex	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
			Psoriasis	01JAN1980		Y
	C4591001 1112 11121015	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1112 11121016	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01SEP2018	30SEP2018	N
	C4591001 1112 11121018	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2008	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1112 11121019	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Depression	01JAN2009		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	04SEP2018	04SEP2018	N
	C4591001 1112 11121020	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01MAR2020	31MAR2020	N
	C4591001 1112 11121021	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2017	31DEC2017	N
	C4591001 1112 11121024	Metabolism and nutrition disorders	Hyperlipidaemia	05MAY2020		Y
		Nervous system disorders	Hemiparesis	05MAY2020	08MAY2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121025	Immune system disorders	Allergy to metals	01JAN1990		Y
			Seasonal allergy	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1112 11121027	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1990		Y
	C4591001 1112 11121031	Infections and infestations	Herpes simplex	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
		Surgical and medical procedures	Contraceptive implant	01JUN2019	30JUN2019	N
	C4591001 1112 11121033	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1112 11121035	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1112 11121038	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1112 11121039	Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1112 11121042	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1112 11121045	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 2002		Y
	C4591001 1112 11121048	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003		Y
	C4591001 1112 11121049	Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1112 11121053	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JUN2003		Y
	C4591001 1112 11121054	Endocrine disorders	Hypothyroidism	01JAN2001		Y
	C4591001 1112 11121055	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1112 11121056	Injury, poisoning and procedural complications	Ligament rupture	01NOV2019	28JUL2020	N
		Surgical and medical procedures	Ligament operation	28JUL2020	28JUL2020	N
			Vasectomy	01JAN1991	01JAN1991	N
	C4591001 1112 11121058	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAR2019	31MAR2019	N
	C4591001 1112 11121062	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JUN2018	30JUN2018	N
	C4591001 1112 11121064	Immune system disorders	Food allergy	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1980		Y
	C4591001 1112 11121066	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2015		Y
	C4591001 1112 11121069	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1112 11121070	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
		Nervous system disorders	Peroneal nerve palsy	01JAN2017		Y
			Sciatica	07JAN2017		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Oophorectomy	01JAN2018	31DEC2018	N
	C4591001 1112 11121071	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	01JUN2015	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Social circumstances	Postmenopause	01JUN2015		Y
		Surgical and medical procedures	Hysterectomy	01JUN2015	01JUN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121073	Infections and infestations	Herpes simplex	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	05FEB2019	05FEB2019	N
	C4591001 1112 11121077	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1112 11121078	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1112 11121083	Infections and infestations	Herpes simplex	01JAN2006		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2004	31DEC2004	N
	C4591001 1112 11121085	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015		Y
	C4591001 1112 11121087	Skin and subcutaneous tissue disorders	Alopecia	01JAN2006		Y
	C4591001 1112 11121088	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1112 11121090	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121098	Metabolism and nutrition disorders	Obesity	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121102	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1112 11121105	Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
	C4591001 1112 11121106	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1112 11121107	Social circumstances	Tobacco user	01JAN2018		Y
	C4591001 1112 11121109	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1112 11121110	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1112 11121119	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	26JUN1997	26JUN1997	N
			Hysterectomy	01NOV2011	30NOV2011	N
	C4591001 1112 11121122	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	18NOV2020	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2016	18NOV2020	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121123	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01NOV2018	30NOV2018	N
	C4591001 1112 11121124	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2001		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2018	31DEC2018	N
			Keratomileusis	12MAR2020	12MAR2020	N
	C4591001 1112 11121125	Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	06AUG2019	06AUG2019	N
	C4591001 1112 11121127	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Urinary tract infection	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1996	31DEC1999	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1112 11121128	Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
	C4591001 1112 11121130	Immune system disorders	Seasonal allergy	01JAN1975		Y
	C4591001 1112 11121132	Cardiac disorders	Sinus tachycardia	01JAN2016		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2016		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121135	Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2013		Y
	C4591001 1112 11121136	Vascular disorders	Hypertension	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN1996		Y
	C4591001 1112 11121137	Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Cardiac disorders	Palpitations	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1112 11121139	Skin and subcutaneous tissue disorders	Acne	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1112 11121146	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1112 11121147	Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1112 11121152	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Psychiatric disorders	Depression	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2012		Y
	C4591001 1112 11121154	Social circumstances	Postmenopause	01JUL2019		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1112 11121156	Hepatobiliary disorders	Cholelithiasis	01JUL2018	31JUL2018	N
		Surgical and medical procedures	Cholecystectomy	01JUL2018		Y
	C4591001 1112 11121158	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
				01JAN2018		Y
				18AUG2020		Y
			Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1112 11121160	Surgical and medical procedures	Permanent contraceptive tubal implant	01JAN2010	31DEC2010	N
	C4591001 1112 11121161	Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1994		Y
	C4591001 1112 11121162	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1112 11121163	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Gender dysphoria	01MAR2017		Y
	C4591001 1112 11121165	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Nerve compression	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1112 11121169	Metabolism and nutrition disorders	Obesity	01JAN1994		Y
	C4591001 1112 11121171	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1112 11121174	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1112 11121175	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1990		Y
	C4591001 1112 11121177	Injury, poisoning and procedural complications	Cervical vertebral fracture	24FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121183	Gastrointestinal disorders	Impaired gastric emptying	01JAN2009		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01MAR2019	31MAR2019	N
	C4591001 1112 11121184	General disorders and administration site conditions	Pain	01APR2019		Y
		Immune system disorders	Allergy to metals	01JAN1990		Y
			Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	20JUL2016	20JUL2016	N
	C4591001 1112 11121185	Immune system disorders	Food allergy	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1112 11121188	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1112 11121189	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Investigations	Precancerous cells present	01AUG2019	31AUG2019	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01AUG2019	31AUG2019	N
	C4591001 1112 11121190	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
	C4591001 1112 11121191	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1112 11121192	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01APR2020		Y
	C4591001 1112 11121193	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1112 11121194	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
	C4591001 1112 11121197	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01APR2020	30APR2020	N
	C4591001 1112 11121199	Renal and urinary disorders	Hypertonic bladder	01JAN2004		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1112 11121200	Surgical and medical procedures Immune system disorders	Intra-uterine contraceptive device insertion Seasonal allergy	01JAN2015	31DEC2015	N Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121201	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1112 11121204	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Insulin resistance	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121208	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Gastrectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1112 11121213	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1112 11121215	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2018	31DEC2018	N
	C4591001 1112 11121216	Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1112 11121217	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1112 11121218	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1112 11121224	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	01JAN2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Leg amputation	01JAN2015	01JAN2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1112 11121225	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1112 11121226	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1112 11121228	Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN2005		Y
	C4591001 1112 11121229	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1112 11121234	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1112 11121239	Endocrine disorders	Hypothyroidism	01SEP2001		Y
		Nervous system disorders	Dizziness	01JUL2019		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1112 11121242	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
	C4591001 1112 11121243	Immune system disorders	Drug hypersensitivity	01JAN2001		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN1978		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1112 11121244	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1990		Y
			Seasonal allergy	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
			Rhinitis perennial	01JAN1991		Y
	C4591001 1112 11121246	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	01JAN2011	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011		Y
	C4591001 1112 11121249	Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1112 11121250	Vascular disorders	Hypertension	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121253	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Social circumstances	Menopause	01MAY2020		Y
	C4591001 1112 11121256	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1112 11121259	Metabolism and nutrition disorders	Obesity	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	09SEP2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
			Keratosis pilaris	01JAN2014		Y
	C4591001 1112 11121260	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1112 11121261	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1112 11121263	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Onychomycosis	01JUL2020		Y
	C4591001 1112 11121264	Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1112 11121265†	Investigations	HIV test positive	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Headache	15JUL2020		Y
	C4591001 1112 11121268	Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1998		Y
	C4591001 1112 11121270†	Immune system disorders	Food allergy	01JAN1991		Y
		Infections and infestations	Hepatitis B	01JAN2009		Y
		Investigations	HIV test positive	01JAN2009		Y
	C4591001 1112 11121271	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
	C4591001 1112 11121272	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1112 11121275	Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2011		Y
			Depression	01APR2009		Y
	C4591001 1112 11121281	Immune system disorders	Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121282	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121289	Immune system disorders	Rubber sensitivity	01JAN2005		Y
	C4591001 1112 11121296	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1112 11121297	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	08MAY2019		Y
			Sinus headache	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JUL2019	31JUL2019	N
	C4591001 1112 11121298	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01FEB2020		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01APR2020		Y
	C4591001 1112 11121299	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121300	Infections and infestations	Hepatitis B	01JAN1992		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1995	31DEC1995	N
			Tibia fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Surgical and medical procedures	Arthrodesis	01FEB2020	29FEB2020	N
			Bone operation	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121301	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121303	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1112 11121304	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
	C4591001 1112 11121305	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1112 11121307	Surgical and medical procedures	Wisdom teeth removal	29SEP2020	29SEP2020	N
	C4591001 1112 11121308	Metabolism and nutrition disorders	Obesity	01APR2020		Y
	C4591001 1112 11121310	Congenital, familial and genetic disorders	Aniridia	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN1973		Y
				01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2018		Y
		Nervous system disorders	Tardive dyskinesia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1112 11121313	Immune system disorders	Food allergy	01JAN2017		Y
			Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
	C4591001 1112 11121315	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1112 11121317	Eye disorders	Cataract	01JAN2008		Y
		Immune system disorders	Seasonal allergy	03NOV2008		Y
	C4591001 1112 11121318†	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Investigations	HIV test positive	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Narcolepsy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1112 11121323	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1112 11121326	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007	13FEB2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	05JAN2017	05JAN2017	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	01JAN2001	N
			Gastrectomy	13FEB2017	13FEB2017	N
			Thyroidectomy	05JAN2017	05JAN2017	N
	C4591001 1112 11121328	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1112 11121332	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1112 11121335	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
	C4591001 1112 11121339	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1112 11121341	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	01JAN2010	N
		Social circumstances	Postmenopause	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2010	01JAN2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1112 11121342	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN1987		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2015		Y
	C4591001 1112 11121343	Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JUN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1112 11121345	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1112 11121346	Immune system disorders	Milk allergy	01JAN1982		Y
			Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
			Rhinitis perennial	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006		Y
	C4591001 1112 11121351	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31AUG2019	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2019	31AUG2019	N
	C4591001 1114 11141001	Eye disorders	Astigmatism	01JAN1990		Y
			Myopia	01JAN1990		Y
		Investigations	Blood testosterone decreased	07AUG2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1114 11141002	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01APR2017		Y
	C4591001 1114 11141003	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Injury, poisoning and procedural complications	Hand fracture	01MAR2020	30APR2020	N
	C4591001 1114 11141007	Eye disorders	Myopia	01AUG2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Depression	01FEB2018		Y
		Renal and urinary disorders	Nephrolithiasis	01AUG1994		Y
	C4591001 1114 11141009	Eye disorders	Presbyopia	01JUN2018		Y
		Immune system disorders	Seasonal allergy	01OCT2018		Y
	C4591001 1114 11141010	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JUN2018		Y
	C4591001 1114 11141012	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1114 11141013	Eye disorders	Myopia	01JAN1992		Y
	C4591001 1114 11141014	Psychiatric disorders	Anxiety	01JAN2007		Y
		Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01MAR2009		Y
		Nervous system disorders	Headache	01SEP2018		Y
			Migraine	01SEP2018		Y
		Psychiatric disorders	Anxiety	01OCT2004		Y
			Depression	01SEP2018		Y
		Renal and urinary disorders	Hypertonic bladder	01OCT2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2004		Y
		Skin and subcutaneous tissue disorders	Acne	01SEP2009		Y
			Eczema	(b) (6) 1999		Y
	C4591001 1114 11141015	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
	C4591001 1114 11141016	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2011		Y
	C4591001 1114 11141021	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01MAR2013		Y
		Psychiatric disorders	Depression	01JAN2018	15DEC2018	N
	C4591001 1114 11141024	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1114 11141027	Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Celiac disease	01OCT2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2015		Y
	C4591001 1114 11141029	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Epilepsy	01JAN1993		Y
			Headache	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1114 11141033	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Peptic ulcer	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menstruation irregular	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
			Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1114 11141034	Metabolism and nutrition disorders	Lactose intolerance	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1114 11141037	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Intervertebral disc protrusion	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1114 11141038	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1114 11141039	Psychiatric disorders	Anger	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1114 11141040	Eye disorders	Myopia	01JAN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01APR2019	30APR2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pharyngeal polyp	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1985		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2020	31JAN2020	N
	C4591001 1114 11141041	Eye disorders	Astigmatism	01AUG2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
			Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm malignant	01JAN2008	18JAN2008	N
		Nervous system disorders	Cerebrovascular accident	01AUG2019	01AUG2019	N
			Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01AUG2017		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2019		Y
			Polycystic ovaries	01JAN2013		Y
		Surgical and medical procedures	Arterial bypass operation	01JAN2019	01JAN2019	N
			Tumour excision	18JAN2008	18JAN2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1114 11141042	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01MAY2019	31MAY2019	N
		Surgical and medical procedures	Rotator cuff repair	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1114 11141051	Congenital, familial and genetic disorders	Factor V deficiency	01JAN2009		Y
		Eye disorders	Astigmatism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2019	24DEC2019	N
		Reproductive system and breast disorders	Menstruation irregular	01FEB2019		Y
	C4591001 1114 11141053	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
	C4591001 1114 11141054	Immune system disorders	Allergy to metals	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1114 11141061	Blood and lymphatic system disorders	Anaemia	01JUL2020		Y
		Eye disorders	Myopia	01JAN2016		Y
		Gastrointestinal disorders	Constipation	01JUL2020		Y
			Diarrhoea	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	07FEB2020		Y
			Seasonal allergy	01JAN1984		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
		Psychiatric disorders	Depression	01JUN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019	29FEB2020	N
		Surgical and medical procedures	Hysterectomy	01FEB2020	29FEB2020	N
	C4591001 1114 11141062	Eye disorders	Myopia	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1114 11141063	Vascular disorders	Hypertension	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01AUG2019		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2020		Y
			Gastroesophageal reflux disease	01DEC2019		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1114 11141064	Cardiac disorders	Arteriospasm coronary	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	31MAY2020	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01MAY2020	31MAY2020	N
	C4591001 1114 11141065	Eye disorders	Myopia	01JAN2004		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1114 11141068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1114 11141069	Eye disorders	Presbyopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2008		Y
	C4591001 1114 11141070	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1114 11141072	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2002		Y
	C4591001 1114 11141074	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1114 11141075	Eye disorders	Myopia	01JAN1993		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Iodine allergy	01JAN2006		Y
			Rubber sensitivity	01JAN2000		Y
			Seasonal allergy	01JUN2020		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
			Tinea versicolour	01JAN1994		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2020		Y
			Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2019		Y
		Reproductive system and breast disorders	Fallopian tube disorder	01JAN2007	31DEC2007	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
	C4591001 1114 11141076	Hepatobiliary disorders	Cholecystitis	01OCT2016		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Product issues	Device malfunction	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Cough	18AUG2020		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2016	31DEC2020	N
			Female sterilisation	01JUN2019	30JUN2020	N
			Uterine dilation and curettage	01MAY2018	31MAY2018	N
	C4591001 1114 11141079	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1114 11141081	Eye disorders	Astigmatism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Headache	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1114 11141083	Eye disorders	Myopia	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1114 11141084	Immune system disorders	Drug hypersensitivity	01MAY2020		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Hand fracture	18FEB2020	18FEB2020	N
			Lower limb fracture	18FEB2020	19FEB2020	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	18FEB2020		Y
		Nervous system disorders	Neuralgia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2019		Y
			Insomnia	01MAR2020		Y
		Surgical and medical procedures	Limb operation	19FEB2020	19FEB2020	N
	C4591001 1114 11141085	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1114 11141087	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	08NOV2007	08NOV2007	N
	C4591001 1114 11141089	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1114 11141093	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01DEC2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Vulvovaginal mycotic infection	01JAN2001		Y
		Nervous system disorders	Headache	01DEC1993		Y
		Psychiatric disorders	Anxiety	01AUG2017		Y
			Depression	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Throat tightness	01MAR2020		Y
	C4591001 1114 11141095	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Otitis media	01JAN2000	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
			Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Menstruation irregular	01JUL2019		Y
	C4591001 1114 11141096	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
		Eye disorders	Myopia	01JAN1986		Y
		Gastrointestinal disorders	Toothache	10JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Depression	01JAN1993		Y
	C4591001 1114 11141097	Cardiac disorders	Cardiac failure chronic	01APR2018		Y
			Coronary artery disease	25AUG2013		Y
		Immune system disorders	Drug hypersensitivity	01AUG2000		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Idiopathic intracranial hypertension	01AUG1997		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1114 11141098	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Bipolar disorder	01JAN2009		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1114 11141100	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1983		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2018	31DEC2018	N
	C4591001 1114 11141103	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Rubber sensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1980		Y
	C4591001 1114 11141105	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Anger	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1114 11141109	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN1987	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Urticaria	01AUG2019		Y
	C4591001 1114 11141111	Eye disorders	Myopia	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1114 11141113	Endocrine disorders	Hypogonadism	01JAN2020		Y
		Eye disorders	Myopia	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Arthroscopy	01JUL2020	01JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Surgical and medical procedures	Myopia correction	01JAN2016	31DEC2016	N
	C4591001 1114 11141115	Eye disorders	Myopia	01SEP1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2008		Y
	C4591001 1114 11141117	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1114 11141118	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2015		Y
		Surgical and medical procedures	Mammoplasty	01MAY2020	31MAY2020	N
	C4591001 1114 11141119	Endocrine disorders	Hypothyroidism	01JAN2018		Y
			Oestrogen deficiency	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Bipolar disorder	01JAN2006		Y
			Borderline personality disorder	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01MAR2014	01MAR2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01MAR2016	01MAR2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1114 11141121	Eye disorders	Hypermetropia	01JAN1980		Y
	C4591001 1114 11141123	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Hepatobiliary disorders	Hepatomegaly	01MAR2019		Y
		Infections and infestations	Cellulitis	01MAR2019	31MAR2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01JAN2007		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161002	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Injury, poisoning and procedural complications	Muscle strain	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Insomnia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1116 11161003	Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
	C4591001 1116 11161006	Surgical and medical procedures	Female sterilisation	01MAR2020	31MAR2020	N
	C4591001 1116 11161007	Psychiatric disorders	Anxiety	01JAN1999		Y
			Bipolar disorder	01JUL2012		Y
		Reproductive system and breast disorders	Ovarian cyst	01APR2002		Y
		Surgical and medical procedures	Female sterilisation	28FEB2005	28FEB2005	N
			Gastrectomy	28DEC2019	28DEC2019	N
	C4591001 1116 11161008	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1116 11161009	Gastrointestinal disorders	Gastric ulcer	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1116 11161012	Psychiatric disorders	Anxiety	01JAN2001		Y
			Attention deficit hyperactivity disorder	01JUL2020		Y
			Depression	01JAN2001		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1116 11161014	Immune system disorders	Multiple allergies	01JAN1999		Y
	C4591001 1116 11161022	Nervous system disorders	Neuralgia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Gastric bypass	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1116 11161029	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JUN2020		Y
		Nervous system disorders	Sinus headache	01JAN2000		Y
	C4591001 1116 11161041	Nervous system disorders	Seizure	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1116 11161043	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1116 11161044	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1116 11161047	Infections and infestations	Folliculitis	01APR2020		Y
	C4591001 1116 11161049	Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Muscle spasms	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Surgical and medical procedures	Spinal operation	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161053	Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Menopause	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01JAN1989		Y
	C4591001 1116 11161054	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Nervous system disorders	Neuralgia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2002		Y
			Insomnia	01JAN2020		Y
		Surgical and medical procedures	Gastrectomy	24DEC2018	24DEC2018	N
			Hysterectomy	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2020		Y
	C4591001 1116 11161058	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scleroderma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	11DEC1998	11DEC1998	N
				20NOV2003	20NOV2003	N
	C4591001 1116 11161059	Gastrointestinal disorders	Abdominal pain	01AUG2019	19SEP2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161071	Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
			Female sterilisation	30SEP1997	30SEP1997	N
			Gastrectomy	01JAN2016	31DEC2016	N
			Mammoplasty	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161072	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2020		Y
		Nervous system disorders	Headache	01JAN1985		Y
			Migraine	01JAN2020		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1973	31DEC1973	N
			Appendicectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Sinus operation	01JAN1988	31DEC1988	N
			Spinal operation	01JAN2019	31DEC2019	N
	C4591001 1116 11161076	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Irlen syndrome	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Autism spectrum disorder	01JAN2009		Y
	C4591001 1116 11161082	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161083	Gastrointestinal disorders	Dyspepsia	01JUL2020		Y
			Gastritis	01JAN2020	31JAN2020	N
			Umbilical hernia	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Hepatic steatosis	01FEB2020		Y
		Injury, poisoning and procedural complications	Tendon rupture	07APR2019	07APR2019	N
		Investigations	Colonoscopy	01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2020		Y
			Arthritis	01APR2020		Y
			Muscle spasms	01MAY2020		Y
			Osteopenia	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Dandruff	01JUL2020		Y
			Seborrhoeic dermatitis	24JUN2020		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Ankle operation	07APR2019	07APR2019	N
			Umbilical hernia repair	01JAN2014	31DEC2014	N
	C4591001 1116 11161085	Infections and infestations	Streptococcal infection	01JAN1974	31DEC1974	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2000	31DEC2000	N
		Investigations	Lipids increased	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1974	31DEC1974	N
			Shoulder operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161091	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		General disorders and administration site conditions	Oedema peripheral	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Intervertebral disc protrusion	01JAN2015	31DEC2019	N
			Neck pain	01JAN2014		Y
		Nervous system disorders	Dyslexia	01JAN1978		Y
			Migraine	01JAN2018		Y
			Radiculopathy	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
			Neck surgery	01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
			Sterilisation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2015		Y
			Raynaud's phenomenon	01JAN1983		Y
	C4591001 1116 11161099	Congenital, familial and genetic disorders	Sickle cell trait	28JAN2020		Y
	C4591001 1116 11161100	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161101	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01APR2020		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	04MAY2017	04MAY2017	N
	C4591001 1116 11161103	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1116 11161104	Hepatobiliary disorders	Cholelithiasis	01DEC2014	31DEC2014	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
			Obsessive-compulsive disorder	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
				01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01DEC2014	31DEC2014	N
			Endometrial ablation	01NOV2006	30NOV2006	N
			Female sterilisation	01SEP2006	30SEP2006	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Lithotripsy	01JAN2007	31DEC2007	N
			Renal artery stent placement	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salpingectomy	01JAN2003	31DEC2003	N
			Sterilisation	01NOV2006	30NOV2006	N
			Uterine dilation and curettage	01JUL2004	31JUL2004	N
	C4591001 1116 11161107	Surgical and medical procedures	Female sterilisation	01JUN2018	30JUN2018	N
			Sterilisation	01JUN2018	30JUN2018	N
	C4591001 1116 11161108	Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1116 11161113	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1116 11161115	Infections and infestations	Appendicitis	01OCT1997	31OCT1997	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003	31DEC2003	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2015	31DEC2015	N
		Social circumstances	Organ donor	01AUG1997	31AUG1997	N
		Surgical and medical procedures	Appendicectomy	01OCT1997	31OCT1997	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2003	31DEC2003	N
	C4591001 1116 11161119	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2007	N
	C4591001 1116 11161138	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1116 11161140	Surgical and medical procedures	Intrauterine contraception	01MAR2017		Y
	C4591001 1116 11161148	Congenital, familial and genetic disorders	Dolichocolon	01JAN2009	31JAN2009	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Uterine prolapse	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Colectomy	01JAN2009	31JAN2009	N
			Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1116 11161154	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006	31DEC2006	N
			Neck pain	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31DEC2016	N
		Social circumstances	Menopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2006	31DEC2006	N
	C4591001 1116 11161157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2017	31DEC2017	N
			Hand fracture	01JAN2010	31DEC2010	N
			Subdural haematoma	(b) (6) 1984	(b) (6) 1984	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Chondroplasty	01JAN2017	31DEC2017	N
			Limb operation	01JAN2010	31DEC2010	N
			Subdural haematoma evacuation	(b) (6) 1984	(b) (6) 1984	N
	C4591001 1116 11161159	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1116 11161164	Injury, poisoning and procedural complications	Craniocerebral injury	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994		Y
			Intervertebral disc protrusion	01JAN1994		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2016		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
			Spinal laminectomy	01JAN1994	31DEC2018	N
				01JAN2006	31DEC2018	N
				01JAN2007	31DEC2018	N
				01JAN2008	31DEC2018	N
			Spinal nerve stimulator implantation	01JAN2019		Y
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1116 11161172	Psychiatric disorders	Autism spectrum disorder	01JAN2018		Y
	C4591001 1116 11161175	Psychiatric disorders	Anxiety	01JAN2003	31DEC2005	N
	C4591001 1116 11161176	Gastrointestinal disorders	Oesophagitis	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01SEP2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc protrusion	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	10OCT2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Female sterilisation	01JUN1999	30JUN1999	N
			Tonsillectomy	01JAN1981	31DEC1981	N
	C4591001 1116 11161178	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
				28AUG2020	28AUG2020	N
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
			Sterilisation	01JAN2015	31DEC2015	N
	C4591001 1116 11161179	Psychiatric disorders	Post-traumatic stress disorder	01JAN2016		Y
		Surgical and medical procedures	Sterilisation	01NOV2019	30NOV2019	N
			Vasectomy	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161180	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
			Sterilisation	01JAN2017	31DEC2017	N
	C4591001 1116 11161185	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1116 11161186	Musculoskeletal and connective tissue disorders	Ligament laxity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161196	Surgical and medical procedures	Female sterilisation	16SEP2019	16SEP2019	N
	C4591001 1116 11161200	Injury, poisoning and procedural complications	Joint dislocation	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2008	31DEC2008	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
			Nerve compression	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Surgical and medical procedures	Bunion operation	01JAN2008	31DEC2008	N
			Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Peripheral nerve decompression	01JAN2018	31DEC2018	N
			Peripheral nerve transposition	01JAN2019	31DEC2019	N
			Shoulder operation	01JAN1998	31DEC1998	N
	C4591001 1116 11161203	Nervous system disorders	Migraine	01JAN1991		Y
		Surgical and medical procedures	Caesarean section	07NOV2006	07NOV2006	N
				24APR2002	24APR2002	N
			Female sterilisation	07NOV2006	07NOV2006	N
	C4591001 1116 11161204	Infections and infestations	Appendicitis perforated	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1116 11161205	Injury, poisoning and procedural complications	Rib fracture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Surgical fixation of rib fracture	01JAN2008	31DEC2008	N
	C4591001 1116 11161214	Eye disorders	Myopia	01JAN2006	31DEC2006	N
		Infections and infestations	Infective tenosynovitis	01FEB2020	29FEB2020	N
		Investigations	Biopsy breast normal	01OCT2010	31OCT2010	N
		Musculoskeletal and connective tissue disorders	Arthritis	01AUG2018	30NOV2018	N
				01JAN2011	31JAN2011	N
				01MAR2015	31MAR2015	N
				01NOV2018	30NOV2018	N
				01OCT2011	31OCT2011	N
			Ligament disorder	01JAN2009	31DEC2009	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Endometriosis	01DEC2004	31DEC2004	N
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Arthrodesis	01JAN2011	31JAN2011	N
				01OCT2011	31OCT2011	N
			Bone lesion excision	01JAN2000	31JAN2000	N
			Carpal tunnel decompression	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Joint debridement	01AUG2018	31AUG2018	N
				01FEB2020	29FEB2020	N
				01MAR2015	31MAR2015	N
				01NOV2018	30NOV2018	N
			Keratomileusis	01JAN2006	31DEC2006	N
			Ligament operation	01JAN2009	31DEC2009	N
	C4591001 1116 11161216	Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1116 11161217	Infections and infestations	Chronic sinusitis	01JAN2015	31DEC2015	N
			Pharyngitis streptococcal	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
			Perinatal depression	08AUG2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1991	31DEC1991	N
			Elbow operation	01JAN1989	31DEC1989	N
			Sinus operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1116 11161224	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014	31DEC2014	N
			Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN2017	31DEC2017	N
			Uterine malposition	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Gastrectomy	01OCT2015	31OCT2015	N
			Mammoplasty	01JAN2015	31DEC2015	N
			Oophorectomy bilateral	01JAN2017	31DEC2017	N
	C4591001 1116 11161225	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Pharyngotonsillitis	01JAN2003	31DEC2003	N
			Vulvovaginal mycotic infection	01JAN2017		Y
		Injury, poisoning and procedural complications	Back injury	01AUG2005	31AUG2005	N
			Fall	01AUG2005	31AUG2005	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Pain in extremity	16AUG2017		Y
		Nervous system disorders	Headache	01JAN1997		Y
			Intracranial aneurysm	16AUG2017	16AUG2017	N
			Ruptured cerebral aneurysm	16APR2017	16APR2017	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01APR2001	30APR2001	N
		Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN1999	31DEC1999	N
				01JAN2002	31DEC2002	N
			Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Miliaria	01JAN2000		Y
			Psoriasis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenotonsillectomy	01JAN2003	31DEC2003	N
			Cerebral endovascular aneurysm repair	01JAN2017	31DEC2017	N
			Haematoma evacuation	01JAN2005	31DEC2005	N
			Hysterectomy	01APR2001	30APR2001	N
			Paranasal sinus polypectomy	01JAN1999	31DEC1999	N
				01JAN2003	31DEC2003	N
		Vascular disorders	Haematoma	01JAN2005	31DEC2005	N
			Hypertension	01JAN2000		Y
	C4591001 1116 11161226	Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1116 11161228	Gastrointestinal disorders	Abdominal hernia	01JAN1983	31DEC1983	N
				01JAN2004	31DEC2004	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2009	31DEC2009	N
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Nerve injury	01JAN1994	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Limb mass	01JAN1994	31DEC1994	N
		Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Sleep disorder	01JUN2020		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1983	31DEC1983	N
				01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Peripheral nerve destruction	01JAN1995	31DEC1995	N
			Removal of foreign body	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1116 11161230	Injury, poisoning and procedural complications	Intervertebral disc injury	01JAN2019	31DEC2019	N
			Limb injury	01JAN2015	31DEC2015	N
			Muscle rupture	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Muscle operation	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
	C4591001 1116 11161240	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Mastectomy	01JAN2002	31DEC2002	N
			Radiotherapy	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1116 11161245	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2019		Y
	C4591001 1116 11161249	Gastrointestinal disorders	Impaired gastric emptying	01JUN2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
			Staphylococcal infection	01JAN2018	31DEC2018	N
		Investigations	Oesophagogastroduodenoscopy	03AUG2020	03AUG2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2007		Y
			Neuropathy peripheral	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Restless legs syndrome	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Pre-eclampsia	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
			Sleep terror	01JAN2008		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Appendectomy	01JAN2005	31DEC2005	N
			Caesarean section	05APR2013	05APR2013	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Female sterilisation	05APR2013	05APR2013	N
			Oophorectomy bilateral	01JAN2016	31DEC2016	N
			Removal of foreign body	01JAN2018	31DEC2018	N
			Uterine dilation and curettage	01JAN2012	31DEC2012	N
	C4591001 1116 11161256	Infections and infestations	Urinary tract infection	01JAN2010		Y
	C4591001 1116 11161259	Injury, poisoning and procedural complications	Femur fracture	01JAN2002	31DEC2002	N
			Ligament rupture	01JAN2017	31DEC2017	N
			Lower limb fracture	01JAN2002	31DEC2002	N
			Road traffic accident	01JAN2002	31DEC2002	N
			Wrist fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Bone operation	01JAN2002	31DEC2002	N
			External fixation of fracture	01JAN2002	31DEC2002	N
			Knee arthroplasty	01JAN2002	31DEC2002	N
			Ligament operation	01JAN2017	31DEC2017	N
			Lymphoma operation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN2002	31DEC2002	N
			Tenotomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161260	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Investigations	Biopsy bone marrow	01JAN2018	31DEC2018	N
			Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Female sterilisation	01JAN2002	31DEC2002	N
			Joint debridement	01JAN2017	31DEC2017	N
	C4591001 1116 11161261	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenotonsillectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161268	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161274	Immune system disorders	Seasonal allergy	01JAN1966		Y
		Investigations	Biopsy skin	01JAN2010	31DEC2010	N
				01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Squamous cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1966		Y
	C4591001 1116 11161284	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2005	31DEC2005	N
	C4591001 1116 11161286	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac operation	(b) (6) 1987	(b) (6) 1987	N
			Plastic surgery	01JAN2001	31DEC2001	N
	C4591001 1116 11161292	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JUN2020		Y
	C4591001 1116 11161299	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2020		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2001		Y
			Synovial cyst	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN1987		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1988	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
			Fracture treatment	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Renal stone removal	01JAN1988	31DEC1988	N
	C4591001 1116 11161301	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
	C4591001 1116 11161305	Reproductive system and breast disorders	Menstruation irregular	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oropharyngeal pain	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Adenoidectomy	01JAN1986	31DEC1986	N
	C4591001 1116 11161307	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1986	31DEC1996	N
		Surgical and medical procedures	Nasal septal operation	01JAN1996	31DEC1996	N
	C4591001 1116 11161308	Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Nasal polypectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1116 11161309	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1116 11161310	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Spinal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1116 11161312	Cardiac disorders	Mitral valve prolapse	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161315	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01OCT2018	31OCT2018	N
		Surgical and medical procedures	Caesarean section	01JAN2010	31JAN2010	N
			Nasal septal operation	01OCT2018	31OCT2018	N
	C4591001 1116 11161317	Injury, poisoning and procedural complications	Craniocerebral injury	01MAY2018	01MAY2018	N
			Wrist fracture	01MAY2018	01MAY2018	N
	C4591001 1116 11161318	Endocrine disorders	Hypothyroidism	01JAN1977		Y
	C4591001 1116 11161320	Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1116 11161321	Gastrointestinal disorders	Barrett's oesophagus	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1982	31DEC1982	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
			Depression	01JAN2005		Y
	C4591001 1116 11161324	Blood and lymphatic system disorders	Anaemia	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1116 11161326	Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Female sterilisation	02JAN2014	02JAN2014	N
			Hysterectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1117 11171011	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1117 11171014	Immune system disorders	Food allergy	01JAN1991		Y
		Nervous system disorders	Migraine with aura	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Substance use	01JAN1994		Y
			Tobacco user	01JAN1995		Y
	C4591001 1117 11171015	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Congenital, familial and genetic disorders	Thalassaemia	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01AUG2010	31AUG2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01AUG2010	31AUG2010	N
			Meniscus operation	01JAN2020	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171017	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Chronic sinusitis	01JAN2008	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016	31DEC2018	N
			Sinus polyp	01JAN2008	31DEC2008	N
		Social circumstances	Alcohol use	01JAN2000		Y
			Substance use	30MAY2020		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2019	31JAN2019	N
	C4591001 1117 11171021	Eye disorders	Visual impairment	01JAN1991		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Infections and infestations	Cellulitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Jaw fracture	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
			Incisional drainage	01JAN2010	31DEC2010	N
			Jaw operation	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2013	31DEC2013	N
	C4591001 1117 11171029	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Alcohol use	01JAN2000		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mastectomy	01APR2018	30APR2018	N
			Oophorectomy bilateral	01AUG2018	31AUG2018	N
			Radiotherapy to breast	01JAN2017	31DEC2017	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1117 11171030	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Food allergy	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Denture wearer	01APR2020		Y
			Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1117 11171035	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Infections and infestations	Tonsillitis	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Benign tumour excision	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1117 11171036	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Alcoholism	01JAN2005	31DEC2017	N
			Anxiety	01JAN2017		Y
			Bipolar disorder	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2017		Y
			Major depression	01JAN2016		Y
			Schizophrenia	01JAN2016		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1117 11171038	Eye disorders	Astigmatism	01JAN2010		Y
			Hypermetropia	01JAN2010		Y
		Gastrointestinal disorders	Nausea	01JAN1983		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Depression	01JAN1983		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Social alcohol drinker	01JAN1998		Y
			Tobacco user	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	28MAY2007	28MAY2007	N
	C4591001 1117 11171045	Endocrine disorders	Hyperthyroidism	01NOV2015	31DEC2015	N
			Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01MAY2020	02JUN2020	N
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2005		Y
			Migraine with aura	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	02JUN2020	02JUN2020	N
			Radioactive iodine therapy	01JAN2015	31DEC2015	N
	C4591001 1117 11171050	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171053	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2006		Y
		Congenital, familial and genetic disorders	Methylenetetrahydrofolate reductase gene mutation	01JAN2006		Y
		Eye disorders	Visual impairment	01JAN2006		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2017	31DEC2017	N
		Infections and infestations	Kidney infection	01JAN2000	31DEC2000	N
			Tonsillitis	01JAN2010	31DEC2010	N
		Investigations	Endoscopy upper gastrointestinal tract	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Folate deficiency	01JAN2006		Y
			Gluten sensitivity	01JAN2010		Y
			Vitamin B12 deficiency	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2016	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	10APR2020	18APR2020	N
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1117 11171058	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
	C4591001 1117 11171061	Gastrointestinal disorders	Umbilical hernia	01JAN1986	31DEC2012	N
		Immune system disorders	Rubber sensitivity	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2012	29FEB2012	N
		Psychiatric disorders	Depression	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Social circumstances	Tobacco user	01JAN1989		Y
		Surgical and medical procedures	Breast tumour excision	01FEB2012	29FEB2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia repair	01JAN2012	31DEC2012	N
	C4591001 1117 11171062	Hepatobiliary disorders	Cholelithiasis	01APR2008	30APR2008	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Wrist fracture	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Cholecystectomy	01APR2008	30APR2008	N
			Wrist surgery	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01MAR2006		Y
	C4591001 1117 11171063	Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2013		Y
	C4591001 1117 11171064	Eye disorders	Visual impairment	01JAN1988		Y
	C4591001 1117 11171065	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1974	31DEC1974	N
				01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Mood swings	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01OCT2018	31OCT2018	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1117 11171066	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Hypersensitivity	01JAN1998		Y
		Infections and infestations	Hepatitis A	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1999	31DEC1999	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1971		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1999	31DEC1999	N
			Mammoplasty	01JAN2013	31DEC2013	N
			Tendon operation	01JAN2016	31DEC2016	N
	C4591001 1117 11171067	Injury, poisoning and procedural complications	Ligament rupture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996	31MAR2019	N
			Rotator cuff syndrome	01OCT2019	31OCT2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01MAR2019	31MAR2019	N
			Ligament operation	01JAN2014	31DEC2014	N
			Rotator cuff repair	01OCT2019	31OCT2019	N
			Vasectomy	01JAN2000	31DEC2000	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171068	Eye disorders	Myopia	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JUN2016		Y
			Depression	01JUN2016		Y
			Gender dysphoria	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2010		Y
		Social circumstances	Substance use	01JAN2013		Y
			Tobacco user	01JAN2017		Y
	C4591001 1117 11171069	Blood and lymphatic system disorders	Anaemia	01JUN2020		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
		Hepatobiliary disorders	Cholecystitis	01NOV2007	30NOV2007	N
		Infections and infestations	Genital herpes	01MAY2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2007	30NOV2007	N
	C4591001 1117 11171070	Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	(b) (6) 1997		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2014	31DEC2014	N
			Ligament rupture	01JAN2017	31DEC2017	N
			Post-traumatic neck syndrome	01AUG2001		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2010		Y
			Migraine	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2011	31DEC2017	N
			Depression	01JAN2011	31DEC2017	N
			Insomnia	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1997		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Social alcohol drinker	01JAN2015		Y
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Continuous positive airway pressure	01JAN2019		Y
			Ligament operation	01JAN2017	31DEC2017	N
			Renal stone removal	01JAN2017	31DEC2017	N
	C4591001 1117 11171073	Eye disorders	Visual impairment	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2007	31DEC2016	N
		Social circumstances	Electronic cigarette user	01JAN2019		Y
			Substance use	01JAN2006		Y
	C4591001 1117 11171074	Psychiatric disorders	Depression	01JUN2020		Y
	C4591001 1117 11171075	Congenital, familial and genetic disorders	Neurofibromatosis	01MAY1983		Y
		Eye disorders	Visual impairment	01JAN1991		Y
		Nervous system disorders	Headache	01JAN1999		Y
		Surgical and medical procedures	Nervous system neoplasm surgery	01DEC2016	31DEC2016	N
	C4591001 1117 11171077	Eye disorders	Visual impairment	01JAN1990		Y
		Immune system disorders	Allergy to animal	01JAN1979		Y
		Investigations	Blood cholesterol increased	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1117 11171078	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
			Intervertebral disc protrusion	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2009		Y
			Perinatal depression	01JAN2009	31DEC2009	N
			Tobacco abuse	01JUN2002		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01DEC2019		Y
		Social circumstances	Substance use	01JAN2005		Y
	C4591001 1117 11171083	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1117 11171084	Eye disorders	Visual impairment	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2014		Y
			Hypersensitivity	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2013		Y
		Surgical and medical procedures	Immune tolerance induction	01JUL2020		Y
	C4591001 1117 11171085	Endocrine disorders	Goitre	01JAN2014		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2015		Y
			Tendon rupture	01JAN1995	31DEC1995	N
			Wrist fracture	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2016		Y
			Scoliosis	(b) (6) 1971		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1971	31DEC2008	N
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2001	31DEC2001	N
			Fracture treatment	01JAN2017	31DEC2017	N
			Nasal septal operation	01JAN2008	31DEC2008	N
			Tenoplasty	01JAN1995	31DEC1995	N
	C4591001 1117 11171087	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1117 11171089	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Nasal polypectomy	20JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1117 11171090	Ear and labyrinth disorders	Deafness bilateral	01JAN1993		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2001		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Hearing aid user	01JAN1992		Y
	C4591001 1117 11171091	Eye disorders	Visual impairment	01JAN2000		Y
		Immune system disorders	Anaphylactic reaction	01JAN2000		Y
			Seasonal allergy	01JAN1999		Y
		Nervous system disorders	Headache	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1117 11171093	Immune system disorders	Hypersensitivity	01JAN1995		Y
			Reaction to colouring	01JAN2011		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Iron deficiency	01JUN2020		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2006		Y
			Scoliosis	01JAN2006		Y
		Nervous system disorders	Paraesthesia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1117 11171095	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
			Rhinitis allergic	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	17DEC1982		Y
	C4591001 1117 11171096	Immune system disorders	Allergy to arthropod sting	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1117 11171099	Eye disorders	Visual impairment	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2013		Y
	C4591001 1117 11171100	Gastrointestinal disorders	Coeliac disease	01JAN2006		Y
			Gastroesophageal reflux disease	01JAN2006		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Tenoplasty	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171101	Immune system disorders	Seasonal allergy	01SEP1990		Y
	C4591001 1117 11171102	Ear and labyrinth disorders	Hypoacusis	01JAN1995		Y
		Eye disorders	Visual impairment	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2015		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2018		Y
	C4591001 1117 11171103	Endocrine disorders	Hypogonadism	20JUL2020		Y
		Eye disorders	Visual impairment	01JAN1972		Y
		Gastrointestinal disorders	Diverticulum	17JAN2020		Y
			Gastroesophageal reflux disease	01JAN2012		Y
			Haemorrhoids	17JUL2020		Y
		General disorders and administration site conditions	Chest pain	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2005		Y
		Infections and infestations	Sinusitis	01JAN1990	31DEC2018	N
			Tinea versicolour	01MAY2019	31DEC2019	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2014		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Myositis	01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2015	N
			Neuropathy peripheral	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Keratomileusis	01JAN2019	31DEC2019	N
			Large intestinal polypectomy	17JUN2020	17JUN2020	N
			Neck surgery	01JAN2015	31DEC2015	N
			Sinus operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1117 11171107	Eye disorders	Visual impairment	01JAN2012		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2012	31DEC2012	N
			Concussion	01JAN2010	31DEC2014	N
			Ligament rupture	01JAN2013	31DEC2013	N
		Investigations	Cardiac murmur	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2011	31DEC2015	N
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2001		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1117 11171108	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Ear infection	02SEP2020	06SEP2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2019	31JUL2019	N
		Surgical and medical procedures	Mammoplasty	01JAN2014	31DEC2014	N
			Rhinoplasty	01JUL2019	31JUL2019	N
	C4591001 1117 11171109	Gastrointestinal disorders	Haemorrhoids	01SEP2019		Y
			Irritable bowel syndrome	01JAN2018		Y
			Rectal fissure	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	(b) (6) 1989		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Gender reassignment therapy	01NOV2019		Y
	C4591001 1117 11171111	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2016		Y
	C4591001 1117 11171113	Infections and infestations	Clostridium difficile infection	01JAN2009	31DEC2009	N
			Pharyngitis streptococcal	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2015		Y
			Ingrowing nail	01JAN2019	31DEC2019	N
		Social circumstances	Alcohol use	01JAN2015		Y
			Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Nail operation	01JAN2019	31DEC2019	N
	C4591001 1117 11171119	Eye disorders	Eye haemorrhage	01FEB2020	31MAY2020	N
			Myopia	01JAN1990		Y
			Vitreous degeneration	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Intervertebral disc protrusion	01JAN2018	31DEC2018	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993	31DEC1995	N
				01MAR2020		Y
	C4591001 1117 11171121	Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Toothache	01JAN2002	31DEC2002	N
		Immune system disorders	Anaphylactic reaction	01JAN1991	31DEC1991	N
			Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
			Chronic sinusitis	01JAN2005		Y
			Pneumonia	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Hip fracture	01DEC2005	31DEC2005	N
			Radius fracture	22JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Upper limb fracture	01JAN1991	31DEC1991	N
		Investigations	Arthroscopy	01DEC2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Arthralgia	25JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Alcohol use	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1996	31DEC1996	N
			Caesarean section	15OCT2016	15OCT2016	N
			Elbow operation	01JAN1991	31DEC1991	N
			Wisdom teeth removal	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1117 11171126	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Social circumstances	Alcohol use	01JAN2016		Y
			Tobacco user	01JAN2019	31JAN2019	N
	C4591001 1117 11171127	Eye disorders	Visual impairment	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN2005		Y
	C4591001 1117 11171129	Eye disorders	Visual impairment	01JAN1983		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Mole excision	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1117 11171131	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Ear infection	01JAN2003	31DEC2005	N
		Social circumstances	Alcohol use	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171132	Gastrointestinal disorders	Haemorrhoids	14JAN2019		Y
			Large intestine polyp	14JAN2019	14JAN2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Social circumstances	Social alcohol drinker	01JAN1983		Y
		Surgical and medical procedures	Polypectomy	14JAN2019	14JAN2019	N
	C4591001 1117 11171134	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Vitamin B12 deficiency	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01MAY2020		Y
		Social circumstances	Social alcohol drinker	01JAN1992		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2016	31DEC2016	N
			Salpingectomy	01JAN2017	31DEC2017	N
	C4591001 1117 11171137	Cardiac disorders	Mitral valve prolapse	01JAN1993		Y
		Eye disorders	Cataract	01JAN1993	31DEC1993	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2004	31DEC2004	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
			Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
			Nocturia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Idiopathic urticaria	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN1993	31DEC1993	N
			Large intestinal polypectomy	01JAN2015	31DEC2015	N
			Meniscus operation	01JAN2004	31DEC2004	N
				01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1117 11171138	Eye disorders	Visual impairment	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01NOV2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1117 11171140	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Injury, poisoning and procedural complications	Joint injury	01NOV2013	31DEC2013	N
			Meniscus injury	01NOV2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2013		Y
			Intervertebral disc protrusion	01FEB2017		Y
		Psychiatric disorders	Anxiety	01SEP2016	31MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Meniscus operation	01DEC2013	31DEC2013	N
		Vascular disorders	Hypertension	01NOV2016	28FEB2017	N
	C4591001 1117 11171143	Eye disorders	Visual impairment	01DEC2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
			Irritable bowel syndrome	01SEP2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tinea versicolour	01JAN2012		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2001	31DEC2001	N
			Cervical vertebral fracture	01JAN2006	31DEC2006	N
			Ligament rupture	01JAN2006	31DEC2006	N
			Wrist fracture	01JAN2006	31DEC2006	N
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2006		Y
			Back pain	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Colon operation	01SEP2019	30SEP2019	N
			Female sterilisation	01JAN1992	31DEC1992	N
			Fracture treatment	01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N
			Spinal fracture treatment	01JAN2007	31DEC2007	N
	C4591001 1117 11171144	Musculoskeletal and connective tissue disorders	Foot deformity	01FEB2004	30JUN2004	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Madarosis	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JUN2004	30JUN2004	N
	C4591001 1117 11171145	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2010	N
			Intervertebral disc protrusion	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1995	31DEC1995	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31JAN2018	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Menopause	01JAN2012		Y
			Social alcohol drinker	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Bunion operation	01JAN2010	31DEC2010	N
			Carpal tunnel decompression	01JAN2018	31JAN2018	N
			Mole excision	01JAN1995	31DEC1995	N
			Spinal operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1117 11171150	Eye disorders	Visual impairment	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2010	31DEC2010	N
		Investigations	Biopsy cervix	01JAN1991	31DEC1991	N
			Human papilloma virus test positive	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2017	31DEC2017	N
		Nervous system disorders	Hypoaesthesia	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			In vitro fertilisation	01JAN2002	31DEC2003	N
	C4591001 1117 11171154	Eye disorders	Visual impairment	01JAN1989		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Vascular disorders	Hypertension	01OCT2015		Y
	C4591001 1117 11171156	Eye disorders	Visual impairment	01JAN1980		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Iron deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1117 11171158	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2015	31DEC2018	N
			Vitamin D deficiency	01JAN2015	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lobular breast carcinoma in situ	01MAY2020	31MAY2020	N
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01MAY2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01MAY2016		Y
			Depression	01JAN2019		Y
		Reproductive system and breast disorders	Premenstrual syndrome	01DEC2015	31DEC2016	N
		Surgical and medical procedures	Breast conserving surgery	01MAY2020	31MAY2020	N
			Intra-uterine contraceptive device insertion	01MAY2016	31MAY2016	N
	C4591001 1117 11171161	Eye disorders	Visual impairment	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Herpes zoster	01JAN2007	31DEC2007	N
		Nervous system disorders	Headache	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN1998	31DEC1998	N
	C4591001 1117 11171169	Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1117 11171170	Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN2005	31DEC2005	N
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01MAR2012		Y
	C4591001 1117 11171171	Eye disorders	Visual impairment	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN1985		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1117 11171172	Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
		Immune system disorders	Hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Social circumstances	Alcohol use	01JAN1982		Y
	C4591001 1117 11171174	Social circumstances	Alcohol use	01JAN1985		Y
			Menopause	01JAN2015		Y
	C4591001 1117 11171178	Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2020		Y
		Social circumstances	Alcohol use	01JUL2020		Y
	C4591001 1117 11171180	Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
			Meniscus injury	01JAN1991	31DEC1991	N
		Nervous system disorders	Hypoaesthesia	01JAN2005	31DEC2009	N
		Social circumstances	Tobacco user	01JAN1993		Y
		Surgical and medical procedures	Ligament operation	01JAN1998	31DEC1998	N
			Meniscus operation	01JAN1991	31DEC1991	N
			Spinal fusion surgery	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1117 11171181	Immune system disorders	Food allergy	(b) (6) 1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN2016	31DEC2017	N
			Meniscus injury	01JAN2016	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Nervous system disorders	Cranial nerve disorder	(b) (6) 1990		Y
		Social circumstances	Tobacco user	01JAN2009		Y
		Surgical and medical procedures	Knee arthroplasty	01MAR2017	31MAR2017	N
	C4591001 1117 11171183	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1117 11171184	Eye disorders	Glaucoma	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2004		Y
			Myalgia	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Social circumstances	Social alcohol drinker	01JAN1990		Y
			Substance use	01JAN2000		Y
			Tobacco user	01JAN1994	31DEC2000 31DEC2017	N N
		Surgical and medical procedures	Bone operation	01JAN2008	31DEC2008	N
	C4591001 1117 11171186	Eye disorders	Visual impairment	01JAN1990		Y
		Gastrointestinal disorders	Abdominal pain upper	24SEP2020		Y
			Cannabinoid hyperemesis syndrome	01JAN2019		Y
		General disorders and administration site conditions	Treatment noncompliance	15MAR2019		Y
		Immune system disorders	Allergy to metals	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2016		Y
			Drug abuse	01JAN2019		Y
				15MAR2019		Y
			Insomnia	01JAN2019		Y
			Suicide attempt	15MAR2019	15MAR2019	N
				24DEC2019	24DEC2019	N
		Vascular disorders	Embolism venous	01JAN2019		Y
	C4591001 1117 11171187	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	22OCT2015	22OCT2015	N
	C4591001 1117 11171189	Immune system disorders	Food allergy	01JAN1995		Y
	C4591001 1117 11171190	Eye disorders	Visual impairment	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01NOV2011		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
		Investigations	Blood testosterone decreased	01SEP2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Headache	01APR2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JUN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2019		Y
			Ligament operation	01JAN2011	31DEC2011	N
	C4591001 1117 11171192	Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
			Wrist fracture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN1996	31DEC1996	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2001		Y
		Social circumstances	Tobacco user	01JAN2001		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1996	31DEC1996	N
			Meniscus operation	01JAN2010	31DEC2010	N
			Wrist surgery	01JAN2010	31DEC2010	N
	C4591001 1117 11171196	Social circumstances	Alcohol use	01JAN2001		Y
	C4591001 1117 11171197	Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Exostosis	01MAY2020	06DEC2020	N
			Intervertebral disc protrusion	01JAN2004		Y
		Social circumstances	Social alcohol drinker	01JAN1996		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1118 11181001	Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Intrauterine contraception	01JUN2019		Y
	C4591001 1118 11181002	Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1118 11181003	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
	C4591001 1118 11181009	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1985		Y
				01JAN2019		Y
			Seasonal allergy	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2020	25NOV2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
	C4591001 1118 11181014	Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2015		Y
	C4591001 1118 11181016	Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1118 11181017	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1118 11181019	Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1118 11181021	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Psychiatric disorders	Drug abuse	01JAN2012		Y
			Nicotine dependence	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1118 11181023	Immune system disorders	Hypersensitivity	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1118 11181025	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1118 11181026	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1118 11181027	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Paroxysmal choreoathetosis	(b) (6) 1998		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1118 11181028	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc degeneration	01JAN2000		Y
			Spondylolisthesis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Bipolar disorder	01JAN2008		Y
	C4591001 1118 11181030	Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Dyspepsia	01JUL2020		Y
				01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
	C4591001 1118 11181032	Gastrointestinal disorders	Pancreatitis	01JAN2015	31DEC2015	N
				01MAY2018	31MAY2018	N
		Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
			Ostectomy	01DEC2011	31DEC2011	N
			Tooth extraction	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1118 11181033	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1118 11181034	Eye disorders	Dry eye	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1118 11181035	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1118 11181040	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1118 11181042	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1118 11181046	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
	C4591001 1118 11181047	Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1118 11181049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Bipolar II disorder	01JUN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1118 11181054	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 1118 11181060	Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Drug hypersensitivity	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1991		Y
	C4591001 1118 11181061	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1118 11181062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
	C4591001 1118 11181063	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1118 11181070	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	C4591001 1118 11181076	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
			Vitamin D deficiency	01NOV2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma of the cervix	01JAN2017	30JUN2017	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JUN2017	30JUN2017	N
	C4591001 1118 11181079	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181081	Blood and lymphatic system disorders	Anaemia	01JAN2007		Y
		Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 1980		Y
		Infections and infestations	Endocarditis	01JAN2011	31DEC2011	N
	C4591001 1118 11181083	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Ankle fracture	27MAY2020	09JUN2020	N
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN2017		Y
		Surgical and medical procedures	Ankle operation	07AUG2020	07AUG2020	N
			Open reduction of fracture	09JUN2020	09JUN2020	N
	C4591001 1118 11181085	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1118 11181086	Congenital, familial and genetic disorders	Asplenia	01JAN2004		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Otitis externa	12AUG2020		Y
			Otitis media	12AUG2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1986		Y
			Bipolar disorder	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
			Splenectomy	01JAN2004	31DEC2004	N
			Thyroidectomy	01JAN2001	31DEC2001	N
	C4591001 1118 11181089	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
		Infections and infestations	Dermatophytosis	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Depression	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
		Surgical and medical procedures	Intrauterine contraception	01JUL2020		Y
	C4591001 1118 11181096	Immune system disorders	Rubber sensitivity	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	26JUL2017	26JUL2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1118 11181097	Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1118 11181100	Gastrointestinal disorders	Anal fistula	01JAN2016	31DEC2016	N
			Rectal fissure	01JAN2014	31DEC2016	N
		Infections and infestations	Herpes zoster	01MAY2020	31MAY2020	N
		Nervous system disorders	Headache	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Surgical and medical procedures	Female sterilisation	21NOV2017	21NOV2017	N
			Lithotripsy	01JAN2018	31DEC2018	N
			Rectal fistula repair	01JAN2016	31DEC2016	N
	C4591001 1118 11181101	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2017		Y
	C4591001 1118 11181103	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
	C4591001 1118 11181104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
			Hiatus hernia	01JAN2013		Y
	C4591001 1118 11181106	Immune system disorders	Food allergy	01JAN2005		Y
	C4591001 1118 11181107	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1118 11181110	Injury, poisoning and procedural complications	Nerve injury	01JAN2019		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181111	General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
				01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	07MAR2007	07MAR2007	N
				13JUN2019	13JUN2019	N
				21JUL2008	21JUL2008	N
			Female sterilisation	21JUL2008		Y
	C4591001 1118 11181112	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2008		Y
		Psychiatric disorders	Drug abuse	01JAN2017		Y
	C4591001 1118 11181115	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Investigations	Biopsy prostate	01AUG2020	31AUG2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
	C4591001 1118 11181116	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Surgical and medical procedures	Bone operation	01APR1997	30APR1997	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1118 11181117	General disorders and administration site conditions	Fatigue	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Complex regional pain syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1118 11181121	Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1118 11181122	Eye disorders	Strabismus	01JAN1971		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
		Immune system disorders	Hypersensitivity	01JAN1975		Y
		Injury, poisoning and procedural complications	Corneal abrasion	19OCT2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
			Sacroiliitis	01JAN2014		Y
			Scoliosis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
			Laryngospasm	01APR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1120 11201001	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Nervous system disorders	Hypoaesthesia	01JAN2017	31DEC2019	N
			Migraine	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
	C4591001 1120 11201005	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
	C4591001 1120 11201013	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201014	Endocrine disorders	Thyroid mass	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis perforated	01JAN1986	31DEC1986	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
			Thyroidectomy	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1120 11201015	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1994		Y
		Nervous system disorders	Facial paralysis	01JAN1992	31DEC1992	N
	C4591001 1120 11201016	Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
			Pleurectomy	01JAN2008	31DEC2008	N
				01JAN2009	31DEC2009	N
	C4591001 1120 11201023	Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
	C4591001 1120 11201024	Nervous system disorders	Headache	01JAN1982		Y
	C4591001 1120 11201028	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
			Trigger finger	14JUL2020	27JUL2020	N
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Tendon sheath incision	27JUL2020	27JUL2020	N
	C4591001 1120 11201029	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2007	31DEC2007	N
	C4591001 1120 11201037	Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1120 11201038	Congenital, familial and genetic disorders	Porokeratosis	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
	C4591001 1120 11201039	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
			Seasonal allergy	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1120 11201042	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1972		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastric neoplasm	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Stomach lesion excision	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1120 11201044	Infections and infestations	Herpes simplex	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia areata	01JAN2000		Y
	C4591001 1120 11201053	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Retinal scar	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Vitrectomy	01JAN2017	31DEC2017	N
	C4591001 1120 11201058	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201061	Endocrine disorders	Thyroid cyst	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Thyroidectomy	01JAN2012	31DEC2012	N
	C4591001 1120 11201062	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1120 11201063	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Appendicectomy	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1120 11201065	Congenital, familial and genetic disorders	Arteriovenous malformation	01JAN2017	31DEC2017	N
		Investigations	Angiogram	01JAN2017	31DEC2017	N
	C4591001 1120 11201068	Immune system disorders	Allergy to animal	01JAN2017		Y
			Mycotic allergy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1120 11201077	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201078	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN2006		Y
	C4591001 1120 11201079	Endocrine disorders	Thyroid mass	01JAN2016	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1120 11201081	Infections and infestations	Genital herpes	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2018	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2003		Y
		Reproductive system and breast disorders	Breast mass	01JAN2003	31DEC2003	N
			Uterine prolapse	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Spinal operation	01JAN2018	31DEC2018	N
	C4591001 1120 11201082	Congenital, familial and genetic disorders	Talipes	(b) (6) 1980	(b) (6) 1980	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
			Talipes correction	(b) (6) 1980	(b) (6) 1980	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201084	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Genital herpes	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN2007	31DEC2007	N
	C4591001 1120 11201085	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1120 11201097	Immune system disorders	Food allergy	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1120 11201098	Nervous system disorders	Neuralgia	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1988		Y
		Surgical and medical procedures	Foot operation	01JAN2019		Y
	C4591001 1120 11201100	Blood and lymphatic system disorders	Anaemia	01MAY2020		Y
		Metabolism and nutrition disorders	Obesity	06AUG2020		Y
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
	C4591001 1120 11201101	Nervous system disorders	Migraine	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
	C4591001 1120 11201104	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2011		Y
			Seasonal allergy	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
			Plantar fasciitis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Surgical and medical procedures	Fascial operation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Tarsal tunnel decompression	04JAN2020	04JAN2020	N
			Urinary bladder suspension	01JAN2016	31DEC2016	N
	C4591001 1120 11201105	General disorders and administration site conditions	Fatigue	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
	C4591001 1120 11201106	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1120 11201108	Immune system disorders	Allergy to animal	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1120 11201110	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201112	Immune system disorders	Allergy to animal	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1120 11201113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Nervous system disorders	Optic neuritis	01JAN2012		Y
	C4591001 1120 11201115	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Nervous system disorders	Hypersomnia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2012		Y
	C4591001 1120 11201116	Injury, poisoning and procedural complications	Uterine rupture	01JAN2008	31DEC2008	N
		Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
			Metabolic surgery	01SEP2018		Y
			Uterine repair	01JAN2008		Y
	C4591001 1120 11201120	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1120 11201130	Injury, poisoning and procedural complications	Ligament sprain	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201133	Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1120 11201139	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2000		Y
	C4591001 1120 11201142	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1120 11201144	Endocrine disorders	Hypoparathyroidism	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019		Y
			Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Parathyroidectomy	01JAN2019	31DEC2019	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
	C4591001 1120 11201148	Renal and urinary disorders	Pollakiuria	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201149	Immune system disorders	Food allergy	01JAN1989		Y
			Seasonal allergy	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1120 11201154	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
	C4591001 1120 11201157	Immune system disorders	Allergy to animal	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201161	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2003		Y
		Nervous system disorders	Epilepsy	01JAN2007		Y
		Psychiatric disorders	Bipolar disorder	01FEB2020		Y
	C4591001 1120 11201165	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN1975		Y
		Surgical and medical procedures	Shoulder operation	01JAN2007	31DEC2007	N
	C4591001 1120 11201168	Psychiatric disorders	Anxiety	01MAR2020		Y
			Bipolar disorder	01JAN2007		Y
			Depression	01MAR2020		Y
	C4591001 1120 11201171	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1120 11201172	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1120 11201181	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1120 11201195	Endocrine disorders	Oestrogen deficiency	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
				01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2007	31DEC2007	N
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Surgical and medical procedures	Craniotomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1120 11201196	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1974		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201198	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
			Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1120 11201202	Nervous system disorders	Headache	01JAN2016		Y
	C4591001 1120 11201205	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1120 11201207	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1992		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN1995		Y
			Post-traumatic stress disorder	01JAN2006		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hysterectomy	01APR2019	30APR2019	N
	C4591001 1120 11201220	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
			Restless legs syndrome	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201223	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1120 11201230	Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1120 11201231	Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01DEC2019		Y
	C4591001 1120 11201236	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN1991		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201237	Immune system disorders	Allergy to animal	01JAN2010		Y
			Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2014	31DEC2014	N
	C4591001 1120 11201238	Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1120 11201240	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1120 11201241	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
	C4591001 1120 11201244	Immune system disorders	Seasonal allergy	01JAN2020		Y
	C4591001 1120 11201250	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN2003		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JUN2020		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Ankle operation	01JAN2011	31DEC2011	N
			Brain operation	01JAN2006	31DEC2006	N
	C4591001 1120 11201252	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019		Y
		Psychiatric disorders	Depression	01APR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1120 11201259	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Traumatic arthritis	01JAN2011		Y
	C4591001 1120 11201261	Cardiac disorders	Angina pectoris	01JAN2005		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Vascular stent insertion	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201265	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201266	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
	C4591001 1120 11201274	Infections and infestations	Papilloma viral infection	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1120 11201275	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2011	31DEC2011	N
			Nasal septum deviation	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Nasal polypectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201277	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2005		Y
	C4591001 1120 11201278	Endocrine disorders	Basedow's disease	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1120 11201279	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201280	Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2015	31DEC2015	N
	C4591001 1120 11201281	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1120 11201286	Endocrine disorders	Hypothyroidism	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
			Bipolar disorder	01APR2020		Y
	C4591001 1120 11201288	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
	C4591001 1120 11201289	Gastrointestinal disorders	Constipation	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1120 11201291	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2018		Y
		Renal and urinary disorders	Bladder spasm	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201293	General disorders and administration site conditions	Cyst	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JUN1972		Y
		Reproductive system and breast disorders	Epididymal cyst	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1120 11201297	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Urinary bladder suspension	01JAN2015	31DEC2015	N
	C4591001 1120 11201298	Metabolism and nutrition disorders	Obesity	23SEP2000		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2011	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201299	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Intervertebral disc protrusion	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1120 11201303	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201305	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1120 11201306	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN2009		Y
	C4591001 1120 11201311	Gastrointestinal disorders	Umbilical hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1997	31DEC2013	N
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
			Hernia repair	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1997	31DEC2013	N
			Mammoplasty	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201315	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1120 11201320	Nervous system disorders	Cerebrovascular accident	13JUL2018	15JUL2018	N
			Headache	01JAN1999		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201322	Congenital, familial and genetic disorders	Factor XI deficiency	01JAN1994		Y
		Gastrointestinal disorders	Proctitis ulcerative	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Nervous system disorders	Headache	01JAN1984		Y
	C4591001 1120 11201323	Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
	C4591001 1120 11201326	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1120 11201331	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2013	N
		Nervous system disorders	Shift work disorder	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1120 11201334	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN1990		Y
				01JAN2003		Y
		Nervous system disorders	Headache	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
	C4591001 1120 11201339	Immune system disorders	Drug hypersensitivity	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN1999		Y
				01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2017	N
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2019		Y
	C4591001 1120 11201342	Immune system disorders	Seasonal allergy	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN1978		Y
			Insomnia	01JAN2012		Y
		Renal and urinary disorders	Urogenital fistula	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN1980		Y
	C4591001 1120 11201343	Injury, poisoning and procedural complications	Ankle fracture	01JAN2014	31DEC2014	N
	C4591001 1120 11201346	Psychiatric disorders	Depression	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Vasectomy	15JUL2020		Y
	C4591001 1120 11201348	Metabolism and nutrition disorders	Hypercholesterolaemia	21SEP2020	21SEP2020	N
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2015		Y
	C4591001 1120 11201352	Gastrointestinal disorders	Inguinal hernia	01JAN1984	31DEC1984	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Orchidectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201356	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Back pain	01APR2020		Y
		Nervous system disorders	Headache	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1120 11201363	Eye disorders	Glaucoma	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1120 11201364	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1999		Y
	C4591001 1120 11201367	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1120 11201371	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Rotator cuff repair	07FEB2020	07FEB2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201386	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Injury, poisoning and procedural complications	Post ablation tubal sterilisation syndrome	01JUL2020	31JUL2020	N
		Investigations	Precancerous cells present	01JAN2019	31JAN2019	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2014	31JUL2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Colectomy	01JAN2019	31JAN2019	N
			Endometrial ablation	01JAN2018	31DEC2018	N
			Hysterectomy	01JUL2020	31JUL2020	N
	C4591001 1120 11201393	Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1120 11201395	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Nervous system disorders	Headache	01JAN1987		Y
			Transient ischaemic attack	01JAN2008	31DEC2008	N
	C4591001 1120 11201398	Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
	C4591001 1120 11201404	General disorders and administration site conditions	Hyperplasia	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201405	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1988		Y
		Immune system disorders	Food allergy	01JAN1990		Y
				01JAN2013		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y
			Post-traumatic stress disorder	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201406	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2019		Y
			Type 2 diabetes mellitus	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201407	Nervous system disorders	Migraine	01JAN2008		Y
	C4591001 1120 11201409	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1120 11201416	Gastrointestinal disorders	Gastroesophageal reflux disease	07FEB2020		Y
	C4591001 1120 11201417	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
	C4591001 1120 11201420	Psychiatric disorders	Anxiety	01JAN2003		Y
			Bipolar disorder	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	18JUN2009	18JUN2009	N
			Ovarian cystectomy	01JAN2011	31DEC2011	N
	C4591001 1120 11201430	Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201431	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01MAR2009	31AUG2009	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
		Surgical and medical procedures	Axillary lymphadenectomy	01MAR2009	31MAR2009	N
			Cholecystectomy	01MAY2009	31MAY2009	N
			Thymectomy	01OCT2013	31OCT2013	N
	C4591001 1120 11201433	Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1121 11211003	Reproductive system and breast disorders	Endometriosis	01JAN2003	30APR2005	N
		Surgical and medical procedures	Hysterectomy	01APR2005	30APR2005	N
	C4591001 1121 11211004	Surgical and medical procedures	Oophorectomy bilateral	01JAN1994	31DEC1994	N
	C4591001 1121 11211005	Surgical and medical procedures	Vasectomy	01DEC2012		Y
	C4591001 1121 11211008	Immune system disorders	Seasonal allergy	01OCT2018		Y
	C4591001 1121 11211012	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2012		Y
		Psychiatric disorders	Anxiety	01OCT2012		Y
	C4591001 1121 11211013	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Surgical and medical procedures	Salpingectomy	01JAN2010	31DEC2010	N
	C4591001 1121 11211014	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1121 11211018	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1121 11211023	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1121 11211025	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1121 11211026	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1121 11211028	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016	30NOV2017	N
		Surgical and medical procedures	Hysterectomy	01NOV2017	30NOV2017	N
	C4591001 1121 11211029	Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1121 11211030	Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1121 11211033	Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1121 11211034	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1121 11211035	Vascular disorders	Hypertension	01APR2011		Y
	C4591001 1121 11211036	Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1121 11211038	Metabolism and nutrition disorders	Gout	01JAN2017		Y
	C4591001 1121 11211044	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1121 11211050	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1121 11211053	Nervous system disorders	Migraine	01OCT2017		Y
		Psychiatric disorders	Depression	01OCT2017		Y
	C4591001 1121 11211060	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1121 11211064	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1121 11211067	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1121 11211076	Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
	C4591001 1121 11211078	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1121 11211082	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1121 11211085	Surgical and medical procedures	Endometrial ablation	01MAY2018		Y
	C4591001 1121 11211087	Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1121 11211091	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1121 11211094	Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1121 11211095	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1121 11211097	Endocrine disorders	Hypothyroidism	01JAN2017		Y
	C4591001 1121 11211099	Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1121 11211111	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1121 11211112	Endocrine disorders	Hyperthyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01AUG2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1121 11211114	Nervous system disorders	Migraine	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1121 11211115	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2019		Y
	C4591001 1121 11211117	Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1121 11211118	Psychiatric disorders	Depression	12FEB2020		Y
	C4591001 1121 11211121	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1121 11211123	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2006	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1122 11221001	Infections and infestations	Latent tuberculosis	03AUG2018		Y
		Psychiatric disorders	Major depression	02MAR2020		Y
	C4591001 1122 11221003	Gastrointestinal disorders	Gastrooesophageal reflux disease	07OCT2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07OCT2019		Y
			Type 2 diabetes mellitus	07OCT2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	24FEB2020		Y
			Intervertebral disc displacement	05AUG2020		Y
			Spinal pain	02MAR2020		Y
		Nervous system disorders	Neuritis	05AUG2020		Y
			Radiculopathy	05AUG2020		Y
		Psychiatric disorders	Depression	07OCT2019		Y
			Post-traumatic stress disorder	18OCT2019		Y
		Vascular disorders	Essential hypertension	07OCT2019		Y
	C4591001 1122 11221005	Musculoskeletal and connective tissue disorders	Arthralgia	08APR2019		Y
			Back pain	08APR2019		Y
		Nervous system disorders	Migraine	08APR2019		Y
	C4591001 1122 11221006	Endocrine disorders	Hypogonadism	15JAN2008		Y
			Hypothyroidism	16FEB2010		Y
		Metabolism and nutrition disorders	Gout	30JAN2014		Y
			Obesity	15AUG2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Neck pain	01JAN2019		Y
			Osteoarthritis	20JUN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01AUG2000		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1996		Y
	C4591001 1122 11221008	Eye disorders	Astigmatism	27JUL2006		Y
		Injury, poisoning and procedural complications	Road traffic accident	25JAN2013	25JAN2013	N
		Investigations	Blood pressure increased	13FEB2006	13FEB2006	N
			Liver function test increased	15FEB2006	15FEB2006	N
		Musculoskeletal and connective tissue disorders	Arthralgia	13FEB2006		Y
		Psychiatric disorders	Generalised anxiety disorder	05JUN2020		Y
			Post-traumatic stress disorder	29MAR2009		Y
			Tobacco abuse	15JAN2009		Y
	C4591001 1122 11221009	Cardiac disorders	Coronary artery disease	25NOV2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23JUL2014		Y
		Vascular disorders	Essential hypertension	04OCT2012		Y
	C4591001 1122 11221012	Surgical and medical procedures	Female sterilisation	27OCT2006	27OCT2006	N
	C4591001 1122 11221014	Endocrine disorders	Hypogonadism	15JAN2008		Y
			Hypothyroidism	16FEB2010		Y
		Metabolism and nutrition disorders	Gout	30JAN2014		Y
			Obesity	15AUG2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Neck pain	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	20JUN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01AUG2000		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1996		Y
	C4591001 1122 11221016	Gastrointestinal disorders	Irritable bowel syndrome	20NOV2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1994		Y
			Obesity	06JAN2017		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
			Lumbar radiculopathy	01JAN1990		Y
		Vascular disorders	Essential hypertension	01JAN1994		Y
	C4591001 1122 11221023	Immune system disorders	Multiple allergies	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1984		Y
	C4591001 1122 11221024	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1122 11221025	Gastrointestinal disorders	Acquired oesophageal web	01JAN2008	31DEC2008	N
			Hiatus hernia	01JAN2008		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Surgical and medical procedures	Oesophageal dilation procedure	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1122 11221027	Investigations	Prostatic specific antigen increased	25JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	18MAR2015		Y
			Hypovitaminosis	07JAN2012		Y
			Overweight	14DEC2011		Y
		Social circumstances	Familial risk factor	15MAR2015		Y
	C4591001 1122 11221028	Investigations	Colonoscopy	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hyperlipidaemia	21JUN2016		Y
			Vitamin D deficiency	27JUL2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	21JUN2016		Y
			Spondylolysis	27JUL2010		Y
		Psychiatric disorders	Generalised anxiety disorder	18AUG2009		Y
		Surgical and medical procedures	Polypectomy	01JAN2002	31DEC2002	N
	C4591001 1122 11221031	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01JUN2007	31AUG2007	N
	C4591001 1122 11221032	Musculoskeletal and connective tissue disorders	Arthralgia	08JUN2020		Y
		Nervous system disorders	Lumbar radiculopathy	08JUN2020		Y
		Psychiatric disorders	Major depression	20FEB2020		Y
	C4591001 1122 11221033	Skin and subcutaneous tissue disorders	Hyperkeratosis	15SEP2020		Y
	C4591001 1122 11221038	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2000		Y
	C4591001 1122 11221040	Eye disorders	Dry eye	21JUL2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	23NOV2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	21MAY2020		Y
	C4591001 1122 11221041	Infections and infestations	Oral herpes	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1122 11221042	Congenital, familial and genetic disorders	Benign familial pemphigus	01MAY2019		Y
		Gastrointestinal disorders	Functional gastrointestinal disorder	01FEB2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2009		Y
		Nervous system disorders	Anosmia	01NOV2009		Y
		Reproductive system and breast disorders	Erectile dysfunction	16APR2014		Y
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 1122 11221045	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Chronic sinusitis	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
			Rhinitis allergic	01JAN2018		Y
	C4591001 1122 11221047	Injury, poisoning and procedural complications	Cartilage injury	01JAN2019		Y
				09SEP2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
			Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	18OCT2019	18OCT2019	N
			Migraine	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1122 11221048	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 1967		Y
	C4591001 1122 11221051	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1122 11221052	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
			Hiatus hernia	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Paraesthesia	01JAN2013		Y
			Post-traumatic headache	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1122 11221053	Cardiac disorders	Cardiomegaly	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN2001		Y
			Viral infection	01JAN2008	31DEC2010	N
		Investigations	Ejection fraction decreased	01JAN2008	31DEC2010	N
			White blood cell count decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2012		Y
			Foot deformity	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1974		Y
			Ingrown hair	01JAN1981		Y
		Surgical and medical procedures	Joint debridement	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Joint resurfacing surgery	01JAN2014	31DEC2014	N
			Shoulder arthroplasty	01JAN1990	31DEC1990	N
			Shoulder operation	01JAN2018	31DEC2018	N
	C4591001 1122 11221054	Psychiatric disorders	Anxiety	01AUG2017		Y
			Insomnia	01AUG2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
			Loop electrosurgical excision procedure	01JAN2013	31DEC2013	N
	C4591001 1122 11221059	Endocrine disorders	Hypothyroidism	01JUL2006	01AUG2006	N
			Hypothyroidism	01JUL2018		Y
		Psychiatric disorders	Depression	01JUL2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2006		Y
	C4591001 1123 11231001	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1123 11231003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1123 11231007	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN1989		Y
	C4591001 1123 11231009	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Insomnia	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000	17AUG2020	N
			Dyspareunia	01JAN2019	17AUG2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1123 11231019	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y
		Surgical and medical procedures	Tenoplasty	01JAN2017	31DEC2017	N
	C4591001 1123 11231022	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1123 11231028	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pineal germinoma	19JUN2018	31AUG2018	N
		Psychiatric disorders	Depression	01MAR2020		Y
		Surgical and medical procedures	Brain operation	25JUN2018	25JUN2018	N
	C4591001 1123 11231029	Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1123 11231030	Endocrine disorders	Hypogonadism	01JUL2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y
	C4591001 1123 11231031	Injury, poisoning and procedural complications	Ligament rupture	01FEB2020	31MAY2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Surgical and medical procedures	Ligament operation	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1123 11231034	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
	C4591001 1123 11231035	Investigations	Arthroscopy	01APR2019	30APR2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	30APR2019	N
			Osteonecrosis	01JAN2001	31DEC2002	N
		Surgical and medical procedures	Ostectomy	01JAN2002	31DEC2002	N
	C4591001 1123 11231038	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1123 11231041	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JUL2015		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Surgical and medical procedures	Vascular graft	01JUN2015	30JUN2015	N
	C4591001 1123 11231042	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1123 11231045	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1123 11231046	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1123 11231048	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1123 11231051	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN2013		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1123 11231052	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1123 11231057	Skin and subcutaneous tissue disorders	Pityriasis	01JAN2003		Y
	C4591001 1123 11231059	Psychiatric disorders	Anxiety	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231062	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1123 11231064	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2013	N
		Surgical and medical procedures	Gastrectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1123 11231067	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	24AUG2010	24AUG2010	N
	C4591001 1123 11231069	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1123 11231072	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
	C4591001 1123 11231073	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018	30APR2019	N
		Psychiatric disorders	Depression	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Gastrectomy	01APR2019	30APR2019	N
	C4591001 1123 11231074	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2020	31JAN2020	N
	C4591001 1123 11231075	Psychiatric disorders	Depression	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Panic disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1123 11231076	Investigations	Rhinitis allergic	01JAN2001		Y
	C4591001 1123 11231077	Immune system disorders	Blood testosterone decreased	20JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Social circumstances	Postmenopause	01FEB2008		Y
	C4591001 1123 11231081	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1123 11231082	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1123 11231083	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1123 11231084	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1123 11231085	Immune system disorders	Allergy to animal	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231088	Social circumstances	Menopause	01JUL2019		Y
	C4591001 1123 11231091	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231094	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1980		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2011	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231099	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Scar	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1123 11231100	Nervous system disorders	Headache	01JAN1993		Y
	C4591001 1123 11231101	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2011	31DEC2019	N
	C4591001 1123 11231102	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mastectomy	01JAN2011	31DEC2011	N
	C4591001 1123 11231104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1123 11231106	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1123 11231108	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Infections and infestations	Fungal infection	01JAN2005		Y
	C4591001 1123 11231109	Injury, poisoning and procedural complications	Intervertebral disc injury	01JAN2017		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
	C4591001 1123 11231114	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1123 11231115	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2017	N
	C4591001 1123 11231116	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1123 11231117	Endocrine disorders	Thyroid mass	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2015	N
		Social circumstances	Organ donor	01FEB2017	28FEB2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Thyroidectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231120	Endocrine disorders	Basedow's disease	01JAN1986	31DEC2015	N
			Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2015	31DEC2015	N
	C4591001 1123 11231121	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1992		Y
	C4591001 1123 11231123	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1123 11231124	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1123 11231127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1123 11231128	Endocrine disorders	Hypothyroidism	01JAN1997		Y
	C4591001 1123 11231132	Surgical and medical procedures	Female sterilisation	01AUG2014	31AUG2014	N
	C4591001 1123 11231135	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
	C4591001 1123 11231136	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1123 11231137	Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Muscle spasms	01JAN2017		Y
			Osteoarthritis	01JAN2015		Y
	C4591001 1123 11231138	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Joint surgery	01JAN2013	31DEC2013	N
	C4591001 1123 11231142	Surgical and medical procedures	Nephrectomy	01FEB2018	28FEB2018	N
			Vasectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231143	Nervous system disorders	Restless legs syndrome	01JAN2016		Y
	C4591001 1123 11231144	Social circumstances	Postmenopause	01DEC2018		Y
	C4591001 1123 11231145	Ear and labyrinth disorders	Eustachian tube stenosis	(b) (6) 1989		Y
			Tinnitus	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2016	31DEC2016	N
	C4591001 1123 11231151	Immune system disorders	Allergy to arthropod sting	01JAN1985		Y
			Food allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Nocturia	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2014	31JAN2014	N
	C4591001 1123 11231152	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1123 11231155	Congenital, familial and genetic disorders	Congenital intestinal malformation	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Colectomy	01JAN2010	31DEC2010	N
	C4591001 1123 11231156	Nervous system disorders	Vestibular migraine	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N
	C4591001 1123 11231157	Immune system disorders	Drug hypersensitivity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1123 11231159	Infections and infestations	Appendicitis	01APR2019	30APR2019	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2004		Y
			Osteoarthritis	01JAN1999		Y
		Renal and urinary disorders	Haematuria	15MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01APR2019	30APR2019	N
			Carpal tunnel decompression	01JAN2004	31DEC2004	N
			Peripheral nerve operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231161	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1123 11231162	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2016	N
			Rotator cuff syndrome	01JAN1998	30SEP2019	N
		Surgical and medical procedures	Bone lesion excision	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01SEP2019	30SEP2019	N
	C4591001 1123 11231163	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01FEB2017	28FEB2017	N
		Surgical and medical procedures	Bunion operation	01FEB2020	29FEB2020	N
			Hysterectomy	01MAY2012	31MAY2012	N
			Urinary bladder suspension	01FEB2017	28FEB2017	N
	C4591001 1123 11231164	Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
	C4591001 1123 11231165	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1123 11231168	Injury, poisoning and procedural complications	Forearm fracture	01MAR2016	30APR2016	N
		Surgical and medical procedures	Open reduction of fracture	01MAR2016	31MAR2016	N
	C4591001 1123 11231170	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Allergy to metals	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30AUG2019		Y
			Depression	01AUG2018		Y
			Generalised anxiety disorder	01AUG2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Vascular disorders	Hypertension	01OCT2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1123 11231172	Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1123 11231173	Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
	C4591001 1123 11231175	Reproductive system and breast disorders	Endometriosis	01JAN1997	31MAY2007	N
		Surgical and medical procedures	Hysterectomy	01MAY2007	31MAY2007	N
	C4591001 1123 11231176	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Mediastinitis	01JAN2018	31DEC2019	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
		Surgical and medical procedures	Venous stent insertion	01JAN2019	31DEC2019	N
		Vascular disorders	Vena cava thrombosis	01JAN2019		Y
	C4591001 1123 11231177	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
	C4591001 1123 11231178	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Umbilical hernia	01JAN2015	31MAR2020	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Tendon rupture	01OCT2014	31MAR2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Foot operation	01MAR2016	31MAR2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01MAY2015	31MAY2015	N
			Hernia repair	01MAR2020	31MAR2020	N
			Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1123 11231179	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1123 11231183	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1123 11231187	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Rubber sensitivity	01JAN2001		Y
			Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1123 11231189	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
	C4591001 1123 11231190	Cardiac disorders	Supraventricular tachycardia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Postpartum haemorrhage	01FEB2019	01FEB2019	N
		Psychiatric disorders	Depression	31JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01FEB2019	01FEB2019	N
	C4591001 1123 11231191	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
				01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31MAR2005	N
		Surgical and medical procedures	Hysterectomy	01MAR2005	31MAR2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231194	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1123 11231195	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1123 11231197	Blood and lymphatic system disorders	Anaemia	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Biliary colic	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Biopsy	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	31JUL2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
			Menometrorrhagia	01JAN1998		Y
		Social circumstances	Organ donor	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Endometrial ablation	01JAN2008	31DEC2008	N
	C4591001 1123 11231199	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1123 11231200	Immune system disorders	Drug hypersensitivity	01JAN1985		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000		Y
				01JAN2009		Y
				01JAN2011		Y
		Injury, poisoning and procedural complications	Ligament rupture	15AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1123 11231202	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1123 11231204	Psychiatric disorders	Anxiety	01DEC2018		Y
			Attention deficit hyperactivity disorder	01DEC2018		Y
			Depression	01DEC2018		Y
	C4591001 1123 11231207	Gastrointestinal disorders	Dental caries	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1123 11231208	Infections and infestations	Herpes simplex	01FEB2005		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Nervous system disorders	Arachnoid cyst	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2018	N
		Surgical and medical procedures	Craniotomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231209	Endocrine disorders	Basedow's disease	01JAN2015		Y
			Hypothyroidism	01JAN1994		Y
		Hepatobiliary disorders	Cholecystitis	01DEC1997	31DEC1997	N
		Immune system disorders	Allergy to plants	01JAN1976		Y
			Drug hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Phaeochromocytoma	01JAN1999	30SEP2000	N
		Reproductive system and breast disorders	Endometriosis	01JAN2003	30NOV2004	N
		Surgical and medical procedures	Adrenalectomy	01SEP2000	30SEP2000	N
			Cholecystectomy	01DEC1997	31DEC1997	N
			Hysterectomy	01NOV2004	30NOV2004	N
	C4591001 1123 11231210	Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231212	Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
	C4591001 1123 11231216	Infections and infestations	Appendicitis	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31JAN2018	N
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1123 11231217	Gastrointestinal disorders	Umbilical hernia	01DEC2019	31DEC2019	N
				01JAN2017	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
	C4591001 1123 11231218	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1123 11231220	Immune system disorders	Allergy to chemicals	01JAN1995		Y
	C4591001 1123 11231221	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Patella fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN2016	31DEC2016	N
	C4591001 1123 11231222	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1123 11231228	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1123 11231229	Psychiatric disorders	Anxiety	01JAN2017		Y
			Major depression	01JAN2017		Y
	C4591001 1123 11231230	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2014		Y
	C4591001 1123 11231232	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1123 11231233	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1995		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1123 11231234	Immune system disorders	Allergy to chemicals	01JAN2016		Y
			Allergy to metals	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
	C4591001 1123 11231235	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	11SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1123 11231236	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
	C4591001 1123 11231237	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1123 11231238	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hypokalaemia	01AUG2019		Y
			Obesity	01JAN1999		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Metabolic surgery	10JUL2019	10JUL2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1123 11231239	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1123 11231240	General disorders and administration site conditions	Fatigue	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Gastric bypass	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231245	Immune system disorders	Seasonal allergy	01JAN1996		Y
	C4591001 1123 11231246	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Renal stone removal	01JAN2016	31DEC2016	N
	C4591001 1123 11231248	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Ligament rupture	01FEB2018	31MAR2018	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Ligament operation	01MAR2018	31MAR2018	N
	C4591001 1123 11231249	Cardiac disorders	Ventricular extrasystoles	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1976		Y
		Surgical and medical procedures	Cardiac ablation	06MAR2020		Y
	C4591001 1123 11231252	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01AUG1982		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2020	N
			Vulvovaginal dryness	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2020	N
	C4591001 1123 11231253	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1974	31DEC1974	N
		Renal and urinary disorders	Nephrolithiasis	28JUL2000	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1123 11231260	Investigations	Blood testosterone decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1123 11231261	Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Intervertebral disc protrusion	01JAN2000		Y
				01JAN2005	31DEC2005	N
			Muscle spasms	01JAN2008		Y
		Nervous system disorders	Essential tremor	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1123 11231262	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1989		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Endometriosis	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1123 11231263	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
	C4591001 1123 11231264	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1123 11231265	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231266	Immune system disorders	Rubber sensitivity	01JAN1992		Y
		Injury, poisoning and procedural complications	Ankle fracture	01DEC2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	24MAR2007	24MAR2007	N
			Open reduction of fracture	01DEC2018	31DEC2018	N
	C4591001 1123 11231267	Injury, poisoning and procedural complications	Meniscus injury	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231268	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	21JUL2017		Y
		Psychiatric disorders	Depression	01JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1123 11231269	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 1123 11231275	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1123 11231276	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1123 11231280	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Renal and urinary disorders	Hypertonic bladder	01FEB2020		Y
		Surgical and medical procedures	Hernia repair	01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1123 11231281	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1980	07FEB2020	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	07FEB2020	07FEB2020	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1123 11231286	Ear and labyrinth disorders	Otosclerosis	01JAN2008	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Stapedectomy	01JAN2018	31DEC2018	N
	C4591001 1123 11231287	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	30MAR2017	N
		Social circumstances	Postmenopause	30MAR2017		Y
		Surgical and medical procedures	Hysterectomy	30MAR2017	30MAR2017	N
	C4591001 1123 11231289	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1123 11231290	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2019		Y
	C4591001 1123 11231291	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1123 11231294	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1123 11231295	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		General disorders and administration site conditions	Fat tissue increased	01JAN2014	31OCT2015	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Mammoplasty	01OCT2015	31OCT2015	N
	C4591001 1123 11231298	Eye disorders	Dry eye	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Vestibular migraine	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1123 11231299	Gastrointestinal disorders	Irritable bowel syndrome	01MAR2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01MAR2017	01SEP2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2006		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01SEP2017	01SEP2017	N
			Salpingectomy	01JAN2018	31DEC2018	N
	C4591001 1123 11231300	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1123 11231301	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
	C4591001 1123 11231302	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Subcutaneous abscess	01MAR2020		Y
	C4591001 1123 11231303	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231305	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231306	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1123 11231307	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1123 11231308	Psychiatric disorders	Anxiety	14DEC2019		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
	C4591001 1123 11231309	Immune system disorders	Seasonal allergy	01JAN1983		Y
	C4591001 1123 11231313	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholestasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01APR2017	30APR2017	N
			Intervertebral disc operation	01MAY2008	31MAY2008	N
	C4591001 1123 11231317	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1123 11231320	Immune system disorders	Drug hypersensitivity	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231321	Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1123 11231322	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN2012	31DEC2012	N
	C4591001 1123 11231323	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	23APR1992		Y
		Musculoskeletal and connective tissue disorders	Jaw disorder	01JAN2015	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Keratomileusis	01JAN2003	31DEC2003	N
			Orthognathic surgery	01JAN2018	31DEC2018	N
	C4591001 1123 11231324	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1123 11231326	Endocrine disorders	Hypothyroidism	01APR2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1123 11231327	Ear and labyrinth disorders	Vertigo	01FEB2020		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2015	31AUG2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2018		Y
		Surgical and medical procedures	Ileostomy	06JUN2020	06JUN2020	N
			Muscle operation	31AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231329	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
	C4591001 1123 11231330	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1123 11231334	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1123 11231336	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Surgical and medical procedures	Abscess drainage	01JAN2004	31DEC2004	N
			Maxillofacial operation	01DEC2018	31DEC2018	N
	C4591001 1123 11231338	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1123 11231339	Immune system disorders	Food allergy	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1123 11231346	Immune system disorders	Seasonal allergy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2017	N
	C4591001 1123 11231350	Surgical and medical procedures	Rhinoplasty	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	16SEP2020		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1123 11231351	Vascular disorders	Hypertension	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2019	31DEC2019	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231352	Surgical and medical procedures	Gastric ulcer surgery	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1123 11231357	Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2020		Y
	C4591001 1123 11231358	Social circumstances	Postmenopause	01MAY2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
		Endocrine disorders	Hypogonadism	01JAN2010		Y
			Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1995	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N
		Immune system disorders	Food allergy	01JAN1972		Y
	C4591001 1123 11231359	Injury, poisoning and procedural complications	Tendon rupture	01JAN2011	31DEC2013	N
		Investigations	Arthroscopy	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Obesity	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
			Neck pain	01JAN2011		Y
			Rotator cuff syndrome	01JAN2011	31DEC2013	N
		Nervous system disorders	Migraine	01JAN2011		Y
		Surgical and medical procedures	Spinal nerve stimulator implantation	01JAN2018		Y
			Tenoplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1123 11231360	Immune system disorders	Food allergy	01JAN1999		Y
			Seasonal allergy	01JAN1993		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1993		Y
	C4591001 1123 11231361	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	29JUL2010	18AUG2010	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Colectomy total	18AUG2010	18AUG2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231362	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
	C4591001 1123 11231364	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Surgical and medical procedures	Gastric bypass	01JAN2017	31DEC2017	N
	C4591001 1123 11231365	Ear and labyrinth disorders	Cerumen impaction	12OCT2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1123 11231366	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2010		Y
			Neck pain	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1123 11231372	Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Umbilical hernia	01JUL2020	31JUL2020	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01DEC2019	31DEC2019	N
		Surgical and medical procedures	Breast conserving surgery	01DEC2018	31DEC2018	N
			Hysterectomy	01DEC2019	31DEC2019	N
			Radiotherapy to breast	01JAN2019	31JAN2019	N
			Umbilical hernia repair	01JUL2020	31JUL2020	N
	C4591001 1123 11231375	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2020		Y
	C4591001 1123 11231381	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1123 11231382	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1123 11231383	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tinea pedis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1123 11231384	Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2006	31DEC2006	N
			Spinal nerve stimulator implantation	01JAN2009		Y
	C4591001 1123 11231386	Investigations	Blood pressure diastolic increased	01JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
			Obesity	01JAN2014		Y
	C4591001 1123 11231392	Cardiac disorders	Ventricular extrasystoles	01JAN2017		Y
		Gastrointestinal disorders	Pancreatitis chronic	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
		Investigations	Blood triglycerides increased	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN2005		Y
	C4591001 1123 11231395	Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
	C4591001 1123 11231397	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2011		Y
	C4591001 1123 11231398	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1123 11231399	Investigations	Cardiac murmur	01JAN1974		Y
	C4591001 1123 11231404	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1123 11231405	Endocrine disorders	Hypogonadism	01JUL2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1123 11231407	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1123 11231408	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1123 11231409	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Mastectomy	17OCT2019	17OCT2019	N
	C4591001 1123 11231411	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2020		Y
	C4591001 1123 11231413	Infections and infestations	Tonsillitis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1123 11231415	Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1123 11231418	Investigations	Arthroscopy	01JAN2017		Y
	C4591001 1123 11231419	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
	C4591001 1123 11231421	Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Keloid scar	01JAN2017		Y
	C4591001 1123 11231423	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	28SEP2016	26NOV2016	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Surgical and medical procedures	Ligament operation	26NOV2016	26NOV2016	N
	C4591001 1123 11231426	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2012		Y
	C4591001 1123 11231427	Congenital, familial and genetic disorders	Vitello-intestinal duct remnant	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Diverticulectomy	01JAN2005	31DEC2005	N
	C4591001 1123 11231429	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2019		Y
		Investigations	Arthroscopy	01JAN2019	31DEC2019	N
	C4591001 1123 11231430	Infections and infestations	Ear infection	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Testicular torsion	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Orchidectomy	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1123 11231433	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1123 11231435	Metabolism and nutrition disorders	Iron deficiency	01DEC2018		Y
		Nervous system disorders	Headache	01DEC2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1123 11231436	Immune system disorders	Allergy to animal	01JAN2018		Y
			Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Deformity thorax	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tympanoplasty	01JAN2016	31DEC2016	N
	C4591001 1123 11231437	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231471	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1123 11231480	Reproductive system and breast disorders	Menstruation irregular	01DEC2019		Y
	C4591001 1123 11231490	Infections and infestations	Ear infection	01JAN2005	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Myringotomy	01JAN2006	31DEC2009	N
	C4591001 1123 11231498	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
			Dermatitis atopic	01JAN2015		Y
	C4591001 1124 11241001	Metabolism and nutrition disorders	Overweight	01JAN2008		Y
		Nervous system disorders	Sciatica	01JAN2013	31DEC2017	N
	C4591001 1124 11241003	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1124 11241005	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN1991	31DEC1992	N
	C4591001 1124 11241010	Immune system disorders	Drug hypersensitivity	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1993		Y
			Insomnia	01JAN1985		Y
	C4591001 1124 11241012	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1124 11241017	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	10JUN2020		Y
	C4591001 1124 11241018	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Eye disorders	Strabismus	01JAN2000	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Strabismus correction	01JAN2016	31DEC2016	N
	C4591001 1124 11241025	Hepatobiliary disorders	Cholecystitis	01OCT2009	31OCT2009	N
		Surgical and medical procedures	Cholecystectomy	01OCT2009	31OCT2009	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1124 11241027	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
			Proteinuria	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970	31DEC1980	N
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
			Renal stone removal	01JAN2013	31DEC2013	N
	C4591001 1124 11241028	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01OCT2019		Y
		Psychiatric disorders	Insomnia	01OCT2019		Y
	C4591001 1124 11241030	Infections and infestations	Mastoiditis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Mastoidectomy	01JAN2005	31DEC2005	N
			Rhinoplasty	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
	C4591001 1124 11241032	Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2004	N
	C4591001 1124 11241036	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1124 11241038	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015		Y
	C4591001 1124 11241039	Surgical and medical procedures	Thyroidectomy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2004	31DEC2004	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2004	N
	C4591001 1124 11241042	Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
		Congenital, familial and genetic disorders	Gaucher's disease	01JAN1976		Y
		General disorders and administration site conditions	Hernia	01JUN2019	30JUN2019	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2005	31DEC2005	N
			Splenectomy	01JAN1983	31DEC1983	N
	C4591001 1124 11241043	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
			Pneumonia	01JAN2005	31DEC2005	N
		Nervous system disorders	Headache	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1124 11241047	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
	C4591001 1124 11241049	Blood and lymphatic system disorders	Anaemia	01JAN2015	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2015	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
	C4591001 1124 11241052	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
	C4591001 1124 11241053	Eye disorders	Chorioretinopathy	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
	C4591001 1124 11241054	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
			Peptic ulcer	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
			Upper limb fracture	01JAN1988	31DEC1988	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2017	N
		Surgical and medical procedures	Ankle operation	01JAN2006	31DEC2006	N
			Fracture treatment	01JAN1988	31DEC1988	N
	C4591001 1124 11241055	Metabolism and nutrition disorders	Gout	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241057	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Hiatus hernia	01JAN2016	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1124 11241058	Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1981		Y
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
			Female sterilisation	01NOV2018	30NOV2018	N
			Oophorectomy bilateral	01NOV2018	30NOV2018	N
	C4591001 1124 11241059	Gastrointestinal disorders	Coeliac disease	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Overweight	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
			Urinary incontinence	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Urinary bladder suspension	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010	31DEC2015	N
	C4591001 1124 11241060	Endocrine disorders	Hypothyroidism	01JAN2009		Y
			Thyroid mass	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1997		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2009	31DEC2009	N
	C4591001 1124 11241061	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2005	31DEC2015	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01MAR2014		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN1995	31DEC1995	N
	C4591001 1124 11241065	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y
		Social circumstances	Postmenopause	01JUL2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
	C4591001 1124 11241067	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN2005		Y
				01JAN2009		Y
			Seasonal allergy	01JAN1982		Y
		Infections and infestations	Pneumonia	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2019		Y
	C4591001 1124 11241068	Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1124 11241069	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1124 11241071	Gastrointestinal disorders	Dysphagia	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Investigations	Biopsy pharynx normal	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2010	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2012	N
			Menstruation irregular	01JAN2009	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
			Bone lesion excision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1124 11241072	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2018	31DEC2018	N
			Menopausal symptoms	01JAN2018		Y
		Social circumstances	Postmenopause	09APR2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1124 11241075	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastritis	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015		Y
	C4591001 1124 11241076	Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Alcoholism	01JAN2008	31DEC2018	N
			Anxiety	01JAN2002		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Renal stone removal	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1124 11241077	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN1977		Y
			Obesity	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN1980		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1977		Y
			Hidradenitis	01JAN2017		Y
	C4591001 1124 11241081	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010	31DEC2014	N
	C4591001 1124 11241083	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Overweight	01JAN2020	31DEC2020	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
	C4591001 1124 11241084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013	31DEC2013	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1124 11241086	Nervous system disorders	Carpal tunnel syndrome	01JAN2007	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1124 11241087	Gastrointestinal disorders	Eosinophilic oesophagitis	01OCT2019	01APR2020	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1124 11241090	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1124 11241092	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1124 11241093	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003	31DEC2009	N
			Sleep apnoea syndrome	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
			Meniscus removal	01JAN2018	31DEC2018	N
			Wisdom teeth removal	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2016	31DEC2019	N
	C4591001 1124 11241094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1124 11241095	Eye disorders	Cataract	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1124 11241096	Injury, poisoning and procedural complications	Ligament rupture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc protrusion	05MAY2020	05MAY2020	N
			Osteoarthritis	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	07JUN2010	07JUN2010	N
				23JUN2017	23JUN2017	N
			Female sterilisation	23JUN2017	23JUN2017	N
			Ligament operation	01JAN2004	31DEC2004	N
				01OCT2016	31OCT2016	N
			Spinal operation	05MAY2020	05MAY2020	N
	C4591001 1124 11241097	Immune system disorders	Drug hypersensitivity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
	C4591001 1124 11241099	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1124 11241100	Gastrointestinal disorders	Diarrhoea	01JAN1997		Y
			Gastroesophageal reflux disease	01JAN2013		Y
			Haematochezia	01JAN1997		Y
			Irritable bowel syndrome	01JAN1997		Y
		Injury, poisoning and procedural complications	Limb injury	01SEP2019	30SEP2019	N
		Investigations	Blood triglycerides increased	01JAN1997		Y
		Metabolism and nutrition disorders	Gout	01JAN2003		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN1997		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01MAR2013	31MAR2013	N
			Shoulder operation	01SEP2019	30SEP2019	N
			Tonsillectomy	01JAN1997	31JAN1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uvulopalatopharyngoplasty	01JAN1997	31JAN1997	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1124 11241102	Cardiac disorders	Ventricular extrasystoles	01JAN2009		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				01JAN2013	31DEC2013	N
			Female sterilisation	01JUN2013	30JUN2013	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1124 11241103	Eye disorders	Cataract	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2020	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2009	31DEC2009	N
		Investigations	Cystoscopy	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Obesity	01JAN1987		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2009	31DEC2009	N
			Cholecystectomy	19AUG2020	19AUG2020	N
			Gastrectomy	30JUL2019	30JUL2019	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N
	C4591001 1124 11241104	Congenital, familial and genetic disorders	Congenital cystic lung	01JAN1976	31DEC1976	N
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN1978	31DEC1978	N
			Tuberculosis	01JAN2006	31DEC2007	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1992	31DEC1992	N
		Investigations	Liver function test increased	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Synovial cyst	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2000		Y
			Nerve compression	01JAN2006	31DEC2006	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2016	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Eye muscle operation	01JAN2007	31DEC2007	N
			Lung cyst removal	01JAN1976	31DEC1976	N
			Peripheral nerve decompression	01JAN2006	31DEC2006	N
			Rhinoplasty	01JAN1992	31DEC1992	N
			Strabismus correction	01JAN2009	31DEC2009	N
			Synovial cyst removal	01JAN2014	31DEC2014	N
	C4591001 1124 11241106	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1124 11241108	General disorders and administration site conditions	Hernia	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
			Blood testosterone decreased	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Gastrectomy	01JAN2008	31DEC2008	N
			Gastric bypass	01JAN2010	31DEC2010	N
			Hernia repair	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Meniscus operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1124 11241109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1991	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Spondylitis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1998		Y
			Sciatica	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01APR2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Open reduction of fracture	01JAN1995	31DEC1995	N
			Spinal operation	01JAN2015	31DEC2015	N
	C4591001 1124 11241111	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01APR1999	30APR1999	N
				01SEP2001	30SEP2001	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1124 11241112	Congenital, familial and genetic disorders	BRCA2 gene mutation	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
			Female sterilisation	01JAN2019		Y
			Salpingo-oophorectomy bilateral	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241113	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN1994		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN1990	31DEC2016	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
	C4591001 1124 11241120	Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2013	N
	C4591001 1124 11241122	Surgical and medical procedures	Wisdom teeth removal	01JAN2020	01JAN2020	N
	C4591001 1124 11241125	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2018	31DEC2018	N
			Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Psychiatric disorders	Anxiety disorder	01JAN2007		Y
			Bipolar disorder	01JAN2007		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Thrombosis	01JAN2017	31DEC2018	N
	C4591001 1124 11241127	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2014		Y
		Psychiatric disorders	Anxiety disorder	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Raynaud's phenomenon	01JAN2001		Y
	C4591001 1124 11241129	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	01JAN2007		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
	C4591001 1124 11241137	Investigations	Blood cholesterol increased	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015	31DEC2018	N
	C4591001 1124 11241141	Psychiatric disorders	Anxiety disorder	01JAN2012		Y
			Depression	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2010		Y
	C4591001 1124 11241142	Investigations	Blood testosterone decreased	01JAN2019		Y
			Blood triglycerides increased	01JAN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241149	Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1124 11241152	Gastrointestinal disorders	Abdominal pain	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2018	31DEC2018	N
		Investigations	Electrocardiogram QT prolonged	01JAN2019		Y
			Laparoscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2017	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2015	N
			Menstruation irregular	01JAN2000		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2018	31DEC2018	N
			Bunion operation	01JAN1999	31DEC1999	N
			Spinal fusion surgery	01JAN2016	31DEC2017	N
	C4591001 1124 11241153	Cardiac disorders	Ventricular extrasystoles	01JAN2008		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Nasal injury	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN1995	31DEC2017	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2017	N
		Surgical and medical procedures	Rhinoplasty	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN2002	31DEC2002	N
	C4591001 1124 11241167	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1971		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Social circumstances	Postmenopause	23OCT2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1124 11241168	Congenital, familial and genetic disorders	Atrial septal defect	01JAN1981	31DEC1993	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2018		Y
			Morton's neuralgia	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2012	31DEC2017	N
			Menorrhagia	01JAN2010	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01APR2020		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN1993	31DEC1993	N
			Caesarean section	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Mastectomy	01JAN2017	31DEC2017	N
			Neurectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Raynaud's phenomenon	01JAN2018		Y
	C4591001 1124 11241170	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Cardiac murmur	01JAN1995		Y
	C4591001 1124 11241174	Cardiac disorders	Supraventricular tachycardia	01JAN1994	31DEC2016	N
		Reproductive system and breast disorders	Uterine polyp	01JAN2019	31JAN2020	N
		Surgical and medical procedures	Cardiac ablation	01JAN2016	31DEC2016	N
			Uterine dilation and curettage	01JAN2020	31JAN2020	N
	C4591001 1124 11241176	Injury, poisoning and procedural complications	Limb injury	01JAN2007	31DEC2007	N
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Surgical and medical procedures	Shoulder operation	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1124 11241178	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000	31DEC2003	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1124 11241179	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JUL2019		Y
		Surgical and medical procedures	Female sterilisation	01MAY2004	31MAY2004	N
	C4591001 1124 11241180	Gastrointestinal disorders	Inguinal hernia	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1996	31DEC1996	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1999	31DEC1999	N
			Rhinoplasty	01JAN1996	31DEC1996	N
	C4591001 1124 11241183	Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc protrusion	01JAN2019		Y
	C4591001 1124 11241184	Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Breast reconstruction	01JAN2011	31DEC2011	N
			Caesarean section	01JAN1998	31DEC1998	N
				01JAN2001	31DEC2001	N
				01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2003	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2003	31DEC2003	N
			Mastectomy	01JAN2011	31DEC2011	N
	C4591001 1124 11241185	Blood and lymphatic system disorders	Anaemia	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2012	31DEC2012	N
			Uterine leiomyoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN1999	31DEC2003	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2018	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Lipoma excision	01JAN2012	31DEC2012	N
			Myomectomy	01JAN2018	31DEC2018	N
	C4591001 1124 11241186	Immune system disorders	Seasonal allergy	01JAN1983		Y
	C4591001 1124 11241187	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
			Meningitis viral	01JAN1997	31DEC1997	N
		Injury, poisoning and procedural complications	Burns third degree	01JAN1987	31DEC1987	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Skin graft	01JAN1987	31DEC1987	N
				01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1124 11241190	Blood and lymphatic system disorders	Anaemia	01JAN1988	31DEC1988	N
		Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1988		Y
		Infections and infestations	Adenoiditis	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Iron deficiency	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Adenoidectomy	01JAN1979	31DEC1979	N
			Tympanoplasty	01JAN1980	31DEC1980	N
	C4591001 1124 11241194	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1124 11241196	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Infections and infestations	Lyme disease	01MAY2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01NOV2009	30NOV2009	N
	C4591001 1124 11241197	Immune system disorders	Sarcoidosis	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Alcoholism	01JAN2004	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar disorder	01JAN2014		Y
			Drug abuse	01JAN2004	31DEC2014	N
	C4591001 1124 11241199	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014	31DEC2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1981	31DEC1981	N
				01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
	C4591001 1124 11241200	Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1124 11241202	Infections and infestations	Dengue fever	01AUG2006	31AUG2006	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1999	31JAN1999	N
	C4591001 1124 11241207	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Infections and infestations	Rhinitis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1996	31DEC2000	N
	C4591001 1124 11241208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01MAR1999	01MAR1999	N
			Cholelithiasis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
				01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01MAR1999	01MAR1999	N
			Keratomileusis	28FEB2005	28FEB2005	N
			Vasectomy	27JUL2001	27JUL2001	N
			Wisdom teeth removal	25JAN1994	25JAN1994	N
	C4591001 1124 11241212	Gastrointestinal disorders	Inguinal hernia	01JAN1971	31DEC1971	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1985	31DEC1985	N
				01JAN2018	31DEC2018	N
			Muscle rupture	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1971	31DEC1971	N
			Knee operation	01JAN1985	31DEC1985	N
				01JAN2018	31DEC2018	N
			Muscle operation	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1124 11241213	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018	31DEC2019	N
	C4591001 1124 11241214	Immune system disorders	Drug hypersensitivity	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Gout	01JAN2018	31DEC2018	N
		Nervous system disorders	Sciatica	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Tenoplasty	01JAN1985	31DEC1985	N
	C4591001 1124 11241216	Gastrointestinal disorders	Anal fistula	01JAN1993	31DEC1993	N
			Inguinal hernia	01JAN1993	31DEC1993	N
			Irritable bowel syndrome	01JAN1991		Y
		Immune system disorders	Contrast media allergy	01JAN2010		Y
			Seasonal allergy	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1993	31DEC1993	N
			Rectal fistula repair	01JAN1993	31DEC1993	N
	C4591001 1124 11241217	Infections and infestations	Herpes simplex	01JAN2019		Y
	C4591001 1124 11241218	Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN1988		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Anxiety disorder	01JAN1984		Y
			Depression	01JAN1984	31DEC2006	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1992	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01MAY2013	31MAY2013	N
			Ligament operation	01JAN2000	31DEC2000	N
	C4591001 1124 11241219	Metabolism and nutrition disorders	Iron deficiency	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1124 11241222	Investigations	Blood cholesterol increased	01JAN2004	31DEC2009	N
			Blood testosterone decreased	01JAN2018	31DEC2020	N
		Nervous system disorders	Headache	01JAN2018		Y
			Sciatica	01JAN2012		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1989		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2006	31DEC2006	N
	C4591001 1124 11241223	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1124 11241224	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
	C4591001 1124 11241225	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
			Depression	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1991		Y
			Cholecystectomy	01JAN1997	31DEC1997	N
			Female sterilisation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1124 11241226	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
	C4591001 1124 11241227	Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1124 11241228	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1124 11241232	Infections and infestations	Tonsillitis	01JUN2020	30JUN2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
	C4591001 1124 11241233	Surgical and medical procedures	Tonsillectomy	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1124 11241234	Surgical and medical procedures	Bunion operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2013	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1124 11241235	Surgical and medical procedures	Myomectomy	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Abdominal pain	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Thoracoplasty	01JAN1993	31DEC1993	N
	C4591001 1125 11251004	Hepatobiliary disorders	Cholelithiasis obstructive	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	28JUN2018	28JUN2018	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1125 11251005	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1125 11251006	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1125 11251007	Cardiac disorders	Tachycardia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Nausea	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1992		Y
		Investigations	Oesophagogastroduodenoscopy	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1125 11251010	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020	31DEC2020	N
		Investigations	Endoscopy	01JUN2020	30JUN2020	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	01JAN2018	31DEC2018	N
			Fallopian tube operation	01JAN2018	31DEC2018	N
			Oesophageal dilation procedure	01JUN2020	30JUN2020	N
	C4591001 1125 11251014	Endocrine disorders	Hyperthyroidism	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Discomfort	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	19AUG2004	19AUG2004	N
			Radioactive iodine therapy	01JAN1994	31DEC1994	N
	C4591001 1125 11251015	Congenital, familial and genetic disorders	Factor V deficiency	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Tenolysis	04AUG2020	04AUG2020	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1125 11251017	General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1125 11251019	Investigations	Hormone level abnormal	01JUN2020		Y
	C4591001 1125 11251020	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Contraceptive implant	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1125 11251021	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1125 11251022	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Surgical and medical procedures	Caesarean section	12DEC2019	12DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intra-uterine contraceptive device insertion	13AUG2020		Y
	C4591001 1125 11251023	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1125 11251024	Eye disorders	Myopia	01JAN2005	31JUL2020	N
		General disorders and administration site conditions	Precancerous condition	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Eye laser surgery	31JUL2020	31JUL2020	N
			Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1125 11251025	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Injury, poisoning and procedural complications	Postoperative adhesion	01JAN1988	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Intracranial pressure increased	01JAN2013		Y
			Restless legs syndrome	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1988	N
		Social circumstances	Postmenopause	01JAN1988		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
			Intestinal resection	01JAN2013	31DEC2013	N
	C4591001 1125 11251027	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Cholecystitis	01NOV2018	30NOV2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2018	30NOV2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251028	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1125 11251029	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1125 11251030	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1125 11251031	General disorders and administration site conditions	Discomfort	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1125 11251033	Immune system disorders	Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1125 11251034	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01SEP2018	30SEP2018	N
	C4591001 1125 11251036	Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2019		Y
	C4591001 1125 11251038	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1125 11251039	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
	C4591001 1125 11251040	Metabolism and nutrition disorders	Obesity	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2018		Y
	C4591001 1125 11251044	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Vitamin D deficiency	01JAN2018		Y
		Social circumstances	Menopause	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251045	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2017		Y
	C4591001 1125 11251049	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1125 11251050	Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1125 11251053	Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1125 11251059	Surgical and medical procedures	Removal of foreign body	01JAN2019	31DEC2019	N
	C4591001 1125 11251061	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Smear cervix abnormal	01DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01DEC2019	31DEC2019	N
	C4591001 1125 11251062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Inguinal hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1125 11251067	Cardiac disorders	Bradycardia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01APR2018	31OCT2018	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Neurectomy	01OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251075	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1125 11251081	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1125 11251086	Social circumstances	Tobacco user	01JAN1995		Y
	C4591001 1125 11251087	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1125 11251091	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2010		Y
	C4591001 1125 11251094	Endocrine disorders	Hypothyroidism	05DEC2019		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1125 11251096	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1125 11251097	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Fibromyalgia	01JAN2017		Y
			Spinal stenosis	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nightmare	01JAN2015		Y
	C4591001 1125 11251098	Surgical and medical procedures	Spinal fusion surgery	23DEC2019	23DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1125 11251101	Skin and subcutaneous tissue disorders	Hypohidrosis	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Reproductive system and breast disorders	Uterine adhesions	01JAN2000	31JAN2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31JAN2000	N
	C4591001 1125 11251102	Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Insomnia	01JAN1994		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1994		Y
	C4591001 1125 11251105	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251106	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1125 11251108	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2017		Y
	C4591001 1125 11251109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1125 11251117	Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1125 11251119	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Uvulopalatopharyngoplasty	01JAN2013	31DEC2013	N
	C4591001 1125 11251124	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1125 11251126	Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1125 11251127	Immune system disorders	Iodine allergy	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2018	30APR2019	N
		Psychiatric disorders	Anxiety	01AUG2019		Y
			Depression	01AUG2019		Y
	C4591001 1125 11251128	Surgical and medical procedures	Osteotomy	01APR2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
	C4591001 1125 11251131	Endocrine disorders	Goitre	01APR2017	16JUL2020	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1125 11251132	Surgical and medical procedures	Thyroidectomy	16JUL2017	16JUL2017	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Nervous system disorders	Tarsal tunnel syndrome	01JAN2019		Y
	C4591001 1125 11251134	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1125 11251135	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
	C4591001 1125 11251136	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251138	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
	C4591001 1125 11251140	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
		Surgical and medical procedures	Benign breast lump removal	01AUG2019	31AUG2019	N
	C4591001 1125 11251146	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1125 11251148	Gastrointestinal disorders	Anal fissure	01JAN2005	31DEC2005	N
			Constipation	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Anal fistula repair	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1125 11251150	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1125 11251151	Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1990		Y
	C4591001 1125 11251152	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1125 11251156	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1125 11251158	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Investigations	Colonoscopy	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN1990		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1125 11251159	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	06MAY2015	06MAY2015	N
		Vascular disorders	Thrombosis	01JAN2012		Y
	C4591001 1125 11251160	General disorders and administration site conditions	Pain	01JAN2009		Y
		Immune system disorders	Allergy to vaccine	01JAN1983		Y
			Drug hypersensitivity	01JAN1981		Y
				01JAN1994		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31DEC2009	N
		Psychiatric disorders	Alcohol abuse	01JAN1988	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Limb operation	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1125 11251162	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2013		Y
	C4591001 1125 11251167	Immune system disorders	Seasonal allergy	01JAN1987		Y
	C4591001 1125 11251168	Gastrointestinal disorders	Dysphagia	01AUG2020	01AUG2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1985		Y
		Investigations	Oesophagogastroduodenoscopy	01AUG2020	01AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1125 11251169	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN1992		Y
				01JAN1994		Y
			Seasonal allergy	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Intervertebral disc protrusion	01JAN2014	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1995	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2011	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septal operation	01JAN2016	31DEC2016	N
			Oophorectomy bilateral	01JAN2003	31DEC2003	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1125 11251170	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1125 11251174	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
			Post-traumatic stress disorder	01JAN2002		Y
	C4591001 1125 11251176	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1125 11251177	Cardiac disorders	Cardiac failure congestive	01JAN2015		Y
			Coronary artery occlusion	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Nausea	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Intervertebral disc protrusion	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	21MAY2015	21MAY2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251178	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2016		Y
				01JAN2017		Y
	C4591001 1125 11251180	Endocrine disorders	Hypothyroidism	01APR2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2020		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1125 11251181	Immune system disorders	Seasonal allergy	01JAN2002		Y
	C4591001 1125 11251182	Infections and infestations	West Nile viral infection	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01NOV2019	30NOV2019	N
	C4591001 1125 11251183	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1125 11251184	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2003		Y
	C4591001 1125 11251193	Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Chemotherapy	01JAN1992	31DEC1992	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric banding	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1125 11251197	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1125 11251198	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1125 11251200	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1125 11251202	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1125 11251207	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1125 11251208	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2008	31DEC2008	N
	C4591001 1125 11251212	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1125 11251213	Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01NOV2017	30NOV2017	N
	C4591001 1125 11251214	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017	31JAN2017	N
	C4591001 1125 11251215	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1125 11251218	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Nervous system disorders	Migraine	01JAN1994		Y
	C4591001 1125 11251219	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Intervertebral disc protrusion	01JAN2013	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2014	31DEC2014	N
	C4591001 1125 11251221	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1125 11251237	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1125 11251238	Immune system disorders	Allergy to animal	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1125 11251243	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1126 11261005	Injury, poisoning and procedural complications	Exposure to communicable disease	01JAN2018	13JAN2020	N
	C4591001 1126 11261006	Endocrine disorders	Autoimmune thyroiditis	08OCT2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	24SEP2019		Y
		Psychiatric disorders	Major depression	21MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	19MAY2008		Y
			Rhinitis allergic	19MAY2008		Y
		Skin and subcutaneous tissue disorders	Urticaria	29DEC2007		Y
	C4591001 1126 11261009	Endocrine disorders	Hypothyroidism	14JAN2005		Y
		Gastrointestinal disorders	Oesophageal stenosis	22NOV2011		Y
		Immune system disorders	Drug hypersensitivity	19FEB2008		Y
			Rubber sensitivity	19FEB2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	08JUN2010		Y
		Surgical and medical procedures	Hormone replacement therapy	07SEP2019		Y
	C4591001 1126 11261010	Congenital, familial and genetic disorders	Atrial septal defect	27JUN2017	13JUL2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	07APR2017		Y
		Nervous system disorders	Cerebellar stroke	29MAR2017	02APR2017	N
		Surgical and medical procedures	Atrial septal defect repair	12JUL2017	12JUL2017	N
		Vascular disorders	Hypertension	07APR2017		Y
			May-Thurner syndrome	28JUN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1126 11261011	Gastrointestinal disorders	Gastroesophageal reflux disease	14DEC2012		Y
		Immune system disorders	Drug hypersensitivity	28SEP1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	12SEP2016		Y
		Renal and urinary disorders	Nephrolithiasis	29JUL2018	09AUG2018	N
		Surgical and medical procedures	Salpingectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	17APR2007		Y
	C4591001 1126 11261012	Nervous system disorders	Migraine	06AUG2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	22NOV2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16JUN2017		Y
	C4591001 1126 11261013	Nervous system disorders	Migraine	20JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07NOV2019		Y
			Sleep apnoea syndrome	26JUL2018		Y
	C4591001 1126 11261014	Immune system disorders	Drug hypersensitivity	17MAR2014		Y
			Food allergy	01JAN2000		Y
	C4591001 1126 11261017	Blood and lymphatic system disorders	Coagulopathy	01MAR2019		Y
		Immune system disorders	Allergy to arthropod sting	13MAR2015		Y
					20MAR2015	N
		Investigations	Human papilloma virus test positive	05APR2019	28JUN2019	N
		Metabolism and nutrition disorders	Iron deficiency	01OCT2015		Y
		Nervous system disorders	Migraine with aura	15JUL2018		Y
		Psychiatric disorders	Major depression	21MAR2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	31MAR2015	01MAR2018	N
		Vascular disorders	Hypertension	18JUN2015	01JUN2016	N
	C4591001 1126 11261018	Gastrointestinal disorders	Diverticulum	21JUN2011		Y
		Immune system disorders	Drug hypersensitivity	31JUL2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	21DEC2017		Y
		Vascular disorders	Aortic arteriosclerosis	31JUL2018		Y
	C4591001 1126 11261019	Metabolism and nutrition disorders	Obesity	24NOV2008		Y
	C4591001 1126 11261021	Cardiac disorders	Coronary artery disease	08JAN2018		Y
			Ischaemic cardiomyopathy	08JAN2018		Y
			Myocardial infarction	04JAN2018	04JAN2018	N
		Gastrointestinal disorders	Diverticulum intestinal	22JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05JUN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	02JUL2018		Y
		Vascular disorders	Hypertension	15APR2008		Y
	C4591001 1126 11261024	Infections and infestations	Rhinitis	15JUL2011		Y
	C4591001 1126 11261029	Surgical and medical procedures	Female sterilisation	31OCT2018	31OCT2018	N
	C4591001 1126 11261030	Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	17MAY2019		Y
	C4591001 1126 11261033	Musculoskeletal and connective tissue disorders	Back pain	28JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Cough variant asthma	09JUL2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal polyps	28OCT2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1126 11261034	Gastrointestinal disorders	Gastroesophageal reflux disease	06JAN2020		Y
	C4591001 1126 11261035	Skin and subcutaneous tissue disorders	Acne	24AUG2017		Y
	C4591001 1126 11261037	Gastrointestinal disorders	Gastroesophageal reflux disease	21APR2019		Y
		Immune system disorders	Food allergy	31JUL2009		Y
		Surgical and medical procedures	Hysterectomy	24MAY2016	24MAY2016	N
	C4591001 1126 11261039	Infections and infestations	Genital herpes simplex	14APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	14APR2020		Y
	C4591001 1126 11261040	Endocrine disorders	Hypothyroidism	09JUL2018		Y
		Infections and infestations	Diverticulitis	01JAN2009	31DEC2009	N
			Herpes simplex	21NOV2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16JUL2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	09JUL2018		Y
		Surgical and medical procedures	Colectomy	01JAN2009	31DEC2009	N
	C4591001 1126 11261041	General disorders and administration site conditions	Pain	03AUG2015		Y
		Nervous system disorders	Epilepsy	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Psoriasis	29APR2003		Y
	C4591001 1126 11261043	Immune system disorders	Drug hypersensitivity	04JUL2001		Y
				11FEB2004		Y
		Infections and infestations	Genital herpes simplex	27MAY2014		Y
		Psychiatric disorders	Anxiety disorder	13MAY2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	17JUL2017		Y
		Surgical and medical procedures	Hysterectomy	27MAY2012	27MAY2012	N
			Salpingectomy	27MAY2012	27MAY2012	N
		Vascular disorders	Hypertension	10MAY2012		Y
	C4591001 1126 11261044	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC2015		Y
	C4591001 1126 11261046	Respiratory, thoracic and mediastinal disorders	Asthma	29DEC2008		Y
	C4591001 1126 11261047	Immune system disorders	Drug hypersensitivity	04MAR2016		Y
				16MAR2018		Y
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	18DEC2018		Y
		Vascular disorders	Hypertension	04APR2014		Y
	C4591001 1126 11261048	Surgical and medical procedures	Cholecystectomy	15DEC2011	15DEC2011	N
	C4591001 1126 11261055	Gastrointestinal disorders	Gastroesophageal reflux disease	22AUG2017		Y
		Immune system disorders	Drug hypersensitivity	22AUG2017		Y
			Rubber sensitivity	22AUG2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1126 11261056	Blood and lymphatic system disorders	Iron deficiency anaemia	09MAR2017		Y
		Immune system disorders	Drug hypersensitivity	02JUN2000		Y
	C4591001 1126 11261060	Psychiatric disorders	Anxiety disorder	21JUL2016		Y
	C4591001 1126 11261061	Eye disorders	Angle closure glaucoma	23NOV2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	22NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	30MAY2020		Y
			Lumbar spinal stenosis	30MAY2020		Y
		Nervous system disorders	Lumbar radiculopathy	01JUN2020		Y
	C4591001 1126 11261063	Endocrine disorders	Hypothyroidism	29JUN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16DEC2010		Y
		Hepatobiliary disorders	Cholelithiasis	27SEP2012	04OCT2012	N
		Immune system disorders	Drug hypersensitivity	29AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	29JUN2007		Y
		Surgical and medical procedures	Cholecystectomy	04OCT2012	04OCT2012	N
	C4591001 1126 11261064	Metabolism and nutrition disorders	Type 2 diabetes mellitus	21DEC2011		Y
	C4591001 1126 11261068	Gastrointestinal disorders	Gastroesophageal reflux disease	20MAR2006		Y
		Psychiatric disorders	Major depression	20JAN2015		Y
		Reproductive system and breast disorders	Cervical dysplasia	21DEC2016	11JUN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	04MAR2005		Y
		Surgical and medical procedures	Gastric bypass	28MAY2008	28MAY2008	N
	C4591001 1126 11261074	Injury, poisoning and procedural complications	Post procedural hypothyroidism	02JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nasopharyngeal cancer	16MAY2018	31OCT2018	N
			Thyroid cancer	29MAY2018	02JUN2018	N
		Surgical and medical procedures	Thyroidectomy	02JUN2018	02JUN2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261076	Endocrine disorders	Hypothyroidism	09SEP2015		Y
	C4591001 1126 11261078	Immune system disorders	Allergy to plants	09JAN2012		Y
			Food allergy	09JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	02MAY2018		Y
		Nervous system disorders	Migraine	03JUL2006		Y
		Psychiatric disorders	Depression	05AUG2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	16APR2013		Y
	C4591001 1126 11261080	Hepatobiliary disorders	Cholelithiasis	01JAN2013	02JAN2013	N
		Metabolism and nutrition disorders	Obesity	26AUG2008		Y
		Psychiatric disorders	Generalised anxiety disorder	14SEP2007		Y
		Reproductive system and breast disorders	Infertility female	05APR2016		Y
			Polycystic ovaries	10SEP2015		Y
		Surgical and medical procedures	Cholecystectomy	02JAN2013	02JAN2013	N
	C4591001 1126 11261081	Immune system disorders	Allergy to arthropod sting	01DEC2015		Y
		Metabolism and nutrition disorders	Obesity	07APR2017		Y
		Psychiatric disorders	Major depression	01DEC2015	23JUN2017	N
	C4591001 1126 11261082	Immune system disorders	Drug hypersensitivity	22NOV2016		Y
	C4591001 1126 11261083	Blood and lymphatic system disorders	Iron deficiency anaemia	05OCT2016	30DEC2019	N
		Immune system disorders	Drug hypersensitivity	06AUG2012		Y
	C4591001 1126 11261086	Gastrointestinal disorders	Gastroesophageal reflux disease	02DEC2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	29MAY2006		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	28NOV2012		Y
	C4591001 1126 11261093	Skin and subcutaneous tissue disorders	Eczema nummular	27JAN2014		Y
		Cardiac disorders	Supraventricular tachycardia	01JAN2006		Y
		Congenital, familial and genetic disorders	Bicuspid aortic valve	01DEC2012		Y
		Immune system disorders	Drug hypersensitivity	11FEB2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2013	31MAY2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	13OCT2009		Y
	C4591001 1126 11261099	Surgical and medical procedures	Electrodesiccation	01MAY2013	31MAY2013	N
		Eye disorders	Open angle glaucoma	19AUG2016		Y
		Hepatobiliary disorders	Gallbladder polyp	01JAN2009	27DEC2018	N
		Surgical and medical procedures	Cholecystectomy	27DEC2018	27DEC2018	N
	C4591001 1126 11261103	Metabolism and nutrition disorders	Hyperlipidaemia	23JUL2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	18DEC2009		Y
			Rhinitis allergic	03JUL2002		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1126 11261104	Gastrointestinal disorders	Gastritis	14APR2017		Y
			Pancreatitis chronic	04MAY2015		Y
		Metabolism and nutrition disorders	Iron deficiency	10JUL2014	04OCT2018	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	10NOV2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	20JUL2009		Y
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Raynaud's phenomenon	31JAN2017		Y
	C4591001 1126 11261109	Musculoskeletal and connective tissue disorders	Arthropathy	15JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1126 11261111	Endocrine disorders	Hypothyroidism	13AUG2015		Y
		Immune system disorders	Drug hypersensitivity	13AUG2015		Y
		Infections and infestations	Genital herpes simplex	13AUG2015		Y
		Reproductive system and breast disorders	Ovarian cyst	25MAR2020		Y
	C4591001 1126 11261113	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09JUN2010		Y
	C4591001 1126 11261114	Ear and labyrinth disorders	Deafness unilateral	03DEC2019		Y
		Immune system disorders	Drug hypersensitivity	13DEC2018		Y
				19NOV2015		Y
			Food allergy	02JUN2018		Y
			Iodine allergy	02JUN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN1999	31DEC1999	N
		Nervous system disorders	Lumbar radiculopathy	15APR2020		Y
			Nerve compression	09JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	08MAR2019		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2013	31DEC2013	N
			Caesarean section	19JUN2020	19JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mastectomy	01JAN2012	31DEC2012	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
	C4591001 1126 11261115	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18APR2019		Y
	C4591001 1126 11261121	Immune system disorders	Drug hypersensitivity	20JUL2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	20NOV2016		Y
		Nervous system disorders	Migraine with aura	07DEC2018		Y
	C4591001 1126 11261124	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	29JAN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
			Bulimia nervosa	01JAN1990		Y
	C4591001 1126 11261126	Gastrointestinal disorders	Dyspepsia	08JUN2017		Y
		Psychiatric disorders	Anxiety	05DEC2016		Y
	C4591001 1126 11261128	Immune system disorders	Allergy to animal	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05AUG2011		Y
		Reproductive system and breast disorders	Erectile dysfunction	07JUL2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	02JUN2000		Y
	C4591001 1126 11261131	Metabolism and nutrition disorders	Hyperlipidaemia	21OCT2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	21OCT2019		Y
	C4591001 1126 11261134	Injury, poisoning and procedural complications	Post procedural hypothyroidism	02JUN2018		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nasopharyngeal cancer	16MAY2018	31OCT2018	N
			Papillary thyroid cancer	29MAY2018	02JUN2018	N
		Surgical and medical procedures	Thyroidectomy	02JUN2018	02JUN2018	N
	C4591001 1126 11261141	Immune system disorders	Drug hypersensitivity	19JUN2015		Y
				26MAY2015		Y
				28MAY2014		Y
		Nervous system disorders	Migraine without aura	05JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	28MAY2014		Y
	C4591001 1126 11261142	Endocrine disorders	Hypothyroidism	16JUL2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	06FEB2017		Y
			Hyperlipidaemia	07APR2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12MAR2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	19NOV2019		Y
			Urticaria	24MAY2007		Y
	C4591001 1126 11261143	Cardiac disorders	Supraventricular tachycardia	18JUN2018		Y
		General disorders and administration site conditions	Chest pain	14APR2010		Y
		Immune system disorders	Drug hypersensitivity	22MAY2001		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	23JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	18JUL2009	09APR2018	N
	C4591001 1126 11261144	Respiratory, thoracic and mediastinal disorders	Asthma	08NOV2006	01JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261145	Cardiac disorders	Acute myocardial infarction	07SEP2018	07SEP2018	N
			Atrial fibrillation	10SEP2018		Y
			Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12SEP2019		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	08DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	23JUL2003		Y
		Surgical and medical procedures	Coronary artery bypass	08SEP2018	08SEP2018	N
		Vascular disorders	Hypertension	20FEB2003		Y
	C4591001 1126 11261148	Gastrointestinal disorders	Small intestinal obstruction	16MAR2019	16MAR2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	14JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JAN2014		Y
			Rhinitis allergic	25OCT2012		Y
		Skin and subcutaneous tissue disorders	Skin mass	03JUN2019	06NOV2019	N
	C4591001 1126 11261149	Immune system disorders	Drug hypersensitivity	30NOV2012		Y
		Metabolism and nutrition disorders	Iron deficiency	23AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	19SEP2014		Y
			Rhinitis allergic	17OCT2017		Y
	C4591001 1126 11261150	Congenital, familial and genetic disorders	Keratosi follicular	17SEP2018		Y
		Eye disorders	Astigmatism	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	13AUG2018		Y
		Metabolism and nutrition disorders	Obesity	09MAY2019		Y
			Type 2 diabetes mellitus	04AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	11JUN2019		Y
			Neck pain	14AUG2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	14AUG2018		Y
		Vascular disorders	Hypertension	04AUG2018		Y
	C4591001 1126 11261151	Gastrointestinal disorders	Large intestine polyp	24OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	07JUN2018		Y
			Sleep apnoea syndrome	14DEC2018		Y
	C4591001 1126 11261157	Gastrointestinal disorders	Gastroesophageal reflux disease	10JAN2020		Y
		General disorders and administration site conditions	Drug intolerance	02APR2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	12JUN2017	N
		Injury, poisoning and procedural complications	Ligament rupture	09MAR2015	23APR2015	N
			Meniscus injury	09MAR2015	23APR2015	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	07NOV2012	28NOV2012	N
		Psychiatric disorders	Anxiety	10OCT2019		Y
		Surgical and medical procedures	Cholecystectomy	12JUN2017	12JUN2017	N
			Chondroplasty	23APR2015	23APR2015	N
			Intervertebral disc operation	28NOV2012	28NOV2012	N
			Ligament operation	23APR2015	23APR2015	N
	C4591001 1126 11261161	Infections and infestations	Genital herpes simplex	15APR2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	12JAN2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2003	N
		Surgical and medical procedures	Myomectomy	01JAN2003	31DEC2003	N
	C4591001 1126 11261166	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	28JUN2019	13AUG2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2016		Y
		Surgical and medical procedures	Rotator cuff repair	13AUG2019	13AUG2019	N
	C4591001 1126 11261170	Congenital, familial and genetic disorders	Factor V Leiden mutation	06NOV2012		Y
		Endocrine disorders	Hypothyroidism	11SEP2018		Y
		Gastrointestinal disorders	Gastrointestinal haemorrhage	17MAY2019	17MAY2019	N
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	10DEC2017	10DEC2017	N
			Premature separation of placenta	10DEC2017	10DEC2017	N
		Psychiatric disorders	Major depression	30JAN2018	01DEC2018	N
		Reproductive system and breast disorders	Infertility female	24AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29MAY2007		Y
			Sleep apnoea syndrome	29MAY2007		Y
	C4591001 1126 11261171	Endocrine disorders	Hypothyroidism	04FEB2019		Y
		Skin and subcutaneous tissue disorders	Vitiligo	04FEB2019		Y
	C4591001 1126 11261172	Psychiatric disorders	Depression	09OCT2019		Y
	C4591001 1126 11261173	Endocrine disorders	Hypothyroidism	04JUN2019		Y
		Immune system disorders	Drug hypersensitivity	17SEP2003		Y
		Nervous system disorders	Migraine	02SEP2009		Y
			Sciatica	09DEC2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Urticaria	11MAR2009		Y
	C4591001 1126 11261177	Immune system disorders	Drug hypersensitivity	01MAR2004		Y
				30JUL2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	09DEC2014		Y
		Nervous system disorders	Carpal tunnel syndrome	17JAN2013	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	07NOV2007		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N
		Vascular disorders	Varicose vein	06NOV2019		Y
	C4591001 1126 11261178	Blood and lymphatic system disorders	Eosinophilia	29JUL2011		Y
		Immune system disorders	Rubber sensitivity	04JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Xanthogranuloma	14JUL2011		Y
		Reproductive system and breast disorders	Menorrhagia	11JUL2018	22AUG2018	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	04JAN2016		Y
			Hyperhidrosis	09DEC2013		Y
		Surgical and medical procedures	Endometrial ablation	22AUG2018	22AUG2018	N
			Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1126 11261182	Respiratory, thoracic and mediastinal disorders	Upper airway resistance syndrome	09NOV2018	01JUL2019	N
	C4591001 1126 11261183	Metabolism and nutrition disorders	Hyperlipidaemia	28MAY2019		Y
	C4591001 1126 11261184	Blood and lymphatic system disorders	Iron deficiency anaemia	03FEB2009		Y
		Skin and subcutaneous tissue disorders	Acne	29SEP2008		Y
	C4591001 1126 11261185	Hepatobiliary disorders	Cholecystitis acute	17NOV2014	25NOV2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	02JUN2011		Y
			Obesity	26MAY2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	21AUG2019		Y
		Surgical and medical procedures	Cholecystectomy	25NOV2014	25NOV2014	N
			Uvulopalatopharyngoplasty	03SEP2019	03SEP2019	N
	C4591001 1126 11261186	Metabolism and nutrition disorders	Obesity	11JAN2019		Y
			Type 2 diabetes mellitus	14FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	06MAY2019		Y
		Vascular disorders	Hypertension	14FEB2019		Y
	C4591001 1126 11261187	Respiratory, thoracic and mediastinal disorders	Asthma	06JUL2015	01SEP2019	N
	C4591001 1126 11261189	Eye disorders	Iritis	18MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibrous histiocytoma	15MAR2019		Y
	C4591001 1126 11261190	Nervous system disorders	Migraine	25AUG2015		Y
	C4591001 1126 11261191	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	20APR2020		Y
	C4591001 1126 11261192	Endocrine disorders	Hypothyroidism	20SEP1996		Y
		Gastrointestinal disorders	Irritable bowel syndrome	20DEC1995		Y
		Immune system disorders	Drug hypersensitivity	13FEB2018		Y
				29SEP1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	22MAY2006		Y
		Skin and subcutaneous tissue disorders	Eczema	17JUL2015		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1126 11261193	Ear and labyrinth disorders	Deafness	08MAR2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	11NOV2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08MAY2003		Y
	C4591001 1126 11261194	Gastrointestinal disorders	Dyspepsia	25APR2019		Y
		Immune system disorders	Iodine allergy	09SEP2020		Y
		Metabolism and nutrition disorders	Obesity	13FEB2019		Y
		Nervous system disorders	Migraine	31JUL2006		Y
		Psychiatric disorders	Anxiety disorder	24DEC2013		Y
			Major depression	14MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14OCT2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	11NOV2016		Y
	C4591001 1126 11261195	Endocrine disorders	Hypothyroidism	08JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	09SEP2010		Y
				28MAY2009		Y
		Infections and infestations	Pharyngitis	04JUN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13OCT2003		Y
			Obesity	08JAN2003		Y
			Type 2 diabetes mellitus	28AUG2001		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	09NOV2005	22SEP2010	N
		Nervous system disorders	Neuropathy peripheral	17MAR2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	28MAR2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	23AUG2006		Y
		Surgical and medical procedures	Intervertebral disc operation	22SEP2010	22SEP2010	N
	C4591001 1126 11261196	Immune system disorders	Allergy to animal	10OCT2019		Y
			Drug hypersensitivity	19FEB2020		Y
				22APR2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	29JAN2007		Y
			Rhinitis allergic	25SEP2007		Y
	C4591001 1126 11261197	Metabolism and nutrition disorders	Vitamin D deficiency	14OCT2018		Y
	C4591001 1126 11261198	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Reproductive system and breast disorders	Infertility female	04OCT2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12MAR2020		Y
			Sleep apnoea syndrome	22DEC2017		Y
		Vascular disorders	Hypertension	03MAY2008		Y
	C4591001 1126 11261201	Gastrointestinal disorders	Gastroesophageal reflux disease	09OCT2017		Y
		Psychiatric disorders	Anxiety disorder	25MAR2020		Y
			Attention deficit hyperactivity disorder	09MAY2018		Y
			Selective eating disorder	15SEP2015	19APR2018	N
	C4591001 1126 11261202	Psychiatric disorders	Attention deficit hyperactivity disorder	12APR2017		Y
	C4591001 1126 11261208	Immune system disorders	Drug hypersensitivity	01JUL2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01SEP2005		Y
	C4591001 1126 11261209	Ear and labyrinth disorders	Motion sickness	02SEP2014		Y
		Nervous system disorders	Migraine	14JUL2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01OCT2019		Y
			Rhinitis allergic	09APR2009		Y
	C4591001 1126 11261210	Respiratory, thoracic and mediastinal disorders	Asthma	30MAY2006		Y
	C4591001 1126 11261211	Infections and infestations	Cellulitis	19OCT2020	29OCT2020	N
	C4591001 1126 11261212	Skin and subcutaneous tissue disorders	Acne	01JUL2018		Y
	C4591001 1126 11261213	Immune system disorders	Seasonal allergy	01APR2011		Y
	C4591001 1126 11261216	Psychiatric disorders	Anxiety disorder	08JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	27APR2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2016		Y
	C4591001 1126 11261217	Gastrointestinal disorders	Tooth impacted	01JAN2020		Y
	C4591001 1126 11261218	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	15JUL2020		Y
		Surgical and medical procedures	Wisdom teeth removal	22JUL2020	22JUL2020	N
	C4591001 1126 11261221	Gastrointestinal disorders	Gastroesophageal reflux disease	03APR2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	27MAR2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261222	Musculoskeletal and connective tissue disorders	Scoliosis	05FEB2020		Y
	C4591001 1126 11261223	Psychiatric disorders	Tic	01JUL2020		Y
	C4591001 1126 11261224	Psychiatric disorders	Attention deficit hyperactivity disorder	30MAR2013		Y
	C4591001 1126 11261226	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1126 11261227	Gastrointestinal disorders	Eosinophilic oesophagitis	09NOV2016	15MAY2020	N
		Immune system disorders	Flour sensitivity	17JAN2020		Y
			Seasonal allergy	16NOV2016		Y
	C4591001 1126 11261228	Congenital, familial and genetic disorders	Phimosis	17AUG2020		Y
		Immune system disorders	Seasonal allergy	10OCT2014		Y
		Nervous system disorders	Migraine	05MAR2014		Y
		Psychiatric disorders	Generalised anxiety disorder	06AUG2019		Y
			Major depression	21JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05MAR2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	10OCT2020		Y
	C4591001 1126 11261232	Psychiatric disorders	Depression	18JAN2019		Y
			Generalised anxiety disorder	18JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07MAY2008		Y
			Rhinitis allergic	19MAY2008		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	06DEC2017		Y
			Urticaria	24APR2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261234	Congenital, familial and genetic disorders	Urethral valves	(b) (6)2003		Y
		Renal and urinary disorders	Hydronephrosis	28SEP2015	18JUN2019	N
		Reproductive system and breast disorders	Epididymal cyst	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	23NOV2016		Y
		Surgical and medical procedures	Urethral operation	(b) (6)2003	(b) (6)2003	N
				30APR2004	30APR2004	N
				30AUG2004	30AUG2004	N
	C4591001 1126 11261236	Immune system disorders	Food allergy	22FEB2010		Y
			Seasonal allergy	09JUL2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11FEB2010		Y
	C4591001 1126 11261237	Gastrointestinal disorders	Gastroesophageal reflux disease	29JUN2017		Y
		Investigations	Body mass index increased	22MAR2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29JUN2017		Y
		Skin and subcutaneous tissue disorders	Acne	15AUG2019		Y
	C4591001 1126 11261238	Psychiatric disorders	Attention deficit hyperactivity disorder	21DEC2015		Y
			Autism spectrum disorder	30NOV2005		Y
	C4591001 1126 11261242	Congenital, familial and genetic disorders	Congenital flat feet	10JUL2014		Y
			Femoral anteversion	10JUL2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	02APR2013		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1126 11261244	Respiratory, thoracic and mediastinal disorders	Asthma	20APR2010		Y
		Skin and subcutaneous tissue disorders	Acne	22JAN2018		Y
	C4591001 1126 11261245	Injury, poisoning and procedural complications	Exposure to communicable disease	14JUL2016	31JUL2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	03FEB2012		Y
		Musculoskeletal and connective tissue disorders	Muscle tightness	09MAY2018		Y
	C4591001 1126 11261247	Respiratory, thoracic and mediastinal disorders	Asthma	16MAY2008		Y
	C4591001 1126 11261252	Psychiatric disorders	Attention deficit hyperactivity disorder	05MAR2012		Y
	C4591001 1126 11261256	Infections and infestations	Appendicitis	01NOV2020	01NOV2020	N
	C4591001 1126 11261257	Immune system disorders	Drug hypersensitivity	25APR2018		Y
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	15MAY2018		Y
		Skin and subcutaneous tissue disorders	Acne	21JUL2020		Y
	C4591001 1126 11261259	Gastrointestinal disorders	Irritable bowel syndrome	09DEC2019		Y
		Injury, poisoning and procedural complications	Concussion	13NOV2016	28FEB2019	N
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2019		Y
			Scoliosis	08JUN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Generalised anxiety disorder	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	26MAR2019		Y
			Menorrhagia	27DEC2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261260	Eye disorders	Iridodialysis	16JUN2008		Y
			Iritis	16JUN2008	23AUG2010	N
		Injury, poisoning and procedural complications	Cataract traumatic	31MAY2016		Y
			Hyphaema	16JUN2008	23AUG2010	N
		Metabolism and nutrition disorders	Iron deficiency	12JUL2019		Y
		Psychiatric disorders	Insomnia	15DEC2018		Y
		Skin and subcutaneous tissue disorders	Acne	07FEB2018		Y
	C4591001 1126 11261261	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	08DEC2011		Y
	C4591001 1127 11271004	Hepatobiliary disorders	Hepatic steatosis	01JAN2011		Y
	C4591001 1127 11271011	Eye disorders	Presbyopia	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Panic disorder	01JAN2005		Y
	C4591001 1127 11271014	Eye disorders	Cataract	01JUL2019		Y
			Eye allergy	01JAN2015		Y
			Hypermetropia	01JAN2017		Y
			Meibomian gland dysfunction	01JAN2010		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Hordeolum	21JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal disorder	01AUG2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1987		Y
			Nerve compression	01AUG2015		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2020		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
	C4591001 1127 11271015	Eye disorders	Myopia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Renal and urinary disorders	Dysuria	01JAN2019		Y
	C4591001 1127 11271016	Eye disorders	Hypermetropia	15JUL2020		Y
		Immune system disorders	Rubber sensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2015		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2015		Y
	C4591001 1127 11271017	Eye disorders	Myopia	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998	31DEC2000	N
	C4591001 1127 11271021	Gastrointestinal disorders	Dyspepsia	25JUL2020		Y
		Nervous system disorders	Headache	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUN2018	01DEC2018	N
	C4591001 1127 11271022	Eye disorders	Astigmatism	01JAN2014		Y
			Myopia	01JAN1988		Y
		Hepatobiliary disorders	Cholelithiasis	01JUN2016		Y
		Infections and infestations	Cellulitis	01MAR2019	31MAR2019	N
			Trichomoniasis	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2016	31MAR2016	N
	C4591001 1127 11271024	Eye disorders	Myopia	01JAN1980		Y
		Nervous system disorders	Headache	01JAN2012	31DEC2019	N
	C4591001 1127 11271025	Immune system disorders	Food allergy	01JAN1995		Y
			Iodine allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2020		Y
	C4591001 1127 11271026	Eye disorders	Astigmatism	01JAN1976		Y
			Myopia	01JAN1976		Y
		Injury, poisoning and procedural complications	Limb injury	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAR2018	31MAR2018	N
		Nervous system disorders	Migraine	01JAN1978		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2013		Y
			Post-traumatic stress disorder	01JUN2018		Y
		Renal and urinary disorders	Nocturia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Finger amputation	01JUN2019	30JUN2019	N
			Hysterectomy	01MAR2018	31MAR2018	N
	C4591001 1127 11271027	Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc degeneration	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2012	31DEC2018	N
	C4591001 1127 11271028	Immune system disorders	Drug hypersensitivity	31MAY2020		Y
			Seasonal allergy	01JAN1991		Y
	C4591001 1127 11271029	Blood and lymphatic system disorders	Anaemia	01JAN1995	31DEC2015	N
		Eye disorders	Astigmatism	01JAN1994		Y
			Myopia	01JAN1994		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2016	31DEC2016	N
			Seizure	01JAN1999		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1995	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1998		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271030	Eye disorders	Amblyopia	01MAR1981		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN1990		Y
			Seasonal allergy	(b) (6) 1978		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01MAR2008	31JAN2018	N
			Osteoarthritis	01MAR2000		Y
		Nervous system disorders	Essential tremor	01MAR2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2005		Y
		Surgical and medical procedures	Arthrodesis	01JAN2018	31JAN2018	N
		Vascular disorders	Hypertension	01MAR1998		Y
	C4591001 1127 11271032	Eye disorders	Astigmatism	01JAN2018		Y
			Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2001		Y
	C4591001 1127 11271033	Eye disorders	Presbyopia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2015		Y
	C4591001 1127 11271036	Eye disorders	Glaucoma	01JAN2009		Y
			Hypermetropia	01JAN1999		Y
			Myopia	01JAN1999		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01AUG1972		Y
			Seasonal allergy	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1999		Y
			Migraine	01JAN2018	01JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1127 11271040	Ear and labyrinth disorders	Deafness	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
			Restless legs syndrome	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1127 11271043	General disorders and administration site conditions	Fatigue	01JUL2020		Y
		Infections and infestations	Oral herpes	01JAN2006		Y
		Psychiatric disorders	Anxiety	01DEC2018		Y
	C4591001 1127 11271047	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1127 11271048	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Astigmatism	01JAN1992		Y
			Myopia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2006		Y
	C4591001 1127 11271052	Ear and labyrinth disorders	Tinnitus	01JAN2020		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1127 11271057	Eye disorders	Myopia	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1998		Y
	C4591001 1127 11271059	Eye disorders	Myopia	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1127 11271068	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Eye disorders	Astigmatism	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1127 11271069	Psychiatric disorders	Depression	01JAN1990		Y
	C4591001 1127 11271070	Endocrine disorders	Oestrogen deficiency	01JAN2001		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN1992		Y
			Vitamin D deficiency	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2001		Y
	C4591001 1127 11271072	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31JAN2016	N
		Vascular disorders	Thrombosis	01JAN2014	31DEC2015	N
	C4591001 1127 11271073	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Suicidal ideation	01JAN2015	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1127 11271076	Immune system disorders	Seasonal allergy	01MAR1996		Y
		Reproductive system and breast disorders	Menorrhagia	01OCT2017	31OCT2017	N
		Surgical and medical procedures	Hysterectomy	01OCT2017	31OCT2017	N
	C4591001 1127 11271077	Immune system disorders	Seasonal allergy	01MAR2010		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1127 11271079	Eye disorders	Blindness unilateral	(b) (6) 1968		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Fatigue	01JAN1998		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	24JUL2020		Y
		Nervous system disorders	Headache	01JAN1998		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1127 11271080	Cardiac disorders	Mitral valve prolapse	01JAN1985		Y
		Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Intervertebral disc degeneration	01JAN2006		Y
			Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1127 11271084	Eye disorders	Myopia	01JAN1979		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1127 11271085	Endocrine disorders	Hypothyroidism	01DEC2019		Y
			Oestrogen deficiency	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Bipolar disorder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005		Y
	C4591001 1127 11271086	Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
			Gastrooesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Allergy to metals	01JAN1993		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1993		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
				01JUL2016		Y
		Vascular disorders	Varicose vein	01JAN2019		Y
	C4591001 1127 11271087	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2011		Y
	C4591001 1127 11271096	Gastrointestinal disorders	Colitis ulcerative	01JAN1997		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2018		Y
	C4591001 1127 11271097	Immune system disorders	Drug hypersensitivity	01MAY2019		Y
			Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
			Dermatitis	01JAN2019		Y
	C4591001 1127 11271099	Eye disorders	Myopia	01JAN2016		Y
	C4591001 1127 11271101	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2000		Y
			Eczema	01JAN2018		Y
	C4591001 1127 11271102	Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1127 11271105	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1127 11271106	General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Salpingo-oophorectomy bilateral	13JUL2020	13JUL2020	N
	C4591001 1127 11271107	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
				01JAN2015		Y
		Metabolism and nutrition disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Fibromyalgia	01JAN2015		Y
			Intervertebral disc degeneration	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Panic attack	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Surgical and medical procedures	Gastric bypass	01JAN2017	31JAN2017	N
			Hysterectomy	01JAN2018	31JAN2018	N
	C4591001 1127 11271109	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Allergy to vaccine	01JAN1975		Y
			Food allergy	01JAN2005		Y
			Seasonal allergy	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
			Bursitis	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast cyst	01JAN2015		Y
			Premenstrual dysphoric disorder	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2010		Y
			Rosacea	01JAN2005		Y
	C4591001 1127 11271112	Cardiac disorders	Myocardial infarction	01JAN2008	31DEC2008	N
		Ear and labyrinth disorders	Tinnitus	01JAN1992		Y
		Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1990		Y
	C4591001 1128 11281001	Hepatobiliary disorders	Cholecystitis	01NOV2001	30NOV2001	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2019	31MAY2019	N
		Social circumstances	Postmenopause	01AUG2016		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2001	30NOV2001	N
			Uterine polypectomy	01MAY2019	31MAY2019	N
	C4591001 1128 11281002	Gastrointestinal disorders	Irritable bowel syndrome	01AUG2012		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
			Insomnia	01JAN2020		Y
			Obsessive-compulsive disorder	01DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1128 11281005	Immune system disorders	Hypersensitivity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Psychiatric disorders	Back pain	01JAN2014		Y
			Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1128 11281012	Musculoskeletal and connective tissue disorders	Neck pain	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1128 11281017	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	14AUG2018	14AUG2018	N
	C4591001 1128 11281018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1997	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2006		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1128 11281020	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1990	31DEC2000	N
			Ovarian cyst	01JAN1990	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2001	31DEC2003	N
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
				01JAN1993	31DEC1993	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Oophorectomy	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
	C4591001 1128 11281021	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1128 11281024	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2003	31DEC2003	N
				01MAY2003	31MAY2003	N
				01MAY2005	31MAY2005	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Breast enlargement	01JUL1986	31JUL1989	N
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
			Mammoplasty	01JUL1989	31JUL1989	N
			Uterine dilation and curettage	01MAY2003	31MAY2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01MAY2005	31MAY2005	N
	C4591001 1128 11281025	Vascular disorders	Hypertension	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1128 11281026	Vascular disorders	Hypertension	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y
			Depression	01FEB2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Gastric banding	01JAN2009		Y
	C4591001 1128 11281028	Vascular disorders	Hypertension	01JAN1984		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Overweight	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1128 11281029	Immune system disorders	Seasonal allergy	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	07APR1999	07APR1999	N
				18AUG1981	18AUG1981	N
				23OCT1995	23OCT1995	N
	C4591001 1128 11281030	Investigations	Blood testosterone decreased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1994		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cyst removal	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1128 11281031	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1997	31DEC2011	N
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
			Nasal septal operation	01JAN2011	31DEC2011	N
	C4591001 1128 11281035	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
			Tonsillitis	01JAN1977	31DEC1977	N
		Investigations	Blood cholesterol increased	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Epilepsy	01JAN1988		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1128 11281038	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1992		Y
		Nervous system disorders	Headache	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Bipolar disorder	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
			Hand dermatitis	01JAN1996		Y
	C4591001 1128 11281042	Immune system disorders	Multiple allergies	01JAN2015		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281045	Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281047	Psychiatric disorders	Depression	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1128 11281049	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01NOV2018	30NOV2018	N
	C4591001 1128 11281050	Vascular disorders	Hypertension	21APR2020		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
	C4591001 1128 11281054	Psychiatric disorders	Anxiety	01JAN2013		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01MAR2001		Y
	C4591001 1128 11281055	Surgical and medical procedures	Ligament operation	01MAY1995	31MAY1995	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1998		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
	C4591001 1128 11281057		Depression	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1128 11281061	Infections and infestations	Appendicitis	01DEC2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01DEC2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281062	Cardiac disorders	Atrial fibrillation	01JAN2010	30APR2011	N
		Hepatobiliary disorders	Cholecystitis	01NOV2003	30NOV2003	N
		Infections and infestations	Appendicitis	01APR2003	30APR2003	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Surgical and medical procedures	Appendectomy	01APR2003	30APR2003	N
			Cholecystectomy	01NOV2003	30NOV2003	N
			Cryotherapy	01APR2011	30APR2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281064	Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	19JUL2016	19JUL2016	N
	C4591001 1128 11281067	Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1128 11281070	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2018		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281071	General disorders and administration site conditions	Pain	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
	C4591001 1128 11281073	Nervous system disorders	Migraine	01JAN1982		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
	C4591001 1128 11281074	Surgical and medical procedures	Caesarean section	01MAR2006	01MAR2006	N
	C4591001 1128 11281078	Infections and infestations	Tonsillitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2013	31DEC2014	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Colectomy	01APR2014	30APR2014	N
			Colon operation	01APR2014	30APR2014	N
			Hysterectomy	01APR2014	30APR2014	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281080	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAY2020		Y
	C4591001 1128 11281083	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01NOV2012	30NOV2012	N
			Post abortion haemorrhage	01NOV2012	30NOV2012	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01NOV2012	30NOV2012	N
			Female sterilisation	01NOV2012	30NOV2012	N
			Uterine dilation and curettage	01NOV2012	30NOV2012	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1128 11281086	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Dry eye	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1128 11281092	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Haemorrhoids	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1998	31DEC1998	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1128 11281093	Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Immune system disorders	Anaphylactic reaction	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Abortion induced	01JAN1999	31DEC1999	N
				01JAN2002	31DEC2002	N
			Appendicectomy	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1128 11281094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1128 11281095	Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
	C4591001 1128 11281096	Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
	C4591001 1128 11281098	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1128 11281102	Gastrointestinal disorders	Dyspepsia	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
	C4591001 1128 11281103	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y
			Muscle spasms	01JAN2008		Y
			Osteopenia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1987		Y
			Restless legs syndrome	01JAN1988		Y
			Seizure	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2018		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1128 11281107	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1128 11281112	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01AUG2019		Y
		Surgical and medical procedures	Gastrectomy	01JAN2017		Y
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1128 11281114	Cardiac disorders	Palpitations	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Myalgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Renal and urinary disorders	Micturition urgency	01JUN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Rhinitis allergic	01JAN2016		Y
	C4591001 1128 11281116	Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Thoracic vertebral fracture	04AUG2018	05AUG2018	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2004	31DEC2004	N
			Medical device removal	05SEP2019	05SEP2019	N
			Spinal fusion surgery	05AUG2018	05AUG2018	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1128 11281117	Hepatobiliary disorders	Cholecystitis	01JAN2019	31DEC2019	N
		Immune system disorders	Iodine allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1994		Y
			Spinal osteoarthritis	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1128 11281119	Surgical and medical procedures	Cholecystectomy	01JAN2019	31JAN2019	N
		Psychiatric disorders	Depression	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1128 11281120	Surgical and medical procedures	Salpingectomy	01JUL2016	31JUL2016	N
		Infections and infestations	Tonsillitis	01JAN1990	31DEC2002	N
		Injury, poisoning and procedural complications	Contusion	01JUL2020		Y
	C4591001 1128 11281123	Surgical and medical procedures	Tonsillectomy	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Herpes zoster	01JAN2006		Y
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1128 11281124	Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
		Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1997		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Gastric bypass	01DEC2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1128 11281125	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1994		Y
	C4591001 1128 11281126	Surgical and medical procedures	Salpingectomy	01AUG2019	31AUG2019	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2016	31DEC2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	31DEC2019	N
	C4591001 1128 11281128	Eye disorders	Strabismus	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	17AUG1995		Y
	C4591001 1128 11281129	Surgical and medical procedures	Eye muscle operation	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN2010	31DEC2010	N
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2010	31DEC2010	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1128 11281132	Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Vascular disorders	Rhinitis allergic	01JAN1978		Y
			Hypertension	01JAN2018		Y
	C4591001 1128 11281134	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1128 11281135	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1128 11281137	Gastrointestinal disorders	Umbilical hernia	01JAN2013	31JAN2014	N
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Gastrectomy	01JUN2014	30JUN2014	N
			Umbilical hernia repair	01JUN2014	30JUN2014	N
	C4591001 1128 11281143	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011	31DEC2016	N
		Reproductive system and breast disorders	Adenomyosis	01JAN2012	31DEC2016	N
		Surgical and medical procedures	Endometrial ablation	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1128 11281145	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Investigations	Precancerous cells present	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Nicotine dependence	01JAN1996		Y
		Surgical and medical procedures	Caesarean section	11MAR2009	11MAR2009	N
			Female sterilisation	11MAR2009	11MAR2009	N
			Loop electrosurgical excision procedure	01JAN2012	31DEC2012	N
	C4591001 1128 11281146	Infections and infestations	Appendicitis	01JUN2019	30JUN2019	N
		Surgical and medical procedures	Appendectomy	01JUN2019	30JUN2019	N
	C4591001 1128 11281147	Gastrointestinal disorders	Large intestine polyp	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Foot operation	01JAN2019	31DEC2019	N
			Nasal polypectomy	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1128 11281151	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
	C4591001 1128 11281152	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1128 11281153	Congenital, familial and genetic disorders	Stargardt's disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1992		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Bipolar disorder	01JAN2005		Y
			Depression	01JAN1995		Y
			Insomnia	01JAN2014		Y
	C4591001 1128 11281155	Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1128 11281156	Injury, poisoning and procedural complications	Upper limb fracture	20JAN2019	31MAR2020	N
			Wrist fracture	20JAN2019	07FEB2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Surgical and medical procedures	Fracture treatment	07FEB2019	07FEB2019	N
			Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1128 11281157	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1128 11281159	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast enlargement	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1128 11281162	Immune system disorders	Seasonal allergy	01JAN1981		Y
	C4591001 1128 11281165	Gastrointestinal disorders	Tooth impacted	01JAN2011	31DEC2011	N
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2011	31DEC2011	N
	C4591001 1128 11281167	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1128 11281168	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Depression	01FEB2020		Y
	C4591001 1128 11281169	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1128 11281170	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
		Nervous system disorders	Migraine	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	24FEB2008	24FEB2008	N
				26JUN2009	26JUN2009	N
	C4591001 1128 11281171	Gastrointestinal disorders	Dyspepsia	01APR2020		Y
		Injury, poisoning and procedural complications	Sinus barotrauma	01JAN1989	31MAY2019	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Sinus operation	01MAY2019	31MAY2019	N
	C4591001 1128 11281173	Gastrointestinal disorders	Dyspepsia	01AUG2020		Y
		Immune system disorders	Seasonal allergy	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
	C4591001 1128 11281174	Eye disorders	Blindness unilateral	(b) (6) 1981		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N
	C4591001 1128 11281176	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Rhinitis allergic	01JAN2001		Y
	C4591001 1128 11281177	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1128 11281178	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Eye disorders	Cataract	01OCT2019		Y
			Chorioretinopathy	01OCT2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1982	31DEC2000	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2004	31DEC2004	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1998		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1973	31DEC1973	N
			Vasectomy	01JAN2013	31DEC2013	N
			Fatigue	01JAN2015		Y
	C4591001 1128 11281181	General disorders and administration site conditions				
		Musculoskeletal and connective tissue disorders	Myalgia	01FEB2020		Y
			Tendonitis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Surgical and medical procedures	Mammoplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281183	Ear and labyrinth disorders	Deafness bilateral	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Injury, poisoning and procedural complications	Tendon rupture	01NOV1995	31JAN1996	N
				01SEP1995	30NOV1995	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Obesity	01JAN1987		Y
			Type 2 diabetes mellitus	01JAN2016		Y
			Vitamin B complex deficiency	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Diabetic dermopathy	01JAN2017		Y
		Surgical and medical procedures	Elbow operation	01JAN1996	31JAN1996	N
				01NOV1995	30NOV1995	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1128 11281184	Nervous system disorders	Migraine	01JAN1987		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN1987	31DEC2006	N
		Surgical and medical procedures	Endometrial ablation	01JAN2006	31DEC2006	N
	C4591001 1128 11281187	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1128 11281188	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999		Y
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Psychiatric disorders	Panic attack	01JAN2007		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01FEB2020		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1128 11281190	Eye disorders	Cataract	01MAY2020	31JUL2020	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cataract operation	01JUL2020	31JUL2020	N
			Intervertebral disc operation	01JAN2018	31DEC2018	N
			Ligament operation	01JAN1993	31DEC1993	N
			Nasal septal operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1128 11281195	Ear and labyrinth disorders	Deafness unilateral	01JAN2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2001	31DEC2001	N
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2009	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1128 11281196	Infections and infestations	Pharyngitis streptococcal	01JAN2000	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1128 11281198	Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1128 11281199	Infections and infestations	Tonsillitis	01JAN1999	31DEC1999	N	
		Immune system disorders	Seasonal allergy	01JAN1975		Y	
	C4591001 1128 11281200	Infections and infestations	Pharyngitis streptococcal	01JAN1970	31DEC1977	N	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2000	31DEC2000	N	
		Skin and subcutaneous tissue disorders	Rash	01JUL2020	05JUL2020	N	
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N	
			Tonsillectomy	01JAN1977	31DEC1977	N	
	C4591001 1128 11281201	Nervous system disorders	Headache	01JAN1998		Y	
		Psychiatric disorders	Insomnia	09AUG2020		Y	
		Surgical and medical procedures	Caesarean section	13NOV2013	13NOV2013	N	
	C4591001 1128 11281202	Psychiatric disorders	Depression	01OCT2019	21APR2005	21APR2005	N
	C4591001 1128 11281204	Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N	
		Psychiatric disorders	Depression	01JAN2013		Y	
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N	
	C4591001 1128 11281208	Nervous system disorders	Headache	01JAN1994		Y	
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y	
	C4591001 1128 11281208	Endocrine disorders	Hypothyroidism	01JAN2010		Y	
		Injury, poisoning and procedural complications	Foot fracture	01JAN2017	31DEC2017	N	
		Nervous system disorders	Migraine	01JAN1980		Y	
		Psychiatric disorders	Depression	01JAN2015		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01AUG2019		Y
		Surgical and medical procedures	Internal fixation of fracture	01JAN2017	31DEC2017	N
			Mammoplasty	01JAN2003	31DEC2003	N
	C4591001 1128 11281209	Eye disorders	Ocular hypertension	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1128 11281210	Gastrointestinal disorders	Tooth impacted	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1128 11281216	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
	C4591001 1128 11281217	Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN2012	31DEC2012	N
			Caesarean section	02NOV2014	02NOV2014	N
				08MAR2001	08MAR2001	N
	C4591001 1128 11281218	Eye disorders	Retinal detachment	01JAN2015	31MAR2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01MAR2019	31MAR2019	N
			Retinopexy	01AUG2017	31AUG2017	N
	C4591001 1128 11281219	Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Gastrectomy	01JAN2016	31DEC2016	N
			Ligament operation	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN2017	31DEC2017	N
	C4591001 1128 11281220	Congenital, familial and genetic disorders	Pectus excavatum	(b) (6) 1979	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Thoracoplasty	01JAN2005	31DEC2005	N
	C4591001 1128 11281222	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1128 11281224	Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Psychiatric disorders	Insomnia	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2007	31JAN2007	N
	C4591001 1128 11281225	Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Ligament operation	01JAN2011	31DEC2011	N
	C4591001 1128 11281227	Nervous system disorders	Thoracic outlet syndrome	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Myectomy	01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rib excision	01JAN2014	31DEC2014	N
	C4591001 1128 11281228	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN1967		Y
			Seasonal allergy	01JAN2004		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Fracture treatment	01JAN1970	31DEC1970	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
	C4591001 1128 11281230	Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1128 11281231	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1128 11281235	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Haemorrhoids	01JUN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	14AUG2020	14AUG2020	N
		Infections and infestations	Pharyngitis streptococcal	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Foot fracture	01MAY2020	31MAY2020	N
			Ligament rupture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN1982		Y
			Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Cholecystectomy	14AUG2020	14AUG2020	N
			Haemorrhoid operation	01JAN2017	31DEC2017	N
			Ligament operation	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281239	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Infections and infestations	Herpes simplex	01JAN2019		Y
	C4591001 1128 11281240	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Meniscus operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1128 11281241	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Food allergy	01JAN2011		Y
			Seasonal allergy	01JAN1970		Y
	C4591001 1128 11281243	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Benign tumour excision	01JAN2006	31DEC2006	N
			Gastric banding	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1128 11281244	Investigations	Cardiac murmur	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1128 11281245	Infections and infestations	Otitis media	01JAN1982		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1989	31DEC1989	N
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Mastoidectomy	01JAN1993	31DEC1993	N
			Otoplasty	01JAN1998	31DEC1998	N
			Otoplasty	01JAN1983	31DEC1983	N
	C4591001 1128 11281246	Nervous system disorders	Migraine	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012	16NOV2015	N
		Surgical and medical procedures	Caesarean section	03JAN2002	03JAN2002	N
				04AUG2006	04AUG2006	N
				18OCT1994	18OCT1994	N
			Hysterectomy	16NOV2015	16NOV2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281247	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Nervous system disorders	Sinus headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1128 11281248	Eye disorders	Strabismus	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Strabismus correction	01JAN2008	31DEC2008	N
	C4591001 1128 11281249	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y
		Skin and subcutaneous tissue disorders	Ingrowing nail	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nail operation	01JAN2010	31DEC2010	N
	C4591001 1128 11281252	Injury, poisoning and procedural complications	Limb injury	01MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1128 11281255	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1128 11281257	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
			Tonsillitis	01JAN1982	31DEC1982	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2002		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2009	31DEC2009	N
			Cystitis interstitial	01JAN2012		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	21AUG2020	21AUG2020	N
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			External nose lesion excision	21AUG2020	21AUG2020	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1982	31DEC1982	N
			Urinary bladder suspension	01JAN2009	31DEC2009	N
	C4591001 1128 11281261	Hepatobiliary disorders	Cholecystitis	01MAR2004	31MAR2004	N
		Infections and infestations	Tonsillitis	01DEC1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01MAR2004	31MAR2004	N
			Tonsillectomy	01DEC1990	31DEC1990	N
	C4591001 1128 11281262	Endocrine disorders	Hypothyroidism	01AUG1979		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG1988		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Iodine allergy	01JAN1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01AUG2018		Y
			Osteoarthritis	01MAR2018		Y
		Psychiatric disorders	Depression	01AUG1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2010		Y
		Skin and subcutaneous tissue disorders	Acne	01MAR2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
			Caesarean section	28MAR2000	28MAR2000	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Endometrial ablation	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1128 11281265	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1128 11281267	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1128 11281268	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1988		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Nicotine dependence	01JAN1999		Y
	C4591001 1128 11281269	Congenital, familial and genetic disorders	Cerebral palsy	(b) (6) 1969		Y
		Surgical and medical procedures	Foot operation	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281272	Infections and infestations	Appendicitis	01APR2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Social circumstances	Tobacco user	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01APR2011	30APR2011	N
	C4591001 1128 11281274	Endocrine disorders	Hyperthyroidism	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1128 11281275	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	28JUN2016	28JUN2016	N
	C4591001 1128 11281276	Hepatobiliary disorders	Cholecystitis	01JUN2018	30JUN2018	N
		Surgical and medical procedures	Cholecystectomy	01JUN2018	30JUN2018	N
	C4591001 1128 11281279	Infections and infestations	Infectious mononucleosis	01JAN2010	31DEC2010	N
			Pharyngitis streptococcal	01JAN2009	31DEC2011	N
			Tonsillitis	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dysplastic naevus	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2004		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2004		Y
		Surgical and medical procedures	Mole excision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01JAN2006	31DEC2006	N
	C4591001 1128 11281281	Surgical and medical procedures	Intrauterine contraception	01JAN2017		Y
	C4591001 1128 11281282	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1128 11281285	Hepatobiliary disorders	Cholecystitis	01JUL2007	31JUL2007	N
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN1981	31DEC1987	N
			Menorrhagia	01JAN1980	31JUL2017	N
		Surgical and medical procedures	Caesarean section	02MAY2007	02MAY2007	N
				18JAN2005	18JAN2005	N
				20FEB2006	20FEB2006	N
				27AUG2003	27AUG2003	N
			Cholecystectomy	01JUL2007	31JUL2007	N
			Endometrial ablation	01JUL2007	31JUL2007	N
			Female sterilisation	01MAY2007		Y
			Mammoplasty	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1128 11281286	Hepatobiliary disorders	Biliary polyp	01JAN1999	31DEC1999	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01APR2005	30APR2005	N
			Urinary tract infection	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01APR2005	30APR2005	N
			Caesarean section	01JAN2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01AUG1999	31AUG1999	N
			Wisdom teeth removal	01JAN1993	31DEC1993	N
	C4591001 1128 11281287	Infections and infestations	Pharyngitis streptococcal	01JAN2002	31DEC2002	N
			Tonsillitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2000	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Fascia release	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1128 11281288	Infections and infestations	Chronic sinusitis	01JAN2015	31JUL2019	N
			Fungal skin infection	15AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2020		Y
		Surgical and medical procedures	Turbinectomy	01JUL2019	31JUL2020	N
	C4591001 1128 11281291	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Gastrectomy	01JAN2014	31DEC2014	N
	C4591001 1128 11281292	Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Muscle spasms	01JAN2013		Y
		Nervous system disorders	Neuralgia	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01NOV2018	30NOV2018	N
	C4591001 1128 11281294	Nervous system disorders	Headache	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1128 11281297	General disorders and administration site conditions	Pain	01JUN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Bronchitis	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Patella fracture	01AUG2012	31AUG2012	N
			Wrist fracture	01JUL2020	31JUL2020	N
				09MAY2019	09MAY2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JUN2011		Y
		Nervous system disorders	Neuralgia	01JUN2011		Y
		Reproductive system and breast disorders	Endometriosis	01JUN2009	30JUN2009	N
			Ovarian cyst	01JUN2009	30JUN2009	N
		Surgical and medical procedures	Endometrial ablation	01JUN2009	30JUN2009	N
			Oophorectomy	01JUN2009	30JUN2009	N
			Open reduction of fracture	01AUG2012	31AUG2012	N
			Ostectomy	01AUG2020	31AUG2020	N
	C4591001 1128 11281299	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Pharyngitis	01JAN2002	31DEC2002	N
		Nervous system disorders	Migraine	01AUG2014		Y
		Surgical and medical procedures	Debridement	01JAN2002	31DEC2002	N
			Tooth extraction	01SEP2014	30SEP2014	N
			Wisdom teeth removal	01NOV2015	30NOV2015	N
	C4591001 1128 11281300	Metabolism and nutrition disorders	Obesity	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281301	Cardiac disorders	Supraventricular tachycardia	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	15DEC2010	15DEC2010	N
	C4591001 1128 11281302	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010		Y
			Polycystic ovaries	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996	31DEC2008	N
		Surgical and medical procedures	Caesarean section	24JUN2017	24JUN2017	N
		Vascular disorders	Raynaud's phenomenon	01JAN2017		Y
	C4591001 1128 11281304	Nervous system disorders	Epilepsy	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
			Rash	01AUG2019		Y
	C4591001 1128 11281305	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1128 11281306	Immune system disorders	Drug hypersensitivity	01FEB2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	29SEP2019	N
			Ligament laxity	01JAN1993		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006	31DEC2006	N
			Nerve compression	01JAN2006	31DEC2006	N
			Neuralgia	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Female sterilisation	01JUN2017	30JUN2017	N
			Peripheral nerve transposition	01JAN2006	31DEC2006	N
			Spinal fusion surgery	29SEP2019	29SEP2019	N
	C4591001 1128 11281309	Hepatobiliary disorders	Cholelithiasis	01FEB1995	17JUL1995	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JUL2008	31JUL2008	N
			Bunion operation	01SEP1995	30SEP1995	N
			Caesarean section	09FEB2000	09FEB2000	N
				17JUL1995	17JUL1995	N
				23AUG2013	23AUG2013	N
				31MAY2011	31MAY2011	N
			Cholecystectomy	17JUL1995	17JUL1995	N
			Gastric bypass	01MAR2007	31MAR2007	N
			Mammoplasty	01JAN2009	31DEC2009	N
			Neuroprosthesis implantation	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1128 11281311	Infections and infestations	Herpes simplex	01JAN2005		Y
			Onychomycosis	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Stress urinary incontinence	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1128 11281312	Surgical and medical procedures	Female sterilisation	01JAN2010		Y
		Infections and infestations	Chronic tonsillitis	01JAN1983	31DEC1985	N
		Psychiatric disorders	Anxiety	01JAN1986		Y
			Obsessive-compulsive disorder	01JAN1986	31DEC1992	N
	C4591001 1128 11281317	Surgical and medical procedures	Tonsillectomy	01JAN1985	31DEC1985	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Investigations	Hysteroscopy	02MAY2019	02MAY2019	N
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Bipolar disorder	01JAN1993		Y
			Depression	01JAN1978		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01MAY2019	31MAY2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Caesarean section	15AUG2000	15AUG2000	N
			Nasal septal operation	01OCT2018	31OCT2018	N
			Vaginal operation	01MAY2019	31MAY2019	N
	C4591001 1128 11281319	Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Appendectomy	01JAN1994	31DEC1994	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee operation	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
			Ligament operation	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1128 11281323	Congenital, familial and genetic disorders	Atrial septal defect	14MAR2018	30APR2018	N
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Cerebrovascular accident	14MAR2018	14MAR2018	N
		Renal and urinary disorders	Glomerulonephritis membranous	01JUN2018	30NOV2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2006	31DEC2006	N
			Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1128 11281324	Ear and labyrinth disorders	Vertigo positional	01JAN2005		Y
		Endocrine disorders	Thyroid cyst	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Hepatobiliary disorders	Cholecystitis	01FEB2020	29FEB2020	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary calcification	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	03JUN1991	03JUN1991	N
				15MAR1990	15MAR1990	N
			Cholecystectomy	01FEB2020	29FEB2020	N
			Thyroid operation	01JAN2010	31DEC2010	N
	C4591001 1128 11281326	Infections and infestations	Tonsillitis	01AUG2002	31AUG2002	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01OCT2019	31OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nasal septal operation	01OCT2019	31OCT2019	N
			Tonsillectomy	01AUG2002	31AUG2002	N
			Wisdom teeth removal	01AUG2020	31AUG2020	N
	C4591001 1128 11281327	Gastrointestinal disorders	Nausea	01JAN2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	31DEC2017	N
		Pregnancy, puerperium and perinatal conditions	Breech presentation	26JUN2006	26JUN2006	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	26JUN2006	26JUN2006	N
			Gastric banding	01JAN1999	31DEC1999	N
			Gastric bypass	01JAN2014	31DEC2014	N
			Joint surgery	01JAN2017	31DEC2017	N
	C4591001 1128 11281328	Surgical and medical procedures	Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1128 11281331	Endocrine disorders	Hypothyroidism	01SEP2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2012		Y
			Neck pain	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01FEB2000		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN2005	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982	27APR2018	N
			Rhinitis allergic	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Nasal septal operation	27AUG2018	27AUG2018	N
	C4591001 1128 11281332	Gastrointestinal disorders	Gastrooesophageal reflux disease	10SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Surgical and medical procedures	Tooth extraction	01JAN2008	31DEC2008	N
			Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281334	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	20JAN2000	20JAN2000	N
				26JUL1998	26JUL1998	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281337	Infections and infestations	Tonsillitis	01JAN1978	31DEC1983	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2006		Y
			Insomnia	01JAN2006		Y
			Post-traumatic stress disorder	01JAN2006		Y
		Surgical and medical procedures	Meniscus operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1128 11281338	Nervous system disorders	Headache	01DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281339	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Vitamin D deficiency	01AUG2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01AUG2019		Y
	C4591001 1128 11281341	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Infections and infestations	Pharyngitis streptococcal	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31JAN2011	N
			Meniscus injury	01JAN2011	31JAN2011	N
		Investigations	Arthroscopy	01AUG2013	31AUG2013	N
		Metabolism and nutrition disorders	Obesity	01JAN1993	31MAR2003	N
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	12SEP2012		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Gastroplasty	31MAR2003	31MAR2003	N
			Knee operation	01JUL2011	31JUL2011	N
			Ligament operation	01JAN2011	31JAN2011	N
			Meniscus operation	01JAN2011	31JAN2011	N
			Tonsillectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Deep vein thrombosis	01JAN2013	31DEC2013	N
	C4591001 1128 11281343	Infections and infestations	Ear infection	01JAN1998	31DEC2001	N
		Nervous system disorders	Headache	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Myringotomy	01JAN2001	31DEC2001	N
	C4591001 1128 11281345	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Nervous system disorders	Cerebrovascular accident	01DEC2013	31DEC2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
			Tooth extraction	01MAY2018	31MAY2018	N
			Vasectomy	01JAN2006	31DEC2006	N
			Wisdom teeth removal	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1128 11281347	Surgical and medical procedures	Wisdom teeth removal	01JAN2009	31DEC2009	N
	C4591001 1128 11281355	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Bone operation	01JAN2008	31DEC2008	N
	C4591001 1128 11281357	Gastrointestinal disorders	Oesophageal achalasia	01JAN2002	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Myalgia	01MAR2017		Y
		Surgical and medical procedures	Oesophagocardiomyotomy	01JAN2003	31DEC2003	N
			Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1128 11281358	Gastrointestinal disorders	Pancreatitis	01JAN2016	31DEC2016	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Fracture treatment	01JAN2003	31DEC2003	N
	C4591001 1128 11281359	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1128 11281363	Gastrointestinal disorders	Abdominal hernia	01APR2008	31OCT2008	N
				01JAN1996	31DEC1999	N
				01JAN1999	31DEC2006	N
				01JAN2006	31DEC2008	N
		Hepatobiliary disorders	Cholelithiasis	01OCT2008	31OCT2008	N
		Infections and infestations	Appendicitis	01OCT2008	31OCT2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1995		Y
			Muscle spasms	01JAN1995		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2011		Y
			Depression	01JAN2011		Y
			Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
			Emphysema	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2017		Y
			Tobacco user	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Abdominal hernia repair	01JAN1999	31DEC1999	N
				01JAN2006	31DEC2006	N
				01JAN2008	31JAN2008	N
				01OCT2008	31OCT2008	N
			Appendicectomy	01OCT2008	31OCT2008	N
			Caesarean section	25NOV1996	25NOV1996	N
			Cholecystectomy	01OCT2008	31OCT2008	N
			Spinal nerve stimulator implantation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1128 11281364	Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Female sterilisation	15JAN2016	15JAN2016	N
	C4591001 1128 11281366	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1128 11281368	Injury, poisoning and procedural complications	Head injury	01JAN1989	31DEC1989	N
		Social circumstances	Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Suture insertion	01JAN1989	31DEC1989	N
	C4591001 1128 11281373	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Skin graft	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281384	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Meningitis	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1128 11281385	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01APR2019	30APR2019	N
			Keratomileusis	01JAN2020	31JAN2020	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1129 11291001	Cardiac disorders	Coronary artery disease	01JAN2017		Y
			Myocardial infarction	01JAN2019	31DEC2019	N
			Myocardial infarction	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1129 11291005	Cardiac disorders	Bundle branch block right	01JAN2010		Y
		Eye disorders	Maculopathy	01JAN2019		Y
			Myopia	01JAN1970		Y
			Retinal tear	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01MAY2020		Y
			Gastroesophageal reflux disease	01MAR2020		Y
			Haemorrhoids	01JAN2015		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Electrocardiogram ST segment depression	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2017		Y
			Vitamin B12 deficiency	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990		Y
			Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1980		Y
		Social circumstances	Tobacco user	01JAN2002	31MAR2020	N
		Surgical and medical procedures	Gastric bypass	20MAR2020	20MAR2020	N
			Retinal operation	01JAN2019		Y
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1129 11291006	Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Diarrhoea	01JAN1990		Y
			Gastroesophageal reflux disease	01JUN2001		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Vitamin B12 deficiency	01JAN2014		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN1999		Y
			Fibromyalgia	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Phyllodes tumour	01JAN1997	31DEC1998	N
			Uterine leiomyoma	01JAN2018		Y
		Nervous system disorders	Central auditory processing disorder	01JAN2007		Y
			Headache	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Perinatal depression	01JAN2004	31DEC2004	N
				01JAN2019	31DEC2019	N
		Renal and urinary disorders	Bladder prolapse	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Breast tumour excision	01JAN1998	31DEC1998	N
			Rhinoplasty	01JAN1998	31DEC1998	N
	C4591001 1129 11291010	Eye disorders	Hypermetropia	01JAN2015		Y
			Myopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN1981		Y
			Hypersensitivity	01JAN1979		Y
		Infections and infestations	Fungal skin infection	01JAN1995		Y
		Injury, poisoning and procedural complications	Head injury	28NOV2018	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	28NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Nervous system disorders	Amnesia	28NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007	30JUN2019	N
		Social circumstances	Ex-tobacco user	01JAN1996	31DEC2002	N
		Surgical and medical procedures	Chondroplasty	28NOV2018	28NOV2018	N
			Muscle operation	18JUN2020	18JUN2020	N
			Rotator cuff repair	18JUN2020	18JUN2020	N
			Hydrocele	30NOV2016	15DEC2016	N
	C4591001 1129 11291014	Congenital, familial and genetic disorders				
		Eye disorders	Astigmatism	01JAN2002		Y
			Myopia	01JAN1994		Y
		Infections and infestations	Epididymitis	30NOV2016	15DEC2016	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Intervertebral disc degeneration	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979	31DEC1995	N
		Surgical and medical procedures	Ankle operation	01JAN1992	31DEC1992	N
	C4591001 1129 11291017	Metabolism and nutrition disorders	Overweight	01JAN1994		Y
		Psychiatric disorders	Alcohol abuse	01JAN2005	31DEC2008	N
			Anxiety	01MAR2020	31JUL2020	N
		Social circumstances	Ex-tobacco user	01JAN2014	31DEC2016	N
	C4591001 1129 11291019	Cardiac disorders	Palpitations	01FEB2020	14FEB2020	N
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2019	31DEC2019	N
			Concussion	01JAN2019	31DEC2019	N
		Investigations	Tuberculin test	16AUG2019	16AUG2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2019	31OCT2019	N
		Surgical and medical procedures	Ear tube insertion	01JAN1974	31DEC1974	N
			Hernia repair	01JAN2015	31DEC2015	N
			Ligament operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291020	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2020	N
	C4591001 1129 11291029	Eye disorders	Amblyopia	01JAN1969		Y
			Myopia	01JAN1969		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Dyspepsia	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1975	31DEC1975	N
			Umbilical hernia	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Peripheral swelling	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN2006		Y
		Infections and infestations	Vulval abscess	01JAN2013		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1995	31DEC1995	N
			Concussion	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Overweight	01JAN2005	31DEC2005	N
			Vitamin D deficiency	01JAN2014		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN1992		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1976		Y
			Reflux nephropathy	01JAN1976		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2019	31JUL2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
			Pleurisy	01JAN1974	31DEC1974	N
		Social circumstances	Tobacco user	01JAN1983	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Gastrectomy	01JAN2019	31DEC2019	N
			Inguinal hernia repair	01JAN1975	31DEC1975	N
			Knee operation	01JAN1995	31DEC1995	N
	C4591001 1129 11291030	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Haemorrhoids	01NOV2018	31DEC2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Infections and infestations	Abscess soft tissue	01AUG2018	30SEP2018	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Back pain	06JUN2006		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
		Social circumstances	Tobacco user	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2015	N
			Intervertebral disc operation	01JAN2015	31DEC2015	N
			Intervertebral disc operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2015	31DEC2016	N
	C4591001 1129 11291040	Eye disorders	Cataract	01JAN2017		Y
			Glaucoma	01JAN2019		Y
			Hypermetropia	01JAN1976		Y
			Myopia	01JAN2014		Y
		Gastrointestinal disorders	Constipation	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN1981		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Overweight	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2016		Y
			Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017		Y
		Nervous system disorders	Trigeminal neuralgia	01JAN2015	31DEC2016	N
		Skin and subcutaneous tissue disorders	Rash	01DEC2015	31JAN2016	N
		Vascular disorders	Hypertension	01JAN2016		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291041	Ear and labyrinth disorders	Eustachian tube dysfunction	01MAR2020		Y
		Eye disorders	Hypermetropia	01JAN2003		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
		General disorders and administration site conditions	Hernia	01JAN1993	31DEC1997	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1993	31DEC1993	N
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Injury, poisoning and procedural complications	Persistent corneal epithelial defect	01APR2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2002	31DEC2006	N
			Uterine prolapse	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Endometrial ablation	01JAN2006		Y
			Hernia repair	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN2016		Y
	C4591001 1129 11291042	Blood and lymphatic system disorders	Anaemia	01MAY2018	30NOV2018	N
		Endocrine disorders	Hypothyroidism	01NOV2018		Y
		Gastrointestinal disorders	Gastric ulcer	01MAY2018	31JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Chest pain	01JAN2016	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01DEC2017	31MAR2019	N
		Nervous system disorders	Migraine	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01DEC2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2004		Y
		Surgical and medical procedures	Thyroidectomy	01NOV2018	30NOV2018	N
	C4591001 1129 11291045	Eye disorders	Hypermetropia	01JAN2016		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017	31DEC2017	N
		General disorders and administration site conditions	Hernia	01JAN2017	30APR2017	N
		Immune system disorders	Contrast media allergy	01JAN2018		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	04APR2018	04APR2018	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291047	Eye disorders	Myopia	01JAN2002	31DEC2002	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Large intestine polyp	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN1983		Y
			Rubber sensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1999		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	16JUL2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
			Headache	01JAN1995		Y
			Migraine	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1988	31DEC1990	N
			Urticaria	01JAN1983		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JUL2019	31JUL2019	N
				01NOV2019	30NOV2019	N
			Keratomileusis	01JAN2002	31DEC2002	N
			Salpingo-oophorectomy	14AUG2013	31DEC2013	N
			Sinus operation	01MAR2019	31MAR2019	N
			Tonsillectomy	01MAR2019	31MAR2019	N
			Transfusion	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01JAN2013		Y
	C4591001 1129 11291054	Eye disorders	Keratoconus	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Large intestine polyp	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
		Nervous system disorders	Headache	01JAN2019		Y
			Sciatica	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Intervertebral disc operation	01AUG2001	31AUG2001	N
	C4591001 1129 11291055	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Glaucoma	14MAY2020		Y
			Myopia	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2003	31DEC2004	N
			Uterine leiomyoma	01JAN2012	31DEC2013	N
		Reproductive system and breast disorders	Cervical dysplasia	22JUL2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
			Thyroidectomy	01JAN2004	31DEC2004	N
	C4591001 1129 11291056	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012	31DEC2019	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1129 11291058	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
				01JAN2010		Y
		Infections and infestations	Arthritis bacterial	01JAN1981	31DEC1981	N
		Investigations	Cardiac murmur	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Hip surgery	01JAN1981	31DEC1981	N
			Oophorectomy	01JAN2019	31DEC2019	N
	C4591001 1129 11291061	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2001		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Miliaria	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	27NOV1996	27NOV1996	N
			Gastric bypass	01NOV2010	30NOV2010	N
			Keratomileusis	01JAN2001	31DEC2001	N
			Spinal operation	01JAN2001	31DEC2001	N
			Uterine dilation and curettage	01JAN2011	31JAN2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291063	Vascular disorders	Hypertension	01JAN2017		Y
		Ear and labyrinth disorders	Deafness neurosensory	01JUL2017		Y
		Immune system disorders	Drug hypersensitivity	01OCT1987		Y
			Dust allergy	01JAN1980		Y
			Mycotic allergy	01JAN1980		Y
			Seasonal allergy	01JAN1987		Y
		Infections and infestations	Toxic shock syndrome	01JUN2003	30JUN2003	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1997	31DEC1997	N
			Patella fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JUL2019		Y
			Osteonecrosis	01AUG2018		Y
			Spinal osteoarthritis	01JAN1980		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01DEC2000	30JUN2001	N
	Psychiatric disorders	Eating disorder	01JAN1979	31DEC1981	N	
	Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N	
		Hip surgery	01JAN2018	31DEC2018	N	
		Therapeutic nerve ablation	01JAN2019	31DEC2019	N	
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1129 11291064	Eye disorders	Myopia	01JAN1984		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1971	31DEC1971	N
		Large intestine polyp	01JAN2018	31DEC2018	N	
	Immune system disorders	Drug hypersensitivity	01JAN1985		Y	
	Infections and infestations	Tonsillitis	01JAN2016		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Skin laceration	17APR2020	31MAY2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
			Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1971	31DEC1971	N
			Polypectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2017	31DEC2019	N
	C4591001 1129 11291069	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Astigmatism	01JAN1996		Y
			Myopia	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1994	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
			Hypertriglyceridaemia	01JUL2020		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Rhinoplasty	01JAN1995	31DEC1995	N
	C4591001 1129 11291070	Eye disorders	Myopia	01JAN1983		Y
		Injury, poisoning and procedural complications	Skull fracture	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1129 11291071	Eye disorders	Hypermetropia	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Fascial rupture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2019	31DEC2019	N
			Uterine leiomyoma	01JAN2011	31DEC2014	N
		Surgical and medical procedures	Bunion operation	01JAN2019	31DEC2019	N
			Fascial operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Neurectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1129 11291072	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
			Urinary tract infection	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Adenoidectomy	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1129 11291073	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1129 11291088	Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Female sterilisation	01JAN2017		Y
	C4591001 1129 11291089	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Infections and infestations	Urinary tract infection	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Skin laceration	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1970		Y
		Social circumstances	Tobacco user	01JAN1992	31DEC2015	N
	C4591001 1129 11291092	Eye disorders	Myopia	01JAN1966		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2001	10SEP2001	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019	31DEC2019	N
			Spinal osteoarthritis	01JAN2005	31DEC2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2019		Y
			Depression	11SEP2001		Y
			Insomnia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	11SEP2001	11SEP2001	N
			Stem cell therapy	01JAN2019	31DEC2019	N
	C4591001 1129 11291096	Cardiac disorders	Bundle branch block left	01JAN2014		Y
			Bundle branch block right	01JAN2014		Y
		Ear and labyrinth disorders	Vertigo	01JAN2013		Y
		Eye disorders	Myopia	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2016		Y
				01MAY2020		Y
			Food allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Transient ischaemic attack	25SEP2019	25SEP2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Implantable cardiac monitor insertion	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1129 11291097	Infections and infestations	Papilloma viral infection	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2001		Y
		Social circumstances	Tobacco user	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Papilloma excision	01JAN2017	31DEC2017	N
	C4591001 1129 11291098	Cardiac disorders	Cardiac failure	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1990		Y
		Infections and infestations	Vulvovaginal candidiasis	26MAY2020	06JUN2020	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
			Blood triglycerides increased	01JAN2014		Y
			Catheterisation cardiac	01JAN2005	31DEC2005	N
			Liver function test increased	23OCT2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2014	31DEC2020	N
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratomileusis	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1129 11291104	Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Eye disorders	Myopia	01JAN1976	31DEC2000	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN1993		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Intervertebral disc protrusion	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JUL2020		Y
	C4591001 1129 11291106	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2018	31DEC2018	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2016		Y
		Eye disorders	Hypermetropia	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1997		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1129 11291120	Eye disorders	Hypermetropia	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Infections and infestations	Bronchitis	14JUN2019	26JUN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2006		Y
			Type 2 diabetes mellitus	01JUN2017		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JUN2002		Y
			Varicose vein	01JAN2000		Y
	C4591001 1129 11291129	Eye disorders	Myopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
			Overweight	01JAN2010		Y
	C4591001 1129 11291135	Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Blood and lymphatic system disorders	Anaemia	01JAN2008		Y
		Eye disorders	Myopia	01JAN2004	13APR2018	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01SEP2019		Y
		Surgical and medical procedures	Keratomileusis	13APR2018	13APR2018	N
	C4591001 1129 11291141	Ear and labyrinth disorders	Deafness	01JAN1969		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	30SEP2017	N
			Large intestine polyp	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Social circumstances	Tobacco user	01JAN1982	31DEC2015	N
		Surgical and medical procedures	Cochlea implant	01JAN2006	31DEC2006	N
	C4591001 1129 11291142	Blood and lymphatic system disorders	Anaemia	01JAN2018	01AUG2020	N
		Cardiac disorders	Ventricular extrasystoles	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Congenital, familial and genetic disorders	Renal fusion anomaly	(b) (6) 1964		Y
		Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1972	31DEC1972	N
				01JAN1974	31DEC1974	N
			Foot fracture	01JAN1972	31DEC1972	N
			Lower limb fracture	01JAN1973	31DEC1973	N
			Rib fracture	01JAN1983	31DEC1983	N
			Skeletal injury	01JAN1975	31DEC1975	N
				01JAN1979	31DEC1979	N
		Investigations	Glycosylated haemoglobin increased	01JAN2013	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Libido decreased	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01DEC1964		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN2002	31DEC2002	N
			Psoriasis	01JAN1972		Y
		Social circumstances	Tobacco user	01JAN1983	31DEC1991	N
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291143	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020	31JUL2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2019		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1129 11291145	Eye disorders	Hypermetropia	01JAN2016		Y
			Myopia	01JAN2016		Y
		Immune system disorders	Allergy to arthropod sting	01JUL2020		Y
			Food allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975	31DEC1980	N
	C4591001 1129 11291148	Surgical and medical procedures	Myringotomy	01JAN1990	31DEC1990	N
	C4591001 1129 11291153	Endocrine disorders	Hypogonadism	01JAN2003		Y
			Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2003		Y
		Social circumstances	Tobacco user	01JAN1971	31DEC1990	N
	C4591001 1129 11291157	Gastrointestinal disorders	Dyspepsia	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
		Immune system disorders	Allergy to animal	01JAN1996		Y
			Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Urinary tract infection	01JAN1998		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN1994		Y
			Eczema	01JAN2000		Y
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
	C4591001 1129 11291163	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Myopia	01JAN2001		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1129 11291164	Endocrine disorders	Hypogonadism	01JAN2012	31DEC2016	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1982	31DEC1989	N
			Wrist fracture	01JAN1986	31DEC1986	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016	31DEC2016	N
			Musculoskeletal chest pain	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN1985		Y
			Migraine	01JAN1986		Y
	C4591001 1129 11291165	Endocrine disorders	Goitre	01JAN2006		Y
		Eye disorders	Hypermetropia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Mite allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
			Vitamin D deficiency	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1987		Y
			Eczema	01JAN2010		Y
			Rosacea	01JAN2018		Y
	C4591001 1129 11291168	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2013	31DEC2013	N
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2013	31DEC2013	N
			Appendicectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1129 11291171	Eye disorders	Myopia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Keratomileusis	01JAN2020	31JAN2020	N
	C4591001 1129 11291178	Eye disorders	Hypermetropia	01JAN2016		Y
			Myopia	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Muscle spasms	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Intervertebral disc operation	01JAN1998	31DEC1998	N
	C4591001 1129 11291181	Injury, poisoning and procedural complications	Hip fracture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	31DEC2009	N
	C4591001 1129 11291185	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Diarrhoea	01JUN2020		Y
			Dyspepsia	01JAN2019		Y
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Allergy to animal	01JAN2018		Y
			Milk allergy	01JAN2019		Y
			Seasonal allergy	01JAN2018		Y
		Investigations	Progesterone decreased	01JUN2020		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2008		Y
			Vitamin B12 deficiency	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2006		Y
			Menstrual disorder	01JAN2019	31DEC2019	N
			Uterine polyp	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Tonsillolith	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1129 11291187	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
	C4591001 1129 11291189	Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
		Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Eye disorders	Hypermetropia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1981		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1129 11291190	Eye disorders	Blindness	01JAN2019		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1979	31DEC1979	N
		Immune system disorders	Seasonal allergy	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Tobacco user	01JAN1983		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2019	31DEC2019	N
	C4591001 1129 11291192	Eye disorders	Myopia	01JAN1972		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN2004	31DEC2014	N
	C4591001 1129 11291193	Eye disorders	Myopia	01JAN1985	31DEC2013	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Urinary tract infection	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2017	31DEC2017	N
			Hand fracture	01JAN2009	31DEC2009	N
			Ligament rupture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
			Back pain	01JAN2001		Y
			Pain in extremity	01JUN2020		Y
			Tendonitis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1996		Y
		Surgical and medical procedures	Ankle operation	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017	31DEC2017	N
	C4591001 1129 11291196	Vascular disorders	Hypertension	01JAN2004		Y
		Ear and labyrinth disorders	Deafness	01JAN1987		Y
		Endocrine disorders	Hypogonadism	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2019		Y
			Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Clostridium difficile colitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2005		Y
			Overweight	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Osteoarthritis	01JAN2001		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
			Sciatica	01JAN2007		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2001		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
	Surgical and medical procedures	Adenoidectomy	01JAN1985	31DEC1985	N	
		Meniscus removal	01FEB2007	28FEB2007	N	
			01JAN2007	31JAN2007	N	
			01JUN2003	30JUN2003	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01SEP2003	30SEP2003	N
			Ossiculoplasty	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1985	31DEC1985	N
			Tympanoplasty	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2005	30APR2020	N
	C4591001 1129 11291197	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
			Overweight	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back disorder	01JAN2015		Y
			Back pain	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01SEP2017	19SEP2017	N
		Nervous system disorders	Headache	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1985		Y
		Surgical and medical procedures	Micrographic skin surgery	19SEP2017	19SEP2017	N
	C4591001 1129 11291201	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tendon sheath incision	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1129 11291202	Eye disorders	Myopia	01JAN2000	31DEC2008	N
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Infections and infestations	Clostridium difficile colitis	01JAN2009	31DEC2009	N
				01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N
			Ligament rupture	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
			Meniscus injury	01JAN1998	31DEC1998	N
				01JAN2019	31DEC2019	N
		Investigations	Endoscopy upper gastrointestinal tract	01JAN2002	31DEC2002	N
				01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Ligament operation	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
			Meniscus operation	01JAN1998	31DEC1998	N
			Thermal ablation	01SEP2020	01SEP2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				08SEP2020	08SEP2020	N
	C4591001 1129 11291209	Vascular disorders	Varicose vein	01JAN2018		Y
		Ear and labyrinth disorders	Tympanic membrane perforation	05OCT1985	31DEC1985	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2016	31DEC2016	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Infections and infestations	Appendicitis	05OCT1976	05OCT1976	N
			Herpes simplex	01JAN1995		Y
			Tonsillitis	05OCT1980	05OCT1980	N
		Renal and urinary disorders	Nocturia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y
		Social circumstances	Tobacco user	01JAN1984	31DEC2006	N
		Surgical and medical procedures	Appendectomy	05OCT1976	05OCT1976	N
			Jaw operation	05OCT1985	05OCT1985	N
			Tonsillectomy	05OCT1985	05OCT1985	N
			Tympanoplasty	05OCT1985	05OCT1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291210	Eye disorders	Myopia	01JAN1994		Y
	C4591001 1129 11291211	Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN1978		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1972	31DEC1972	N
			Irritable bowel syndrome	01JAN1984		Y
		General disorders and administration site conditions	Cyst	01JAN2018		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2010		Y
			Tobacco user	01JAN1980	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN1972	31DEC1972	N
	C4591001 1129 11291212	Eye disorders	Myopia	01JAN1987	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2001		Y
		Surgical and medical procedures	Photorefractive keratectomy	01JAN2001	31DEC2001	N
		Vascular disorders	White coat hypertension	01JAN2016		Y
	C4591001 1129 11291213	Eye disorders	Presbyopia	01JAN2006		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypercholesterolaemia	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1996	31DEC2010	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1129 11291216	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
			Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1129 11291220	Eye disorders	Presbyopia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Social circumstances	Tobacco user	01JAN1985	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
		Eye disorders	Myopia	01JAN2006		Y
	C4591001 1129 11291223	Gastrointestinal disorders	Abdominal pain	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Pilonidal cyst	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015	31DEC2017	N
			Overweight	01JAN2010	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Renal and urinary disorders	Micturition disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
		Surgical and medical procedures	Spinal operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013	31DEC2017	N
	C4591001 1129 11291224	Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Infections and infestations	Hepatitis A	01DEC1982	01FEB1983	N
		Metabolism and nutrition disorders	Overweight	01JAN1966		Y
		Renal and urinary disorders	Nocturia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291228	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Trigger finger	01JUL2020		Y
		Renal and urinary disorders	Nocturia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1975	31DEC1975	N
			Joint debridement	01JAN2016	31DEC2016	N
				01JAN2020	31JAN2020	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1129 11291229	Eye disorders	Hypermetropia	01JAN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Renal and urinary disorders	Haematuria	01JAN2019	30JUN2020	N
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
	C4591001 1129 11291238	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1992	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Nervous system disorders	Nerve compression	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Abdominal hernia repair	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
			Peripheral nerve decompression	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1129 11291244	Congenital, familial and genetic disorders	Congenital multiplex arthrogyposis	(b) (6) 1984		Y
		Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
			Keratomileusis	01JAN2017	31DEC2017	N
	C4591001 1129 11291245	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1129 11291249	Injury, poisoning and procedural complications	Clavicle fracture	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1992		Y
	C4591001 1129 11291252	Eye disorders	Myopia	01JAN1996	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Nervous system disorders	Shift work disorder	01JAN2015	31DEC2018	N
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1129 11291255	Eye disorders	Myopia	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN2019	31DEC2019	N
	C4591001 1129 11291256	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2008	31DEC2008	N
			Hand fracture	01JAN2017	31DEC2017	N
			Radius fracture	01JAN2008	31DEC2008	N
			Ulna fracture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN2008	31DEC2008	N
	C4591001 1129 11291257	Injury, poisoning and procedural complications	Clavicle fracture	(b) (6) 2003	31OCT2003	N
			Concussion	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1129 11291258	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN2018	31DEC2018	N
	C4591001 1129 11291260	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2007		Y
		Investigations	Bronchoscopy	01JAN2016	31DEC2016	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
	C4591001 1129 11291261	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Injury, poisoning and procedural complications	Ankle fracture	01FEB2020	29FEB2020	N
				01JAN2018	31DEC2018	N
			Radius fracture	01JAN2006	31DEC2006	N
				01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Scoliosis surgery	12FEB2019	12FEB2019	N
	C4591001 1129 11291262	Congenital, familial and genetic disorders	Congenital flat feet	(b) (6) 2003	31DEC2017	N
		Gastrointestinal disorders	Aphthous ulcer	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
		Social circumstances	Tobacco user	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Foot operation	01MAR2017	31MAR2017	N
				01MAY2017	31MAY2017	N
	C4591001 1129 11291263	Eye disorders	Myopia	01JAN2014		Y
	C4591001 1129 11291264	Eye disorders	Myopia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2007	31DEC2007	N
			Hand fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010	31DEC2010	N
			Insomnia	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1129 11291265	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
	C4591001 1130 11301001	Gastrointestinal disorders	Eosinophilic oesophagitis	08JUL2015		Y
			Gastrooesophageal reflux disease	16SEP2009		Y
			Irritable bowel syndrome	02JUN2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	19MAR2010		Y
		Psychiatric disorders	Generalised anxiety disorder	22AUG2018		Y
		Vascular disorders	Essential hypertension	22SEP2010		Y
	C4591001 1130 11301002	Endocrine disorders	Hypothyroidism	16MAR2017		Y
		General disorders and administration site conditions	Fatigue	05FEB2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	11APR2013		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	06FEB2014		Y
			Osteoarthritis	29MAY2019		Y
		Renal and urinary disorders	Nephrolithiasis	16APR2012	16APR2012	N
		Reproductive system and breast disorders	Menorrhagia	29DEC2016		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Essential hypertension	16MAR2020		Y
			Raynaud's phenomenon	06FEB2014		Y
	C4591001 1130 11301014	Congenital, familial and genetic disorders	Congenital aortic anomaly	11DEC2018		Y
			Congenital aortic stenosis	22AUG2016		Y
	C4591001 1130 11301015	Surgical and medical procedures	Intrauterine contraception	20JUL2018		Y
	C4591001 1130 11301021	Gastrointestinal disorders	Gastrooesophageal reflux disease	22MAY2017		Y
		Infections and infestations	Herpes simplex	15FEB2016		Y
			Staphylococcal infection	19SEP2012	31OCT2012	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	28JUL2017		Y
			Eating disorder	10JUL2013		Y
			Major depression	28JUL2017		Y
	C4591001 1130 11301026	Ear and labyrinth disorders	Deafness bilateral	28DEC2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	04OCT2007		Y
			Oesophagitis	19JUL2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	11SEP2009		Y
			Hyperlipidaemia	17AUG2016		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1969		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	08AUG2012		Y
	C4591001 1130 11301028	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	26SEP2002		Y
	C4591001 1130 11301032	Musculoskeletal and connective tissue disorders	Scoliosis	19MAR2018		Y
		Psychiatric disorders	Anxiety	19MAR2018		Y
			Insomnia	22AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Major depression	08APR2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	22JAN2019		Y
	C4591001 1130 11301033	Blood and lymphatic system disorders	Anaemia	11SEP2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	12OCT2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	29JAN2009		Y
		Psychiatric disorders	Anxiety	17JUN2008		Y
	C4591001 1130 11301043	Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2008		Y
		Nervous system disorders	Syncope	27AUG2014	27AUG2014	N
	C4591001 1130 11301044	Immune system disorders	Food allergy	21FEB2018		Y
			Seasonal allergy	21FEB2018		Y
		Infections and infestations	Otitis media chronic	21FEB2018		Y
		Metabolism and nutrition disorders	Obesity	28MAY2014		Y
		Psychiatric disorders	Major depression	20JUN2018		Y
		Renal and urinary disorders	Nephrolithiasis	02NOV2018	02NOV2018	N
	C4591001 1130 11301045	Congenital, familial and genetic disorders	Gilbert's syndrome	30OCT2012		Y
		Musculoskeletal and connective tissue disorders	Growth retardation	(b) (6) 1987		Y
		Psychiatric disorders	Anxiety disorder	03DEC2009		Y
	C4591001 1130 11301046	Metabolism and nutrition disorders	Vitamin D deficiency	13MAY2010	27APR2012	N
		Musculoskeletal and connective tissue disorders	Arthralgia	15MAY2010	31DEC2015	N
			Spinal pain	15MAY2010	31DEC2015	N
		Psychiatric disorders	Depression	13MAY2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Fibrocystic breast disease	04JUL2005		Y
	C4591001 1130 11301047	Endocrine disorders	Hypothyroidism	10FEB2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	10FEB2011	29JUL2019	N
		Surgical and medical procedures	Thyroidectomy	29JUL2019	29JUL2019	N
	C4591001 1130 11301049	Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
		Surgical and medical procedures	Thoracic operation	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
			Thoracotomy	01JAN2003	31DEC2003	N
	C4591001 1130 11301051	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1983		Y
		Nervous system disorders	Migraine	29APR2015		Y
			Restless legs syndrome	11MAR2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	16SEP2019		Y
			Major depression	15JUL2014		Y
			Parasomnia	10MAR2015		Y
		Renal and urinary disorders	Nephrolithiasis	01DEC2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	15JUL2014		Y
		Vascular disorders	Essential hypertension	15JUL2014		Y
	C4591001 1130 11301052	Infections and infestations	Urinary tract infection	23AUG2017		Y
		Metabolism and nutrition disorders	Obesity	10MAR2011		Y
		Psychiatric disorders	Anxiety disorder	10MAR2017		Y
			Depression	10MAR2011		Y
		Surgical and medical procedures	Mammoplasty	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1130 11301054	Metabolism and nutrition disorders	Vitamin B12 deficiency	08OCT2017		Y
			Vitamin D deficiency	08OCT2017		Y
		Reproductive system and breast disorders	Dysmenorrhoea	11SEP2019		Y
			Menorrhagia	11SEP2019		Y
	C4591001 1130 11301056	Immune system disorders	Seasonal allergy	11APR2007		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	17MAR2015		Y
		Psychiatric disorders	Major depression	19DEC2002		Y
			Panic disorder	19DEC2002		Y
		Skin and subcutaneous tissue disorders	Psoriasis	30MAY2012		Y
		Surgical and medical procedures	Hysterectomy	26NOV2008		Y
	C4591001 1130 11301058	Infections and infestations	Genital herpes simplex	01JUN2006		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JUL2019		Y
		Social circumstances	Postmenopause	17APR2019		Y
		Surgical and medical procedures	Intrauterine contraception	17APR2019		Y
	C4591001 1130 11301059	Gastrointestinal disorders	Anal fissure	15APR2015		Y
		Psychiatric disorders	Anxiety	10OCT2016		Y
			Major depression	10OCT2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15APR2015		Y
			Sleep apnoea syndrome	02JUL2018		Y
	C4591001 1130 11301063	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1130 11301064	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Nervous system disorders	Carpal tunnel syndrome	21SEP2016		Y
			Migraine without aura	01JAN1996		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13NOV2017		Y
	C4591001 1130 11301073	Investigations	Blood testosterone decreased	01JUN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	04NOV2014		Y
	C4591001 1130 11301074	Respiratory, thoracic and mediastinal disorders	Asthma	02JAN2014		Y
			Asthma exercise induced	24JAN2012		Y
	C4591001 1130 11301075	Metabolism and nutrition disorders	Overweight	22OCT2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	22OCT2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	22OCT2015		Y
			Major depression	20APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30MAR2018		Y
	C4591001 1130 11301077	Endocrine disorders	Autoimmune thyroiditis	18JUL2014		Y
		Metabolism and nutrition disorders	Overweight	15JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	21APR2011		Y
		Surgical and medical procedures	Female sterilisation	11JUN2015	11JUN2015	N
			Salpingo-oophorectomy unilateral	11JUN2015	11JUN2015	N
	C4591001 1130 11301078	Congenital, familial and genetic disorders	Type V hyperlipidaemia	28AUG2018		Y
		Metabolism and nutrition disorders	Iron deficiency	12OCT2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	14OCT2015		Y
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	31OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	25JAN2016		Y
	C4591001 1130 11301081	Injury, poisoning and procedural complications	Joint injury	03DEC2008	03DEC2009	N
		Metabolism and nutrition disorders	Lipid metabolism disorder	26MAR2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	03DEC2008	03DEC2009	N
		Psychiatric disorders	Alcoholism	28MAR2000	13JUN2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	04SEP2015		Y
			Cough	01JAN1982		Y
			Sleep apnoea syndrome	08JUN2011		Y
		Surgical and medical procedures	Vasectomy	19DEC2002	19DEC2002	N
		Vascular disorders	Hypertension	01APR2003		Y
	C4591001 1130 11301082	Hepatobiliary disorders	Gallbladder disorder	28FEB2006	28AUG2006	N
			Hepatomegaly	01JAN2006		Y
			Liver disorder	01JAN2006		Y
		Metabolism and nutrition disorders	Gout	21JAN2005		Y
			Obesity	17JAN2015		Y
	C4591001 1130 11301083	Blood and lymphatic system disorders	Thrombocytopenia	07MAY2007	08MAY2007	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	28AUG2018		Y
			Myofascial pain syndrome	18JUL2014		Y
		Surgical and medical procedures	Female sterilisation	12MAY2007	12MAY2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1130 11301084	Investigations	Blood glucose	02FEB2018		Y
		Metabolism and nutrition disorders	Hyperglycaemia	18SEP1990		Y
			Hypoglycaemia	18SEP1990		Y
			Obesity	01NOV2016		Y
			Type 1 diabetes mellitus	18SEP1990		Y
		Surgical and medical procedures	Drug delivery device placement	28JAN2014		Y
	C4591001 1130 11301085	Nervous system disorders	Intention tremor	17DEC2019		Y
			Migraine	01JAN2003		Y
		Psychiatric disorders	Autism spectrum disorder	(b) (6) 1984		Y
			Depression	01JAN2002		Y
	C4591001 1130 11301086	Musculoskeletal and connective tissue disorders	Back pain	21OCT2007		Y
		Surgical and medical procedures	Vasectomy	15JAN2013	15JAN2013	N
	C4591001 1130 11301087	Metabolism and nutrition disorders	Obesity	03DEC2014		Y
			Type 2 diabetes mellitus	31DEC2009		Y
		Nervous system disorders	Facial paralysis	05JUN2020		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	12APR2018		Y
			Major depression	18JUL2007		Y
		Surgical and medical procedures	Endometrial ablation	27FEB2012	27FEB2012	N
	C4591001 1130 11301088	Infections and infestations	Genital herpes simplex	25JUL2008		Y
		Metabolism and nutrition disorders	Obesity	19APR2002		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	06JUL2006		Y
				23MAR2007		Y
			Myofascial pain syndrome	31AUG2006		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	14FEB2003		Y
	C4591001 1130 11301089	Surgical and medical procedures	Cholecystectomy	01NOV2003	01NOV2003	N
		Blood and lymphatic system disorders	Iron deficiency anaemia	05FEB2018		Y
		General disorders and administration site conditions	Fatigue	29MAY2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	06JUN2018		Y
			Generalised anxiety disorder	20MAR2018		Y
			Insomnia	11JUL2018		Y
			Major depression	08MAR2018		Y
			Social anxiety disorder	08MAR2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	26APR2018		Y
	C4591001 1130 11301090	Skin and subcutaneous tissue disorders	Acne	23MAY2018		Y
		Endocrine disorders	Hypogonadism male	19DEC2013		Y
			Hypothyroidism	19DEC2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal cancer	19JAN2015	25FEB2015	N
		Surgical and medical procedures	Intramedullary rod insertion	31MAR2014	31MAR2014	N
			Sigmoidectomy	25FEB2015	25FEB2015	N
		Vascular disorders	Essential hypertension	29SEP2016		Y
	C4591001 1130 11301091	Immune system disorders	Drug hypersensitivity	09NOV2012		Y
			Seasonal allergy	16AUG2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	16AUG2010		Y
	C4591001 1130 11301092	Immune system disorders	Seasonal allergy	03JUN1999		Y
		Infections and infestations	Herpes simplex	22JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	25OCT2001		Y
	C4591001 1130 11301093	Metabolism and nutrition disorders	Hypertriglyceridaemia	05APR2017		Y
		Renal and urinary disorders	Nephrolithiasis	02AUG2015	02AUG2015	N
		Vascular disorders	Hypertension	05APR2017		Y
	C4591001 1130 11301094	Musculoskeletal and connective tissue disorders	Back pain	22JUL2003		Y
			Intervertebral disc protrusion	02MAY2019		Y
		Nervous system disorders	Radiculopathy	02MAY2019		Y
		Psychiatric disorders	Alcohol abuse	01JAN1998	26JUN2003	N
			Anxiety	01JAN2002		Y
			Drug abuse	01JAN1998	26JUN2003	N
			Major depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Psoriasis	31OCT2006		Y
			Seborrhoeic dermatitis	31OCT2006		Y
		Vascular disorders	Essential hypertension	26AUG2008		Y
	C4591001 1130 11301097	Metabolism and nutrition disorders	Vitamin D deficiency	16SEP2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	23OCT2014		Y
		Skin and subcutaneous tissue disorders	Acne	25JAN2011	24FEB2011	N
	C4591001 1130 11301099	Metabolism and nutrition disorders	Hyperlipidaemia	20MAR2018		Y
	C4591001 1131 11311002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	01SEP2019	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	30NOV2018	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN1996	31DEC1996	N
			Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1131 11311004	Eye disorders	Glaucoma	01JAN2014		Y
		Hepatobiliary disorders	Hyperbilirubinaemia	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2003	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1993		Y
		Social circumstances	Corrective lens user	01JAN1993		Y
	C4591001 1131 11311011	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Haematochezia	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015	31DEC2015	N
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1131 11311015	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01DEC2019		Y
				01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01DEC2019	29FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2004		Y
	C4591001 1131 11311016	Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Investigations	Colonoscopy normal	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1989	31DEC1989	N
			Cancer surgery	01APR2019	30APR2019	N
			Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1131 11311017	Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2018		Y
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal osteoarthritis	01JAN2015		Y
			Tendonitis	01JAN2016		Y
		Nervous system disorders	Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1990	29FEB2020	N
			Insomnia	01JAN1990		Y
		Surgical and medical procedures	Fracture treatment	01JAN1992	31DEC1992	N
				01JAN2000	31DEC2000	N
	C4591001 1131 11311018	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sciatica	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Social circumstances	Tobacco user	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
			Intrauterine contraception	01JAN2017		Y
	C4591001 1131 11311020	Investigations	Blood cholesterol increased	01JAN2016		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2015	N
		Social circumstances	Tobacco user	01JAN1996		Y
		Surgical and medical procedures	Spinal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1131 11311024	Eye disorders	Hypermetropia	01JAN1997		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
			Impaired gastric emptying	01JAN2003		Y
		Immune system disorders	Anaphylactic reaction	01JAN1995		Y
			Drug hypersensitivity	01JAN1990		Y
				01JAN1995		Y
			Mycotic allergy	01JAN1995		Y
			Rubber sensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Herpes simplex	01AUG2018		Y
		Nervous system disorders	Headache	01JAN2003		Y
			Migraine	01JAN2003		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Corrective lens user	01JAN1997		Y
			Orthodontic appliance user	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Benign breast lump removal	01MAR2020	31MAR2020	N
	C4591001 1131 11311026	Cardiac disorders	Ventricular extrasystoles	01JAN2013		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1997		Y
			Dysphagia	01JAN2018		Y
			Inguinal hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN1973		Y
		Infections and infestations	Osteomyelitis	01JAN1974	31DEC1974	N
		Nervous system disorders	Migraine with aura	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1985		Y
			Tobacco user	01JAN1992	31DEC1993	N
		Surgical and medical procedures	Adenoidectomy	01JAN1972	31DEC1972	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1131 11311031	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Herpes zoster	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
	C4591001 1131 11311032	Eye disorders	Myopia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Tobacco user	01JAN1998	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311035	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2014	30SEP2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Hiatus hernia	01JAN2014		Y
		Immune system disorders	Anaphylactic reaction	01JAN2015	31DEC2015	N
			Seasonal allergy	01JAN1988		Y
		Injury, poisoning and procedural complications	Repetitive strain injury	01JUN2020	31JUL2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	30SEP2018	N
				01MAR2014	30APR2014	N
		Nervous system disorders	Cerebrovascular accident	01MAR2014	31MAR2014	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
		Surgical and medical procedures	Atrial septal defect repair	01SEP2014	30SEP2014	N
			Caesarean section	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Skin neoplasm excision	01APR2014	30APR2014	N
				01SEP2018	30SEP2018	N
			Transfusion	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Aortic dilatation	01JAN2014		Y
	C4591001 1131 11311038	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Hiatus hernia	01JAN2010		Y
		Injury, poisoning and procedural complications	Neck injury	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2013		Y
		Nervous system disorders	Headache	01JAN2013		Y
			Migraine with aura	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Panic attack	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
			Stress urinary incontinence	01JAN2014		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN1985	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000	31DEC2010	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
			Continuous positive airway pressure	01JAN2000	31DEC2010	N
			Endometrial ablation	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1999	31DEC1999	N
			Uvulopalatopharyngoplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1131 11311041	Eye disorders	Hypermetropia	01JAN1992		Y
		Gastrointestinal disorders	Dyspepsia	01AUG2019		Y
			Rectal prolapse	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Limb asymmetry	01JAN2014		Y
			Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN1994		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1993	31DEC1993	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1974		Y
			Rosacea	01JAN2012		Y
			Urticaria	01JAN2004		Y
		Social circumstances	Blood donor	01JAN1989		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Nasal polypectomy	01JAN1993	31DEC1993	N
			Rectal prolapse repair	01JAN2016	31DEC2016	N
			Astigmatism	01JAN2018		Y
	C4591001 1131 11311042	Eye disorders				
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2001	31DEC2001	N
			Lithotripsy	01JAN2015	31DEC2015	N
	C4591001 1131 11311045	Infections and infestations	Cat scratch disease	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diverticulitis	01JAN2002	31DEC2002	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
		Social circumstances	Blood donor	01JAN1997		Y
			Ex-tobacco user	01JAN1999	31DEC2015	N
		Surgical and medical procedures	Axillary lymphadenectomy	01JAN2010	31DEC2010	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Intestinal resection	01JAN2002	31DEC2002	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1131 11311046	Eye disorders	Hypermetropia	01JAN1986		Y
			Myopia	01JAN1986		Y
		Gastrointestinal disorders	Dental caries	01JAN2019	28SEP2020	N
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Injury, poisoning and procedural complications	Ligament rupture	01MAY2019		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1999		Y
		Social circumstances	Corrective lens user	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01FEB2019	28FEB2019	N
	C4591001 1131 11311048	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
			Skin bacterial infection	01JAN2017		Y
			Tonsillitis	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1997	31DEC1997	N
			Uterine operation	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
	C4591001 1131 11311049	Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Urinary tract infection	01JAN1983	31DEC1987	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
			Renal surgery	01JAN1987	31DEC1987	N
			Urethral repair	01JAN1997	31DEC1997	N
	C4591001 1131 11311050	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Muscle spasms	01JAN2000		Y
			Neck pain	01JAN2015		Y
			Sacroiliitis	01JAN2015		Y
			Scoliosis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2015		Y
			Spondylitis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Neurogenic bladder	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1991	31DEC1991	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1131 11311051	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2017	31DEC2017	N
		Social circumstances	Blood donor	01JAN2011	31DEC2018	N
	C4591001 1131 11311053	Gastrointestinal disorders	Gastrooesophageal reflux disease	13AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Gastroenteritis	01JUL2019	30SEP2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2020		Y
		Social circumstances	Menopause	01FEB2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Mole excision	01FEB2020	29FEB2020	N
				01JAN2018	31DEC2018	N
	C4591001 1131 11311061	Eye disorders	Presbyopia	01JAN2018		Y
		Surgical and medical procedures	Chondroplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311062	Cardiac disorders	Palpitations	01JAN2012		Y
		Congenital, familial and genetic disorders	Cancer gene carrier	01JAN2004		Y
		Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
			Pharyngitis streptococcal	01JAN2000	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2008		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1993		Y
		Social circumstances	Corrective lens user	01JAN1985		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Mastectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1131 11311064	Eye disorders	Hypermetropia	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1998		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
	C4591001 1131 11311065	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2003		Y
		Nervous system disorders	Febrile convulsion	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vocal cord paralysis	01JUL2019	31OCT2019	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2016	31DEC2016	N
		Social circumstances	Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31JAN2011	N
				01JUL2013	31JUL2013	N
			Phlebectomy	01MAY2020	31MAY2020	N
	C4591001 1131 11311069	Cardiac disorders	Ventricular extrasystoles	01JAN2000	31DEC2014	N
		Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2015	31DEC2018	N
		Ear and labyrinth disorders	Meniere's disease	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Nausea	01JAN2010		Y
		General disorders and administration site conditions	Treatment noncompliance	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1991	31DEC1991	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2010	31DEC2010	N
		Nervous system disorders	Dizziness	01JAN2014	31DEC2018	N
			Migraine	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN2013	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Social circumstances	Corrective lens user	01JAN1977		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2008	31DEC2008	N
			Craniotomy	20NOV2018	20NOV2018	N
			Endometrial ablation	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2004	31DEC2004	N
			Thyroidectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1131 11311071	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Compartment syndrome	01JAN2002	31DEC2009	N
			Tendonitis	01OCT2019	30JUN2020	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Bipolar II disorder	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1985		Y
			Tobacco user	01JAN1997	31DEC2007	N
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2005		Y
			Fasciotomy	01JAN2009	31DEC2009	N
	C4591001 1131 11311073	Eye disorders	Hypermetropia	01JAN1987		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18AUG2020		Y
			Type 2 diabetes mellitus	01NOV2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2018	31DEC2018	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Social circumstances	Blood donor	01JAN1992	31DEC1993	N
			Ex-tobacco user	01JAN1992	31DEC2012	N
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2009		Y
			Skin neoplasm excision	01DEC2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1131 11311076	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Myopia	01JAN1983		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
			Urticaria	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1983		Y
	C4591001 1131 11311078	Vascular disorders	Raynaud's phenomenon	01JAN2019		Y
	C4591001 1131 11311079	Eye disorders	Myopia	01JAN1989		Y
		General disorders and administration site conditions	Injection site swelling	01JAN1980	31DEC1980	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1980		Y
		Social circumstances	Blood donor	01JAN2000	15JUL2020	N
			Corrective lens user	01JAN1989		Y
			Tobacco user	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
			Cholecystectomy	01MAR2018	31MAR2018	N
	C4591001 1131 11311080	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JUL2016	31JUL2017	N
		Reproductive system and breast disorders	Endometriosis	01JAN1992	31DEC2018	N
		Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	01JAN1994	31DEC1994	N
		Social circumstances	Blood donor	01JAN1995	31DEC1998	N
			Corrective lens user	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01DEC2018	31DEC2018	N
			Lymphadenectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1131 11311081	Immune system disorders	Milk allergy	01JAN2017		Y
			Seasonal allergy	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1992		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013	31DEC2014	N
			Headache	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN2005	31DEC2005	N
	C4591001 1131 11311083	Cardiac disorders	Supraventricular tachycardia	01JAN2004	31DEC2004	N
		Eye disorders	Myopia	01JAN2000	31DEC2005	N
		Gastrointestinal disorders	Constipation	01JAN1984		Y
			Gastroesophageal reflux disease	30OCT2019		Y
			Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Nervous system disorders	Tarsal tunnel syndrome	01JAN2014		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2019	30NOV2019	N
		Surgical and medical procedures	Cardiac ablation	01JAN2004	31DEC2004	N
			Eye laser surgery	01JAN2005	31DEC2005	N
			Gastrectomy	30OCT2019	30OCT2019	N
	C4591001 1131 11311085	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Eye disorders	Chorioretinopathy	01JAN2014		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1993	31DEC2005	N
		Investigations	Cardiac murmur	01JAN1987		Y
		Psychiatric disorders	Insomnia	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
		Surgical and medical procedures	Chondroplasty	01JAN2005	31DEC2005	N
			Hernia repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1131 11311086	Gastrointestinal disorders	Inguinal hernia	01JAN1981	31DEC1981	N
			Pancreatitis	01JAN2005	31DEC2006	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2009		Y
		Infections and infestations	Hepatitis C	01JAN2009	31DEC2018	N
		Psychiatric disorders	Alcohol abuse	01JAN2003	31DEC2009	N
			Drug abuse	01JAN2003	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN1981	31DEC1981	N
	C4591001 1131 11311087	Infections and infestations	Chronic tonsillitis	01JAN2015	31DEC2017	N
		Social circumstances	Tobacco user	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1131 11311090	Immune system disorders	Anaphylactic reaction	01JAN1996		Y
			Seasonal allergy	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN1998	30APR2000	N
	C4591001 1131 11311091	Eye disorders	Myopia	01JAN2009		Y
		Injury, poisoning and procedural complications	Road traffic accident	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Neck pain	01FEB2020	29FEB2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2011	31DEC2018	N
		Social circumstances	Corrective lens user	01JAN2009		Y
	C4591001 1131 11311092	Eye disorders	Hypermetropia	01JAN2017		Y
		Gastrointestinal disorders	Gastritis	01JAN1997	31DEC1997	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01APR2020		Y
		Social circumstances	Blood donor	01JAN2010		Y
			Corrective lens user	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ligament operation	01JAN2006	31DEC2006	N
			Tenoplasty	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1131 11311093	Eye disorders	Myopia	01JAN1981	31DEC2000	N
		Gastrointestinal disorders	Nausea	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JUL2017	31JUL2017	N
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN1995		Y
			Vitamin B12 deficiency	01JAN2013		Y
			Vitamin D deficiency	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1977		Y
			Rosacea	01JAN1976		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2012	31DEC2012	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Fracture treatment	01JUL2017	31JUL2017	N
			Tonsillectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1131 11311094	Eye disorders	Myopia	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2019		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311097	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2018		Y
		Ear and labyrinth disorders	Tinnitus	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Investigations	Biopsy breast normal	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2005		Y
			Urticaria	01JAN1978		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
	C4591001 1131 11311099	Eye disorders	Hypermetropia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1987		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Tobacco user	01JAN2000	31DEC2005	N
	C4591001 1131 11311102	Eye disorders	Hypermetropia	01JAN2018	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01DEC2018	30SEP2019	N
		Surgical and medical procedures	Mole excision	01JAN2015	31DEC2015	N
	C4591001 1131 11311103	Eye disorders	Hypermetropia	01JAN1992		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Infections and infestations	Presumed ocular histoplasmosis syndrome	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Corrective lens user	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Eye laser surgery	01JAN2001	31DEC2001	N
			Gastric bypass	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2006	31DEC2006	N
			Knee operation	01JAN2008	31DEC2008	N
			Hypermetropia	01JAN1995		Y
	C4591001 1131 11311104	Eye disorders				
		Investigations	Anti-platelet antibody positive	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1997		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
			Immunoglobulin therapy	01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN1999	31DEC1999	N
	C4591001 1131 11311106	Congenital, familial and genetic disorders	Retinitis pigmentosa	01JAN1977		Y
		Eye disorders	Cataract	01JAN2003	31DEC2007	N
			Hypermetropia	01JAN2007		Y
			Myopia	01JAN1977		Y
			Presbyopia	01JAN2007		Y
		Injury, poisoning and procedural complications	Skin laceration	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01FEB2019	31AUG2019	N
			Tendonitis	01JAN2013		Y
		Reproductive system and breast disorders	Testicular torsion	01JAN1993	31DEC1994	N
		Social circumstances	Corrective lens user	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
			Testes exploration	01JAN1994	31DEC1994	N
			Wound closure	01JAN1985	31DEC1985	N
	C4591001 1131 11311107	Eye disorders	Myopia	01JAN2007		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
	C4591001 1131 11311109	Surgical and medical procedures	Bone operation	01JAN2008	31DEC2008	N
		Eye disorders	Presbyopia	01JAN2006		Y
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
				01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2015	N
		Social circumstances	Blood donor	01JAN1982		Y
			Corrective lens user	01JAN2006		Y
			Postmenopause	01FEB2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Micrographic skin surgery	01JAN2015	31DEC2015	N
	C4591001 1131 11311111	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN1978	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN1992	31DEC1999	N
		Surgical and medical procedures	Fracture treatment	01JAN2005	31DEC2005	N
			Wisdom teeth removal	01JAN1994	31DEC1994	N
	C4591001 1131 11311112	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN1989	31OCT2012	N
			Retinal tear	01JAN2008	31DEC2008	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2017		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
				01JAN2018		Y
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	02FEB2016	02FEB2016	N
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Depression	01JAN1993		Y
			Somatic symptom disorder	01JAN2000		Y
				01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	02FEB2016	N
					31DEC2014	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2005		Y
		Surgical and medical procedures	Eye laser surgery	01OCT2012	31OCT2012	N
			Eye operation	01JAN2008	31DEC2008	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	02FEB2016	02FEB2016	N
			Transfusion	02FEB2016	02FEB2016	N
	C4591001 1131 11311113	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood prolactin increased	01FEB2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01FEB2014		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01MAR2017	31MAR2017	N
			Gestational diabetes	01JAN2020	31MAR2020	N
			Gestational hypertension	01JAN2016	31DEC2017	N
				01JAN2019	31MAR2020	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01AUG2020		Y
			Urticaria	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	01MAR2020	31MAR2020	N
			Female sterilisation	01MAR2020	31MAR2020	N
			Uterine dilation and curettage	01FEB2015	28FEB2015	N
	C4591001 1131 11311116	Cardiac disorders	Atrioventricular block first degree	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Myopia	01JAN1998		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1998	31DEC1998	N
			Constipation	01JAN1991	31DEC2019	N
			Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2000	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Back pain	01JAN2015		Y
			Pain in extremity	01JAN2020		Y
			Temporomandibular joint syndrome	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
			Bipolar disorder	01JAN1995	31DEC2013	N
			Depression	01JAN1995		Y
			Insomnia	01JAN2000		Y
			Obsessive-compulsive disorder	01JAN1995		Y
			Post-traumatic stress disorder	01JAN1995		Y
		Social circumstances	Corrective lens user	01JAN1998		Y
			Tobacco user	01JAN2005	31DEC2013	N
		Surgical and medical procedures	Varicocele repair	01JAN1998	31DEC1998	N
	C4591001 1131 11311117	Blood and lymphatic system disorders	Anaemia	01JAN1997	31OCT2019	N
		Ear and labyrinth disorders	Vertigo	01JAN2006		Y
		Endocrine disorders	Hyperthyroidism	01MAR2019	31MAR2020	N
		Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN1985		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2010	31DEC2010	N
		Investigations	Low density lipoprotein increased	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019	31MAR2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Tendonitis	01JAN2007		Y
		Nervous system disorders	Headache	01JAN1997		Y
			Migraine	01JAN1997		Y
			Syncope	01FEB2020	29FEB2020	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN1991	31DEC1993	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1993		Y
		Surgical and medical procedures	Ureteric repair	01JAN1989	31DEC1989	N
	C4591001 1131 11311124	Congenital, familial and genetic disorders	Hereditary non-polyposis colorectal cancer syndrome	01JAN2017		Y
		Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1977		Y
			Hiatus hernia	01JAN2012		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1993	31DEC1993	N
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Perinatal depression	01JAN2001	31DEC2002	N
				01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Internal fixation of fracture	01JAN1993	31DEC1993	N
			Photorefractive keratectomy	01JAN2005	31DEC2005	N
	C4591001 1131 11311129	Psychiatric disorders	Obsessive-compulsive disorder	01JAN2012		Y
	C4591001 1131 11311131	Eye disorders	Chorioretinopathy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypermetropia	01JAN1983		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercalcaemia	01JAN2006	31DEC2007	N
			Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016		Y
			Spinal osteoarthritis	01JAN2004		Y
			Tendonitis	01JAN2008		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1983		Y
			Ex-tobacco user	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Adenoidectomy	01JAN1979	31DEC1979	N
			Continuous positive airway pressure	01JAN2019		Y
			Parathyroidectomy	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1979	31DEC1979	N
			Vasectomy	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311132	Eye disorders	Myopia	01JAN1991		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2009		Y
			Dyspepsia	01JAN2009		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN2011		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2013		Y
		Nervous system disorders	Dizziness	01MAY2020	31MAY2020	N
			Headache	01JAN1992		Y
			Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2015	31DEC2019	N
			Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	30NOV2019	N
		Skin and subcutaneous tissue disorders	Urticaria	01JUL2020	31AUG2020	N
		Social circumstances	Corrective lens user	01JAN1991		Y
			Tobacco user	01JAN1991		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1994	31DEC1994	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311134	Ear and labyrinth disorders	Tinnitus	01JAN1996		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1973	31DEC1973	N
		Immune system disorders	Contrast media allergy	01JAN1992		Y
			Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2013		Y
			Hypokalaemia	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Calculus urinary	01JAN1989		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Eye muscle operation	01JAN1986	31DEC1986	N
			Inguinal hernia repair	01JAN1973	31DEC1973	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
			Tooth extraction	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1131 11311136	Endocrine disorders	Basedow's disease	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Diastasis recti abdominis	03SEP2020		Y
		Social circumstances	Blood donor	01JAN1980	31DEC1991	N
			Ex-tobacco user	01JAN1988	31MAR2020	N
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2012		Y
			Hernia repair	01JAN1968	31DEC1968	N
			Tonsillectomy	01JAN1974		Y
	C4591001 1131 11311138	Cardiac disorders	Mitral valve prolapse	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2005		Y
		Surgical and medical procedures	Bunion operation	01JAN2006		Y
			Tonsillectomy	01JAN1980		Y
	C4591001 1131 11311142	Eye disorders	Hypermetropia	01JAN2010		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
			Dyspepsia	01JAN2005		Y
			Dysphagia	01JAN1965		Y
			Oesophageal stenosis	01JAN1965		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01DEC2019	30APR2020	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Cancer surgery	01APR2020	30APR2020	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Oesophageal dilation procedure	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1131 11311143	Gastrointestinal disorders	Dental caries	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Cardiac murmur	01JAN1993		Y
	C4591001 1131 11311144	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1983		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018	31DEC2018	N
		Social circumstances	Blood donor	01JAN1984		Y
			Corrective lens user	01JAN1985		Y
	C4591001 1131 11311147	Surgical and medical procedures	Liposuction	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Diarrhoea	01JAN2015		Y
			Dyspepsia	01JAN2012		Y
			Gastric ulcer	01JAN2000	31DEC2006	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01OCT2019		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1999		Y
		Surgical and medical procedures	Appendectomy	01JAN1992	31DEC1992	N
			Continuous positive airway pressure	01JAN2015		Y
			Myringotomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1131 11311148	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2017		Y
		Eye disorders	Myopia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1131 11311152	Congenital, familial and genetic disorders	Eagle Barrett syndrome	01JAN2019		Y
			Factor V Leiden mutation	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2009		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Major depression	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1131 11311153	Blood and lymphatic system disorders	Anaemia	01JAN1993	31DEC2000	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1990		Y
		General disorders and administration site conditions	Fatigue	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Infections and infestations	Herpes zoster	01JAN1993	31DEC1993	N
			Pharyngitis streptococcal	01MAY2019	31MAY2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Fibromyalgia	01JAN2014		Y
		Nervous system disorders	Hypersomnia	01JAN2010	31DEC2014	N
			Migraine	01JAN1994	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Periodic limb movement disorder	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1997		Y
			Insomnia	01JAN2014		Y
			Libido decreased	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Social circumstances	Tobacco user	01JAN1996	31DEC2005	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
			Mammoplasty	01JAN2014	31DEC2014	N
			Meniscus operation	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
	C4591001 1131 11311157	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Investigations	Blood cholesterol increased	01AUG2020		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2001		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1997		Y
		Social circumstances	Corrective lens user	01JAN1994		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2004	31DEC2004	N
	C4591001 1131 11311158	Cardiac disorders	Palpitations	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1991		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1131 11311160	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012	31DEC2017	N
	C4591001 1131 11311161	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
			Irritable bowel syndrome	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes zoster	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Renal and urinary disorders	Nephrotic syndrome	01JAN1984	31DEC1986	N
			Renal atrophy	01JAN1984		Y
		Surgical and medical procedures	Bunion operation	01JAN2019	31DEC2019	N
			Renal surgery	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1131 11311162	Eye disorders	Myopia	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311167	Surgical and medical procedures	Spinal laminectomy	01JAN2019	31DEC2019	N
		Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Cardiac murmur	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1998	31DEC2008	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN2015		Y
			Bronchitis chronic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
			Urticaria	01JAN1982		Y
		Surgical and medical procedures	Eye laser surgery	01FEB2020	29FEB2020	N
			Female sterilisation	01JAN2015		Y
			Hysterectomy	01JAN2018	31DEC2018	N
			Uterine dilation and curettage	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
	C4591001 1131 11311172	Vascular disorders	Hypertension	01JAN2007		Y
		Eye disorders	Presbyopia	01JAN2002		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	15JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Tobacco user	01JAN1992	31DEC2000	N
		Surgical and medical procedures	Dental implantation	01MAR2020		Y
			Knee arthroplasty	01JUN2020	30JUN2020	N
			Spinal fusion surgery	01OCT2017	31OCT2017	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1131 11311173	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1992		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
	C4591001 1131 11311178	Immune system disorders	Meniscus operation	01JAN2005	31DEC2005	N
			Drug hypersensitivity	01DEC2005		Y
			Seasonal allergy	01AUG2005		Y
		Infections and infestations	Fungal infection	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
			Type 2 diabetes mellitus	01MAR2018		Y
		Psychiatric disorders	Anxiety	01MAR2020	30APR2020	N
			Insomnia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Social circumstances	Corrective lens user	01JAN1989	30JUN2018	N
		Surgical and medical procedures	Eye laser surgery	01JUN2018	30JUN2018	N
			Nasal septal operation	01DEC2005	31DEC2005	N
			Tonsillectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311181	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1131 11311182	Eye disorders	Diabetic retinopathy	01JUN2018		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2002		Y
		Psychiatric disorders	Depression	01MAR1985		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Ankle operation	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1131 11311183	Congenital, familial and genetic disorders	Cerebral palsy	01JAN1974		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1988		Y
		General disorders and administration site conditions	Chronic fatigue syndrome	01JAN2008		Y
		Immune system disorders	Rubber sensitivity	01JAN1986		Y
			Seasonal allergy	01JAN1984		Y
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Surgical and medical procedures	Arthrodesis	01JAN1990	31DEC1990	N
			Pilonidal sinus repair	01JAN1994	31DEC1994	N
			Tendon transfer	01JAN1990	31DEC1990	N
			Tenotomy	01JAN1979	31DEC1979	N
	C4591001 1131 11311184	Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUN2018		Y
		Social circumstances	Corrective lens user	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Meniscus operation	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Vasectomy	01JAN2016	31DEC2016	N
			Vision correction operation	01JAN2012	31DEC2012	N
	C4591001 1131 11311190	Immune system disorders	Seasonal allergy	01JAN1987	31DEC1995	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2000	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987	31DEC1995	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1990	31DEC1990	N
			Nasal septal operation	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1131 11311193	Gastrointestinal disorders	Colitis ulcerative	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Road traffic accident	01MAY2019	31MAY2019	N
			Skin injury	01MAY2019	31JUL2019	N
		Metabolism and nutrition disorders	Gout	01JAN2011	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
			Depression	01JAN2000		Y
			Obsessive-compulsive disorder	01JAN1990		Y
		Surgical and medical procedures	Fracture treatment	01JAN1997	31DEC1997	N
			Skin graft	01MAY2019	31MAY2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311201	Blood and lymphatic system disorders	Anaemia	01JAN2009		Y
		Eye disorders	Myopia	01JAN1986		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Social circumstances	Corrective lens user	01JAN1986		Y
		Surgical and medical procedures	Dental prosthesis placement	01JAN2013		Y
	C4591001 1131 11311205	Eye disorders	Myopia	01JAN1989		Y
		Gastrointestinal disorders	Dysphagia	01AUG2018	06AUG2020	N
		General disorders and administration site conditions	Adverse drug reaction	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1989		Y
			Ex-tobacco user	01JAN1988	31DEC2004	N
			Substance use	01JAN1989	31DEC2003	N
		Surgical and medical procedures	Oesophageal dilation procedure	06AUG2020	06AUG2020	N
			Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1131 11311209	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
			Osteoarthritis	01JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Joint resurfacing surgery	01JAN2017	31DEC2017	N
			Spinal laminectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1131 11311219	General disorders and administration site conditions	Adverse drug reaction	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2006		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1131 11311220	Immune system disorders	Anaphylactic reaction	01JAN2002		Y
		Infections and infestations	Herpes zoster	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Joint injury	01JAN1995	31DEC2002	N
		Social circumstances	Blood donor	01JAN1996	31MAR2020	N
			Tobacco user	01JAN1995	31DEC2018	N
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2010		Y
			Knee arthroplasty	01JAN2002	31DEC2002	N
	C4591001 1131 11311221	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2010	N
		Eye disorders	Myopia	01JAN2004	31DEC2004	N
		Nervous system disorders	Seizure	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1131 11311228	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2005		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1991	31DEC1991	N
		Immune system disorders	Anaphylactic reaction	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2016		Y
			Seizure	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2003		Y
		Social circumstances	Tobacco user	01JAN2003		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1131 11311229	Gastrointestinal disorders	Abdominal hernia	01JAN1994	31DEC1994	N
			Gastroesophageal reflux disease	01JAN2003	31DEC2003	N
		Hepatobiliary disorders	Hepatic steatosis	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01FEB2013		Y
		Psychiatric disorders	Depression	01JAN2003	31DEC2003	N
			Insomnia	01JAN2003		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2004	31DEC2004	N
			Tonsillar hypertrophy	01JAN2005	31DEC2005	N
		Social circumstances	Corrective lens user	01JAN2005		Y
			Tobacco user	01JAN2013		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1994	31DEC1994	N
			Adenoidectomy	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1131 11311230	Cardiac disorders	Supraventricular extrasystoles	01MAR2020		Y
		Gastrointestinal disorders	Gingival recession	01JAN1993	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Investigations	Blood cholesterol increased	01JAN1989	31DEC1989	N
		Renal and urinary disorders	Haematuria	01JAN1993	31DEC1993	N
		Reproductive system and breast disorders	Perineal cyst	01APR2018	31OCT2018	N
		Surgical and medical procedures	Gingival graft	01JAN2016	31DEC2016	N
			Salivary gland operation	01JAN1991	31DEC1991	N
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1131 11311232	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN1982		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Trichotillomania	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Social circumstances	Corrective lens user	01JAN1982		Y
		Surgical and medical procedures	Eye laser surgery	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1986	31DEC1986	N
			Wisdom teeth removal	01JAN1993	31DEC1993	N
	C4591001 1131 11311233	Congenital, familial and genetic disorders	Deafness congenital	(b) (6) 1974		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood glucose increased	01JAN2019		Y
		Surgical and medical procedures	Cochlea implant	01JAN2019		Y
			Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1131 11311241	Eye disorders	Blindness unilateral	01JAN1970		Y
			Hypermetropia	01JAN1970		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1982		Y
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1970		Y
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2015	N
			Hypertension	01JAN1995		Y
	C4591001 1131 11311243	Eye disorders	Myopia	01JAN2005		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
			Tobacco user	01JAN1998	31DEC2003	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311246	Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
				01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
			Migraine	01JAN2014	31DEC2014	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2009		Y
		Social circumstances	Blood donor	01JAN2003		Y
		Surgical and medical procedures	Bone graft	01JAN2008	31DEC2008	N
			Caesarean section	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Carpal tunnel decompression	01JAN2017	31DEC2017	N
			Dental implantation	01JAN2008		Y
			Endometrial ablation	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2016	31DEC2016	N
			Transfusion	01JAN2016	31DEC2016	N
	C4591001 1131 11311252	General disorders and administration site conditions	Disease susceptibility	16OCT2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Continuous positive airway pressure	01APR2020		Y
	C4591001 1131 11311254	Blood and lymphatic system disorders	Anaemia	01JAN2004	31DEC2008	N
		Gastrointestinal disorders	Constipation	01JAN2006	31DEC2008	N
			Dyspepsia	01JAN2006	31DEC2008	N
		General disorders and administration site conditions	Adverse drug reaction	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Tinea versicolour	01JAN2008		Y
		Investigations	Human papilloma virus test positive	01JAN1993	31DEC2006	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1131 11311257	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Genital herpes	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
		Nervous system disorders	Trigeminal neuralgia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1998		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
	C4591001 1131 11311260	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1988	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1988		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Uterine dilation and curettage	01JAN2002	31DEC2002	N
	C4591001 1131 11311263	Cardiac disorders	Cardiomyopathy	01JAN2019		Y
		Immune system disorders	Rubber sensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
			Snoring	01JAN2009		Y
		Surgical and medical procedures	Tongue tie operation	01JAN2003	31DEC2003	N
	C4591001 1131 11311264	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2014		Y
	C4591001 1131 11311265	Eye disorders	Myopia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
	C4591001 1131 11311266	Eye disorders	Hypermetropia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2020	31JAN2020	N
	C4591001 1131 11311267	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Generalised anxiety disorder	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
		Surgical and medical procedures	Orchidectomy	01JAN2004	31DEC2004	N
	C4591001 1131 11311268	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Panic disorder	01JAN2019		Y
			Sleep disorder	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1131 11311269	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Tooth extraction	01JAN2013	31DEC2013	N
	C4591001 1131 11311270	Eye disorders	Myopia	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
			Menorrhagia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Psoriasis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1131 11311271	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
	C4591001 1131 11311272	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Tension headache	01SEP2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
			Menorrhagia	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01AUG2020	31AUG2020	N
	C4591001 1131 11311273	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2016		Y
	C4591001 1131 11311274	Eye disorders	Hypermetropia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Dyslexia	01JAN2009		Y
			Migraine	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
	C4591001 1131 11311276	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Cardiac murmur functional	01JAN2008		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUL2020	31JUL2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311279	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
	C4591001 1133 11331001	Eye disorders	Myopia	01JUN2010		Y
		Infections and infestations	Appendicitis	01DEC1991	31DEC1991	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2008		Y
			Type 2 diabetes mellitus	01JUN2019		Y
		Psychiatric disorders	Anxiety	01AUG2008		Y
			Bipolar disorder	01AUG2008		Y
			Post-traumatic stress disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Vascular disorders	Hypertension	01AUG2008		Y
	C4591001 1133 11331003	Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Caesarean section	07APR1989	07APR1989	N
				14APR2003	14APR2003	N
			Meniscus operation	01JAN2014	31DEC2014	N
			Oophorectomy	01JAN1981	31DEC1981	N
	C4591001 1133 11331004	Eye disorders	Myopia	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331011	Eye disorders	Blindness unilateral	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
			Postmenopause	01JAN2010		Y
		Vascular disorders	Varicose vein	01JAN2012		Y
	C4591001 1133 11331014	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331016	Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1133 11331019	Eye disorders	Hypermetropia	01JAN1976		Y
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1133 11331028	Eye disorders	Hypermetropia	01JUL2011		Y
		Gastrointestinal disorders	Dyspepsia	01JUL2000		Y
		Infections and infestations	Appendicitis	01JAN1969		Y
		Psychiatric disorders	Anxiety	01JUL1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Vascular disorders	Hypertension	01JUL2018		Y
	C4591001 1133 11331030	Eye disorders	Presbyopia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JAN1983		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1994	31DEC1994	N
	C4591001 1133 11331041	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Mole excision	01JAN1998	31DEC1998	N
	C4591001 1133 11331043	Eye disorders	Hypermetropia	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1133 11331044	Cardiac disorders	Tachycardia	01JAN2019		Y
	C4591001 1133 11331045	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331047	Injury, poisoning and procedural complications	Humerus fracture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Bone operation	01JAN2007	31DEC2007	N
	C4591001 1133 11331048	Eye disorders	Hypermetropia	01JAN1991		Y
			Myopia	01JAN1991		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Caesarean section	16AUG2008	16AUG2008	N
				20MAY2016	20MAY2016	N
				23JUL2011	23JUL2011	N
			Ovarian cystectomy	01JAN2014	31DEC2014	N
			Salpingo-oophorectomy unilateral	01JAN2014	31DEC2014	N
	C4591001 1133 11331050	Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331051	Surgical and medical procedures	Tonsillectomy	01JAN1980	31DEC1980	N
		Eye disorders	Presbyopia	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	07FEB2015		Y
			Intervertebral disc protrusion	01JAN2000	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Ex-tobacco user	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2000	31DEC2000	N
				01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
				01JAN1972	31DEC1972	N
				01JAN2018		Y
	C4591001 1133 11331052	Eye disorders	Presbyopia	01JAN2018		Y
		Infections and infestations	Abscess limb	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN1987		Y
		Social circumstances	Ex-tobacco user	01JAN1990	31DEC1990	N
	C4591001 1133 11331054	Surgical and medical procedures	Abscess drainage	01JAN2014	31DEC2014	N
		Eye disorders	Myopia	01JAN2001		Y
		Infections and infestations	Bronchitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Overweight	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUL2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Synovial cyst	01JAN1985	31DEC1985	N
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JUL2009		Y
			Depression	01JUL2009		Y
			Insomnia	01JUL2009		Y
			Post-traumatic stress disorder	01JUL2009		Y
		Vascular disorders	Hypertension	01JUL2009		Y
	C4591001 1133 11331058	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Drug abuse	01JAN2019	31JAN2020	N
		Surgical and medical procedures	Caesarean section	02APR2009	02APR2009	N
				07JUN2012	07JUN2012	N
				09JUN2002	09JUN2002	N
	C4591001 1133 11331059	Eye disorders	Hypermetropia	01JAN2019		Y
			Vision blurred	01JAN2019		Y
		Nervous system disorders	Epilepsy	01JAN2019		Y
			Seizure	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Peripheral nerve neurostimulation	01JAN2014		Y
	C4591001 1133 11331060	Eye disorders	Hypermetropia	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Retinoblastoma	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Eye operation	01JAN1994	31DEC1994	N
	C4591001 1133 11331062	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN2004		Y
		Social circumstances	Corrective lens user	01JAN1985		Y
			Ex-tobacco user	01JAN1989	31DEC2004	N
		Surgical and medical procedures	Shoulder operation	01MAR2014	31MAR2014	N
	C4591001 1133 11331063	Investigations	Smear cervix abnormal	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Cervicectomy	01JAN1995	31DEC1995	N
	C4591001 1133 11331066	Eye disorders	Hypermetropia	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Solar lentigo	01JAN2015		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
			Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1133 11331069	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JUL2019		Y
		Social circumstances	Ex-tobacco user	01JAN1992	31DEC2000	N
	C4591001 1133 11331070	Surgical and medical procedures	Salpingectomy	01JAN2008	31JAN2008	N
	C4591001 1133 11331072	Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
			Mammoplasty	01JAN2007	31DEC2007	N
	C4591001 1133 11331074	Eye disorders	Blindness unilateral	(b) (6) 1975		Y
	C4591001 1133 11331079	Immune system disorders	Allergy to chemicals	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2013	31DEC2014	N
		Surgical and medical procedures	Adenoidectomy	01JAN1998	31DEC1998	N
			Mammoplasty	01AUG2018	31AUG2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1133 11331083	Eye disorders	Myopia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2010	N
		Surgical and medical procedures	Abdominoplasty	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Liposuction	01JAN2006	31DEC2006	N
	C4591001 1133 11331088	Eye disorders	Myopia	01JAN2019		Y
	C4591001 1133 11331093	Social circumstances	Ex-tobacco user	01JAN2014	31DEC2020	N
	C4591001 1133 11331096	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1982	31OCT2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
	C4591001 1133 11331097	Surgical and medical procedures	Caesarean section	09NOV1995	09NOV1995	N
				11AUG1992	11AUG1992	N
			Female sterilisation	09NOV1995	09NOV1995	N
	C4591001 1133 11331102	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Ex-tobacco user	01JAN1989	31DEC1990	N
	C4591001 1133 11331103	Eye disorders	Hypermetropia	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1984		Y
	C4591001 1133 11331105	Eye disorders	Myopia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1999	31DEC1999	N
	C4591001 1133 11331106	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
		Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2007	31DEC2007	N
	C4591001 1133 11331111	Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
	C4591001 1133 11331113	Eye disorders	Myopia	01JAN1990	31DEC2000	N
		General disorders and administration site conditions	Cyst	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Hair transplant	01JAN2016	31DEC2016	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Neck surgery	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2000	31DEC2000	N
	C4591001 1133 11331115	Eye disorders	Hypermetropia	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastritis	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2020		Y
		Social circumstances	Ex-tobacco user	01JAN2001	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1133 11331117	Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2014	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Surgical and medical procedures	Lipoma excision	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1133 11331119	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Surgical and medical procedures	Breast cyst excision	01JAN2014	31DEC2014	N
			Intra-uterine contraceptive device insertion	01JAN2011		Y
	C4591001 1133 11331121	Eye disorders	Myopia	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	13OCT2006	13OCT2006	N
			Intra-uterine contraceptive device insertion	01JAN2012		Y
			Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1133 11331122	Eye disorders	Hypermetropia	01JAN1978		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1133 11331123	Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331125	Eye disorders	Hypermetropia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Mammoplasty	01NOV1995	30NOV1995	N
	C4591001 1133 11331129	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Social circumstances	Ex-tobacco user	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Caesarean section	29AUG2008	29AUG2008	N
			Mammoplasty	01JUL2017	31JUL2017	N
	C4591001 1133 11331130	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
	C4591001 1133 11331131	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Bipolar disorder	01JAN2019		Y
			Schizophrenia	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2010	N
	C4591001 1133 11331132	Eye disorders	Myopia	01JAN2019		Y
	C4591001 1133 11331135	Surgical and medical procedures	Mammoplasty	01APR2015	30APR2015	N
	C4591001 1133 11331138	Eye disorders	Myopia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01FEB2013	28FEB2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01FEB2015	28FEB2015	N
			Hysterectomy	01NOV2017	30NOV2017	N
	C4591001 1133 11331139	Eye disorders	Myopia	01DEC2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Hip fracture	01SEP2005	30SEP2005	N
			Upper limb fracture	10JAN2020	10JAN2020	N
		Social circumstances	Tobacco user	01JAN1995		Y
		Surgical and medical procedures	Elbow operation	10JAN2020	10JAN2020	N
			Hip surgery	01SEP2005	30SEP2005	N
	C4591001 1133 11331140	Vascular disorders	Hypertension	01JAN1998		Y
		Eye disorders	Presbyopia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Caesarean section	16MAY1984	16MAY1984	N
				19APR1996	19APR1996	N
			Female sterilisation	19APR1996	19APR1996	N
	C4591001 1133 11331142	Social circumstances	Corrective lens user	01JAN2016		Y
			Ex-tobacco user	01JAN1994	31DEC2000	N
	C4591001 1133 11331144	Eye disorders	Myopia	01JAN1989		Y
		Social circumstances	Ex-tobacco user	01JAN1997	31DEC2002	N
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
			Female sterilisation	20JUN2009	20JUN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331145	Immune system disorders	Iodine allergy	01JAN2014	31DEC2014	N
		Infections and infestations	Bronchitis	01JAN2010	31DEC2010	N
			Tonsillitis	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990	31DEC1995	N
		Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1133 11331149	Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
	C4591001 1133 11331150	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Myopia	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331151	Eye disorders	Myopia	01JAN1993	31DEC1993	N
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Nervous system disorders	Tension headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Surgical and medical procedures	Keratomileusis	01JAN2013	31DEC2013	N
	C4591001 1133 11331152	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y
		Surgical and medical procedures	Caesarean section	01MAY1999	01MAY1999	N
				07MAR2004	07MAR2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				13MAR1998	13MAR1998	N
			Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1133 11331158	Eye disorders	Presbyopia	01JAN2018		Y
	C4591001 1133 11331162	Eye disorders	Myopia	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1133 11331166	Eye disorders	Myopia	01JAN2002		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2014	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Nasal septal operation	01JAN2005	31DEC2005	N
			Wisdom teeth removal	01JAN2006	31DEC2006	N
	C4591001 1133 11331170	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1982		Y
		Immune system disorders	Food allergy	01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
			Tonsillitis	01JAN1992	31DEC1992	N
		Nervous system disorders	Essential tremor	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331175	Eye disorders	Myopia	01JAN2012		Y
			Presbyopia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Cartilage injury	01FEB2016	30NOV2016	N
				01NOV2016	01NOV2016	N
		Metabolism and nutrition disorders	Patella fracture	01FEB2000	29FEB2000	N
			Hyperlipidaemia	01JAN2012		Y
			Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01FEB2016	30NOV2016	N
		Psychiatric disorders	Bipolar disorder	01JAN1965		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	30APR2004	30APR2004	N
			Rotator cuff repair	01NOV2016	01NOV2016	N
	C4591001 1133 11331178	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2015	31DEC2015	N
		Social circumstances	Ex-tobacco user	01JAN2004	31DEC2019	N
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Mammoplasty	01JAN1996	31DEC1996	N
			Polypectomy	01JAN2015	31DEC2015	N
	C4591001 1133 11331185	Gastrointestinal disorders	Colitis ulcerative	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1133 11331186	Eye disorders	Presbyopia	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
	C4591001 1133 11331188	Eye disorders	Myopia	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1133 11331193	Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
	C4591001 1133 11331195	Eye disorders	Hypermetropia	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN1983		Y
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Varicocele	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1979	31DEC1979	N
			Varicocele repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331198	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1989		Y
		Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
			Meniscus operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331202	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331203	Eye disorders	Hypermetropia	01JAN2020		Y
			Myopia	01JAN2020		Y
		Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Skull fracture	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019	19MAY2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Prostatic disorder	01MAR2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2004		Y
		Social circumstances	Ex-tobacco user	01JAN1996	31DEC2003	N
		Surgical and medical procedures	Cranial operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1133 11331206	Eye disorders	Presbyopia	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
			Postmenopause	01JAN2015		Y
	C4591001 1133 11331208	Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2019	31JAN2019	N
	C4591001 1133 11331209	Ear and labyrinth disorders	Deafness unilateral	01JAN1996		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tympanic membrane perforation	01JAN1992	31DEC1996	N
		Gastrointestinal disorders	Constipation	01JAN1997		Y
		Injury, poisoning and procedural complications	Foreign body in ear	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Back pain	05AUG2020	17AUG2020	N
		Surgical and medical procedures	Tympanoplasty	01JAN1996	31DEC1996	N
	C4591001 1133 11331210	Infections and infestations	Hepatitis A	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Mammoplasty	01NOV2018	30NOV2018	N
	C4591001 1133 11331216	Injury, poisoning and procedural complications	Thermal burn	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Burn operation	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1133 11331226	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1133 11331228	Eye disorders	Myopia	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331230	Ear and labyrinth disorders	Deafness bilateral	01JAN1970		Y
		Eye disorders	Myopia	01JAN1982		Y
		Immune system disorders	Food allergy	01JAN1976		Y
		Infections and infestations	Tonsillitis	01NOV2013	30NOV2013	N
		Investigations	Blood pressure increased	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331236	Eye disorders	Presbyopia	01DEC2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JUN2018	30JUN2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01SEP2009	30SEP2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01SEP2001	30APR2002	N
			Uterine cancer	01APR2002	31MAY2002	N
		Renal and urinary disorders	Urogenital fistula	01JUN2002	30JUN2002	N
		Surgical and medical procedures	Cholecystectomy	01JUN2018	30JUN2018	N
			Fracture treatment	01SEP2005	30SEP2005	N
			Gastrectomy	01OCT2017		Y
			Hysterectomy	01MAY2002	31MAY2002	N
			Oophorectomy	01APR2002	30APR2002	N
				01SEP2001	30SEP2001	N
			Tonsillectomy	01JAN1980	31DEC1980	N
			Urogenital fistula repair	01JUN2002	30JUN2002	N
	C4591001 1133 11331240	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Hiatus hernia	01JUL2012	31JUL2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Food allergy	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Psychiatric disorders	Bipolar disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Gastric bypass	01JUL2012	31JUL2012	N
			Hernia hiatus repair	01JUL2012	31JUL2012	N
	C4591001 1133 11331246	Eye disorders	Myopia	01JAN2003		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002		Y
		Surgical and medical procedures	Myopia correction	01JAN2006	31JAN2006	N
	C4591001 1133 11331248	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2019	31DEC2019	N
	C4591001 1133 11331252	Social circumstances	Corrective lens user	01JAN2019		Y
	C4591001 1133 11331255	Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331256	Eye disorders	Myopia	01JAN1991		Y
	C4591001 1133 11331257	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Social circumstances	Corrective lens user	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1133 11331258	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1133 11331259	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Injury, poisoning and procedural complications	Thermal burn	15SEP2019	31JAN2020	N
		Surgical and medical procedures	Plastic surgery	01JAN2016	31DEC2016	N
			Skin graft	15SEP2019	31JAN2020	N
	C4591001 1133 11331263	Surgical and medical procedures	Caesarean section	23OCT2001	23OCT2001	N
	C4591001 1133 11331264	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Eye disorders	Myopia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01FEB2015		Y
			Depression	01JAN2016		Y
		Social circumstances	Ex-tobacco user	01SEP2008	30SEP2008	N
		Surgical and medical procedures	Female sterilisation	01JUN2016	30JUN2016	N
	C4591001 1133 11331265	Eye disorders	Myopia	01JAN1986		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1133 11331266	Eye disorders	Hypermetropia	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Bronchitis	01JAN1971		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
			Osteoarthritis	01AUG2016		Y
		Surgical and medical procedures	Abdominoplasty	17FEB2017	17FEB2017	N
			Caesarean section	20MAY2001	20MAY2001	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2015		Y
			Vertebroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1133 11331267	Eye disorders	Pterygium	01JAN1994	31DEC1994	N
		Hepatobiliary disorders	Cholelithiasis	01MAY2002	31MAY2002	N
		Injury, poisoning and procedural complications	Radius fracture	01JAN1980	31DEC1980	N
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2002	31MAY2002	N
			Fracture treatment	01JAN1980	31DEC1980	N
			Pterygium operation	01JAN1994	31DEC1994	N
			Vasectomy	01OCT2004	31OCT2004	N
	C4591001 1133 11331272	Eye disorders	Hypermetropia	01JAN1990		Y
		Injury, poisoning and procedural complications	Skull fracture	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Skull fracture treatment	01JAN1977	31DEC1977	N
	C4591001 1133 11331273	Eye disorders	Myopia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331274	Eye disorders	Hypermetropia	01JAN2012		Y
	C4591001 1133 11331275	Eye disorders	Myopia	01JAN2016		Y
		Social circumstances	Ex-tobacco user	01DEC1994	31DEC2016	N
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1133 11331276	Immune system disorders	Dust allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972	31DEC1978	N
	C4591001 1133 11331278	Infections and infestations	Tonsillitis	01NOV1995	30NOV1995	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JUN1998	30JUN1999	N
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Scoliosis surgery	01JUN1999	30JUN1999	N
			Tonsillectomy	01NOV1995	30NOV1995	N
	C4591001 1133 11331282	Eye disorders	Myopia	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2018	31DEC2019	N
		Surgical and medical procedures	Spinal decompression	01DEC2019	31DEC2019	N
	C4591001 1133 11331283	Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Renal and urinary disorders	Urinary retention	01JAN2017		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973	31DEC1976	N
	C4591001 1133 11331291	Vascular disorders	Hypertension	01JAN1976		Y
		Eye disorders	Presbyopia	01JAN2014		Y
	C4591001 1133 11331292	Infections and infestations	Bronchitis	01JAN1985	31DEC1988	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
	C4591001 1133 11331293	Eye disorders	Bipolar disorder	01JAN2001		Y
			Myopia	01JAN1998		Y
		Hepatobiliary disorders	Cholelithiasis	01MAY2011	30JUN2011	N
		Immune system disorders	Hypersensitivity	01JUL1987		Y
		Infections and infestations	Appendicitis	01SEP2010	30SEP2010	N
		Psychiatric disorders	Anxiety	01JUL2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT1995		Y
		Social circumstances	Menopause	01AUG2019		Y
		Surgical and medical procedures	Appendectomy	01SEP2011	30SEP2011	N
			Caesarean section	05APR2006	05APR2006	N
				07MAY2004	07MAY2004	N
			Cholecystectomy	01JUN2011	30JUN2011	N
	C4591001 1133 11331294	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN1993		Y
			Myopia	01JAN1993		Y
		Social circumstances	Corrective lens user	01JAN1993		Y
	C4591001 1133 11331295	Social circumstances	Electronic cigarette user	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	15DEC2018	15DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331296	Gastrointestinal disorders	Gastritis	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Tonsillitis	01DEC2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
			Mammoplasty	01OCT2011	31OCT2011	N
			Tonsillectomy	01DEC2018	31DEC2018	N
	C4591001 1133 11331301	Social circumstances	Tobacco user	01JUN1985		Y
	C4591001 1133 11331303	Metabolism and nutrition disorders	Obesity	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Back pain	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Gastric bypass	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1133 11331307	Eye disorders	Myopia	01MAY2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	01APR1995	30APR1995	N
		Social circumstances	Corrective lens user	01MAY2005		Y
		Surgical and medical procedures	Ankle operation	01APR1995	30APR1995	N
	C4591001 1133 11331308	Eye disorders	Myopia	01JAN2001		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon rupture	01MAR2019	31MAR2019	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JUL2019		Y
	C4591001 1133 11331313	Surgical and medical procedures	Tenoplasty	01MAR2019	31MAR2019	N
		Eye disorders	Myopia	01JAN1982		Y
		Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Appendectomy	01JAN2007	31DEC2007	N
			Caesarean section	17JUN1988	17JUN1988	N
			Mammoplasty	01JAN2000	31DEC2000	N
	C4591001 1133 11331316	Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
	C4591001 1133 11331317	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31JAN2016	N
			Vasectomy	01DEC2013	31DEC2013	N
	C4591001 1133 11331320	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
	C4591001 1133 11331321	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
			Postmenopause	01JUL2014		Y
		Surgical and medical procedures	Caesarean section	19JUL1989	19JUL1989	N
	C4591001 1133 11331322	Eye disorders	Myopia	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Food allergy	07JUL2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP2010	30SEP2010	N
		Skin and subcutaneous tissue disorders	Urticaria	07JUL2017	07JUL2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	28AUG1995	28AUG1995	N
			Hysterectomy	20DEC2010	20DEC2010	N
	C4591001 1133 11331324	Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Social circumstances	Alcohol use	01JAN1996		Y
			Ex-tobacco user	01JUN1996	31JAN2010	N
			Substance use	01JUN1996	31DEC1998	N
	C4591001 1133 11331328	Eye disorders	Myopia	01JAN1990		Y
		Investigations	Alanine aminotransferase increased	11DEC2019		Y
	C4591001 1133 11331329	Eye disorders	Myopia	01JAN2004		Y
		Gastrointestinal disorders	Tooth impacted	01JUL2010	30NOV2010	N
		Infections and infestations	Tinea versicolour	01JUN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2010	30JUN2010	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01SEP2010	30NOV2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Wisdom teeth removal	01NOV2010	30NOV2010	N
	C4591001 1133 11331332	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1133 11331333	Eye disorders	Presbyopia	01JAN2016	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2016	31DEC2019	N
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2010	31DEC2010	N
	C4591001 1133 11331334	Eye disorders	Hypermetropia	01JAN1991		Y
			Myopia	01JAN1991		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Social circumstances	Tobacco user	01OCT2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1133 11331335	Eye disorders	Presbyopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Ligament operation	01JAN2012	31DEC2012	N
	C4591001 1133 11331336	Eye disorders	Hypermetropia	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989	31DEC1994	N
	C4591001 1133 11331337	Eye disorders	Rhinitis allergic	01JAN2018		Y
			Hypermetropia	01JUL2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1133 11331338	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Eye disorders	Astigmatism	01JAN2004	31DEC2015	N
		Gastrointestinal disorders	Tooth impacted	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Vision correction operation	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1133 11331340	Eye disorders	Presbyopia	01JAN2018		Y
		Infections and infestations	Genital herpes	01JAN1994		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN1992	31DEC1995	N
		Surgical and medical procedures	Ligament operation	01JAN2002	31DEC2002	N
	C4591001 1133 11331341	Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1133 11331346	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2003		Y
			Constipation	01JAN2010		Y
			Dyspepsia	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1992		Y
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Herpes zoster	01JAN2017		Y
			Urinary tract infection	01JAN1978	30JUN2020	N
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN1994	31DEC1994	N
			Tibia fracture	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994		Y
			Systemic lupus erythematosus	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1982		Y
			Dermatitis allergic	01JAN1984		Y
			Urticaria	01JAN1984		Y
		Surgical and medical procedures	Abdominoplasty	01MAR2020	31MAR2020	N
			Female sterilisation	01JAN1998	31DEC1998	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N
			Liposuction	01MAR2020	31MAR2020	N
			Mammoplasty	01JAN1998	31DEC1998	N
	C4591001 1133 11331348	Eye disorders	Myopia	01JAN1994		Y
		Injury, poisoning and procedural complications	Burns second degree	01APR2020	31JUL2020	N
		Psychiatric disorders	Anxiety	01SEP2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01SEP2008		Y
	C4591001 1133 11331350	Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	09MAY2011	09MAY2011	N
				30APR2007	30APR2007	N
	C4591001 1133 11331351	Infections and infestations	Tinea versicolour	01JAN2019		Y
		Social circumstances	Ex-tobacco user	01JAN1998	31DEC2005	N
	C4591001 1133 11331352	Eye disorders	Myopia	01JAN1995		Y
		Surgical and medical procedures	Mammoplasty	01JAN2012	31JAN2012	N
			Rhinoplasty	01JUN2005	30JUN2005	N
	C4591001 1133 11331354	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1968	31DEC1968	N
		Eye disorders	Hypermetropia	01JAN1968		Y
			Strabismus	01JAN1968	31DEC1968	N
		Surgical and medical procedures	Pyloromyotomy	01JAN1968	31DEC1968	N
			Strabismus correction	01JAN1968	31DEC1968	N
	C4591001 1133 11331355	Ear and labyrinth disorders	Deafness unilateral	01JAN2019		Y
		Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331357	Eye disorders	Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331360	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Dust allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1133 11331363	Injury, poisoning and procedural complications	Limb injury	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Shoulder operation	01JAN2008	31DEC2008	N
	C4591001 1133 11331365	Eye disorders	Presbyopia	01JAN2018		Y
		Infections and infestations	Appendicitis	01MAY2002	31MAY2002	N
		Reproductive system and breast disorders	Endometriosis	01JAN2007	30APR2014	N
		Social circumstances	Postmenopause	01APR2014		Y
		Surgical and medical procedures	Appendicectomy	01MAY2002	31MAY2002	N
			Endometriosis ablation	01NOV2008	30NOV2008	N
			Hysterectomy	01APR2014	30APR2014	N
			Oophorectomy bilateral	01APR2014	30APR2014	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1133 11331367	Eye disorders	Presbyopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Appendicitis	01JUL1984	31JUL1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Hand fracture	01OCT2008	31AUG2009	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JUL1989	31DEC2015	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1984		Y
		Social circumstances	Ex-tobacco user	26JUL1983	31AUG2014	N
			Postmenopause	07NOV2015		Y
		Surgical and medical procedures	Appendectomy	01JUL1984	31JUL1984	N
			Nasal septal operation	01JUL2015	31JUL2015	N
			Open reduction of fracture	01AUG2009	31AUG2009	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331370	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal melanoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cancer surgery	01JAN2019	31DEC2019	N
	C4591001 1133 11331374	Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN1998	31DEC1998	N
		Nervous system disorders	Multiple sclerosis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331376	Eye disorders	Diabetic retinopathy	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Overweight	01JAN2019		Y
			Type 1 diabetes mellitus	01JAN1982		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Salpingo-oophorectomy bilateral	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1133 11331378	Eye disorders	Presbyopia	01JUL2019		Y
		Hepatobiliary disorders	Cholelithiasis	01FEB2006	28FEB2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Social circumstances	Ex-tobacco user	01JAN1993	08AUG2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Mammoplasty	01JAN2011	31JAN2011	N
			Skin cosmetic procedure	01FEB2000	29FEB2000	N
	C4591001 1133 11331379	Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2001		Y
			Nasal septum deviation	01JAN2001	31DEC2001	N
	C4591001 1133 11331385	Social circumstances	Ex-tobacco user	01JAN1980	31DEC1988	N
	C4591001 1133 11331387	Immune system disorders	Food allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Ankle fracture	01NOV2017	30NOV2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Internal fixation of fracture	01JAN2017	31DEC2017	N
	C4591001 1133 11331388	Eye disorders	Myopia	01JAN2019		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2006	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1977	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
			Intervertebral disc protrusion	01JAN1999	31DEC2002	N
		Nervous system disorders	Migraine	01JAN1989		Y
			Tension headache	01JAN1989		Y
		Social circumstances	Tobacco user	01JAN1989		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2002	31DEC2002	N
			Female sterilisation	01JAN2002	31DEC2002	N
			Intervertebral disc operation	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1977	31DEC1977	N
			Umbilical hernia repair	01JAN2007	31DEC2007	N
	C4591001 1133 11331389	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Social circumstances	Substance use	01JAN2009		Y
			Tobacco user	01JAN2009		Y
	C4591001 1133 11331393	Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	17DEC2017	27DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	01JAN1995	N
		Investigations	Colonoscopy	27DEC2017	27DEC2017	N
			Heart rate irregular	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2013	16DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	20SEP2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN1995	01JAN1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	26DEC2002	26DEC2002	N
			Hysterectomy	20SEP2018	20SEP2018	N
			Large intestinal polypectomy	27DEC2017	27DEC2017	N
	C4591001 1133 11331395	Surgical and medical procedures	Caesarean section	17MAY2006	17MAY2006	N
	C4591001 1133 11331397	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Food allergy	01JAN1982		Y
	C4591001 1133 11331398	Eye disorders	Myopia	01JAN1986		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Overweight	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Fracture treatment	01JAN1980	31DEC1980	N
	C4591001 1133 11331401	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Appendix cancer	01NOV2000	30NOV2000	N
		Reproductive system and breast disorders	Ovarian cyst	01NOV2000	30NOV2000	N
	C4591001 1133 11331404	Surgical and medical procedures	Mammoplasty	01JAN2018	31DEC2018	N
	C4591001 1133 11331406	Gastrointestinal disorders	Inguinal hernia	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1973	31DEC1973	N
	C4591001 1133 11331408	Immune system disorders	Food allergy	01JAN2018		Y
	C4591001 1133 11331409	Eye disorders	Hypermetropia	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Nervous system disorders	Haemorrhagic stroke	16DEC2019	16DEC2019	N
		Social circumstances	Ex-tobacco user	01JAN1992	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331410	Endocrine disorders	Hypogonadism male	01JAN2014		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Inguinal hernia	01JAN2014	31DEC2014	N
			Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteonecrosis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hip surgery	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2014	31DEC2014	N
			Ligament operation	01JAN1993	31DEC1993	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1133 11331411	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Food allergy	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01FEB2003		Y
			Osteoarthritis	01MAY2006		Y
		Reproductive system and breast disorders	Endometriosis	01MAY2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31MAY2001	N
			Ovarian cyst	01MAR1999	31MAR1999	N
			Polycystic ovaries	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Surgical and medical procedures	Ovarian cystectomy	01MAR1999	31MAR1999	N
	C4591001 1133 11331413	Eye disorders	Myopia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	01JAN2005	31DEC2005	N
	C4591001 1133 11331414	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Injury, poisoning and procedural complications	Jaw fracture	01JAN1996	31DEC1996	N
			Lower limb fracture	01JAN1982	31DEC1982	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN1990		Y
		Surgical and medical procedures	Fracture reduction	01JAN1996	31DEC1996	N
			Knee operation	01JAN1982	31DEC1982	N
	C4591001 1133 11331418	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
	C4591001 1133 11331419	Eye disorders	Myopia	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Substance use	01JAN2011		Y
			Tobacco user	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331422	Social circumstances	Corrective lens user	01SEP2019		Y
	C4591001 1133 11331423	Infections and infestations	Tonsillitis	01JAN1998	31DEC1998	N
		Psychiatric disorders	Depression	01JAN2016		Y
			Drug abuse	01JAN2005	31DEC2016	N
			Insomnia	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1133 11331427	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2018		Y
	C4591001 1133 11331428	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Aphthous ulcer	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Milk allergy	01JAN2010		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1133 11331432	Eye disorders	Myopia	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Reproductive system and breast disorders	Testicular torsion	01JAN1998	31DEC1998	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1986		Y
		Surgical and medical procedures	Orchidopexy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331435	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2000		Y
		Investigations	Seasonal allergy	01JAN1975		Y
		Reproductive system and breast disorders	Cardiac murmur	01JAN1976		Y
		Social circumstances	Menorrhagia	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Corrective lens user	01JAN2015		Y
	C4591001 1133 11331438	Skin and subcutaneous tissue disorders	Uterine dilation and curettage	01JAN2013	31DEC2013	N
			Skin lesion	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Skin lesion removal	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331440	Eye disorders	Myopia	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Biopsy cervix	01JAN2018	31DEC2018	N
			Precancerous cells present	01JAN2018	31DEC2018	N
		Social circumstances	Ex-tobacco user	01JAN2000	31DEC2011	N
		Surgical and medical procedures	Mammoplasty	01JAN2009	31DEC2009	N
	C4591001 1133 11331441	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Iodine allergy	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal hamartoma	01JAN2007		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1133 11331448	Psychiatric disorders	Anxiety	01AUG2020		Y
	C4591001 1133 11331450	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2007		Y
		Psychiatric disorders	Bipolar disorder	01JAN1991		Y
		Social circumstances	Tobacco user	01JAN2005		Y
	C4591001 1133 11331456	Eye disorders	Myopia	01JAN2016		Y
		Metabolism and nutrition disorders	Overweight	01APR2020		Y
		Social circumstances	Ex-tobacco user	01JAN1989	31JAN2017	N
	C4591001 1133 11331460	Eye disorders	Myopia	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
	C4591001 1133 11331461	Immune system disorders	Dust allergy	01JAN1984		Y
		Infections and infestations	Hepatitis A	01JAN1989	31DEC1989	N
			Tonsillitis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1133 11331462	Immune system disorders	Food allergy	01JAN1994		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Nasal septum deviation	01JAN2005	31DEC2005	N
			Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331463	Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1984		Y
		Surgical and medical procedures	Mammoplasty	17SEP2009	17SEP2009	N
	C4591001 1133 11331465	Congenital, familial and genetic disorders	Thalassaemia beta	01MAY2020		Y
		Investigations	Human papilloma virus test positive	01JAN2015		Y
		Metabolism and nutrition disorders	Hypovitaminosis	01JAN2019		Y
	C4591001 1133 11331467	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1969	31DEC1969	N
		Eye disorders	Astigmatism	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2014	01APR2014	N
		Social circumstances	Corrective lens user	01JAN2012		Y
		Surgical and medical procedures	Acoustic neuroma removal	01APR2014	01APR2014	N
			Appendicectomy	01JAN2017	31DEC2017	N
			Pyloromyotomy	01JAN1969	31DEC1969	N
	C4591001 1133 11331468	Eye disorders	Hypermetropia	01JAN1997	31DEC2007	N
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	15JUL2013		Y
			Keratomileusis	01JAN2007	31DEC2007	N
			Mammoplasty	09APR2009	09APR2009	N
	C4591001 1133 11331473	Infections and infestations	Sinusitis	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1133 11331474	Surgical and medical procedures	Adenoidectomy	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Forearm fracture	01MAY1981	31MAY1981	N
		Investigations	Blood testosterone decreased	01JUN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01MAY2012	31DEC2012	N
		Social circumstances	Corrective lens user	01JAN2018		Y
	C4591001 1133 11331475	Eye disorders	Myopia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Surgical and medical procedures	Vasectomy	01JAN2012		Y
	C4591001 1133 11331476	Congenital, familial and genetic disorders	Haemoglobinopathy	01JAN2014		Y
		Eye disorders	Astigmatism	01JAN1995		Y
		Gastrointestinal disorders	Gastritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1133 11331478	Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1133 11331479	Eye disorders	Myopia	01JAN2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1133 11331480	Injury, poisoning and procedural complications	Hand fracture	01JAN2017	31DEC2017	N
			Upper limb fracture	01JAN2017	31DEC2017	N
			Wrist fracture	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Elbow operation	01JAN2017	31DEC2017	N
			Limb operation	01JAN2017	31DEC2017	N
			Wrist surgery	01JAN2017	31DEC2017	N
	C4591001 1133 11331484	Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Facial bones fracture	01SEP2012	30SEP2012	N
		Surgical and medical procedures	Abdominoplasty	01JUL2011	31JUL2011	N
			Rhinoplasty	01SEP2012	30SEP2012	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1133 11331485	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1133 11331489	Eye disorders	Hypermetropia	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1133 11331490	Eye disorders	Myopia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Femur fracture	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1133 11331491	Surgical and medical procedures	Bone cyst excision	01JAN2003	31DEC2003	N
		Eye disorders	Presbyopia	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN1989		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2011	31DEC2011	N
			Caesarean section	27OCT2007	27OCT2007	N
				31MAY2010	31MAY2010	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2011	31DEC2011	N
	C4591001 1133 11331492	Vascular disorders	Hypertension	01JAN2018		Y
		Eye disorders	Myopia	01JAN2012		Y
	C4591001 1133 11331495	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN2016	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN2019	01JAN2019	N
				05SEP2013	05SEP2013	N
				13SEP2016	13SEP2016	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN2019	01JAN2019	N
	C4591001 1133 11331496†	Eye disorders	Myopia	01JAN1976		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
			Umbilical hernia	01NOV2017	30NOV2017	N
		Investigations	HIV test positive	21DEC1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN1995		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1133 11331497	Social circumstances	Ex-tobacco user	01JAN2017	31DEC2017	N
	C4591001 1133 11331498	Gastrointestinal disorders	Umbilical hernia	01OCT2005	31OCT2005	N
		Injury, poisoning and procedural complications	Cartilage injury	01JUL2018	31JUL2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Overweight	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2005		Y
		Surgical and medical procedures	Chondroplasty	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01OCT2005	31OCT2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331499	Eye disorders	Presbyopia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN1982	31AUG2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Rhinoplasty	01JAN2010	31DEC2010	N
			Spinal operation	01AUG2018	31AUG2018	N
			Vasectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331501	Eye disorders	Presbyopia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	16SEP1994	16SEP1994	N
	C4591001 1133 11331502	Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1998	31DEC1998	N
		Social circumstances	Ex-tobacco user	01JAN1988	26APR2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Lithotripsy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331504	Eye disorders	Astigmatism	01JAN1987		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Radius fracture	01JAN1996	31DEC1996	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
	C4591001 1133 11331505	Eye disorders	Presbyopia	01OCT2019		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
			Herpes zoster	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
	C4591001 1133 11331506	Eye disorders	Myopia	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JUN2017	30JUN2017	N
			Rotator cuff repair	01DEC2018	31DEC2018	N
			Tonsillectomy	01JAN1982	31DEC1982	N
			Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1133 11331508	Eye disorders	Presbyopia	01JAN2017		Y
	C4591001 1133 11331509	Eye disorders	Presbyopia	01JUL2014		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31JUL2017	N
		Surgical and medical procedures	Hysterectomy	01JUL2017	31JUL2017	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1133 11331510	Endocrine disorders	Basedow's disease	01JAN2014	31DEC2015	N
			Hypothyroidism	01NOV2015		Y
		Immune system disorders	Dust allergy	01JAN1995		Y
		Surgical and medical procedures	Thyroidectomy	01OCT2015	31OCT2015	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1133 11331511	Eye disorders	Myopia	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1133 11331512	Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
	C4591001 1133 11331515	Eye disorders	Myopia	01JAN1976		Y
		Infections and infestations	Breast abscess	01JUN2020	30JUN2020	N
		Injury, poisoning and procedural complications	Pelvic fracture	01MAY2019	31JAN2020	N
			Wrist fracture	01MAY2019	31MAY2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN1991		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1976		Y
		Surgical and medical procedures	Abscess drainage	01JUN2020	30JUN2020	N
			Wrist surgery	01MAY2019	31MAY2019	N
	C4591001 1133 11331521	Eye disorders	Hypermetropia	01DEC2019		Y
				01JAN1992	01APR2010	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Foot fracture	01NOV2015	31JAN2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1999	31DEC2002	N
		Surgical and medical procedures	Eye laser surgery	01APR2010	01APR2010	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1133 11331522	Eye disorders	Presbyopia	01MAR2020		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01OCT2018		Y
		Social circumstances	Corrective lens user	01MAR2020		Y
			Ex-tobacco user	01JAN1996	31DEC2009	N
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01OCT2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331523	Gastrointestinal disorders	Dental caries	01JUL2020	31JUL2020	N
	C4591001 1133 11331524	Eye disorders	Hypermetropia	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1133 11331525	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN2005	31DEC2010	N
		Surgical and medical procedures	Medical cannabis therapy	01APR2020		Y
	C4591001 1133 11331526	Cardiac disorders	Myocardial infarction	04MAR2018	05MAR2018	N
		Eye disorders	Myopia	01JAN2018		Y
			Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2010		Y
			Trigger finger	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Social circumstances	Ex-tobacco user	01JAN2000	31DEC2013	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN2008	31DEC2008	N
			Stent placement	04MAR2018	04MAR2018	N
		Vascular disorders	Hypertension	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331528	Immune system disorders	Drug hypersensitivity	(b) (6) 1980		Y
		Nervous system disorders	Nerve compression	01NOV2007	31OCT2011	N
		Social circumstances	Ex-tobacco user	01JAN1998	31DEC2012	N
		Surgical and medical procedures	Peripheral nerve decompression	01OCT2011	31OCT2011	N
	C4591001 1133 11331529	Eye disorders	Presbyopia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01APR2000	30APR2000	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01APR2000	30APR2000	N
	C4591001 1133 11331530	Eye disorders	Hypermetropia	01JAN1971		Y
			Myopia	01JAN1971		Y
			Presbyopia	01JAN1971		Y
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	31DEC2018	N
		Social circumstances	Tobacco user	01JAN2018		Y
	C4591001 1133 11331531	Injury, poisoning and procedural complications	Femur fracture	01JAN1996	31DEC1996	N
		Social circumstances	Corrective lens user	01JAN2019		Y
			Substance use	01JAN1983	31DEC2018	N
			Tobacco user	01JAN1984		Y
		Surgical and medical procedures	Fracture treatment	01JAN1996	31DEC1996	N
	C4591001 1133 11331532	Eye disorders	Myopia	01JAN1997		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Social circumstances	Ex-tobacco user	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1133 11331533	Ear and labyrinth disorders	Deafness bilateral	01JAN1981		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Social circumstances	Postmenopause	01FEB2019		Y
			Tobacco user	01JAN1983		Y
		Surgical and medical procedures	Caesarean section	21DEC1992	21DEC1992	N
				29MAY1988	29MAY1988	N
			Cholecystectomy	01JAN1989	31DEC1989	N
			Female sterilisation	01JAN1995		Y
					31DEC1995	N
	C4591001 1133 11331534	Eye disorders	Presbyopia	01JAN2005		Y
		Social circumstances	Ex-tobacco user	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Female sterilisation	07JAN1994	07JAN1994	N
	C4591001 1133 11331535	Social circumstances	Tobacco user	01JAN1999		Y
	C4591001 1133 11331536	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN2005	31DEC2006	N
	C4591001 1133 11331537	Eye disorders	Hypermetropia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
	C4591001 1133 11331539	Endocrine disorders	Goitre	01JAN2012		Y
		Eye disorders	Presbyopia	19OCT2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1994		Y
			Hiatus hernia	01JAN1994		Y
			Umbilical hernia	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01APR2020		Y
		Renal and urinary disorders	Urethral disorder	01JAN2017	31DEC2017	N
		Social circumstances	Ex-tobacco user	01JAN1996	31DEC2009	N
		Surgical and medical procedures	Diverticulectomy	01JAN2017	31DEC2017	N
			Intra-uterine contraceptive device insertion	01MAR2015	31MAR2015	N
	C4591001 1133 11331540	Ear and labyrinth disorders	Deafness unilateral	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Nervous system disorders	Neuralgia	01MAR2005	31MAR2005	N
		Social circumstances	Ex-tobacco user	01AUG2001	31JAN2020	N
		Surgical and medical procedures	Neurosurgery	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1133 11331541	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01SEP2020		Y
		Social circumstances	Ex-tobacco user	01JAN1999	31DEC2000	N
		Surgical and medical procedures	Liposuction	01JAN2018	31DEC2018	N
			Mammoplasty	01JUN2020	30JUN2020	N
	C4591001 1133 11331542	Eye disorders	Hypermetropia	01JAN1976		Y
			Myopia	01JAN1976		Y
		Infections and infestations	Hepatitis C	01MAR2020	22OCT2020	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
	C4591001 1133 11331543	Surgical and medical procedures	Knee arthroplasty	01JAN2005	31DEC2005	N
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tooth infection	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2008	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2009		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2014	31DEC2014	N
			Uterine disorder	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2010		Y
			Nasal congestion	01JAN2010		Y
			Rhinitis allergic	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2014		Y
		Social circumstances	Ex-tobacco user	01JAN1998	31DEC2010	N
			Substance use	01JAN2019		Y
		Surgical and medical procedures	Breast cyst excision	01JAN2014	31DEC2014	N
			Loop electrosurgical excision procedure	01JAN2014	31DEC2014	N
			Removal of foreign body	01JAN2006	31DEC2006	N
			Wisdom teeth removal	01JAN2008	31DEC2008	N
	C4591001 1133 11331545	Eye disorders	Myopia	01JAN1990		Y
	C4591001 1133 11331546	Eye disorders	Presbyopia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000	31DEC2000	N
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Lipoma excision	01JAN2000	31DEC2000	N
	C4591001 1133 11331547	Eye disorders	Myopia	01JAN1983		Y
		Injury, poisoning and procedural complications	Foot fracture	01DEC2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
			Foot operation	01DEC2007	31DEC2007	N
	C4591001 1133 11331548	Immune system disorders	Allergy to animal	(b) (6) 1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1992		Y
	C4591001 1133 11331549	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2018		Y
	C4591001 1133 11331550	Immune system disorders	Hypersensitivity	01JAN2005		Y
	C4591001 1133 11331551	Eye disorders	Presbyopia	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Caesarean section	01AUG2012	01AUG2012	N
				03OCT2007	03OCT2007	N
				06MAR2006	06MAR2006	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1133 11331552	Eye disorders	Myopia	01JAN1990		Y
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	13JAN2013	13JAN2013	N
				24AUG2016	24AUG2016	N
			Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1133 11331553	Eye disorders	Myopia	01JAN1979		Y
		Infections and infestations	Herpes zoster	01JAN1999	31DEC1999	N
		Psychiatric disorders	Drug abuse	01JAN1989	31DEC1992	N
		Social circumstances	Alcohol use	01JAN1984		Y
			Tobacco user	01JAN1985		Y
	C4591001 1133 11331554	Eye disorders	Presbyopia	01JAN2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1133 11331555	Eye disorders	Myopia	01JAN1997		Y
		General disorders and administration site conditions	Cyst	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Wrist fracture	01MAY2014	31MAY2014	N
		Reproductive system and breast disorders	Varicocele	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977	31DEC1990	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cyst removal	01JAN2018	31DEC2018	N
			Open reduction of fracture	01MAY2014	31MAY2014	N
			Thoracic operation	01JAN2018	31DEC2018	N
			Varicocele repair	01JAN2004	31DEC2004	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1133 11331556	Injury, poisoning and procedural complications	Wrist fracture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Wrist surgery	01JAN2015	31DEC2015	N
	C4591001 1133 11331557	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Social circumstances	Ex-tobacco user	01JAN1990	31JAN2020	N
	C4591001 1133 11331558	Eye disorders	Hypermetropia	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331559	Eye disorders	Myopia	01JAN1988		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1982	31DEC1987	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1985	31DEC1985	N
		Social circumstances	Ex-tobacco user	01JAN1997	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1133 11331560	Social circumstances	Ex-tobacco user	01JAN1982	31DEC2019	N
			Substance use	01JAN1988		Y
	C4591001 1133 11331561	Eye disorders	Presbyopia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Ligament operation	01JAN2015		Y
			Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1133 11331562	Eye disorders	Hypermetropia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN2015	31JAN2015	N
			Tonsillitis	01JUN2007	30JUN2007	N
		Psychiatric disorders	Anxiety	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Benign breast lump removal	01DEC2018	28FEB2019	N
			Tonsillectomy	01JUN2007	30JUN2007	N
	C4591001 1133 11331563	Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Immune system disorders	Food allergy	01JAN1975		Y
			Iodine allergy	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1133 11331564	Immune system disorders	Dust allergy	01JAN2005		Y
	C4591001 1133 11331565	Immune system disorders	Food allergy	01JAN2000		Y
	C4591001 1133 11331566	Congenital, familial and genetic disorders	Dextrocardia	(b) (6) 1986		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Angioplasty	01JAN1987	31DEC1987	N
				01JAN1988	31DEC1988	N
				01JAN1989	31DEC1989	N
				01JAN1990	31DEC1990	N
				01JAN1997	31DEC1997	N
				(b) (6) 1986	(b) (6) 1986	N
			Cardiac operation	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
				01JAN1999	31DEC1999	N
				(b) (6) 1986	(b) (6) 1986	N
			Cardiac pacemaker insertion	01JAN2007	31AUG2016	N
			Cardiac pacemaker removal	01JAN2016	31DEC2016	N
			Implantable defibrillator insertion	01AUG2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Renal stone removal	01JAN2008	31DEC2008	N
			Vocal cord operation	01JAN2015	31DEC2015	N
	C4591001 1133 11331567	Eye disorders	Myopia	01JAN2000	31DEC2014	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
			Keratomileusis	01JAN2016	31DEC2016	N
	C4591001 1133 11331568	Social circumstances	Tobacco user	01JAN1998		Y
	C4591001 1133 11331570	Surgical and medical procedures	Caesarean section	04JUL2012	04JUL2012	N
			Female sterilisation	04JUL2012	04JUL2012	N
	C4591001 1133 11331571	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	30SEP2020	N
		Musculoskeletal and connective tissue disorders	Scoliosis	(b) (6) 1978		Y
		Psychiatric disorders	Drug abuse	01JAN2016	31DEC2018	N
		Social circumstances	Tobacco user	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
			Knee arthroplasty	01SEP2020	30SEP2020	N
	C4591001 1133 11331572	Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Ex-tobacco user	01JAN1995	31DEC2019	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1981	31DEC1981	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1133 11331573	Eye disorders	Myopia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2006	31DEC2006	N
			Depression	01JAN2006		Y
	C4591001 1133 11331574	Eye disorders	Hypermetropia	01JAN1973	31DEC1973	N
			Myopia	01JAN1973		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2016		Y
		Social circumstances	Tobacco user	01MAR2020		Y
		Surgical and medical procedures	Bone lesion excision	01AUG2017	31AUG2017	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Tendon transfer	01AUG2017	31AUG2017	N
			Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331575	Eye disorders	Hypermetropia	01JAN1990		Y
	C4591001 1133 11331577	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2018		Y
		Social circumstances	Alcohol use	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	13SEP2006	13SEP2006	N
				19NOV2009	19NOV2009	N
				20JUL2004	20JUL2004	N
	C4591001 1133 11331578	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2009		Y
			Food allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1993	31DEC1993	N
			Jaw fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2018		Y
	C4591001 1133 11331579	Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Social circumstances	Tobacco user	01JAN1995	31DEC1999	N
	C4591001 1133 11331580	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331581	Eye disorders	Myopia	01JAN1981		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1972	31DEC1972	N
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1994	31DEC1994	N
	C4591001 1133 11331582†	Investigations	HIV test positive	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN1996	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331583	Renal and urinary disorders	Nephrolithiasis	22FEB2020		Y
		Social circumstances	Tobacco user	01JAN2011		Y
	C4591001 1133 11331584	Eye disorders	Hypermetropia	01JAN1978		Y
		Hepatobiliary disorders	Cholecystitis	03SEP2013	03SEP2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019		Y
			Osteoarthritis	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
			Nasal septum deviation	01JAN1976		Y
		Surgical and medical procedures	Cholecystectomy	03SEP2013	03SEP2013	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1133 11331585	Gastrointestinal disorders	Constipation	01JAN1976		Y
			Gastric ulcer	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2014	31JUL2014	N
		Social circumstances	Corrective lens user	01JAN2016		Y
	C4591001 1133 11331586	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Eye disorders	Hypermetropia	01JAN1984		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Ex-tobacco user	01FEB1992	28FEB2010	N
		Surgical and medical procedures	Cardiac ablation	01JAN2014	31DEC2014	N
			Implantable cardiac monitor insertion	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1977	31DEC1977	N
			Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
		Eye disorders	Myopia	01JAN2005		Y
	C4591001 1133 11331587	Infections and infestations	Tooth infection	24FEB2020	24FEB2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Social circumstances	Substance use	01JAN2016		Y
		Surgical and medical procedures	Tongue tie operation	01JAN2006	31DEC2006	N
			Wisdom teeth removal	24FEB2020	24FEB2020	N
	C4591001 1133 11331588	Eye disorders	Myopia	01JAN1988	31DEC2005	N
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Keratomileusis	01JAN2005	31DEC2005	N
	C4591001 1133 11331589	Eye disorders	Presbyopia	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis acute	01OCT2005	31OCT2005	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2005	31OCT2005	N
	C4591001 1133 11331591	Congenital, familial and genetic disorders	Myocardial bridging	01JAN1979		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN2019		Y
		Investigations	Cardiac murmur	01JAN1979	31DEC1979	N
			Catheterisation cardiac	01MAY2019	31MAY2019	N
			Heart rate irregular	01JAN1984		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Nasal congestion	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cardiac operation	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331592	Injury, poisoning and procedural complications	Radius fracture	01JAN2009	31DEC2009	N
	C4591001 1133 11331593	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1133 11331594	Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1133 11331595	Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N
		Social circumstances	Corrective lens user	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tobacco user	01JAN2010		Y
	C4591001 1133 11331596	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Social circumstances	Tobacco user	01JAN1989	31DEC1994	N
		Surgical and medical procedures	Caesarean section	01NOV2018	30NOV2018	N
				01OCT2016	31OCT2016	N
			Female sterilisation	01NOV2018	30NOV2018	N
	C4591001 1133 11331598	Eye disorders	Myopia	01JAN2000		Y
	C4591001 1133 11331600	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1133 11331601	Surgical and medical procedures	Vasectomy	01JUL2019	31JUL2019	N
	C4591001 1133 11331602	Eye disorders	Myopia	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR1998	31DEC2012	N
	C4591001 1133 11331603	Eye disorders	Myopia	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331604	Eye disorders	Presbyopia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1991	31DEC1991	N
				01JAN1999	31DEC1999	N
				01JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1133 11331606	Infections and infestations	Herpes zoster	01JAN2006		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331609	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Tobacco user	01JAN2019		Y
	C4591001 1133 11331610	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01OCT2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Social circumstances	Tobacco user	01JAN1997	31DEC2005	N
		Surgical and medical procedures	Skin operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331612	Eye disorders	Hypermetropia	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1133 11331613	Social circumstances	Tobacco user	01JAN1993		Y
	C4591001 1133 11331614	Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1133 11331615	Blood and lymphatic system disorders	Spherocytic anaemia	01JAN1977		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Food allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1133 11331616	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1995		Y
	C4591001 1133 11331618†	Eye disorders	Myopia	01JAN1990		Y
		Infections and infestations	Herpes zoster	01JAN2010		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2015	31DEC2015	N
		Investigations	HIV test positive	01JAN2010		Y
		Surgical and medical procedures	Muscle operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331619	Congenital, familial and genetic disorders	Hydrocele	01JAN1998	31DEC1998	N
		Endocrine disorders	Hypogonadism male	01JAN2015		Y
		Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Allergy to animal	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Hydrocele operation	01JAN1998	31DEC1998	N
	C4591001 1133 11331621	Eye disorders	Presbyopia	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331622	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Nasal septum deviation	01JAN1992	31DEC2006	N
		Surgical and medical procedures	Nasal septal operation	01JAN2006	31DEC2006	N
	C4591001 1133 11331624	Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1992	31DEC1993	N
		Immune system disorders	Food allergy	01JAN2004		Y
			Rubber sensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
			Tonsillitis	01JAN1992	31DEC1993	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2002	31DEC2002	N
			Foot fracture	01JAN1998	31DEC1998	N
			Hand fracture	01JAN1998	31DEC1998	N
			Rib fracture	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tibia fracture	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
			Inguinal hernia repair	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1133 11331625	Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01MAR2014	31MAR2014	N
			Caesarean section	04DEC2019	04DEC2019	N
	C4591001 1133 11331626	Nervous system disorders	Migraine	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1996	31DEC2009	N
		Surgical and medical procedures	Caesarean section	26SEP2014	26SEP2014	N
	C4591001 1133 11331627	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Eye disorders	Myopia	01JAN1991		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2004	31DEC2004	N
			Humerus fracture	01JAN2004	31DEC2004	N
			Tibia fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014		Y
		Social circumstances	Ex-tobacco user	01JAN2003	28FEB2003	N
		Surgical and medical procedures	Bone operation	01MAY2004	31MAY2004	N
			Mammoplasty	01MAY2014	31MAY2014	N
				01SEP2020	30SEP2020	N
			Scar excision	01JUL2016	31JUL2016	N
	C4591001 1133 11331628	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1133 11331629	Social circumstances	Ex-tobacco user	01JAN1995	31DEC2015	N
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Large intestine polyp	01JUL2019	31JUL2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1133 11331630	Congenital, familial and genetic disorders	Postmenopause	01APR2019		Y
			Gilbert's syndrome	01JAN2010		Y
		Eye disorders	Strabismus	(b) (6) 1985	31DEC2000	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
		Surgical and medical procedures	Eye operation	01JAN1986	31DEC1986	N
				01JAN2000	31DEC2000	N
			Rhinoplasty	01JAN2003	31DEC2003	N
	C4591001 1133 11331631	Eye disorders	Myopia	01JAN2002	06JUN2020	N
		General disorders and administration site conditions	Pain	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Eye laser surgery	06JUN2020	06JUN2020	N
	C4591001 1133 11331632	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1973		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Ex-tobacco user	01JAN1985	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN1997	31DEC1997	N
	C4591001 1133 11331633	Eye disorders	Hypermetropia	01JAN1988		Y
		Immune system disorders	Food allergy	01JAN1990		Y
			Iodine allergy	01JAN2007		Y
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
			Nasal septal operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1133 11331634	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
	C4591001 1133 11331636	Eye disorders	Hypermetropia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Nervous system disorders	Tremor	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Substance use	01JAN2019		Y
			Tobacco user	01JAN1977		Y
	C4591001 1133 11331637	Surgical and medical procedures	Caesarean section	24MAY2016	24MAY2016	N
			Female sterilisation	19SEP2018	19SEP2018	N
			Mammoplasty	17OCT2013	17OCT2013	N
	C4591001 1133 11331638	Eye disorders	Myopia	01JAN1985	30APR2016	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Gastric bypass	01NOV2015	30NOV2015	N
			Keratomileusis	01APR2016	30APR2016	N
			Vasectomy	01JUN2018	30JUN2018	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1133 11331639	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1133 11331640	Cardiac disorders	Palpitations	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JUN2017		Y
			Attention deficit hyperactivity disorder	01JUN2017		Y
		Surgical and medical procedures	Rhinoplasty	01AUG2016	31AUG2016	N
	C4591001 1133 11331641	Eye disorders	Presbyopia	01JAN1983		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN1965	31DEC1965	N
			Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2017		Y
			Type 2 diabetes mellitus	01JUL2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01OCT2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01OCT2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1993	31JUL2012	N
		Reproductive system and breast disorders	Prostatic disorder	01OCT2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN1983		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1965	31DEC1965	N
			Prostatectomy	01DEC2017	31DEC2017	N
			Renal stone removal	01JUL2012	31JUL2012	N
		Vascular disorders	Hypertension	01OCT2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331642	Eye disorders	Presbyopia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	06NOV2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	12SEP2006	12SEP2006	N
			Meningioma surgery	01DEC2015	31DEC2015	N
	C4591001 1133 11331643	Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Wrist surgery	01JAN2010	31DEC2010	N
	C4591001 1133 11331644	Social circumstances	Alcohol use	01FEB2009		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
	C4591001 1133 11331645	Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1133 11331646	Eye disorders	Presbyopia	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
			Tonsillitis	01JAN1989	31DEC1989	N
		Social circumstances	Corrective lens user	01JAN2018		Y
	C4591001 1133 11331647	Immune system disorders	Food allergy	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	08MAR2019	08MAR2019	N
	C4591001 1133 11331648	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Social circumstances	Alcohol use	01JAN2001		Y
	C4591001 1134 11341005	Investigations	Cardiac murmur	01JAN2016		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1994	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1134 11341007	Musculoskeletal and connective tissue disorders	Back pain	01DEC2019		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01APR2004	30APR2004	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1134 11341008	Immune system disorders	Food allergy	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01AUG1984	31AUG1984	N
	C4591001 1134 11341012	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01NOV2013		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1134 11341013	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1134 11341018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1134 11341028	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Allergy to chemicals	01JAN1986		Y
			Rubber sensitivity	(b) (6) 1969		Y
		Nervous system disorders	Dizziness	01MAY2020	31DEC2020	N
			Migraine	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01MAY2020	31DEC2020	N
	C4591001 1134 11341031	Vascular disorders	Rhinitis perennial	(b) (6) 1969		Y
	C4591001 1134 11341033	Gastrointestinal disorders	Hypertension	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1984		Y
			Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Menorrhagia	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Endometrial ablation	01MAR2020	31MAR2020	N
			Shoulder operation	01JAN2015	31DEC2015	N
	C4591001 1134 11341039	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1134 11341041	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2007	31DEC2007	N
	C4591001 1134 11341046	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1994		Y
		Injury, poisoning and procedural complications	Muscle strain	01AUG2020		Y
		Nervous system disorders	Migraine	01JAN2006		Y
	C4591001 1134 11341054	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Cellulitis	01JAN2005	31DEC2005	N
			Staphylococcal infection	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341060	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Lipoma excision	01JAN1992	31DEC1992	N
			Synovial cyst removal	01JAN2010	31DEC2010	N
	C4591001 1134 11341068	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN1999		Y
				01JAN2003		Y
			Hypersensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Night sweats	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2013	31DEC2013	N
			In vitro fertilisation	01JAN2013	31DEC2013	N
	C4591001 1134 11341070	Eye disorders	Myopia	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
			Hepatic steatosis	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1134 11341072	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Bone operation	01JAN1991	31DEC1991	N
	C4591001 1134 11341077	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1134 11341086	Injury, poisoning and procedural complications	Ligament rupture	01JUN2017	30JUN2019	N
			Meniscus injury	01JUL2017	30NOV2018	N
		Musculoskeletal and connective tissue disorders	Myalgia	11JUL2020	12JUL2020	N
		Surgical and medical procedures	Ligament operation	01JUL2019	31JUL2019	N
			Meniscus operation	01NOV2018	30NOV2018	N
	C4591001 1134 11341088	Investigations	Blood cholesterol increased	01JAN2017		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1980	31DEC1980	N
			Neck surgery	01JAN1985	31DEC1985	N
				01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341089	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1134 11341093	Endocrine disorders	Hypothyroidism	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Rubber sensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1134 11341104	Immune system disorders	Food allergy	01JAN1990		Y
	C4591001 1134 11341106	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341107	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Loop electrosurgical excision procedure	01JAN2002	31DEC2002	N
	C4591001 1134 11341111	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1134 11341112	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Surgical and medical procedures	Knee operation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341116	Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Nephrolithiasis	01FEB2018	28FEB2018	N
		Surgical and medical procedures	Mole excision	01JUL2016	31JUL2016	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1134 11341117	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Dumping syndrome	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Colonoscopy normal	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1985	31JAN2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	31JAN2019	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1134 11341118	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1134 11341129	Gastrointestinal disorders	Large intestinal obstruction	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Explorative laparotomy	01JAN1981	31DEC1981	N
	C4591001 1134 11341134	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1134 11341147	Infections and infestations	Onychomycosis	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
	C4591001 1134 11341149	General disorders and administration site conditions	Drug intolerance	01JAN2004		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Muscle strain	01MAY2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Vitamin D deficiency	01JAN2017		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Cervical laser therapy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1134 11341151	Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
	C4591001 1134 11341153	Infections and infestations	Tonsillitis	01JAN1990	31DEC1993	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Mastectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1134 11341154	Injury, poisoning and procedural complications	Ligament rupture	01JAN2018	31JAN2018	N
			Tendon rupture	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Ligament operation	01JAN2018	31JAN2018	N
			Tenoplasty	01JAN2004	31DEC2004	N
	C4591001 1134 11341157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Nervous system disorders	Migraine	01JAN1994		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1134 11341169	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1134 11341174	Musculoskeletal and connective tissue disorders	Back pain	01JUN2020		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
	C4591001 1134 11341176	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2007	31JUL2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Urinary bladder suspension	01JUL2019	31JUL2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine dilation and curettage	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
	C4591001 1134 11341177	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			Skin graft	01JAN1991	31DEC1991	N
	C4591001 1134 11341183	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2008	31DEC2008	N
			Foot deformity	01JAN2010	31DEC2010	N
			Intervertebral disc compression	01JAN2016		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2008	31DEC2008	N
			Toe operation	01JAN2010	31DEC2010	N
	C4591001 1134 11341184	Injury, poisoning and procedural complications	Ligament rupture	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1134 11341188	Immune system disorders	Allergy to metals	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Skin cyst excision	01JAN2005	31DEC2005	N
	C4591001 1134 11341190	Immune system disorders	Allergy to animal	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341192	Immune system disorders	Seasonal allergy	01JAN1987		Y
	C4591001 1134 11341203	Investigations	Cardiac murmur	01JAN1999		Y
	C4591001 1134 11341204	Cardiac disorders	Stress cardiomyopathy	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Catheterisation cardiac	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1134 11341210	Injury, poisoning and procedural complications	Tendon rupture	01JAN2019		Y
	C4591001 1134 11341211	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1134 11341213	Surgical and medical procedures	Wisdom teeth removal	01JAN2011	31DEC2011	N
	C4591001 1134 11341222	Infections and infestations	Pneumonia	01MAR2017	31MAR2017	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1134 11341224	Injury, poisoning and procedural complications	Tibia fracture	01JAN2011	31DEC2011	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013		Y
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
	C4591001 1134 11341225	Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Tonsillectomy	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341226	Infections and infestations	Tonsillitis	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1134 11341228	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2017		Y
	C4591001 1134 11341232	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
	C4591001 1134 11341234	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Seizure	08FEB2012		Y
					08FEB2012	N
	C4591001 1134 11341235	Cardiac disorders	Tachyarrhythmia	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1134 11341236	Gastrointestinal disorders	Anal fissure	16AUG2020		Y
			Gastrooesophageal reflux disease	01JAN2017		Y
			Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01OCT2016		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
			Bipolar disorder	01JAN1990		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	04AUG2020	04AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1134 11341237	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1134 11341241	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN1994	31DEC1994	N
	C4591001 1134 11341242	Congenital, familial and genetic disorders	Cerebral palsy	01JAN1988		Y
		Surgical and medical procedures	Ankle operation	01JAN1992	31DEC1992	N
	C4591001 1134 11341244	Nervous system disorders	Narcolepsy	01JAN2015		Y
	C4591001 1134 11341247	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Pregnancy, puerperium and perinatal conditions	Delivery	16DEC2018	16DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1992	31DEC1992	N
			Gastrectomy	01JAN2012	31DEC2012	N
	C4591001 1134 11341248	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
				01OCT2018		Y
			Seasonal allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01OCT2018	31OCT2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendonitis	01JAN2001		Y
				01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2011		Y
			Tension headache	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01OCT2018	31OCT2018	N
	C4591001 1134 11341249	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Urinary tract infection	23AUG2020	29AUG2020	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Blood triglycerides increased	01JAN2018		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01SEP2019		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
			Myomectomy	01JAN2015	31DEC2015	N
			Uterine dilation and curettage	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341253	Gastrointestinal disorders	Gastric ulcer	01JAN2012	31DEC2012	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
				01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1134 11341254	Surgical and medical procedures	Gastrointestinal ulcer management	01JAN2012	31DEC2012	N	
		Ear and labyrinth disorders	Hypoacusis	01JAN2005		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y	
				01JAN2005		Y	
				Seasonal allergy	01JAN2000		Y
		Infections and infestations	Pharyngitis streptococcal	01MAR2003	30SEP2005	N	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2002	31DEC2002	N	
		Nervous system disorders	Intracranial aneurysm	01JAN2005	31DEC2005	N	
			Serotonin syndrome	01JAN2014	31DEC2014	N	
		Psychiatric disorders	Anxiety	01JAN2012		Y	
			Depression	01JAN2012		Y	
			Post-traumatic stress disorder	01JAN2012		Y	
		Reproductive system and breast disorders	Breast mass	01JAN1999	31DEC1999	N	
		Surgical and medical procedures	Adenotonsillectomy	01JAN2005	31DEC2005	N	
			Brain operation	01FEB2005	28FEB2005	N	
		Breast conserving surgery	01JAN1999	31DEC1999	N		
		Cholecystectomy	01JAN2010	31DEC2010	N		
		Mole excision	01JAN2002	31DEC2002	N		
	C4591001 1134 11341259	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y	
		Immune system disorders	Seasonal allergy	01JAN2010		Y	
		Investigations	Blood cholesterol increased	01JAN2010		Y	
			Blood testosterone decreased	01JAN2018		Y	
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y	
		Psychiatric disorders	Depression	01JAN2012		Y	
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1134 11341260	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01FEB2020		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Rash	01AUG2020		Y
	C4591001 1134 11341263	Cardiac disorders	Supraventricular tachycardia	01JAN2001	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
	C4591001 1134 11341268	Eye disorders	Myopia	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	03SEP2020	03SEP2020	N
	C4591001 1134 11341269	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1134 11341276	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Infections and infestations	Pilonidal cyst	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	05AUG2020	09AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis perennial	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dandruff	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Lipoma excision	01JAN2005	31DEC2005	N
			Pilonidal sinus repair	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341280	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1134 11341281	Gastrointestinal disorders	Umbilical hernia	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2014		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2009	31DEC2009	N
	C4591001 1134 11341283	Ear and labyrinth disorders	Meniere's disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Bone deformity	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1983	31DEC1983	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
			Foot operation	01JAN2000	31DEC2000	N
			Nasal septal operation	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341286	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1999	31DEC1999	N
	C4591001 1134 11341290	Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1996	31DEC1996	N
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Meniscus operation	01JAN1996	31DEC1996	N
			Vasectomy	01JAN2006	31DEC2006	N
			Dyspepsia	01JAN2019		Y
	C4591001 1134 11341292	Gastrointestinal disorders				
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Tension headache	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN1990	31DEC1990	N
			Delivery	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Reproductive system and breast disorders	Uterine disorder	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1134 11341295	Gastrointestinal disorders	Umbilical hernia	01NOV2019	30NOV2019	N
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
			Meniscus injury	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1997	31DEC1997	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2000	31DEC2000	N
			Ligament operation	01JAN2000	31DEC2000	N
			Shoulder arthroplasty	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1995	31DEC1995	N
			Umbilical hernia repair	01NOV2019	30NOV2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1985		Y
				01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1988	31DEC1991	N
		Reproductive system and breast disorders	Endometriosis	01JAN2010	31DEC2014	N
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
			Hysterectomy	01APR2014	30APR2014	N
			Spinal operation	01AUG2000	31AUG2000	N
				01DEC1991	31DEC1991	N
				01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1988	31DEC1988	N
		Injury, poisoning and procedural complications	Tendon rupture	01AUG2019	31DEC2019	N
		Psychiatric disorders	Binge eating	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01DEC2019		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Tenoplasty	01AUG2019	31DEC2019	N
	C4591001 1134 11341301	Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1134 11341303	Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Angioedema	01JAN2018		Y
			Chronic spontaneous urticaria	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341304	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1134 11341308	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Knee operation	01JAN2009	31DEC2009	N
	C4591001 1134 11341313	Injury, poisoning and procedural complications	Spinal cord injury	01JAN2011	31DEC2013	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341314	Congenital, familial and genetic disorders	Marfan's syndrome	01JAN1998		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2015	31DEC2015	N
			Wrist fracture	01JUL2020		Y
		Surgical and medical procedures	Aortic aneurysm repair	01JAN2017	31DEC2017	N
			Fracture treatment	01JAN2015	31DEC2015	N
				10AUG2020	10AUG2020	N
		Vascular disorders	Aortic aneurysm	01JAN2017	31DEC2017	N
	C4591001 1134 11341315	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Surgical and medical procedures	Hernia repair	01JAN2013	31DEC2013	N
	C4591001 1134 11341317	Infections and infestations	Pharyngitis streptococcal	01JAN1985	31DEC1985	N
			Tonsillitis	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Investigations	Blood oestrogen decreased	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
			Insomnia	01JAN2006		Y
		Surgical and medical procedures	Mammoplasty	01JAN2014	31DEC2014	N
			Tenoplasty	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1134 11341321	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN1998		Y
				01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Reproductive system and breast disorders	Ovarian mass	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2010		Y
			Cough	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Ovarian lesion excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341322	Nervous system disorders	Tension headache	01JAN2004		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2004		Y
	C4591001 1134 11341323	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2004		Y
			Insomnia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Abdominoplasty	01JAN2019	31DEC2019	N
			Caesarean section	01JAN2000	31DEC2000	N
				01JAN2004	31DEC2004	N
			Mammoplasty	01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341324	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2011	31DEC2011	N
		Renal and urinary disorders	Urethral stenosis	01JAN1996	31DEC2006	N
		Surgical and medical procedures	Tenoplasty	01JAN2011	31DEC2011	N
			Urinary tract operation	01JAN2006	31DEC2006	N
	C4591001 1134 11341325	Injury, poisoning and procedural complications	Joint dislocation	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Joint arthroplasty	01JAN2001	31DEC2001	N
	C4591001 1134 11341326	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN1989		Y
				01JAN2011		Y
		Psychiatric disorders	Seasonal allergy	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian rupture	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Liver transplant	01JAN2014	31DEC2014	N
			Oophorectomy	01JAN2004	31DEC2004	N
	C4591001 1134 11341327	Surgical and medical procedures	Inguinal hernia repair	01JAN1999	31DEC1999	N
	C4591001 1134 11341328	Immune system disorders	Drug hypersensitivity	01OCT2017		Y
			Food allergy	01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Investigations	Endoscopy	01DEC2017	31DEC2017	N
				01OCT2019	31OCT2019	N
				01SEP2018	30SEP2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				11SEP2017	11SEP2017	N
			Lumbar puncture	11SEP2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	11SEP2017	09DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01AUG2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1134 11341330	Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341332	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1134 11341335	General disorders and administration site conditions	Generalised oedema	01JAN2015		Y
		Immune system disorders	Allergic oedema	01JUN2020		Y
			Drug hypersensitivity	01JAN2005		Y
				01JAN2011		Y
				09FEB2012		Y
		Infections and infestations	Staphylococcal infection	20JUN2020	20JUN2020	N
					30JUN2020	N
		Metabolism and nutrition disorders	Hypernatraemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
			Temporomandibular joint syndrome	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN1981		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2014	31DEC2014	N
			Debridement	20JUN2020	20JUN2020	N
			Exeresis	01JAN2005	31DEC2005	N
			Spinal laminectomy	20JUN2018	20JUN2018	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N
	C4591001 1134 11341336	Injury, poisoning and procedural complications	Cartilage injury	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2005		Y
		Surgical and medical procedures	Shoulder operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1134 11341337	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1134 11341338	Immune system disorders	Food allergy	01JAN2003		Y
				01MAR2018		Y
			Iodine allergy	01JAN2001		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Foot fracture	25JUL2020	25JUL2020	N
		Nervous system disorders	Migraine	01JAN1991		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC2010	N
			Menopausal symptoms	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1134 11341340	Gastrointestinal disorders	Hysterectomy	01JAN2010	31DEC2010	N	
			Gastroesophageal reflux disease	01JAN2005		Y	
		Immune system disorders	Rubber sensitivity	01JAN2005		Y	
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N	
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1997	31DEC1997	N	
				01JAN2018	31DEC2018	N	
			Plantar fasciitis	01JAN1998	31DEC1998	N	
			Trigger finger	01FEB2020	29FEB2020	N	
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2005	31DEC2005	N	
		Social circumstances	Postmenopause	01JAN2017		Y	
		Surgical and medical procedures	Bunion operation	01JAN1997	31DEC1997	N	
				01JAN2018	31DEC2018	N	
			Fascia release	01JAN1998	31DEC1998	N	
			Tendon sheath incision	01FEB2020	29FEB2020	N	
		Tonsillectomy	01JAN2008	31DEC2008	N		
	C4591001 1134 11341344	Immune system disorders	Drug hypersensitivity	01JAN1988		Y	
				01JAN1996		Y	
			Seasonal allergy	01JAN2015		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2015	31JAN2016	N	
			Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2003	31DEC2003	N	
				01JAN2007	31DEC2007	N	
				01JAN2013	31DEC2013	N	
	Social circumstances	Postmenopause	01JUN2015		Y		

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast reconstruction	01JAN2016	31DEC2016	N
			Mastectomy	05MAY2015	05MAY2015	N
			Uterine dilation and curettage	01JAN2003	31DEC2003	N
				01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N
	C4591001 1134 11341348	Gastrointestinal disorders	Abdominal hernia	01JAN1988	31DEC1998	N
				01JAN1995	31DEC1995	N
			Constipation	01JAN1985		Y
			Gastroesophageal reflux disease	01JAN2017		Y
			Umbilical hernia	01JAN1993	31DEC1993	N
		Immune system disorders	Seasonal allergy	01JAN1971		Y
		Infections and infestations	Ear infection	01JAN1971	31DEC1972	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Nervous system disorders	Headache	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1972	31DEC1972	N
			Umbilical hernia repair	01JAN1993	31DEC1993	N
	C4591001 1134 11341351	Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Back injury	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995		Y
			Rhinitis perennial	01JAN1977		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Nasal septal operation	01JAN1995	31DEC1995	N
	C4591001 1134 11341355	Injury, poisoning and procedural complications	Contusion	13SEP2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Mammoplasty	01JAN2000	31DEC2000	N
	C4591001 1134 11341356	Investigations	Hepatic enzyme increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1992	31DEC1992	N
				01JAN1997	31DEC1997	N
		Surgical and medical procedures	Bunion operation	01JAN1992	31DEC1992	N
				01JAN1997	31DEC1997	N
	C4591001 1134 11341363	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Intestinal resection	01JAN2016	31DEC2016	N
	C4591001 1134 11341364	Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1134 11341365	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341370	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2004		Y
			Insomnia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1134 11341372	Cardiac disorders	Cardiac failure chronic	01NOV2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2014		Y
			Impaired gastric emptying	29AUG2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2010		Y
			Hypertriglyceridaemia	01NOV2010		Y
			Type 2 diabetes mellitus	01NOV2010		Y
		Psychiatric disorders	Anxiety	01JAN2012	31DEC2015	N
			Depression	01JAN2012	31DEC2015	N
		Vascular disorders	Hypertension	01NOV2010		Y
	C4591001 1134 11341373	Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341378	Infections and infestations	Hepatitis C	01JAN2018		Y
	C4591001 1134 11341379	Gastrointestinal disorders	Tooth impacted	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Oral surgery	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341381	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Bunion operation	01JAN2002	31DEC2002	N
	C4591001 1134 11341385	Eye disorders	Myopia	01JAN1983	31DEC2000	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2015	31DEC2015	N
			Caesarean section	01JAN1998	31DEC1998	N
				01JAN2002	31DEC2002	N
			Cholecystectomy	01JAN1999	31DEC1999	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Gastric bypass	01JUN2020	30JUN2020	N
	C4591001 1134 11341389	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Umbilical hernia	01JAN2005	31DEC2005	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN2005	31DEC2005	N
	C4591001 1134 11341392	Cardiac disorders	Supraventricular tachycardia	01JAN2002	30JUN2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Surgical and medical procedures	Cardiac ablation	01JUN2017	30JUN2017	N
	C4591001 1134 11341393	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Pilonidal cyst	01JAN2014	31DEC2014	N
		Nervous system disorders	Sinus headache	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1996		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN2014	31DEC2014	N
	C4591001 1134 11341397	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Adenomyosis	01JAN2016		Y
		Surgical and medical procedures	Limb operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1134 11341399	Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
			Post-traumatic stress disorder	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1134 11341404	Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2018		Y
				01JAN2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
			Caesarean section	01JAN1998	31DEC1998	N
				01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Endometrial ablation	01JAN2006	31DEC2006	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
	C4591001 1134 11341406	Congenital, familial and genetic disorders	Retinitis pigmentosa	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341407	Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1134 11341408	Vascular disorders	Hypertension	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341413	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1997	31DEC1997	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31MAY1995	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1997	31DEC1997	N
			Breast conserving surgery	01JAN2006	31DEC2006	N
			Laparoscopic surgery	01MAY1995	31MAY1995	N
		Vascular disorders	Lymphoedema	01JAN1998		Y
	C4591001 1134 11341416	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Varicocele	01JAN1995	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Surgical and medical procedures	Nasal septum deviation	01JAN2008	31DEC2018	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Varicocele repair	01JAN2000	31DEC2000	N
	C4591001 1134 11341420	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2006	31DEC2006	N
			Wrist fracture	01MAR2020	31MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Fracture treatment	01MAR2020	31MAR2020	N
			Knee operation	01JAN2006	31DEC2006	N
	C4591001 1134 11341421	Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
	C4591001 1134 11341425	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1134 11341426	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1134 11341435	Endocrine disorders	Hypothyroidism	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1987		Y
		Investigations	Arthroscopy	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2001		Y
			Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Bipolar disorder	01JAN1992		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Shoulder operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1134 11341436	Musculoskeletal and connective tissue disorders	Arthralgia	13SEP2018		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1134 11341437	General disorders and administration site conditions	Cyst	01JAN2001	31DEC2001	N
		Immune system disorders	Allergy to vaccine	01JAN1992		Y
			Drug hypersensitivity	01APR2020		Y
				01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAY2019	31AUG2019	N
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01AUG2019	31AUG2019	N
			Limb operation	01JAN2001	31DEC2001	N
	C4591001 1134 11341438	Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
			Wisdom teeth removal	10SEP2020	19SEP2020	N
	C4591001 1135 11351001	Eye disorders	Hypermetropia	01JAN2018		Y
	C4591001 1135 11351004	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1135 11351006	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	25FEB2008	25FEB2008	N
				30MAR2009	30MAR2009	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1135 11351007	Eye disorders	Presbyopia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Surgical and medical procedures	Bunion operation	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1135 11351009	Congenital, familial and genetic disorders	Renal aplasia	(b) (6) 1989		Y
		Eye disorders	Myopia	01JAN2001		Y
		Immune system disorders	Food allergy	01JAN2005		Y
			Seasonal allergy	01JAN1995		Y
	C4591001 1135 11351011	Eye disorders	Myopia	01JAN2005		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2013	31DEC2013	N
	C4591001 1135 11351016	Endocrine disorders	Hypogonadism	01JAN2019		Y
		Eye disorders	Hypermetropia	01JAN2009		Y
		Hepatobiliary disorders	Hepatic steatosis	07DEC2018		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2014		Y
			Hypokalaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal adenoma	07DEC2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1135 11351017	Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1135 11351018	Musculoskeletal and connective tissue disorders	Exostosis	01AUG2007	31AUG2007	N
		Surgical and medical procedures	Bone lesion excision	01AUG2007	31AUG2007	N
			Mammoplasty	01FEB2015	28FEB2015	N
	C4591001 1135 11351020	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1135 11351021	Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
	C4591001 1135 11351023	Congenital, familial and genetic disorders	Thyroglossal cyst	01FEB2020	29FEB2020	N
		Immune system disorders	Contrast media allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010	31DEC2019	N
		Surgical and medical procedures	Gastrectomy	01JAN2019	31DEC2019	N
	C4591001 1135 11351024	Eye disorders	Myopia	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	24JUL2020	24JUL2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1135 11351025	Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351026	Cardiac disorders	Cardiac failure congestive	01JUN2018		Y
		Investigations	Heart rate irregular	01JUN2018	30JUN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01DEC2019		Y
			Heart valve replacement	01DEC2018	31DEC2018	N
		Vascular disorders	Thrombosis	01DEC2018	28FEB2019	N
	C4591001 1135 11351027	Eye disorders	Myopia	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1135 11351029	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
	C4591001 1135 11351030	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Chondroplasty	01JAN2012	31DEC2012	N
			Intervertebral disc operation	01JAN2015	31DEC2015	N
	C4591001 1135 11351036	Gastrointestinal disorders	Oesophagitis	01JAN2020		Y
		Infections and infestations	Periodontal destruction	01JAN2008	31DEC2010	N
		Surgical and medical procedures	Bone graft	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1135 11351037	Eye disorders	Hypermetropia	03AUG2020		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2020	13JUL2020	N
		Psychiatric disorders	Depression	01JAN2015	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1135 11351038	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351040	Eye disorders	Myopia	01JAN1996		Y
		Gastrointestinal disorders	Inguinal hernia	01APR1986	30APR1986	N
		Surgical and medical procedures	Inguinal hernia repair	01APR1986	30APR1986	N
	C4591001 1135 11351041	Eye disorders	Astigmatism	01JAN2000		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Perinatal depression	01DEC2018	31DEC2019	N
	C4591001 1135 11351042	Eye disorders	Myopia	01JAN2003		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
			Limb injury	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Chondroplasty	01JAN2010	31DEC2010	N
			Ligament operation	01JAN2011	31DEC2011	N
	C4591001 1135 11351044	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1135 11351052	Blood and lymphatic system disorders	Anaemia	01JAN2006		Y
		Congenital, familial and genetic disorders	Talipes	01JAN1976	31DEC1976	N
		Eye disorders	Myopia	01JAN1990	31DEC2009	N
		Gastrointestinal disorders	Aphthous ulcer	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
			Depression	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Surgical and medical procedures	Keratomileusis	01JAN2009	31DEC2009	N
			Talipes correction	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351053	Eye disorders	Hypermetropia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lip squamous cell carcinoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Cancer surgery	01JAN2006	31DEC2006	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351054	Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1135 11351057	Eye disorders	Myopia	01JAN1985		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1135 11351058	Eye disorders	Myopia	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351059	Ear and labyrinth disorders	Deafness unilateral	01JAN2017		Y
			Meniere's disease	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1135 11351060	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1995		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Caesarean section	12OCT2005	12OCT2005	N
	C4591001 1135 11351061	Injury, poisoning and procedural complications	Hand fracture	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2019		Y
		Surgical and medical procedures	Fracture treatment	01JAN1992	31DEC1992	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1135 11351065	Eye disorders	Myopia	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	17FEB2017	17FEB2017	N
				27JAN1999	27JAN1999	N
				29NOV2019	29NOV2019	N
			Female sterilisation	29NOV2019	29NOV2019	N
	C4591001 1135 11351067	Eye disorders	Hypermetropia	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1999	31DEC1999	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
	C4591001 1135 11351068	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Prostatic disorder	01JAN2019		Y
	C4591001 1135 11351069	Skin and subcutaneous tissue disorders	Acne	01JAN1984		Y
		Eye disorders	Myopia	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019		Y
			Trigger finger	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Surgical and medical procedures	Tendon operation	01JUL2020	31JUL2020	N
			Tendon sheath incision	01MAY2020	31MAY2020	N
	C4591001 1135 11351072	Vascular disorders	Hypertension	01JAN2019		Y
		Eye disorders	Myopia	01JAN2018		Y
		Injury, poisoning and procedural complications	Fibula fracture	01FEB2017	28FEB2017	N
			Road traffic accident	01FEB2017	28FEB2017	N
		Surgical and medical procedures	Bone operation	01FEB2017	28FEB2017	N
	C4591001 1135 11351073	Endocrine disorders	Hypothyroidism	01JAN1997		Y
			Thyroid mass	01JAN1997	31DEC1997	N
		Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2012		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN1997	31DEC1997	N
	C4591001 1135 11351075	Cardiac disorders	Bradycardia	01JAN2008		Y
	C4591001 1135 11351080	Gastrointestinal disorders	Umbilical hernia	01JAN1997	31DEC1997	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1997	31DEC1997	N
	C4591001 1135 11351082	Eye disorders	Myopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
				01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2014	N
		Surgical and medical procedures	Lithotripsy	01JAN2014	31DEC2014	N
	C4591001 1135 11351083	Gastrointestinal disorders	Rectal prolapse	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
		Surgical and medical procedures	Otoplasty	01JAN2015	31DEC2015	N
			Rectal prolapse repair	01JAN2015	31DEC2015	N
	C4591001 1135 11351084	Eye disorders	Astigmatism	01JAN1998		Y
			Myopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1995		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351085	Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2018		Y
	C4591001 1135 11351088	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1135 11351090	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Nervous system disorders	Headache	01JAN1985		Y
			Migraine	01JAN1985		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1135 11351091	Eye disorders	Myopia	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1135 11351095	Injury, poisoning and procedural complications	Ligament rupture	01SEP2019	30SEP2019	N
		Surgical and medical procedures	Ligament operation	01SEP2019	30SEP2019	N
	C4591001 1135 11351097	Eye disorders	Presbyopia	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
		Surgical and medical procedures	Dental implantation	01JAN1995	31DEC1995	N
				01JAN2018	31DEC2018	N
			Ligament operation	01JAN1992	31DEC1992	N
	C4591001 1135 11351099	Congenital, familial and genetic disorders	Colour blindness	01JAN1988		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Retrognathia	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Jaw operation	01JAN1999	31DEC1999	N
	C4591001 1135 11351100	Eye disorders	Hypermetropia	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2014	31DEC2018	N
		Surgical and medical procedures	Ligament operation	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
	C4591001 1135 11351103	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2016	31DEC2016	N
	C4591001 1135 11351104	Gastrointestinal disorders	Tooth impacted	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
		Surgical and medical procedures	Knee operation	01MAR1997	31DEC1997	N
				01MAY1996	31DEC1996	N
			Wisdom teeth removal	01APR2001	31DEC2001	N
	C4591001 1135 11351105	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Gastric ulcer	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351109	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
			Eczema	01JAN1997	31DEC1999	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2008	31DEC2008	N
	C4591001 1135 11351111	Eye disorders	Myopia	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Pain in extremity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Dental implantation	01JAN2015	31DEC2015	N
	C4591001 1135 11351112	Injury, poisoning and procedural complications	Hand fracture	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Limb operation	01JAN1996	31DEC1996	N
	C4591001 1135 11351113	Immune system disorders	Food allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Limb operation	01JAN2017	31DEC2017	N
	C4591001 1135 11351114	Eye disorders	Astigmatism	01JAN2007		Y
			Myopia	01JAN2007		Y
		Immune system disorders	Allergy to plants	01JAN1999		Y
			Food allergy	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1999		Y
		Surgical and medical procedures	Papilloma excision	01AUG2020	01AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351119	Eye disorders	Myopia	01JAN1979		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2002	11JUN2020	N
		Surgical and medical procedures	Cystocele repair	11JUN2020	11JUN2020	N
			Mammoplasty	01NOV2012	30NOV2012	N
	C4591001 1135 11351120	Gastrointestinal disorders	Tooth impacted	01JAN2019	30NOV2019	N
		Surgical and medical procedures	Wisdom teeth removal	01NOV2019	30NOV2019	N
	C4591001 1135 11351121	Eye disorders	Myopia	01JAN1984		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Seasonal affective disorder	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1135 11351124	Immune system disorders	Anaphylactic reaction	01JAN2000	31DEC2000	N
			Food allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hyperlipidaemia	01JAN2016		Y
	C4591001 1135 11351126	Gastrointestinal disorders	Constipation	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Food allergy	01JAN1988		Y
			Seasonal allergy	01JAN1988		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01MAY2020	31MAY2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Nervous system disorders	Complex regional pain syndrome	01JAN1988		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Depression	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Dermatitis acneiform	01JAN1988		Y
	C4591001 1135 11351127	Eye disorders	Myopia	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	04JUN2008	04JUN2008	N
				20AUG2009	20AUG2009	N
	C4591001 1135 11351129	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1135 11351134	Eye disorders	Myopia	01JAN2007		Y
	C4591001 1135 11351136	Eye disorders	Myopia	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Surgical and medical procedures	Keratomileusis	01JAN1999	31DEC1999	N
	C4591001 1135 11351139	Eye disorders	Myopia	01JAN2005		Y
	C4591001 1135 11351142	Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Knee operation	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351144	Eye disorders	Myopia	01JAN2005		Y
	C4591001 1135 11351145	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2001		Y
	C4591001 1135 11351148	Eye disorders	Myopia	01JAN2000		Y
	C4591001 1135 11351151	Eye disorders	Hypermetropia	01JAN1993		Y
	C4591001 1135 11351152	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Drug hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1135 11351154	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1135 11351155	Eye disorders	Hypermetropia	01JAN1982		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1982		Y
	C4591001 1135 11351156	Eye disorders	Hypermetropia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2010	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
			Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2011	31DEC2011	N
			Turbinoplasty	01JAN2011	31DEC2011	N
	C4591001 1135 11351158	Eye disorders	Myopia	01JAN1987		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2014	31DEC2014	N
	C4591001 1135 11351163	Ear and labyrinth disorders	Tinnitus	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Infections and infestations	Adenoiditis	01JAN1992	31DEC1992	N
			Nasopharyngitis	01JUL2020	31JUL2020	N
			Tonsillitis	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Tendon injury	09JUL2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1135 11351164	Vascular disorders	Hypertension	01JAN2010		Y	
		Eye disorders	Astigmatism	01JAN2000		Y	
				Myopia	01JAN1976		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2005		Y	
				Facial bones fracture	01JAN1976	31DEC1976	N
				Ulna fracture	01JAN2005		Y
		Investigations	Arthroscopy	01JUL2018	31JUL2018	N	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y	
			Type 2 diabetes mellitus	01JAN2016		Y	
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y	
		Surgical and medical procedures	Eye operation	01JAN1996	31DEC1996	N	
			Ostectomy	01JAN2005	31DEC2005	N	
			Osteotomy	01AUG2019	31DEC2019	N	
			Rhinoplasty	01JAN1976	31DEC1976	N	
	C4591001 1135 11351166	Vascular disorders	Hypertension	01JAN2016		Y	
		Eye disorders	Myopia	01JAN2005		Y	
		Gastrointestinal disorders	Vomiting	01JAN1999	31DEC1999	N	
		Immune system disorders	Food allergy	01JAN1997		Y	
			Seasonal allergy	01JAN1997		Y	
		Investigations	Oesophagoscopy	01JAN1999	31DEC1999	N	
		Psychiatric disorders	Anxiety	01JAN2019		Y	
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y	
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N	
		Eye disorders	Hypermetropia	01JAN2000		Y	
	C4591001 1135 11351168						

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1135 11351169	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
			Obesity	01JAN1967		Y
			Overweight	01JAN1967		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	01JAN2012	31DEC2012	N
	C4591001 1135 11351170	Eye disorders	Myopia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1135 11351171	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1135 11351172	Eye disorders	Myopia	01JAN2002	31DEC2019	N
			Strabismus	01JAN1991		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN1994		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Photorefractive keratectomy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Strabismus correction	01JAN1991	31DEC1991	N
	C4591001 1135 11351175	Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Allergy to metals	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1135 11351176	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2017		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
			Overweight	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2006		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Gastrectomy	01JAN2012	31DEC2012	N
			Orthopaedic procedure	01JAN2007	31DEC2011	N
			Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1135 11351177	Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Female sterilisation	01JAN2008	31DEC2008	N
	C4591001 1135 11351179	Eye disorders	Myopia	01JAN1998		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1135 11351184	Eye disorders	Hypermetropia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Injury, poisoning and procedural complications	Jaw fracture	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997	31DEC1998	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Upper-airway cough syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1978	31DEC1978	N
			Orthognathic surgery	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN1998	31DEC1998	N
	C4591001 1135 11351190	Eye disorders	Myopia	01JAN2001		Y
	C4591001 1135 11351191	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Overweight	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Urethral stenosis	01JAN1994	31DEC1994	N
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2018	31DEC2018	N
			Urethral operation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351194	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351195	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
	C4591001 1135 11351198	Eye disorders	Myopia	01JAN2008		Y
	C4591001 1135 11351199	Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Depression	01JAN2009		Y
			Post-traumatic stress disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1135 11351200	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
		Surgical and medical procedures	Craniotomy	(b) (6) 1992	(b) (6) 1992	N
			Foetal surgery	(b) (6) 1992	(b) (6) 1992	N
	C4591001 1135 11351201	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1135 11351203	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Overweight	01JAN2012		Y
	C4591001 1135 11351205	Eye disorders	Hypermetropia	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1135 11351206	Injury, poisoning and procedural complications	Back injury	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2011	31DEC2011	N
	C4591001 1135 11351207	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN2007		Y
			Food allergy	01JAN2007		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	03JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Lipoma excision	01JAN2017	31DEC2017	N
	C4591001 1135 11351208	Immune system disorders	Allergy to arthropod sting	01JAN1994		Y
	C4591001 1135 11351212	Eye disorders	Astigmatism	01JAN2004		Y
			Hypermetropia	01JAN1980		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Surgical and medical procedures	Mammoplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351213	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1135 11351214	Gastrointestinal disorders	Coeliac disease	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2014		Y
	C4591001 1135 11351217	Infections and infestations	Tonsillitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1135 11351220	Eye disorders	Myopia	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
			Overweight	01JAN1994		Y
		Surgical and medical procedures	Gastrectomy	01JAN2016	31DEC2016	N
	C4591001 1135 11351221	Gastrointestinal disorders	Inguinal hernia	01JAN1983	31DEC1983	N
		Infections and infestations	Tonsillitis	04AUG2020	04AUG2020	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1983	31DEC1983	N
			Tonsillectomy	04AUG2020	04AUG2020	N
	C4591001 1135 11351222	Cardiac disorders	Supraventricular tachycardia	01JAN2010	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N
	C4591001 1135 11351225	Gastrointestinal disorders	Inguinal hernia	01JAN2006	31DEC2006	N
		Renal and urinary disorders	Urinary incontinence	01JAN2009	31DEC2011	N
		Social circumstances	Corrective lens user	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Inguinal hernia repair	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351226	Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1995	31DEC1995	N
				01JAN1997	31DEC1997	N
	C4591001 1135 11351228	Hepatobiliary disorders	Gallbladder polyp	10JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10AUG2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015	31DEC2015	N
	C4591001 1135 11351229	Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1997	31DEC1997	N
		Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1135 11351230	Surgical and medical procedures	Tonsillectomy	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1988	31DEC1988	N
		Infections and infestations	Meningitis	01JAN1984	31DEC1984	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1988	31DEC1988	N
			Ligament operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1135 11351231	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2017		Y
		Investigations	Biopsy breast	01JAN1993	31DEC1993	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal neoplasm	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Benign tumour excision	01JAN2014	31DEC2014	N
			Breast conserving surgery	01JAN1993	31DEC1993	N
			Endometriosis ablation	01JAN1989	31DEC1989	N
	C4591001 1135 11351234	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1135 11351235	Eye disorders	Astigmatism	01JAN2017		Y
			Hypermetropia	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
	C4591001 1135 11351239	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2018	23JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Overweight	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Surgical and medical procedures	Nasal septal operation	23JUL2020	23JUL2020	N
	C4591001 1135 11351241	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1135 11351242	Eye disorders	Myopia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
	C4591001 1135 11351243	Eye disorders	Myopia	01JAN2000		Y
		General disorders and administration site conditions	Cyst	01JAN2000	31DEC2000	N
		Immune system disorders	Food allergy	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
		Surgical and medical procedures	Cyst removal	01JAN2000	31DEC2000	N
	C4591001 1135 11351244	Surgical and medical procedures	Mastectomy	01JAN2010	31DEC2010	N
	C4591001 1135 11351245	Eye disorders	Hypermetropia	01JAN1992	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351247	Eye disorders	Myopia	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
			Umbilical hernia	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1984	31DEC1984	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
			Diverticulitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1993		Y
		Psychiatric disorders	Tachyphrenia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Rhinitis allergic	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
			Caesarean section	14SEP1981	14SEP1981	N
			Cholecystectomy	01JAN1984	31DEC1984	N
			Gastric bypass	01JAN2016	31DEC2016	N
			Intestinal resection	01JAN2018	31DEC2018	N
			Skin operation	01JAN2019	31DEC2019	N
			Umbilical hernia repair	01JAN2019	31DEC2019	N
		Eye disorders	Myopia	01JAN1972		Y
	C4591001 1135 11351248	Gastrointestinal disorders	Inguinal hernia	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
			Overweight	01JAN2004		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1966	31DEC1966	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351250	Eye disorders	Astigmatism	01JAN2001		Y
				01JAN2008		Y
			Hypermetropia	01JAN2001		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
			Gastroesophageal reflux disease	01AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Obesity	01JAN1989		Y
			Overweight	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN1985	31DEC1985	N
			Mammoplasty	01FEB2020	29FEB2020	N
			Orchidectomy	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1135 11351251	Eye disorders	Myopia	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
	C4591001 1135 11351253	Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351256	Eye disorders	Hypermetropia	01JAN2017		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Food allergy	01JAN1976		Y
			Seasonal allergy	01JAN1979		Y
		Injury, poisoning and procedural complications	Epicondylitis	01FEB2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1135 11351259	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Surgical and medical procedures	Oocyte harvest	01JAN2006	31DEC2006	N
				01JAN2013	31DEC2013	N
	C4591001 1135 11351262	Eye disorders	Myopia	01JAN1984	31DEC1984	N
					31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012	31DEC2015	N
		Surgical and medical procedures	Keratomileusis	01JAN1998	31DEC1998	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351263	Injury, poisoning and procedural complications	Ankle fracture	01NOV2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	01NOV2013	30NOV2013	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1135 11351264	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
	C4591001 1135 11351265	Immune system disorders	Food allergy	01JAN1996		Y
			Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Ligament rupture	01AUG2020		Y
		Psychiatric disorders	Dysphemia	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1135 11351267	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008		Y
	C4591001 1135 11351268	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1997	31DEC2000	N
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2007		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2000	31DEC2000	N
	C4591001 1135 11351269	Eye disorders	Dacryostenosis acquired	01JAN2013		Y
			Hypermetropia	01JAN1989		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament injury	01JAN2011	31DEC2011	N
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Dacryocystorhinostomy	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Ligament operation	01JAN2011	31DEC2011	N
		Eye disorders	Myopia	01JAN2001		Y
	C4591001 1135 11351274	Injury, poisoning and procedural complications	Ligament rupture	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N
	C4591001 1135 11351276	Eye disorders	Myopia	01JAN1983		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01AUG2020		Y
			Uterine leiomyoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Caesarean section	01AUG2006	31AUG2006	N
				01JAN2000	31JAN2000	N
			Cholecystectomy	01MAR2000	31MAR2000	N
			Gastric bypass	01JUN2003	30JUN2003	N
			Hysterectomy	01MAR2018	31MAR2018	N
	C4591001 1135 11351279	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351281	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Herpes zoster	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1135 11351282	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1135 11351284	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2018		Y
			Colitis microscopic	01JAN2018		Y
		Immune system disorders	Allergy to chemicals	01JAN2015		Y
			Drug hypersensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2000	31DEC2010	N
			Upper limb fracture	01JAN2015	31DEC2018	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01APR2020	30APR2020	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2020	31DEC2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Elbow operation	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Oophorectomy bilateral	01JAN2018	31DEC2018	N
			Orthognathic surgery	01JAN2010	31DEC2010	N
	C4591001 1135 11351285	Eye disorders	Hypermetropia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1135 11351286	Eye disorders	Myopia	01JAN2009	31DEC2009	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
			Back pain	01JAN2003		Y
			Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Headache	01JAN1995		Y
			Migraine	01JAN1995		Y
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
			Ligament operation	01JAN2014		Y
					31DEC2014	N
			Meniscus operation	01JAN2014		Y
	C4591001 1135 11351287	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	02NOV1988	02NOV1988	N
	C4591001 1135 11351288	Eye disorders	Hypermetropia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Nervous system disorders	Dyslexia	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
	C4591001 1135 11351290	Eye disorders	Myopia	01JAN2006		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2005		Y
	C4591001 1135 11351291	Surgical and medical procedures	Caesarean section	15OCT2015	15OCT2015	N
				17MAY2014	17MAY2014	N
				25FEB2020	25FEB2020	N
			Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1135 11351292	Ear and labyrinth disorders	Tinnitus	01JAN2003		Y
			Tympanic membrane perforation	01JAN2003		Y
		Eye disorders	Astigmatism	01JAN2003		Y
			Myopia	01JAN2003		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2003		Y
		General disorders and administration site conditions	Hernia	01JAN2003		Y
		Infections and infestations	Bronchitis	01JAN1981	31DEC1984	N
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
			Overweight	01JAN2006		Y
		Surgical and medical procedures	Hernia repair	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351293	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
				01JAN2010		Y
			Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2010	31DEC2019	N
			Depression	01JAN2010	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1135 11351295	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
	C4591001 1135 11351297	Eye disorders	Hypermetropia	01JAN1976		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JUL2011	01JUL2011	N
				29JUL2004	29JUL2004	N
	C4591001 1135 11351301	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012	31DEC2012	N
	C4591001 1135 11351304	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Overweight	01JAN2015		Y
	C4591001 1135 11351307	Eye disorders	Myopia	01JAN1997	31DEC2014	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
			Headache	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
			Keratomileusis	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia repair	01JAN2019	31DEC2019	N
	C4591001 1135 11351308	Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Haemorrhoids	01FEB2019	31DEC2019	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2019	31JAN2019	N
		Surgical and medical procedures	Haemorrhoid operation	01FEB2019	28FEB2019	N
			Limb operation	01JAN2019	31JAN2019	N
			Tympanoplasty	01JAN2007	31DEC2007	N
	C4591001 1135 11351313	Eye disorders	Myopia	01JAN1991		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Overweight	01JAN2010		Y
	C4591001 1135 11351315	Eye disorders	Hypermetropia	01JAN2007		Y
		Gastrointestinal disorders	Dyspepsia	01JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
			Overweight	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1989	31DEC2015	N
		Surgical and medical procedures	Nasal septal operation	01JAN2015		Y
	C4591001 1135 11351322	Eye disorders	Myopia	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1135 11351323	Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351326	Eye disorders	Hypermetropia	01JAN1995		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1135 11351327	Eye disorders	Myopia	01JAN1992	31DEC2015	N
			Retinal tear	01JAN2005	31DEC2005	N
		Investigations	Hysteroscopy	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Contact lens therapy	01JAN2015	31DEC2015	N
			In vitro fertilisation	01JAN2016	31DEC2016	N
			Retinal operation	01JAN2005	31DEC2005	N
			Uterine dilation and curettage	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2016	30APR2016	N
	C4591001 1135 11351328	Eye disorders	Presbyopia	01FEB2019		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Tenoplasty	01JAN2018	31DEC2018	N
	C4591001 1135 11351330	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
			Tonsillitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Obesity	01JAN1984		Y
			Overweight	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1983	31DEC1983	N
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1135 11351331	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1135 11351332	Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1135 11351334	Eye disorders	Myopia	01JAN1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
			Overweight	01JAN1995		Y
		Surgical and medical procedures	Mole excision	01JAN2006	31DEC2006	N
	C4591001 1135 11351335	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Eye disorders	Myopia	01JAN1982		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351336	Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1135 11351338	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Myopia	01JAN1978		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN2008	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Skin neoplasm excision	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1135 11351341	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1135 11351342	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351343	Immune system disorders	Drug hypersensitivity	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN1992		Y
		Surgical and medical procedures	Mammoplasty	01JAN2011	31DEC2011	N
	C4591001 1135 11351346	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Hepatitis A	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351347	Gastrointestinal disorders	Inguinal hernia	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2003	31DEC2003	N
	C4591001 1135 11351349	General disorders and administration site conditions	Precancerous condition	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008	31DEC2015	N
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2011	31DEC2011	N
	C4591001 1135 11351350	Skin and subcutaneous tissue disorders	Keloid scar	01JAN2015		Y
	C4591001 1135 11351351	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Overweight	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1135 11351359	Eye disorders	Astigmatism	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Tonsillolith	01JAN2017		Y
	C4591001 1135 11351360	Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Myopia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
	C4591001 1135 11351361	Eye disorders	Myopia	01JAN2003		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC2016	N
		Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
	C4591001 1135 11351362	Blood and lymphatic system disorders	Anaemia	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1995		Y
	C4591001 1135 11351365	Ear and labyrinth disorders	Tinnitus	01JAN2018	31DEC2020	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
			Pneumonia	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Sciatic nerve injury	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1998		Y
			Overweight	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351367	Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
			Localised infection	23AUG2020	30AUG2020	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
		Surgical and medical procedures	Ankle operation	01JAN2013	31DEC2013	N
			Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351368	Eye disorders	Myopia	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351369	Immune system disorders	Food allergy	01JAN2010		Y
	C4591001 1135 11351370	Eye disorders	Myopia	01JAN2000		Y
	C4591001 1135 11351373	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1135 11351374	Eye disorders	Myopia	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Mole excision	01JAN2003	31DEC2003	N
			Nasal septal operation	01JAN2003	31DEC2003	N
	C4591001 1135 11351375	Eye disorders	Myopia	01JAN2011		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2018		Y
	C4591001 1135 11351376	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Autism spectrum disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Obsessive-compulsive disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1993		Y
			Eczema	01JAN1998		Y
	C4591001 1135 11351377	Eye disorders	Cataract	01JAN2011	31DEC2012	N
			Presbyopia	01JAN2017		Y
		Immune system disorders	Iodine allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975	31DEC1982	N
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1975	31DEC1975	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1135 11351378	Investigations	Arthroscopy	01JUL2020	31JUL2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2019		Y
		Psychiatric disorders	Bipolar disorder	01JAN2007		Y
	C4591001 1135 11351379	Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1135 11351381	Eye disorders	Myopia	01JAN2000	31DEC2002	N
		Surgical and medical procedures	Keratomileusis	01JAN2002	31DEC2002	N
	C4591001 1135 11351382	Eye disorders	Myopia	01JAN1983		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2019	31DEC2019	N
	C4591001 1135 11351384	Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2007	31DEC2007	N
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Overweight	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1135 11351387	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
			Overweight	01JAN2012		Y
	C4591001 1135 11351391	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
	C4591001 1135 11351392	Eye disorders	Myopia	01JAN2002		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Foot operation	01JAN2010	31DEC2010	N
	C4591001 1135 11351393	Congenital, familial and genetic disorders	Coarctation of the aorta	01JAN2004	31DEC2004	N
		Infections and infestations	Syphilis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Aortic valve replacement	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1135 11351394	Eye disorders	Hypermetropia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Overweight	01JAN2008		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Oophorectomy	01JAN1985	31DEC1985	N
	C4591001 1135 11351399	Surgical and medical procedures	Caesarean section	17JAN2013	17JAN2013	N
				29AUG2011	29AUG2011	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351400	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
			Overweight	01JAN2020		Y
	C4591001 1135 11351401	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Infections and infestations	Nasopharyngitis	01JAN2012	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
			Lactose intolerance	01JAN2016		Y
			Overweight	01JAN2019	30JUN2020	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2012	31DEC2015	N
	C4591001 1135 11351403	Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
			Overweight	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Surgical and medical procedures	Colectomy	01JUL2018	31JUL2018	N
	C4591001 1135 11351404	Eye disorders	Myopia	01JAN2002		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1135 11351405	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
			Overweight	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351408	Eye disorders	Myopia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Reproductive system and breast disorders	Breast pain	01JAN2019	28JAN2020	N
		Surgical and medical procedures	Mammoplasty	01JAN2019	31DEC2019	N
			Mastectomy	28JAN2020	28JAN2020	N
	C4591001 1135 11351410	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2013	31DEC2015	N
		Surgical and medical procedures	Skin lesion removal	01JAN2014	31DEC2014	N
	C4591001 1135 11351411	Eye disorders	Myopia	01JAN1986		Y
		Injury, poisoning and procedural complications	Jaw fracture	04APR1985	04APR1985	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Overweight	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Tracheostomy	04APR1985	04APR1985	N
	C4591001 1135 11351412	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
	C4591001 1135 11351414	Eye disorders	Myopia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1135 11351415	Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	13MAR2020		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1135 11351416	Eye disorders	Myopia	01JAN1991		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1135 11351417	Eye disorders	Myopia	01JAN1995	31DEC2000	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2007	31DEC2007	N
			Tibia fracture	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Surgical and medical procedures	Bone operation	01JAN2007	31DEC2007	N
			Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1135 11351418	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
			Overweight	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2020		Y
			Postmenopause	01JAN2007		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Caesarean section	18DEC1995	18DEC1995	N
				18JUN2001	18JUN2001	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351421	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1135 11351422	Congenital, familial and genetic disorders	Acrocephalosyndactyly	(b) (6) 1991		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Eye disorders	Astigmatism	01JAN2015		Y
		General disorders and administration site conditions	Pain	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Bipolar disorder	01JAN2017		Y
			Depression	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Cranioplasty	01JAN1993	31DEC1993	N
				01JAN1996	31DEC1996	N
	C4591001 1135 11351423	Eye disorders	Diabetic retinopathy	01JAN2005		Y
			Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2017		Y
		Infections and infestations	Urinary tract infection	01JAN2016		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN1993	31DEC1993	N
			Female sterilisation	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric banding	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2010		Y
			Mammoplasty	01JAN1993	31DEC1993	N
				01JAN2018	31DEC2018	N
	C4591001 1135 11351425	Immune system disorders	Food allergy	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1135 11351428	Eye disorders	Myopia	01JAN2019		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1135 11351429	Infections and infestations	Tonsillitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1135 11351430	Eye disorders	Myopia	01JAN2011		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1135 11351431	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Tympanoplasty	01JAN2015	31DEC2015	N
	C4591001 1135 11351432	Eye disorders	Hypermetropia	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01APR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351433	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1135 11351434	Eye disorders	Myopia	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Nervous system disorders	Epilepsy	01NOV2013	31MAY2017	N
			Migraine	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996	31DEC2000	N
		Surgical and medical procedures	Brain lobectomy	01MAY2017	31MAY2017	N
	C4591001 1135 11351435	Congenital, familial and genetic disorders	Haemoglobinopathy	01JAN2014		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1135 11351436	Immune system disorders	Food allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Overweight	01JAN2017		Y
	C4591001 1135 11351437	Eye disorders	Astigmatism	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Rhinitis allergic	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2019		Y
	C4591001 1135 11351438	Eye disorders	Hypermetropia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
			Overweight	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Uvulopalatopharyngoplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1135 11351439	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Gastrointestinal disorders	Toothache	01OCT2019		Y
		General disorders and administration site conditions	Chest pain	01FEB2020	29FEB2020	N
			Pain	01JAN2012		Y
		Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351440	Eye disorders	Myopia	01JAN1988		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN2002		Y
			Seasonal allergy	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Overweight	01JAN1980		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1135 11351441	Eye disorders	Myopia	01JAN1989		Y
		Reproductive system and breast disorders	Ovarian cyst	01MAR2015	31MAR2015	N
		Surgical and medical procedures	Ovarian operation	01MAR2015	31MAR2015	N
	C4591001 1135 11351442	Blood and lymphatic system disorders	Anaemia	01MAR2020		Y
		Eye disorders	Myopia	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1135 11351443	Metabolism and nutrition disorders	Overweight	01AUG2020		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1135 11351444	Eye disorders	Hypermetropia	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Overweight	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1986	31DEC1986	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351445	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Infections and infestations	Herpes zoster	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1135 11351446	Eye disorders	Hypermetropia	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1967	31DEC1967	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1991	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Caesarean section	18OCT1997	18OCT1997	N
			Hernia repair	01JAN1967	31DEC1967	N
	C4591001 1135 11351448	Eye disorders	Myopia	01JAN1986		Y
		Gastrointestinal disorders	Constipation	01AUG2020		Y
			Dyspepsia	01JAN2012		Y
			Irritable bowel syndrome	19DEC2017	30SEP2020	N
		Immune system disorders	Drug hypersensitivity	01APR2020		Y
			Food allergy	01JAN2005		Y
			Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
			Overweight	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	02NOV2015		Y
			Rotator cuff syndrome	01JAN2015		Y
			Scoliosis	01JAN1986		Y
		Psychiatric disorders	Anxiety	21NOV2019		Y
			Depression	23APR2019		Y
			Insomnia	02NOV2015		Y
		Surgical and medical procedures	Benign breast lump removal	01AUG2015	01AUG2015	N
			Caesarean section	21NOV2006	21NOV2006	N
				29AUG1995	29AUG1995	N
	C4591001 1135 11351449	General disorders and administration site conditions	Cyst	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Cyst removal	01JAN1998	31DEC1998	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1135 11351450	Eye disorders	Myopia	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
	C4591001 1135 11351451	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Eye disorders	Presbyopia	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN1999		Y
				01JAN2015		Y
			Rubber sensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004	31DEC2004	N
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anogenital warts	01JAN1991	31DEC1991	N
		Nervous system disorders	Migraine	01JAN1991		Y
			Sciatica	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2012		Y
			Post-traumatic stress disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Eczema	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Gastric banding	01JAN2004	31DEC2014	N
	C4591001 1135 11351452	Reproductive system and breast disorders	Ovarian cyst	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Caesarean section	30JUL2011	30JUL2011	N
			Oophorectomy	01JAN2000	31DEC2000	N
	C4591001 1135 11351453	Eye disorders	Myopia	01JAN2009		Y
	C4591001 1135 11351454	Congenital, familial and genetic disorders	Cleft palate	01JAN1988	31DEC2004	N
		Eye disorders	Myopia	01JAN1997	31DEC2015	N
		Immune system disorders	Food allergy	01JAN1988		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Cleft palate repair	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratomileusis	01JAN2015	31DEC2015	N
	C4591001 1135 11351455	Eye disorders	Myopia	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1135 11351457	Blood and lymphatic system disorders	Anaemia	01SEP2020		Y
		Eye disorders	Astigmatism	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
		Psychiatric disorders	Sleep disorder	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01DEC2019		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
			Permanent contraceptive tubal implant	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1135 11351459	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01AUG2020		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1135 11351460	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1999		Y
		Reproductive system and breast disorders	Varicocele	01JAN2003	31DEC2011	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Surgical and medical procedures	Varicocele repair	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351461	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
		Psychiatric disorders	Anxiety	01FEB2011		Y
			Depression	01FEB2011		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y
	C4591001 1135 11351462	Eye disorders	Myopia	01JAN1996		Y
		Gastrointestinal disorders	Constipation	01JAN1976		Y
			Gastroesophageal reflux disease	01JAN2003		Y
			Inguinal hernia	01JAN1987	31DEC1987	N
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Infections and infestations	Herpes zoster	01MAY2020	31MAY2020	N
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2012	31DEC2013	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1987	31DEC1987	N
	C4591001 1135 11351463	Eye disorders	Heterophoria	01JAN2008		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN1999	31DEC2012	N
		Investigations	Biopsy breast	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
			Neck pain	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2015		Y
				01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Insomnia	01JAN2015		Y
			Menstruation irregular	01JAN2007		Y
			Polycystic ovaries	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2006		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1135 11351464	Eye disorders	Hypermetropia	01JAN1998		Y
			Myopia	01JAN1998		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1135 11351465	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351466	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Infections and infestations	Staphylococcal infection	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	08SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351467	Eye disorders	Myopia	01JAN1996		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
	C4591001 1135 11351468	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1990	31DEC1990	N
				01JAN1994	31DEC1994	N
				01JAN2012	31DEC2012	N
			Ligament rupture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN1974		Y
			Overweight	01JAN1974		Y
		Surgical and medical procedures	Chondroplasty	01JAN1990	31DEC1990	N
				01JAN1994	31DEC1994	N
				01JAN2012	31DEC2012	N
			Ligament operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1135 11351469	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2017	31DEC2017	N
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1974	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351470	Eye disorders	Myopia	01JAN2019		Y
		Infections and infestations	Tonsillitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Overweight	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	25OCT2005	25OCT2005	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1135 11351471	Eye disorders	Myopia	01JAN1983		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1135 11351472	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1983	31DEC1983	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1135 11351473	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN1980	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN1980	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Salivary gland neoplasm	01JAN2004	31DEC2004	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine leiomyoma	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2007		Y
		Surgical and medical procedures	Parotidectomy	01JAN2004	31DEC2004	N
	C4591001 1135 11351475	Eye disorders	Myopia	01JAN1994		Y
		Infections and infestations	Sinusitis	01JAN1992	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1994		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2006	31DEC2006	N
			Wisdom teeth removal	01JAN2000	31DEC2000	N
	C4591001 1135 11351476	Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
		Nervous system disorders	Neuralgia	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
	C4591001 1135 11351477	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1135 11351479	Gastrointestinal disorders	Gastrointestinal pain	01JAN2017		Y
		Investigations	Endoscopy	01JAN2017	31DEC2017	N
			Magnetic resonance imaging	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2007		Y
		Social circumstances	Corrective lens user	01JUL2020		Y
	C4591001 1135 11351480	Eye disorders	Myopia	01JAN1988		Y
		Gastrointestinal disorders	Anal fissure	01JAN2000	31DEC2000	N
			Constipation	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1979		Y
		Surgical and medical procedures	Anorectal operation	01JAN2000	31DEC2000	N
			Caesarean section	03OCT1995	03OCT1995	N
				04MAR1992	04MAR1992	N
	C4591001 1135 11351482	Eye disorders	Myopia	01JAN2005		Y
		Injury, poisoning and procedural complications	Face injury	21AUG2011	21AUG2011	N
			Limb injury	21AUG2011	21AUG2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Limb operation	21AUG2011	21AUG2011	N
			Plastic surgery to the face	21AUG2011	21AUG2011	N
	C4591001 1135 11351483	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN2019	31DEC2019	N
	C4591001 1135 11351484	Eye disorders	Myopia	01JAN2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Obesity	01JAN1978		Y
			Overweight	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
			Rhinitis allergic	01JAN1972		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351485	Ear and labyrinth disorders	Deafness	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Hypermetropia	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
			Inguinal hernia	01JAN1976	31DEC1976	N
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2014		Y
		Surgical and medical procedures	Hydrocele operation	01JAN1976	31DEC1976	N
			Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1135 11351486	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2015	N
		Gastrointestinal disorders	Tooth impacted	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
	C4591001 1135 11351487	Surgical and medical procedures	Wisdom teeth removal	01JAN2009	31DEC2009	N
		Eye disorders	Myopia	01JAN2016		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2008	31DEC2008	N
		General disorders and administration site conditions	Cyst	01JAN1999	31DEC1999	N
		Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2013	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Limb operation	01JAN1999	31DEC1999	N
	C4591001 1135 11351488	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1135 11351489	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
			Overweight	01JAN2011		Y
	C4591001 1135 11351490	Eye disorders	Myopia	01JAN1981		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1978	31DEC1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
		Social circumstances	Postmenopause	01JUL2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1135 11351491	Eye disorders	Myopia	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01AUG2020	31AUG2020	N
	C4591001 1135 11351492	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2016		Y
		Nervous system disorders	Thoracic outlet syndrome	01JAN2016		Y
	C4591001 1135 11351493	Eye disorders	Myopia	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
	C4591001 1135 11351494	Eye disorders	Myopia	01JAN1975		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
	C4591001 1135 11351495	Eye disorders	Myopia	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1135 11351496	Eye disorders	Myopia	01JAN1988		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015		Y
	C4591001 1135 11351497	Surgical and medical procedures	Rhinoplasty	01JAN2019	31DEC2019	N
	C4591001 1135 11351498	Eye disorders	Hypermetropia	01JAN2014		Y
			Myopia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1135 11351499	Blood and lymphatic system disorders	Anaemia	01JAN2012	31DEC2016	N
		Eye disorders	Myopia	01JAN1990	31DEC2004	N
		Gastrointestinal disorders	Tooth impacted	01JAN1996	31DEC1996	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Genital herpes	01JAN2013		Y
			Urinary tract infection	01JAN2018	31DEC2018	N
		Investigations	Biopsy breast	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN1984	31DEC2014	N
			Overweight	01JAN1984	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2009	31DEC2010	N
		Renal and urinary disorders	Urogenital haemorrhage	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Endometrial ablation	01JAN2011	31DEC2011	N
			Gastric bypass	01JAN2010	31DEC2010	N
			Keratomileusis	01JAN2004	31DEC2004	N
			Mammoplasty	01JAN2014	31DEC2014	N
			Skin cosmetic procedure	01JAN2014	31DEC2014	N
			Wisdom teeth removal	01JAN1996	31DEC1996	N
	C4591001 1135 11351500	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Tension headache	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1135 11351501	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1983	31DEC1983	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Limb operation	01JAN1983	31DEC1983	N
	C4591001 1135 11351502	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1982	31DEC1985	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Ligament operation	01JAN1985	31DEC1985	N
	C4591001 1135 11351503	Eye disorders	Myopia	01JAN1978		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Tooth impacted	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN1975		Y
			Overweight	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nasal operation	01JAN2010	31DEC2010	N
			Tenoplasty	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
	C4591001 1135 11351505	Gastrointestinal disorders	Malocclusion	01JAN1975	31DEC1993	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18NOV2019		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Orthognathic surgery	01JAN1993	31DEC1993	N
	C4591001 1135 11351506	Eye disorders	Presbyopia	01JAN2016		Y
		Infections and infestations	Sinusitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2014		Y
	C4591001 1135 11351508	Eye disorders	Astigmatism	01JAN1982		Y
			Myopia	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
	C4591001 1135 11351509	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1985		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Bronchitis	01JAN1985	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
			Rhinitis allergic	01JAN1979		Y
	C4591001 1135 11351510	Eye disorders	Myopia	01JAN1996	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
			Overweight	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	19OCT2020		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Keratomileusis	01JAN2016	31DEC2016	N
	C4591001 1135 11351511	Social circumstances	Corrective lens user	01JAN1986		Y
	C4591001 1135 11351512	Immune system disorders	Food allergy	01JAN1989		Y
			Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1135 11351513	Gastrointestinal disorders	Abdominal pain	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351514	Eye disorders	Astigmatism	01JAN2008		Y
			Myopia	01JAN2008		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC2000	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN2009	31DEC2009	N
	C4591001 1135 11351516	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Meniscus operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351517	Gastrointestinal disorders	Gastrointestinal inflammation	16DEC2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Overweight	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
	C4591001 1135 11351518	Eye disorders	Myopia	01JAN2004		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2008		Y
		Infections and infestations	Herpes zoster	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2018		Y
			Eczema	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2008		Y
	C4591001 1135 11351519	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Food allergy	01JAN1986		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1135 11351520	Eye disorders	Hypermetropia	01JAN1985		Y
			Strabismus	01JAN1985	31DEC1985	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN1995		Y
			Food allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Eczema	01JAN1980		Y
		Surgical and medical procedures	Strabismus correction	01JAN1985		Y
			Wisdom teeth removal	01JAN1998	31DEC1998	N
	C4591001 1135 11351521	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
			Overweight	01JAN1988		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2001	31DEC2001	N
	C4591001 1135 11351522	Eye disorders	Myopia	01JAN2008		Y
	C4591001 1135 11351523	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
				01JAN2012		Y
				01JAN2016		Y
			Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2010	31DEC2016	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01SEP2020	30SEP2020	N
			Temporomandibular joint surgery	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1135 11351524	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
			Dyspnoea exertional	01JAN2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2004	31DEC2004	N
	C4591001 1135 11351525	Cardiac disorders	Bradycardia	01JAN2019		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Eye disorders	Myopia	01JAN2013		Y
		Reproductive system and breast disorders	Prostatic calcification	01FEB2020		Y
	C4591001 1135 11351526	Eye disorders	Myopia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Nasal septal operation	01JAN1998	31DEC1998	N
	C4591001 1135 11351527	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Ligament injury	01JAN1994	31DEC2010	N
		Metabolism and nutrition disorders	Overweight	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Ligament operation	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008	31DEC2008	N
				01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1135 11351528	Eye disorders	Hypermetropia	01JAN1995		Y
		Gastrointestinal disorders	Tooth impacted	01JAN1999	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Adenoiditis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1981	31DEC1981	N
			Wisdom teeth removal	01JAN1999	31DEC1999	N
				01JAN2003	31DEC2003	N
	C4591001 1135 11351529	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1135 11351530	Eye disorders	Myopia	01JAN2013		Y
	C4591001 1135 11351531	Endocrine disorders	Hyperthyroidism	01JAN2000	31DEC2016	N
		Eye disorders	Astigmatism	01JAN1995		Y
			Hypermetropia	01JAN1995		Y
		Gastrointestinal disorders	Constipation	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1135 11351532	Eye disorders	Myopia	01JAN1991	31DEC2007	N
				01JAN2019		Y
			Presbyopia	01JAN2018		Y
		Immune system disorders	Dust allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Overweight	01JAN2003		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2003		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Fracture treatment	01JAN2014	31DEC2014	N
			Keratomileusis	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351533	Eye disorders	Myopia	01JAN1998		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
			Overweight	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1135 11351534	Eye disorders	Myopia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1998	31DEC1998	N
			Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Catheter placement	01JAN1998	31DEC1998	N
	C4591001 1135 11351535	Eye disorders	Presbyopia	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
	C4591001 1135 11351536	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Radius fracture	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Internal fixation of fracture	01JAN1988	31DEC1988	N
			Open reduction of fracture	01JAN1988	31DEC1988	N
	C4591001 1135 11351537	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Allergy to animal	01JAN1997		Y
			Drug hypersensitivity	01JAN2004	31DEC2004	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2004		Y
	C4591001 1135 11351538	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
					31DEC2008	N
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Infective myositis	01JAN2007	31DEC2007	N
			Staphylococcal infection	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Obesity	01JAN2018		Y
			Overweight	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007	31DEC2008	N
		Surgical and medical procedures	Abscess drainage	01AUG2007	31AUG2007	N
				01AUG2008	31AUG2008	N
	C4591001 1135 11351539	Eye disorders	Myopia	01JAN1993		Y
	C4591001 1135 11351540	Eye disorders	Myopia	01JAN1992		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
			Tooth impacted	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2008	31DEC2008	N
	C4591001 1135 11351541	Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N
			Tooth impacted	01JAN2009	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1980	31DEC1980	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1135 11351542	Eye disorders	Myopia	01JAN1993	31DEC2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
			Overweight	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2019		Y
	C4591001 1135 11351543	Eye disorders	Myopia	01JAN1994		Y
			Presbyopia	01JAN1994		Y
		Metabolism and nutrition disorders	Overweight	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1975		Y
				01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cerebrovascular accident	01FEB2013	28FEB2013	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
		Surgical and medical procedures	Knee operation	01JAN1979	31DEC1979	N
	C4591001 1135 11351544	Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Infections and infestations	Tonsillitis	01JAN1991	31DEC1991	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1135 11351545	Eye disorders	Myopia	01JAN1991		Y
	C4591001 1135 11351546	Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1135 11351547	Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Tooth impacted	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351548	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2018	10DEC2018	N
		Surgical and medical procedures	Caesarean section	02JAN1997	02JAN1997	N
				29SEP1994	29SEP1994	N
			Thyroidectomy	10DEC2018	10DEC2018	N
	C4591001 1135 11351549	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1135 11351550	Congenital, familial and genetic disorders	Phimosis	01JAN2000	31DEC2008	N
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Myopia	01JAN1998		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin B12 deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN1996		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Circumcision	01JAN2008	31DEC2008	N
	C4591001 1135 11351551	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Urethral repair	01JAN1986	31DEC1986	N
			Vasectomy	01JAN2005	31DEC2005	N
			Vasectomy	01OCT2020	01OCT2020	N
	C4591001 1135 11351552	Congenital, familial and genetic disorders	Developmental glaucoma	01JAN2014		Y
		Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Sinusitis	01JAN2010		Y
			Tonsillitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2010		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Rhinitis allergic	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Eczema	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1135 11351553	Gastrointestinal disorders	Inguinal hernia	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Hernia repair	01JAN2019	31DEC2019	N
	C4591001 1135 11351554	Eye disorders	Myopia	01JAN1986		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
	C4591001 1135 11351555	Eye disorders	Myopia	01JAN2001		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Allergy to chemicals	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN1993		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2013	31DEC2013	N
	C4591001 1135 11351556	Eye disorders	Presbyopia	01JAN2015		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1135 11351557	Endocrine disorders	Hypothyroidism	01JAN1990	31DEC2005	N
		Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Overweight	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	09MAY1997	09MAY1997	N
			Thyroidectomy	01JAN2005	31DEC2005	N
			Wisdom teeth removal	01JAN1984	31DEC1984	N
	C4591001 1135 11351558	Gastrointestinal disorders	Constipation	01JAN2020		Y
			Diverticulum	01JAN2020	31DEC2020	N
		Infections and infestations	Herpes simplex	01JAN2016	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
		Surgical and medical procedures	Intervertebral disc operation	24MAY2017	24MAY2017	N
	C4591001 1135 11351559	Vascular disorders	Hypertension	01JUN2016		Y
		Eye disorders	Myopia	01JAN1987	31DEC2008	N
			Presbyopia	01JAN2019		Y
		Gastrointestinal disorders	Abdominal distension	01JAN2000		Y
		Immune system disorders	Food allergy	01JAN1976		Y
		Infections and infestations	Tinea pedis	01JAN1988		Y
		Injury, poisoning and procedural complications	Ligament injury	13AUG2006		Y
		Investigations	Blood triglycerides increased	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2015		Y
			Migraine	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
			Sleep apnoea syndrome	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1135 11351560	Surgical and medical procedures	Keratomileusis	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
			Overweight	01JAN2014		Y
		Psychiatric disorders	Depression	01SEP2020		Y
		Surgical and medical procedures	Dental operation	04JUN2019	04JUN2019	N
			Knee operation	23MAR2014	23MAR2014	N
			Wisdom teeth removal	01JAN2019	04JAN2019	N
	C4591001 1135 11351561	Eye disorders	Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Colitis ischaemic	01JAN2015		Y
			Intestinal obstruction	01SEP2019	30SEP2019	N
			Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2019	31DEC2019	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Intestinal operation	01SEP2019	31DEC2019	N
			Renal stone removal	01JAN2010	31DEC2010	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN2002	31DEC2002	N
	C4591001 1135 11351562	Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Overweight	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2019		Y
	C4591001 1135 11351563	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1135 11351564	Surgical and medical procedures	Gastric bypass	01JAN2016		Y
		Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Overweight	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2000	31DEC2000	N
			Shoulder operation	01JAN2011	31DEC2011	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1135 11351565	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2019	N
		Nervous system disorders	Migraine	01JAN1994		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01DEC2019	31DEC2019	N
			Ovarian cystectomy	01JAN1995	31DEC1995	N
	C4591001 1135 11351566	Eye disorders	Myopia	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Obesity	01FEB2020		Y
			Overweight	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2011	31DEC2011	N
		Nervous system disorders	Generalised tonic-clonic seizure	01JAN1998		Y
		Psychiatric disorders	Depression	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988	31DEC2002	N
		Surgical and medical procedures	Anal fistula repair	01JAN2007	31DEC2007	N
			Appendicectomy	01JAN1999	31DEC1999	N
			Bursa removal	01JAN2011	31DEC2011	N
			Caesarean section	01SEP2020	01SEP2020	N
				24SEP2018	24SEP2018	N
			Wisdom teeth removal	01JAN1997	31DEC1997	N
	C4591001 1135 11351567	Eye disorders	Myopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009	31DEC2009	N
			Seasonal allergy	01JAN1999		Y
		Infections and infestations	Gonorrhoea	01JAN2014	31DEC2014	N
			Pilonidal cyst	01JAN2014	31DEC2016	N
			Syphilis	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Pilonidal sinus repair	01JAN2016	31DEC2016	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1135 11351568	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
	C4591001 1135 11351569	Eye disorders	Myopia	01JAN1976		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1978	31DEC1980	N
			Nasal septum deviation	01JAN1978	31DEC2008	N
			Sleep apnoea syndrome	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2004		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1980	31DEC1980	N
			Nasal septal operation	01JAN2008	31DEC2008	N
			Uvulopalatopharyngoplasty	01JAN1999	31DEC1999	N
	C4591001 1135 11351571	Eye disorders	Amblyopia	01JAN1985		Y
			Myopia	01JAN1998		Y
			Strabismus	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Nasal septal operation	01JAN2006	31DEC2006	N
			Strabismus correction	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351572	Endocrine disorders	Hypothyroidism	01JAN2009	31DEC2009	N
		Eye disorders	Myopia	01JAN1994		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
			Ear infection	01SEP2020	07SEP2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	12DEC2018		Y
			Attention deficit hyperactivity disorder	17MAY2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Keratomileusis	01JAN2010	31DEC2010	N
	C4591001 1135 11351573	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 1 diabetes mellitus	01JUL1994		Y
	C4591001 1136 11361001	Injury, poisoning and procedural complications	Meniscus injury	01JAN2004	31DEC2004	N
		Investigations	Arthroscopy	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1136 11361002	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2010	31DEC2012	N
		Reproductive system and breast disorders	Amenorrhoea	01JAN2010	31DEC2010	N
			Dysfunctional uterine bleeding	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1979		Y
	C4591001 1136 11361004	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1136 11361006	Immune system disorders	Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1136 11361007	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1136 11361010	Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
	C4591001 1136 11361012	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2013	31DEC2018	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2002	31DEC2002	N
	C4591001 1136 11361013	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1136 11361018	Injury, poisoning and procedural complications	Muscle rupture	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Shoulder operation	01JAN2007	31DEC2007	N
	C4591001 1136 11361020	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1136 11361021	Eye disorders	Cataract	01JAN2013	01JAN2013	N
			Retinal detachment	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1999	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	01JAN2013	N
			Meniscus operation	01JAN1999	31DEC1999	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1136 11361024	Ear and labyrinth disorders	Hypoacusis	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005	31DEC2007	N
		Immune system disorders	Allergy to chemicals	01JAN1984		Y
			Dust allergy	01JAN1984		Y
			Hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1984		Y
		Infections and infestations	Pneumonia	01JAN1970	31DEC1970	N
				01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN1977	31DEC1977	N
			Hand fracture	01JAN1980	31DEC1980	N
			Rib fracture	01JAN2005	31DEC2005	N
		Psychiatric disorders	Panic attack	01JAN2000	31DEC2005	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1984		Y
	C4591001 1136 11361026	Eye disorders	Myopia	01JAN1990	31DEC2007	N
		Infections and infestations	Oral herpes	01JAN1984		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Vision correction operation	01JAN2007	31DEC2007	N
	C4591001 1136 11361027	Injury, poisoning and procedural complications	Limb injury	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Orthopaedic procedure	01JAN2015	31DEC2015	N
	C4591001 1136 11361029	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Infections and infestations	Pneumonia	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2013	N
		Nervous system disorders	Epilepsy	01JAN2002		Y
			Migraine	01JAN1991		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Nasal polyps	01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Sinus operation	01JAN2014	31DEC2014	N
	C4591001 1136 11361030	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
	C4591001 1136 11361034	Blood and lymphatic system disorders	Increased tendency to bruise	01JAN2003		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	(b) (6) 2002		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1136 11361035	Ear and labyrinth disorders	Deafness	01JAN2004		Y
			Otosclerosis	01JAN2004		Y
		Eye disorders	Myopia	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN1998	31DEC1998	N
			Prosthesis implantation	01JAN2004	31DEC2004	N
	C4591001 1136 11361036	Eye disorders	Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2015	31DEC2015	N
			Neck injury	01JAN2015	31DEC2015	N
			Road traffic accident	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1136 11361039	Surgical and medical procedures	Spinal operation	01JAN2016	31DEC2016	N
		Eye disorders	Myopia	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Injury, poisoning and procedural complications	Fall	01JAN1993	31DEC1993	N
			Lower limb fracture	01JAN1993	31DEC1993	N
	C4591001 1136 11361040	Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Injury, poisoning and procedural complications	Muscle injury	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2007	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1990	31DEC1994	N
	C4591001 1136 11361043	Surgical and medical procedures	Peripheral nerve transposition	01JAN2008	31DEC2008	N
		Eye disorders	Myopia	01JAN1997		Y
		Immune system disorders	Allergy to plants	01JAN2012		Y
			Drug hypersensitivity	01JAN2012		Y
				01JAN2018		Y
		Infections and infestations	Tonsillitis	01APR2019	30APR2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1136 11361045	Surgical and medical procedures	Tonsillectomy	01APR2019	31DEC2019	N
		Congenital, familial and genetic disorders	Falot's tetralogy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1982		Y
		Injury, poisoning and procedural complications	Procedural pain	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Pulmonary valve replacement	01FEB2019	28FEB2019	N
			Tetralogy of Fallot repair	01JAN1982	31DEC1982	N
				01JAN1985	31DEC1985	N
	C4591001 1136 11361046	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1993	31DEC1993	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2011	31DEC2011	N
		Investigations	Arthroscopy	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	08MAR2019	08MAR2019	N
			Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1136 11361048	Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2005	N
	C4591001 1136 11361049	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1136 11361054	Endocrine disorders	Androgen deficiency	01FEB2015		Y
		Infections and infestations	Diverticulitis	01FEB2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2009	31MAY2009	N
		Surgical and medical procedures	Skin neoplasm excision	01MAY2009	31DEC2009	N
			Vasectomy	01APR2007	01APR2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361058	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1136 11361063	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1136 11361065	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1136 11361067	Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Reproductive system and breast disorders	Menorrhagia	01MAR2013	31MAR2013	N
		Surgical and medical procedures	Caesarean section	02JAN2006	02JAN2006	N
			Hysterectomy	01MAR2013	31MAR2013	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1136 11361073	Congenital, familial and genetic disorders	Congenital uterine anomaly	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2019	31DEC2020	N
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Endometrial ablation	01JAN2016	31DEC2016	N
	C4591001 1136 11361082	Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Food allergy	01JAN2012		Y
			Iodine allergy	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	19APR2019	19APR2019	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361083	Investigations	Blood cholesterol increased	01JAN2020	31JUL2020	N
			White blood cell count decreased	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
	C4591001 1136 11361084	Endocrine disorders	Hyperthyroidism	01JAN2017		Y
		Eye disorders	Myopia	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1136 11361086	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Infections and infestations	Bronchitis	01JAN2005	31DEC2005	N
			Pneumonia	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendectomy	01JAN2007	31DEC2007	N
			Meniscus operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1136 11361087	Immune system disorders	Allergy to animal	01JAN1986		Y
			Dust allergy	01JAN1986		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1986		Y
		Surgical and medical procedures	Otoplasty	01JAN1982	31DEC1982	N
	C4591001 1136 11361091	Eye disorders	Astigmatism	01JAN2006		Y
			Myopia	01JAN2006		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2005	31DEC2005	N
			Skin laceration	22NOV2001	22NOV2001	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Autism spectrum disorder	01JAN2011		Y
			Depression	01JAN2017		Y
			Obsessive-compulsive disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1998		Y
		Surgical and medical procedures	Tendon operation	22NOV2001	22NOV2001	N
	C4591001 1136 11361092	Immune system disorders	Allergy to animal	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal obstruction	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
			Nasal septal operation	01DEC2019	31DEC2019	N
	C4591001 1136 11361094	Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1985	31DEC1985	N
		Investigations	Human papilloma virus test positive	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019		Y
			Vulval cancer	01JAN2015	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	03MAR2015	03MAR2015	N
			Vulval operation	01JAN2016	31DEC2016	N
	C4591001 1136 11361095	Congenital, familial and genetic disorders	Cleft lip	01JAN1984	31DEC1984	N
			Cleft palate	01JAN1984	31DEC1984	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Cleft lip repair	01JAN1984	31DEC1984	N
			Cleft palate repair	01JAN1984	31DEC1984	N
	C4591001 1136 11361099	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
			Haemorrhoids thrombosed	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
			Pneumonia	01JAN1985	31DEC1985	N
			Tonsillitis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01JAN2015		Y
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01MAY2000		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Haemorrhoid operation	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN2001	31DEC2001	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361101	Eye disorders	Presbyopia	01JAN2016		Y
		Immune system disorders	Dust allergy	01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
			Bronchitis	01JAN2012	31DEC2012	N
			Hepatitis B	01JAN1997		Y
			Pneumonia	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1966	31DEC1986	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2000	31DEC2000	N
			Rhinoplasty	01JAN1986	31DEC1986	N
	C4591001 1136 11361108	Immune system disorders	Dust allergy	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Neck surgery	01JAN1999	31DEC1999	N
	C4591001 1136 11361109	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1995	31DEC1995	N
			Musculoskeletal foreign body	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN1995	31DEC1995	N
			Removal of foreign body	01JAN1994	31DEC1994	N
	C4591001 1136 11361111	Eye disorders	Strabismus	01JAN1993	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Strabismus correction	01JAN1999	31DEC1999	N
	C4591001 1139 11391001	Eye disorders	Myopia	30JUN1990		Y
		Immune system disorders	Seasonal allergy	30JUN2017		Y
	C4591001 1139 11391007	Eye disorders	Myopia	30JUN1984		Y
		Immune system disorders	Seasonal allergy	30JUN2015		Y
		Injury, poisoning and procedural complications	Foot fracture	15JAN2019	30JUN2019	N
		Nervous system disorders	Tension headache	30JUN2005		Y
		Vascular disorders	Hypertension	30JUN2005	30JUN2008	N
	C4591001 1139 11391010	Eye disorders	Myopia	30JUN1998		Y
		Immune system disorders	Seasonal allergy	30JUN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2015		Y
	C4591001 1139 11391015	Immune system disorders	Seasonal allergy	30JUN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2020		Y
		Nervous system disorders	Neuralgia	30JUN2019		Y
		Renal and urinary disorders	Nephrolithiasis	26OCT2019	26OCT2019	N
	C4591001 1139 11391016	Eye disorders	Myopia	30JUN1995		Y
		Nervous system disorders	Tension headache	30JUN2005		Y
		Surgical and medical procedures	Vasectomy	30JUN2012	30JUN2012	N
	C4591001 1139 11391021	Eye disorders	Hypermetropia	30JUN2012		Y
		Infections and infestations	Appendicitis	30JUN2000	30JUN2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Wrist fracture	30JUN1995	30JUN1995	N
	C4591001 1139 11391023	Eye disorders	Hypermetropia	30JUN1980		Y
		Injury, poisoning and procedural complications	Limb injury	30JUN2016	30JUN2016	N
		Investigations	Blood testosterone decreased	30JUN2017		Y
		Nervous system disorders	Vestibular migraine	30JUN2017		Y
		Psychiatric disorders	Anxiety	30JUN1995		Y
	C4591001 1139 11391025	Surgical and medical procedures	Shoulder operation	30JUN2016	30JUN2016	N
		Eye disorders	Myopia	30JUN1980		Y
		Gastrointestinal disorders	Umbilical hernia	30JUN2009	30JUN2009	N
		Immune system disorders	Seasonal allergy	30JUN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2005		Y
		Surgical and medical procedures	Abdominal hernia repair	30JUN2009	30JUN2009	N
			Hysterectomy	30JUN2012	30JUN2012	N
			Pilonidal sinus repair	30JUN2018	30JUN2018	N
	C4591001 1139 11391027	Injury, poisoning and procedural complications	Muscle strain	30JUN2017		Y
	C4591001 1139 11391028	Eye disorders	Myopia	30JUN1993		Y
		Immune system disorders	Drug hypersensitivity	30JUN2016		Y
		Injury, poisoning and procedural complications	Skin laceration	10JUL2020	10JUL2020	N
	C4591001 1139 11391029	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2017		Y
		Immune system disorders	Seasonal allergy	30JUN2015		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	03AUG2020	03AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2020		Y
			Dermatitis contact	11MAY2020		Y
	C4591001 1139 11391037	Eye disorders	Myopia	30JUN1984		Y
		Immune system disorders	Allergy to animal	30JUN2001		Y
			Seasonal allergy	30JUN2001		Y
		Injury, poisoning and procedural complications	Foot fracture	30JUN2017	30JUN2017	N
			Rib fracture	30JUN1989	30JUN1989	N
		Nervous system disorders	Hypersomnia	30JUN2010		Y
		Psychiatric disorders	Anxiety	30JUN2019		Y
			Depression	30JUL2000		Y
		Skin and subcutaneous tissue disorders	Eczema	15FEB2020		Y
	C4591001 1139 11391041	Surgical and medical procedures	Mammoplasty	30JUN2008	30JUN2008	N
		Immune system disorders	Seasonal allergy	30JUN2005		Y
		Investigations	Blood cholesterol increased	30JUN2001	30JUN2002	N
		Surgical and medical procedures	Bunion operation	15NOV2019	15NOV2019	N
			Spinal laminectomy	30APR2005	30APR2005	N
	C4591001 1139 11391042	Immune system disorders	Seasonal allergy	30JUN2016		Y
		Surgical and medical procedures	Orchidopexy	30JUN1979	30JUN1979	N
	C4591001 1139 11391044	Eye disorders	Myopia	30JUN1987		Y
		Immune system disorders	Drug hypersensitivity	30JUN1995		Y
			Seasonal allergy	30JUN2019		Y
		Infections and infestations	Urinary tract infection	15MAR2020	15MAR2020	N
		Nervous system disorders	Headache	30JUN2000		Y
	C4591001 1139 11391048	Eye disorders	Myopia	30JUN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Tension headache	15NOV2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	15NOV2019		Y
	C4591001 1139 11391049	Surgical and medical procedures	Scar excision	30JUN2019	30JUN2019	N
		Eye disorders	Presbyopia	30JUN2008		Y
		Immune system disorders	Drug hypersensitivity	30JUN1995		Y
		Injury, poisoning and procedural complications	Foot fracture	30JUN2001	30JUN2001	N
	C4591001 1139 11391052	Surgical and medical procedures	Tonsillectomy	30JUN2005	30JUN2005	N
		Injury, poisoning and procedural complications	Joint dislocation	30JUN2002	30JUN2002	N
			Wrist fracture	30JUN1998	30JUN1998	N
	C4591001 1139 11391053	Nervous system disorders	Migraine	30JUN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN1998		Y
		Immune system disorders	Seasonal allergy	30JUN1984		Y
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1984		Y
		Surgical and medical procedures	Female sterilisation	30JUN2017	30JUN2017	N
			Oophorectomy	30JUN2010		Y
	C4591001 1139 11391058	Nervous system disorders	Headache	30JUN1990		Y
			Nerve compression	30JUN1990		Y
		Skin and subcutaneous tissue disorders	Acanthosis	30JUN2010		Y
		Vascular disorders	Hypertension	30JUN2000		Y
	C4591001 1139 11391062	Eye disorders	Myopia	30JUN2000		Y
		Immune system disorders	Drug hypersensitivity	30JUN2005		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rubber sensitivity	30JUN2006		Y
		Infections and infestations	Latent tuberculosis	30JUN1997	30JUN1997	N
			Urinary tract infection	30JUN1995	30JUN2018	N
		Investigations	Cardiac murmur	(b) (6) 1993		Y
		Nervous system disorders	Narcolepsy	30JUN2018		Y
			Tension headache	30JUN2000		Y
		Psychiatric disorders	Depression	30JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2000		Y
		Surgical and medical procedures	Tonsillectomy	30JUN2012	30JUN2012	N
	C4591001 1139 11391065	Eye disorders	Myopia	30JUN2010		Y
		Immune system disorders	Rubber sensitivity	30JUN2000		Y
			Seasonal allergy	30JUN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2010		Y
	C4591001 1139 11391070	Eye disorders	Myopia	30JUN1988		Y
		Immune system disorders	Food allergy	30JUN2020		Y
			Seasonal allergy	30JUN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2017		Y
	C4591001 1139 11391071	Musculoskeletal and connective tissue disorders	Arthralgia	15JAN2020		Y
		Psychiatric disorders	Anxiety	15FEB2020		Y
			Attention deficit hyperactivity disorder	30JUN1998		Y
			Insomnia	30JUN2010		Y
	C4591001 1139 11391072	Immune system disorders	Rubber sensitivity	30JUN2005		Y
			Seasonal allergy	30JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Lower limb fracture	30JUN1987	30JUN1987	N
	C4591001 1139 11391073	Skin and subcutaneous tissue disorders	Hand dermatitis	30JUN2010		Y
		Eye disorders	Astigmatism	30JUN1995		Y
	C4591001 1139 11391076	Nervous system disorders	Sinus headache	30JUN2010		Y
		Eye disorders	Myopia	30JUN2010		Y
	C4591001 1139 11391081	Nervous system disorders	Sinus headache	30JUN2010		Y
		Surgical and medical procedures	Vasectomy	30JUN2016	30JUN2016	N
		Eye disorders	Myopia	30JUN2000		Y
	C4591001 1139 11391083	Injury, poisoning and procedural complications	Arthropod bite	30JUN2010		Y
		Social circumstances	Postmenopause	30JUN2017		Y
		Eye disorders	Astigmatism	30JUN2018		Y
	C4591001 1139 11391086	Immune system disorders	Drug hypersensitivity	30JUN2008		Y
			Seasonal allergy	30JUN2006		Y
		Nervous system disorders	Cluster headache	30JUN2012		Y
			Tension headache	30JUN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2018		Y
		Hepatobiliary disorders	Cholelithiasis	30JUN2009	30JUN2009	N
		Immune system disorders	Seasonal allergy	30JUN2000		Y
		Infections and infestations	Tonsillitis	30JUN2007	30JUN2007	N
		Psychiatric disorders	Anxiety	30JUN2017		Y
		Surgical and medical procedures	Cholecystectomy	30JUN2009	30JUN2009	N
			Gastric bypass	30JUN2009	30JUN2009	N
			Mammoplasty	30JUN2016	30JUN2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	30JUN2007	30JUN2007	N
	C4591001 1139 11391087	Eye disorders	Astigmatism	30JUN1992		Y
			Myopia	30JUN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN1994		Y
		Immune system disorders	Hypersensitivity	30JUN1980		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	30JUN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1980		Y
	C4591001 1139 11391089	Gastrointestinal disorders	Irritable bowel syndrome	30JUN2010	30JUN2014	N
		Immune system disorders	Seasonal allergy	30JUN2008		Y
		Nervous system disorders	Essential tremor	30JUN2012		Y
			Tension headache	30JUN2012		Y
	C4591001 1139 11391090	Cardiac disorders	Mitral valve incompetence	30JUN2020		Y
		Eye disorders	Dry eye	30JUN2010		Y
			Presbyopia	30JUN2006		Y
		Nervous system disorders	Syncope	19JAN2020	20JAN2020	N
		Surgical and medical procedures	Cyst removal	15JAN2001	15JAN2001	N
				15NOV2000	15NOV2000	N
			Hip arthroplasty	19FEB2016	19FEB2016	N
				27MAY2015	27MAY2015	N
	C4591001 1139 11391091	Congenital, familial and genetic disorders	Gilbert's syndrome	30JUN2014	30JUN2018	N
		Eye disorders	Myopia	30JUN1993		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	15JUL2020	25JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391094	Eye disorders	Astigmatism	30JUN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	30JUN1998		Y
	C4591001 1139 11391099	Eye disorders	Glaucoma	30JUN2015		Y
			Myopia	30JUN1985		Y
		Immune system disorders	Drug hypersensitivity	30JUN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	30JUN2014		Y
		Psychiatric disorders	Panic attack	30JUN2009		Y
		Reproductive system and breast disorders	Endometriosis	30JUN2018		Y
		Surgical and medical procedures	Hysterectomy	30JUN2009	30JUN2009	N
		Vascular disorders	Hypertension	30JUN2014		Y
	C4591001 1139 11391100	General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN1996		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1139 11391101	Immune system disorders	Seasonal allergy	30JUN2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	30JUN2001	30JUN2001	N
		Surgical and medical procedures	Shoulder operation	30JUN2001	30JUN2001	N
	C4591001 1139 11391102	Ear and labyrinth disorders	Tympanic membrane perforation	30JUN1999	30JUN1999	N
		Eye disorders	Myopia	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2017		Y
		Surgical and medical procedures	Tympanoplasty	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391103	Immune system disorders	Drug hypersensitivity	30JUN1982		Y
	C4591001 1139 11391106	Congenital, familial and genetic disorders	Checkpoint kinase 2 gene mutation	30JUN2009		Y
		Eye disorders	Myopia	30JUN1996		Y
		Immune system disorders	Drug hypersensitivity	30JUN2010		Y
		Nervous system disorders	Migraine	30JUN1990		Y
		Reproductive system and breast disorders	Cervical dysplasia	30JUN2009	30JUN2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1990		Y
	C4591001 1139 11391107	Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2017		Y
		Nervous system disorders	Headache	30JUN2015		Y
		Surgical and medical procedures	Appendicectomy	15MAR2007	15MAR2007	N
			Wisdom teeth removal	15DEC2015	15DEC2015	N
	C4591001 1139 11391108	Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2000		Y
		Immune system disorders	Hypersensitivity	30JUN1995		Y
			Seasonal allergy	30JUN1995		Y
		Nervous system disorders	Headache	30JUN1995		Y
		Psychiatric disorders	Anxiety	30JUN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1996		Y
		Surgical and medical procedures	Chondroplasty	01FEB2018	01FEB2018	N
			Salpingectomy	01MAY2016	01MAY2016	N
	C4591001 1139 11391109	Eye disorders	Myopia	29JUN1979		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Road traffic accident	30JUN1990	30JUN1999	N
		Musculoskeletal and connective tissue disorders	Arthralgia	30JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Haemothorax	30JUN1990	30JUN1999	N
		Surgical and medical procedures	Thoracotomy	30JUN1990	30JUN1990	N
	C4591001 1139 11391110	Immune system disorders	Seasonal allergy	30JUN1989		Y
		Injury, poisoning and procedural complications	Muscle strain	30JUN2020		Y
	C4591001 1139 11391112	Injury, poisoning and procedural complications	Cartilage injury	15FEB2020	15FEB2020	N
		Investigations	Arthroscopy	15FEB2020	15FEB2020	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1139 11391113	Injury, poisoning and procedural complications	Ligament rupture	15FEB2017	15APR2017	N
		Surgical and medical procedures	Ligament operation	15APR2017	15APR2017	N
	C4591001 1139 11391114	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	30JUN1970		Y
		Surgical and medical procedures	Cholecystectomy	31JAN2020	31DEC2020	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1139 11391116	Nervous system disorders	Epilepsy	30JUN2009		Y
		Psychiatric disorders	Autism spectrum disorder	14MAR2020		Y
	C4591001 1139 11391117	Immune system disorders	Seasonal allergy	30JUN2000		Y
	C4591001 1139 11391119	Endocrine disorders	Hypothyroidism	30JUN2010		Y
		Eye disorders	Myopia	30JUN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	30JUN1990		Y
		Infections and infestations	Chronic sinusitis	30JUN1992	30JUN1993	N
		Surgical and medical procedures	Caesarean section	19APR1990	19APR1993	N
			Sinus operation	15SEP1993	15SEP1993	N
			Wisdom teeth removal	30JUN1990	30JUN1990	N
	C4591001 1139 11391120	Musculoskeletal and connective tissue disorders	Synovial cyst	15SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	15JAN2018	01MAR2018	N
		Nervous system disorders	Headache	30JUN2000		Y
		Psychiatric disorders	Anxiety	30JUN2011		Y
		Surgical and medical procedures	Hysterectomy	01MAR2018	01MAR2018	N
			In vitro fertilisation	30JUN2010	30JUN2010	N
	C4591001 1139 11391125	Eye disorders	Astigmatism	30JUN1999		Y
		Psychiatric disorders	Depression	30JUN1999		Y
	C4591001 1139 11391127	Eye disorders	Myopia	30JUN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2016		Y
		Immune system disorders	Allergy to animal	(b) (6) 1978		Y
			Seasonal allergy	30JUN2010		Y
		Injury, poisoning and procedural complications	Radius fracture	14JUN2020	18JUN2020	N
		Musculoskeletal and connective tissue disorders	Tendonitis	15JUL2020		Y
		Psychiatric disorders	Anxiety	30JUN1998		Y
			Depression	30JUN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1989		Y
		Surgical and medical procedures	Bone operation	18JUN2020	18JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391130	Infections and infestations	Tonsillitis	30JUN2013	30JUN2013	N
		Nervous system disorders	Tension headache	30JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2010		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2004		Y
	C4591001 1139 11391131	Nervous system disorders	Tension headache	30JUN2015		Y
	C4591001 1139 11391132	General disorders and administration site conditions	Pyrexia	30JUN2009	30JUN2009	N
		Injury, poisoning and procedural complications	Wrist fracture	30JUN2015	30JUN2015	N
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
		Surgical and medical procedures	Tonsillectomy	30JUN2009	30JUN2009	N
	C4591001 1139 11391133	Injury, poisoning and procedural complications	Hip fracture	10NOV2019	15JAN2020	N
			Upper limb fracture	30JUN2008	30JUN2008	N
		Surgical and medical procedures	Elbow operation	30JUN2008	30JUN2008	N
	C4591001 1139 11391134	Cardiac disorders	Bradycardia neonatal	(b) (6) 2004	(b) (6) 2004	N
		Injury, poisoning and procedural complications	Clavicle fracture	30JUN2012	30JUN2012	N
			Concussion	30JUN2015	30JUN2019	N
		Nervous system disorders	Dyslexia	30JUN2009		Y
		Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2004	(b) (6) 2004	N
		Respiratory, thoracic and mediastinal disorders	Infantile apnoea	(b) (6) 2004	(b) (6) 2004	N
		Surgical and medical procedures	Hernia repair	(b) (6) 2004	(b) (6) 2004	N
			Wound closure	30SEP2020	30SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391135	Injury, poisoning and procedural complications	Concussion	30JUN2009	30JUN2017	N
		Nervous system disorders	Dyslexia	30JUN2009		Y
		Pregnancy, puerperium and perinatal conditions	Premature baby	(b) (6) 2004	(b) (6) 2004	N
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	31AUG2020		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2008	30JUN2008	N
	C4591001 1139 11391138	Eye disorders	Myopia	30JUN2015		Y
		Immune system disorders	Drug hypersensitivity	30JUN2003		Y
		Injury, poisoning and procedural complications	Upper limb fracture	15JAN2020	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	30JUN2018		Y
		Surgical and medical procedures	Ear tube insertion	30JUN2003	30JUN2004	N
	C4591001 1139 11391139	Injury, poisoning and procedural complications	Eye injury	06NOV2020	20NOV2020	N
			Foot fracture	15NOV2016	15FEB2018	N
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2020		Y
		Surgical and medical procedures	Toe operation	15FEB2018	15FEB2018	N
	C4591001 1139 11391140	Immune system disorders	Seasonal allergy	30JUL2017		Y
		Infections and infestations	Otitis externa	16NOV2020	23NOV2020	N
		Injury, poisoning and procedural complications	Clavicle fracture	30JUN2008	30JUN2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020	30AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391141	Eye disorders	Dry eye	30JUN2020		Y
		Injury, poisoning and procedural complications	Limb injury	30JUN2016	30JUN2016	N
		Metabolism and nutrition disorders	Gluten sensitivity	15JUN2013		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2020		Y
		Surgical and medical procedures	Foot operation	30JUN2016	30JUN2016	N
	C4591001 1139 11391142	Skin and subcutaneous tissue disorders	Acne	30JUN2019		Y
	C4591001 1139 11391143	Ear and labyrinth disorders	Deafness bilateral	(b) (6) 2004		Y
		Immune system disorders	Seasonal allergy	30JUN2006		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2018		Y
	C4591001 1139 11391146	Injury, poisoning and procedural complications	Ligament sprain	30JUN2015		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2014		Y
	C4591001 1139 11391147	Gastrointestinal disorders	Coeliac disease	30JUN2019		Y
		Psychiatric disorders	Anxiety	30JUN2020		Y
			Attention deficit hyperactivity disorder	30JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30JUN2018		Y
	C4591001 1139 11391148	Injury, poisoning and procedural complications	Upper limb fracture	30JUN2016	30JUN2016	N
			Wrist fracture	30JUN2016	30JUN2016	N
		Psychiatric disorders	Insomnia	12AUG2020		Y
	C4591001 1139 11391149	Eye disorders	Myopia	30JUN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2015		Y
		Immune system disorders	Food allergy	30JUN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	30JUN2015		Y
		Infections and infestations	Urinary tract infection	13NOV2020	19NOV2020	N
		Injury, poisoning and procedural complications	Pelvic fracture	30JUN2016	30JUN2016	N
			Wrist fracture	30JUN2014	30JUN2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2004		Y
		Skin and subcutaneous tissue disorders	Dermatitis	15NOV2020		Y
	C4591001 1139 11391150	Immune system disorders	Dust allergy	30JUN2015		Y
		Injury, poisoning and procedural complications	Upper limb fracture	30JUN2009	30JUN2009	N
				30JUN2017	30JUN2017	N
		Nervous system disorders	Headache	30JUN2019		Y
		Skin and subcutaneous tissue disorders	Acne	30JUN2019		Y
	C4591001 1139 11391153	Eye disorders	Myopia	30JUN2018		Y
	C4591001 1139 11391160	Eye disorders	Myopia	30JUN2018		Y
		Immune system disorders	Allergy to arthropod sting	15JUN2020		Y
		Surgical and medical procedures	Wisdom teeth removal	15OCT2019	15OCT2019	N
	C4591001 1139 11391164	Reproductive system and breast disorders	Menorrhagia	15MAY2020		Y
		Skin and subcutaneous tissue disorders	Acne cystic	15JAN2019		Y
	C4591001 1139 11391167	Blood and lymphatic system disorders	Anaemia	01JAN2015	31DEC2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2017		Y
		Reproductive system and breast disorders	Menorrhagia	30JUN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401001	Immune system disorders	Seasonal allergy	01SEP1989	30JUN1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01SEP2019		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2004	31OCT2004	N
	C4591001 1140 11401006	Injury, poisoning and procedural complications	Foot fracture	01OCT2012	15NOV2012	N
		Surgical and medical procedures	Pilonidal sinus repair	02FEB2015	01OCT2017	N
	C4591001 1140 11401009	Immune system disorders	Allergy to animal	01AUG1988		Y
			Allergy to arthropod sting	01AUG1988		Y
			Drug hypersensitivity	01AUG1988		Y
			Food allergy	01AUG1988		Y
		Metabolism and nutrition disorders	Gout	01SEP2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV1985		Y
	C4591001 1140 11401010	Surgical and medical procedures	Carpal tunnel decompression	01AUG2018	01AUG2018	N
				01FEB2019	01FEB2019	N
	C4591001 1140 11401011	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
	C4591001 1140 11401015	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
	C4591001 1140 11401016	Immune system disorders	Drug hypersensitivity	01APR2016		Y
				01JUN1991		Y
		Nervous system disorders	Migraine	01JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401017	Psychiatric disorders	Anxiety	01JAN2006		Y
	C4591001 1140 11401020	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Gastric banding	01JAN2009	31DEC2009	N
		Vascular disorders	Raynaud's phenomenon	01JAN1996		Y
	C4591001 1140 11401021	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1140 11401022	Gastrointestinal disorders	Impaired gastric emptying	01OCT2006		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Psychiatric disorders	Anxiety	01APR1999		Y
			Obsessive-compulsive disorder	01APR1999		Y
		Reproductive system and breast disorders	Polycystic ovaries	01AUG1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Surgical and medical procedures	Toe operation	01AUG2007	01AUG2007	N
			Tonsillectomy	01FEB2010	01FEB2010	N
	C4591001 1140 11401023	Immune system disorders	Seasonal allergy	01MAY1990		Y
		Investigations	Lipids increased	01OCT2010		Y
		Psychiatric disorders	Anxiety	01OCT2010		Y
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1140 11401024	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tinea pedis	01MAR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401025	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
			Depression	01JUL2020		Y
			Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1140 11401027	Surgical and medical procedures	Caesarean section	15DEC2016	15DEC2016	N
				15JUL2015	15JUL2015	N
	C4591001 1140 11401028	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
			Irritable bowel syndrome	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	01JAN2003	N
			Ear operation	01JAN2001	01JAN2001	N
	C4591001 1140 11401030	Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1140 11401031	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015		Y
		Immune system disorders	Seasonal allergy	01AUG2010		Y
	C4591001 1140 11401032	Gastrointestinal disorders	Large intestinal obstruction	01OCT2015	01OCT2015	N
	C4591001 1140 11401033	Immune system disorders	Seasonal allergy	01SEP1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JUN1999	31DEC1999	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01NOV2007	30NOV2007	N
	C4591001 1140 11401037	Gastrointestinal disorders	Coeliac disease	01JAN2003		Y
			Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01FEB2012	29FEB2012	N
			Inguinal hernia repair	01MAY1983	31MAY1983	N
	C4591001 1140 11401039	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Post procedural pulmonary embolism	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2003		Y
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2013	31DEC2013	N
			Thyroid operation	01JAN2001	31DEC2001	N
	C4591001 1140 11401040	Surgical and medical procedures	Tonsillectomy	01APR1981	01APR1981	N
			Vasectomy	01SEP2012	01SEP2012	N
	C4591001 1140 11401044	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2008		Y
	C4591001 1140 11401045	Immune system disorders	Drug hypersensitivity	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Umbilical hernia repair	01JUN1998	01JUN1998	N
	C4591001 1140 11401046	Cardiac disorders	Supraventricular tachycardia	01JAN2011	30APR2016	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Infectious mononucleosis	25DEC2019	07JAN2020	N
		Surgical and medical procedures	Cardiac ablation	01APR2016	30APR2016	N
	C4591001 1140 11401049	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2011		Y
			Seasonal allergy	01APR1982		Y
		Metabolism and nutrition disorders	Obesity	01AUG2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR1982		Y
		Surgical and medical procedures	Adenotonsillectomy	01AUG1984	01AUG1984	N
		Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1140 11401050	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1140 11401051	Immune system disorders	Seasonal allergy	01AUG1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1986	01AUG1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401052	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01APR2009		Y
		Psychiatric disorders	Depression	01APR2001	01APR2015	N
		Surgical and medical procedures	Vasectomy	01JUN2017	01JUN2017	N
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1140 11401053	Endocrine disorders	Hypothyroidism	01AUG1987		Y
		Immune system disorders	Seasonal allergy	01SEP1985		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	04NOV2018	04NOV2018	N
			Hernia hiatus repair	01AUG2012	01AUG2012	N
			Urinary bladder suspension	01APR1999	01APR1999	N
	C4591001 1140 11401054	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	01JUL2012	31JUL2012	N
				01JUL2015	31JUL2015	N
	C4591001 1140 11401055	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Investigations	Vitamin D decreased	01AUG2014		Y
		Surgical and medical procedures	Inguinal hernia repair	01NOV2015	01NOV2015	N
			Tonsillectomy	01OCT1974	01OCT1974	N
	C4591001 1140 11401057	Blood and lymphatic system disorders	Anaemia	01SEP2014		Y
		Cardiac disorders	Coronary artery disease	01SEP2016		Y
		Gastrointestinal disorders	Constipation	01AUG2016		Y
			Gastrooesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01AUG2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG1990		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01AUG1977	01AUG1977	N
			Appendicectomy	01JUL2017	01JUL2017	N
			Mammoplasty	01AUG2006	01AUG2006	N
	C4591001 1140 11401059	Surgical and medical procedures	Intervertebral disc operation	01OCT2015	01OCT2015	N
			Ligament operation	01FEB1996	01FEB1996	N
			Mammoplasty	01MAR2011	01MAR2011	N
			Tonsillectomy	01FEB1997	01FEB1997	N
	C4591001 1140 11401061	Surgical and medical procedures	Vasectomy	01OCT2013	01OCT2013	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1140 11401062	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2003		Y
	C4591001 1140 11401063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Infections and infestations	Onychomycosis	01FEB2020		Y
	C4591001 1140 11401065	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2010		Y
	C4591001 1140 11401068	Immune system disorders	Seasonal allergy	01AUG2000		Y
		Infections and infestations	Herpes simplex	01AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2007		Y
		Psychiatric disorders	Anxiety	01AUG2008		Y
			Depression	01AUG2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2012	01JAN2012	N
	C4591001 1140 11401069	Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Lithotripsy	01JAN2014	31DEC2014	N
	C4591001 1140 11401070	Immune system disorders	Seasonal allergy	01APR2020		Y
	C4591001 1140 11401071	Cardiac disorders	Atrial fibrillation	01FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2018		Y
		Surgical and medical procedures	Shoulder operation	01JAN1986	01JAN1986	N
			Spinal fusion surgery	01FEB2003	01FEB2003	N
			Tonsillectomy	01JAN1975	01JAN1975	N
		Vascular disorders	Hypertension	01DEC2016		Y
	C4591001 1140 11401072	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of adrenal gland	01OCT2010		Y
		Surgical and medical procedures	Appendicectomy	01OCT2010	31OCT2010	N
	C4591001 1140 11401073	Immune system disorders	Food allergy	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1140 11401074	Immune system disorders	Seasonal allergy	01APR2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2016		Y
		Surgical and medical procedures	Limb operation	01NOV1999	01NOV1999	N
			Vasectomy	01JAN2020	01JAN2020	N
		Vascular disorders	Hypertension	01NOV2016		Y
	C4591001 1140 11401079	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
	C4591001 1140 11401084	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2010		Y
		Surgical and medical procedures	Rotator cuff repair	28FEB2020	28FEB2020	N
	C4591001 1140 11401085	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2018		Y
		Psychiatric disorders	Anxiety	01FEB2010		Y
			Depression	01FEB2010		Y
		Surgical and medical procedures	Mammoplasty	01JUN2018	01JUN2018	N
	C4591001 1140 11401088	Cardiac disorders	Mitral valve prolapse	01AUG2018		Y
		Immune system disorders	Seasonal allergy	01AUG1998		Y
		Psychiatric disorders	Anxiety	01AUG2010		Y
			Depression	01AUG2010		Y
		Surgical and medical procedures	Nephrectomy	28SEP1986	28SEP1986	N
			Tonsillectomy	01AUG1991	01AUG1991	N
			Varicose vein operation	01OCT2015	01OCT2015	N
	C4591001 1140 11401092	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Infections and infestations	Herpes zoster	01AUG1997		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2006		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAR2020		Y
		Psychiatric disorders	Migraine	01JAN1995		Y
			Anxiety	01APR2004		Y
			Sleep disorder	01AUG2019		Y
	C4591001 1140 11401093	Surgical and medical procedures	Appendectomy	01FEB1993	01FEB1993	N
			Inguinal hernia repair	01SEP1998	01SEP1998	N
			Tenoplasty	01MAY2007	01MAY2007	N
	C4591001 1140 11401094	Immune system disorders	Seasonal allergy	01APR1976		Y
	C4591001 1140 11401097	Cardiac disorders	Bradycardia	01AUG2019	09JUN2020	N
		Immune system disorders	Seasonal allergy	01AUG1977		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2013		Y
			Neck pain	30MAY2016		Y
		Nervous system disorders	Headache	30MAY2016		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	09JUN2020		Y
			Intervertebral disc operation	01JUL2019		Y
			Spinal fusion surgery	01JUL2016		Y
			Spinal nerve stimulator implantation	01SEP2016		Y
	C4591001 1140 11401100	Immune system disorders	Seasonal allergy	01MAR2020		Y
	C4591001 1140 11401101	Surgical and medical procedures	Tonsillectomy	01AUG1980	01AUG1980	N
	C4591001 1140 11401106	Immune system disorders	Seasonal allergy	01MAY1992		Y
		Psychiatric disorders	Anxiety	01SEP2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01SEP2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1991		Y
		Surgical and medical procedures	Tonsillectomy	01JUL2003	01JUL2003	N
	C4591001 1140 11401108	Immune system disorders	Allergy to animal	01APR1974		Y
			Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JUL2007		Y
		Nervous system disorders	Migraine	01AUG2016		Y
			Neuropathy peripheral	01JUL2007		Y
		Psychiatric disorders	Anxiety	01DEC2012		Y
			Depression	01DEC2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR1974		Y
	C4591001 1140 11401109	Immune system disorders	Allergy to animal	01JAN1979		Y
			Food allergy	01JAN1979		Y
			Seasonal allergy	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
	C4591001 1140 11401110	Immune system disorders	Seasonal allergy	01APR2016		Y
	C4591001 1140 11401112	Immune system disorders	Seasonal allergy	01APR1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01SEP2010	01OCT2010	N
		Psychiatric disorders	Anxiety	01SEP1998		Y
		Surgical and medical procedures	Meningioma surgery	01OCT2010	01OCT2010	N
	C4591001 1140 11401115	Blood and lymphatic system disorders	Leukopenia	01AUG2015		Y
	C4591001 1140 11401116	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2005		Y
		Social circumstances	Organ donor	01JAN2014		Y
	C4591001 1140 11401118	Investigations	Blood testosterone decreased	01AUG2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2010		Y
		Surgical and medical procedures	Appendicectomy	01MAR1996	01MAR1996	N
			Intervertebral disc operation	01APR2001	01APR2001	N
			Shoulder operation	01MAY2012	01MAY2012	N
				01SEP2015	01SEP2015	N
		Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1140 11401124	Immune system disorders	Seasonal allergy	01MAY1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2010		Y
			Obesity	01JUN2012		Y
			Type 2 diabetes mellitus	01JUN2008		Y
		Nervous system disorders	Migraine	01JUN1995		Y
		Psychiatric disorders	Anxiety	01JUN2016		Y
			Depression	01JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY1977		Y
		Social circumstances	Postmenopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Umbilical hernia repair	01JUN2011	01JUN2011	N
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1140 11401127	Immune system disorders	Seasonal allergy	01MAY2016		Y
		Metabolism and nutrition disorders	Obesity	01JUN2017		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1140 11401129	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01MAR2010		Y
		Infections and infestations	Herpes simplex	01AUG2000		Y
		Metabolism and nutrition disorders	Obesity	01JUN1990		Y
		Psychiatric disorders	Hallucination	01JAN1992		Y
				01JAN1997		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2010		Y
				01JAN2012		Y
				01JAN2014		Y
		Surgical and medical procedures	Gastric bypass	01JAN2014	01JAN2014	N
			Tonsillectomy	01FEB1995	01FEB1995	N
	C4591001 1140 11401130	Psychiatric disorders	Depression	01AUG2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1140 11401135	Infections and infestations	Chronic sinusitis	01SEP2012		Y
	C4591001 1140 11401137	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01FEB2004	01FEB2004	N
			Rhinoplasty	01MAY1996	01MAY1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401148	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN1984	01AUG2018	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2017	01MAY2017	N
			Hysterectomy	01AUG2018	01AUG2018	N
	C4591001 1140 11401149	Gastrointestinal disorders	Vomiting	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01MAY2012	01MAY2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01MAY1994		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01MAY1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAY2010	24FEB2020	N
		Nervous system disorders	Migraine	01MAY1985		Y
		Psychiatric disorders	Anxiety	01MAY2010		Y
			Sleep disorder	01AUG2018		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2016		Y
			Urticaria	01JAN2017		Y
		Surgical and medical procedures	Gastrectomy	01JAN2018	01JAN2018	N
			Hysterectomy	24FEB2020	24FEB2020	N
	C4591001 1140 11401150	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2018	31OCT2018	N
			Chondroplasty	01JAN2012	31JAN2012	N
			Osteotomy	01JAN2018		Y
			Shoulder operation	01JAN2016	31JAN2016	N
			Spinal operation	01JAN2012	31JAN2012	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1140 11401151	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Psychiatric disorders	Anxiety	01MAY2019		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2009	01JUN2009	N
	C4591001 1140 11401153	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1140 11401154	Psychiatric disorders	Depression	01JUN2018		Y
		Surgical and medical procedures	Arthrodesis	03FEB2020	03APR2020	N
	C4591001 1140 11401158	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1140 11401159	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1140 11401160	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Oophorectomy	01OCT2000	30NOV2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401164	Metabolism and nutrition disorders	Hyperlipidaemia	03JUL2012		Y
			Type 2 diabetes mellitus	10JUN2020		Y
		Psychiatric disorders	Depression	11MAR2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	22JUL2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01MAY1966	01MAY1966	N
			Nasal septal operation	01MAR1992	01MAR1992	N
			Tonsillectomy	01SEP1970	01SEP1970	N
		Vascular disorders	Hypertension	11NOV2013		Y
	C4591001 1140 11401166	Reproductive system and breast disorders	Menopausal symptoms	01NOV2018		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000		Y
	C4591001 1140 11401170	Injury, poisoning and procedural complications	Joint dislocation	01JUN1987	01DEC1987	N
		Metabolism and nutrition disorders	Obesity	01JUN1987		Y
		Nervous system disorders	Intracranial aneurysm	01MAY2017		Y
			Migraine	01AUG1990		Y
		Psychiatric disorders	Anxiety	01OCT2000		Y
			Depression	01OCT2000		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN1987		Y
		Surgical and medical procedures	Gastrectomy	01MAR2014	01MAR2014	N
			Joint dislocation reduction	01DEC1987	01DEC1987	N
	C4591001 1140 11401177	Surgical and medical procedures	Shoulder operation	08AUG2019	08AUG2019	N
	C4591001 1140 11401178	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01AUG1996		Y
		Nervous system disorders	Restless legs syndrome	01JUL2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01AUG2019		Y
			Depression	01AUG2020		Y
			Insomnia	01JUN2020		Y
		Surgical and medical procedures	Gastric bypass	01OCT2016	01OCT2016	N
			Hysterectomy	01APR2013	01APR2013	N
			Joint arthroplasty	01JUN2020	01JUN2020	N
			Salivary gland operation	01JUL2013	01JUL2013	N
	C4591001 1140 11401180	Immune system disorders	Seasonal allergy	01AUG1996		Y
		Surgical and medical procedures	Umbilical hernia repair	01AUG2012	01AUG2012	N
	C4591001 1140 11401184	Nervous system disorders	Seizure	01MAR2017		Y
		Surgical and medical procedures	Inguinal hernia repair	(b) (6) 1970	(b) (6) 1970	N
			Thyroidectomy	01NOV2009	01NOV2009	N
	C4591001 1140 11401187	Endocrine disorders	Autoimmune thyroiditis	01AUG2002		Y
			Basedow's disease	01AUG2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2016		Y
			Seasonal allergy	01AUG1997		Y
		Infections and infestations	Chronic sinusitis	01AUG2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2002		Y
		Psychiatric disorders	Anxiety	01AUG1995		Y
		Surgical and medical procedures	Appendicectomy	01SEP1995	01SEP1995	N
			Caesarean section	10MAR2000	10MAR2000	N
			Cholecystectomy	01SEP1997	01SEP1997	N
			Sinus operation	23JUN2020	23JUN2020	N
			Tonsillectomy	01AUG1972	01AUG1972	N
			Varicose vein operation	01AUG2005	01AUG2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1140 11401198	Social circumstances	Menopause	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Endometrial ablation	01AUG2014	01AUG2014	N
	C4591001 1140 11401201	Immune system disorders	Seasonal allergy	01AUG2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JUN2013	01JUN2013	N
			Pyloroplasty	(b) (6) 1984	(b) (6) 1984	N
	C4591001 1140 11401202	Immune system disorders	Seasonal allergy	01AUG2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2017		Y
		Surgical and medical procedures	Cholecystectomy	01OCT1993	01OCT1993	N
			Hysterectomy	01OCT2019	01OCT2019	N
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1140 11401203	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Social circumstances	Postmenopause	01AUG2018		Y
		Surgical and medical procedures	Female sterilisation	01JUN1995	01JUN1995	N
			Gastrostomy	09SEP1989	09SEP1989	N
			Gastrostomy tube removal	09OCT1989	09OCT1989	N
			Jaw operation	09SEP1989	09SEP1989	N
	C4591001 1140 11401206	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01AUG2018		Y
		Surgical and medical procedures	Limb reconstructive surgery	01AUG1999	01AUG1999	N
	C4591001 1140 11401209	Immune system disorders	Seasonal allergy	01AUG2000		Y
		Surgical and medical procedures	Appendicectomy	01AUG2016	01AUG2016	N
			Ligament operation	01AUG1987	01AUG1987	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401210	Immune system disorders	Seasonal allergy	01AUG2010		Y
	C4591001 1140 11401214	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01AUG2017		Y
	C4591001 1140 11401215	Social circumstances	Postmenopause	01JUN2013		Y
		Surgical and medical procedures	Female sterilisation	13SEP1986	13SEP1986	N
	C4591001 1140 11401216	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01MAY2003	01MAY2003	N
	C4591001 1140 11401219	Surgical and medical procedures	Female sterilisation	01JUL2004	01JUL2004	N
			Hip arthroplasty	01JUL2017	01JUL2017	N
			Spinal laminectomy	01JUL2000	01JUL2000	N
	C4591001 1140 11401231	Endocrine disorders	Hypogonadism	01AUG2014		Y
		Immune system disorders	Hypersensitivity	01JAN2019		Y
		Psychiatric disorders	Anxiety	01MAY1995		Y
			Depression	01MAY1995		Y
		Renal and urinary disorders	Nephrolithiasis	01MAY2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01FEB1979	01FEB1979	N
	C4591001 1140 11401232	Psychiatric disorders	Anxiety	01APR2018		Y
	C4591001 1140 11401239	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401243	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
			Depression	01JAN2017		Y
	C4591001 1140 11401249	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Lipoma excision	01JAN2017	31DEC2017	N
			Sinus operation	01JAN2018	31DEC2018	N
	C4591001 1140 11401250	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1982		Y
		Pregnancy, puerperium and perinatal conditions	Habitual abortion	01JAN1992	31DEC2001	N
		Reproductive system and breast disorders	Endometriosis	01JAN1988	31DEC2001	N
		Social circumstances	Menopause	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
				01JAN2004	31DEC2004	N
			Laparoscopic surgery	01JAN1990	31DEC1990	N
				01JAN1994	31DEC1994	N
			Salpingectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1140 11401251	Immune system disorders	Seasonal allergy	01AUG1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2005		Y
			Type 2 diabetes mellitus	01AUG2010		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Attention deficit hyperactivity disorder	01AUG1998		Y
		Vascular disorders	Hypertension	01AUG2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401252	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2005	30JUN2015	N
			Depression	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	07APR2016	07APR2016	N
	C4591001 1140 11401255	Immune system disorders	Seasonal allergy	01AUG2000		Y
		Surgical and medical procedures	Knee operation	01SEP2000	01SEP2000	N
				01SEP2001	01SEP2001	N
			Tonsillectomy	01SEP1972	01SEP1972	N
	C4591001 1140 11401257	Immune system disorders	Seasonal allergy	01AUG2000		Y
	C4591001 1140 11401259	Injury, poisoning and procedural complications	Hip fracture	01JAN2016	31DEC2016	N
			Road traffic accident	01JAN2016	31DEC2016	N
			Wrist fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Autism spectrum disorder	01JAN2003		Y
			Generalised anxiety disorder	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN2003		Y
	C4591001 1140 11401262	Immune system disorders	Seasonal allergy	01APR2015		Y
	C4591001 1140 11401264	Immune system disorders	Seasonal allergy	01APR2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2004		Y
		Surgical and medical procedures	Abdominoplasty	01MAY2005	31MAY2005	N
			Mammoplasty	01MAY2005	31MAY2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401272	Eye disorders	Chorioretinopathy	01NOV2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Seasonal allergy	01JAN1983		Y
			Seasonal allergy	01JAN1973		Y
		Skin and subcutaneous tissue disorders	Eczema	01AUG2020		Y
	C4591001 1140 11401279	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2019	31OCT2019	N
			Soft tissue sarcoma	01MAY2009	31AUG2009	N
	C4591001 1140 11401281	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Sinus operation	01JAN2019	31DEC2019	N
	C4591001 1140 11401282	Injury, poisoning and procedural complications	Road traffic accident	11NOV2016	11NOV2016	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Surgical and medical procedures	Surgery	11NOV2016	24JUN2020	N
	C4591001 1140 11401284	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle twitching	01JAN2014		Y
	C4591001 1140 11401285	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Panic attack	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01APR2008	30APR2008	N
	C4591001 1140 11401290	Gastrointestinal disorders	Gastric ulcer	01DEC1993	25DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01MAR2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01APR2004	01APR2009	N
	C4591001 1140 11401294	Reproductive system and breast disorders	Endometriosis	01JUN2009	30JUN2012	N
		Surgical and medical procedures	Caesarean section	12MAR2016	12MAR2016	N
				20JUN2018	20JUN2018	N
	C4591001 1140 11401299	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1140 11401301	Injury, poisoning and procedural complications	Limb injury	01DEC2015	31DEC2015	N
		Surgical and medical procedures	Limb operation	01DEC2015	31DEC2015	N
	C4591001 1140 11401303	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Pyelonephritis	01OCT1995	31OCT1995	N
	C4591001 1140 11401304	Congenital, familial and genetic disorders	Congenital hearing disorder	(b) (6) 1983		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2009		Y
	C4591001 1140 11401306	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Eye allergy	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Injury, poisoning and procedural complications	Avulsion fracture	01JAN2007	31DEC2007	N
			Foot fracture	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Paraparesis	01SEP2020		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2007	31DEC2007	N
	C4591001 1140 11401308	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Rubber sensitivity	01JAN2007		Y
		Infections and infestations	Onychomycosis	01JAN2012		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01APR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dysplastic naevus	01JAN2004		Y
		Reproductive system and breast disorders	Menopausal symptoms	01SEP2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01APR2018		Y
		Surgical and medical procedures	Tonsillectomy	01MAR1978	31MAR1978	N
	C4591001 1140 11401310	Immune system disorders	Seasonal allergy	01APR2014		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
			Depression	01NOV2019		Y
	C4591001 1140 11401311	Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1140 11401314	Surgical and medical procedures	Hernia repair	01JAN2006	31DEC2006	N
	C4591001 1140 11401316	Reproductive system and breast disorders	Menorrhagia	01DEC2018		Y
	C4591001 1140 11401318	Psychiatric disorders	Anxiety	01JAN2013		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y
	C4591001 1140 11401319	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1140 11401321	Gastrointestinal disorders	Tooth impacted	28JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord dysfunction	01NOV2018		Y
	C4591001 1141 11411003	Musculoskeletal and connective tissue disorders	Scoliosis	01MAR2007	31MAR2007	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2007		Y
		Surgical and medical procedures	Spinal fusion surgery	01MAR2007	31MAR2007	N
	C4591001 1141 11411005	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Rubber sensitivity	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Breast mass	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1141 11411006	Blood and lymphatic system disorders	Anaemia	01MAR2010	31MAR2018	N
		Infections and infestations	Tonsillitis	01JUN2004	30JUN2004	N
		Nervous system disorders	Headache	01JUN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JUN2004	30JUN2004	N
	C4591001 1141 11411007	Eye disorders	Myopia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2006		Y
	C4591001 1141 11411008	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Hypersensitivity	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Joint surgery	01JAN2012	31DEC2012	N
	C4591001 1141 11411010	Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
	C4591001 1141 11411011	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Surgical and medical procedures	Ligament operation	06SEP2019	06SEP2019	N
	C4591001 1141 11411012	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2019		Y
			Psoriasis	01JAN2016		Y
	C4591001 1141 11411013	Immune system disorders	Seasonal allergy	01MAR2010		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1141 11411014	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN1990	31DEC2000	N
			Ear infection	01JAN1984	31DEC2000	N
			Pharyngitis streptococcal	01JAN1987	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1990	31DEC1990	N
			Sinus operation	01JAN2000	31DEC2000	N
	C4591001 1141 11411016	Eye disorders	Eyelid ptosis	01JAN1998		Y
			Myopia	01JAN2009		Y
		Gastrointestinal disorders	Gingival discomfort	01JAN2012	31DEC2013	N
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2014		Y
		Surgical and medical procedures	Gingival operation	01JAN2013	31DEC2013	N
	C4591001 1141 11411017	Infections and infestations	Bronchitis	01JAN1997	31DEC2000	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1997	31DEC2002	N
	C4591001 1141 11411018	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01OCT2003		Y
		Infections and infestations	Herpes zoster	01SEP2016	10SEP2016	N
			Influenza	16FEB2020	23FEB2020	N
			Pharyngitis streptococcal	01JAN1991	31DEC1993	N
			Sinusitis	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
			Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	04JUN1995	04JUN1995	N
			Nasal septal operation	01DEC2010	31DEC2010	N
			Tonsillectomy	01JUL1993	31JUL1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411019	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1991		Y
		Surgical and medical procedures	Seasonal allergy	01JAN1985		Y
			Mammoplasty	01JAN2016	31DEC2016	N
	C4591001 1141 11411020	Congenital, familial and genetic disorders	Ventricular septal defect	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN2012	31DEC2019	N
	C4591001 1141 11411021	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01DEC2018		Y
	C4591001 1141 11411022	Injury, poisoning and procedural complications	Ligament rupture	06MAY2006	22MAY2006	N
			Radius fracture	15APR2004	30MAY2004	N
	C4591001 1141 11411023	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
	C4591001 1141 11411024	Injury, poisoning and procedural complications	Incisional hernia	01MAY2019	31AUG2019	N
			Limb injury	01NOV2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Organ donor	01AUG2014	31AUG2014	N
		Surgical and medical procedures	Abdominal hernia repair	01AUG2019	31AUG2019	N
			Peripheral nerve operation	01DEC2019	31DEC2019	N
	C4591001 1141 11411025	Ear and labyrinth disorders	Eustachian tube dysfunction	01JAN1984	31DEC1985	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Infections and infestations	Tonsillitis	01JAN1984	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1141 11411026	Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Joint instability	01APR2011	30APR2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979	31DEC2001	N
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Capsulorrhaphy	01JAN2011	31DEC2011	N
	C4591001 1141 11411027	Gastrointestinal disorders	Coeliac disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Rubber sensitivity	01JAN2003		Y
		Infections and infestations	Ear infection	01JAN1983	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2001		Y
			Depression	01JAN1997		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1984	31DEC1984	N
	C4591001 1141 11411029	Eye disorders	Myopia	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratosis pilaris	01JAN2009		Y
	C4591001 1141 11411030	Gastrointestinal disorders	Diverticulum	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
	C4591001 1141 11411031	Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01NOV2019	31JAN2020	N
			Headache	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1985	31DEC1993	N
			Dyspnoea exertional	01MAR2020		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1141 11411032	Infections and infestations	Bacterial vaginosis	31JUL2020		Y
		Nervous system disorders	Headache	01AUG2017		Y
		Psychiatric disorders	Anxiety	01JUN2018		Y
			Attention deficit hyperactivity disorder	01JUL2017		Y
			Depression	01JUN2018		Y
		Surgical and medical procedures	Contraception	01DEC2019		Y
	C4591001 1141 11411033	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2003	31DEC2003	N
			Lower limb fracture	01JAN2002	31DEC2002	N
		Nervous system disorders	Headache	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1141 11411036	Endocrine disorders	Hypothyroidism	01MAY2017		Y
		Eye disorders	Myopia	01JAN1999		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Major depression	01JAN2011		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2002		Y
	C4591001 1141 11411037	Blood and lymphatic system disorders	Iron deficiency anaemia	31DEC2018	31MAR2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2015		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
			Vulvovaginal mycotic infection	20JUL2020		Y
		Vascular disorders	Essential hypertension	31JAN2020		Y
	C4591001 1141 11411038	Eye disorders	Myopia	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
	C4591001 1141 11411041	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Social circumstances	Menopause	04JAN2019		Y
	C4591001 1141 11411042	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Infections and infestations	Bronchitis	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ear infection	01JAN1978	31DEC1986	N
			Sinusitis	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2020		Y
		Nervous system disorders	Headache	01JAN1982		Y
		Psychiatric disorders	Anxiety disorder	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1141 11411044	Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Repetitive strain injury	01JAN1998		Y
		Nervous system disorders	Headache	01JAN1998		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
	C4591001 1141 11411045	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2015		Y
	C4591001 1141 11411046	Surgical and medical procedures	Tympanoplasty	15JUN2005	15JUN2005	N
	C4591001 1141 11411048	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Persistent depressive disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1141 11411049	Endocrine disorders	Hypothyroidism	01MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	01JAN2018		Y
		Infections and infestations	Appendicitis	01OCT2019	31OCT2019	N
			Ear infection	01JAN1969	31DEC1969	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Nervous system disorders	Headache	01JAN1991		Y
		Surgical and medical procedures	Appendectomy	01OCT2019	31OCT2019	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1141 11411050	Gastrointestinal disorders	Inguinal hernia	01JAN1987	15MAR1987	N
				15MAR1987	15MAR1987	N
			Intestinal perforation	15SEP1979	15SEP1979	N
		General disorders and administration site conditions	Vaccination site reaction	14APR2019	15APR2019	N
		Immune system disorders	Seasonal allergy	15SEP1975	15SEP1975	N
		Renal and urinary disorders	Renal cyst	03NOV2018		Y
		Surgical and medical procedures	Rotator cuff repair	12JUL2012	12JUL2012	N
		Vascular disorders	Hypertension	15MAY2018		Y
	C4591001 1141 11411051	Blood and lymphatic system disorders	Anaemia	01JAN1991		Y
		Endocrine disorders	Goitre	01JAN2011		Y
	C4591001 1141 11411053	Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2018		Y
	C4591001 1141 11411054	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	07AUG2010		Y
			Obesity	07AUG2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	26MAY2015	26MAY2015	N
		Nervous system disorders	Ischaemic stroke	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menometrorrhagia	26MAY2015	26MAY2015	N
			Uterine polyp	26MAY2015	26MAY2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2015	31DEC2015	N
				26MAY2015	26MAY2015	N
	C4591001 1141 11411055	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01AUG2013		Y
		Ear and labyrinth disorders	Eustachian tube dysfunction	01JAN1988	31DEC1998	N
		Eye disorders	Myopia	01JAN1996		Y
		General disorders and administration site conditions	Pain	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1998	31DEC1998	N
	C4591001 1141 11411056	Injury, poisoning and procedural complications	Limb traumatic amputation	01AUG2019	31DEC2019	N
	C4591001 1141 11411057	Cardiac disorders	Wolff-Parkinson-White syndrome	01DEC1990	01DEC1990	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC1996		Y
		Musculoskeletal and connective tissue disorders	Costochondritis	01DEC1996	01DEC2016	N
		Psychiatric disorders	Anxiety	01DEC2015		Y
			Attention deficit hyperactivity disorder	10JUN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac ablation	01DEC1990	01DEC1990	N
			Prostatic urethral lift procedure	01JUN2018	01JUN2018	N
	C4591001 1141 11411060	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Fracture nonunion	01JAN1999	31DEC1999	N
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1141 11411061	Eye disorders	Dry eye	13FEB2013		Y
			Iris disorder	12DEC2013		Y
			Ocular hypertension	01JAN2006		Y
		Investigations	HLA marker study	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Femoroacetabular impingement	01DEC2019	31DEC2019	N
			Osteoarthritis	01DEC2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Iris melanoma	28JAN2014		Y
	C4591001 1141 11411062	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
	C4591001 1141 11411064	Eye disorders	Myopia	01JAN1994	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Nervous system disorders	Headache	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Keratomileusis	01JAN2012	31DEC2012	N
	C4591001 1141 11411065	Nervous system disorders	Headache	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006	31DEC2006	N
	C4591001 1141 11411067	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1141 11411068	Immune system disorders	Seasonal allergy	01MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	19JUN2018		Y
		Nervous system disorders	Migraine	01JUN2001		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1141 11411070	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Major depression	01JAN2008		Y
	C4591001 1141 11411072	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1141 11411073	Hepatobiliary disorders	Cholelithiasis	01APR2008	01APR2008	N
		Psychiatric disorders	Perinatal depression	11JAN2011	01JUN2011	N
		Surgical and medical procedures	Cholecystectomy	01APR2008	01APR2008	N
	C4591001 1141 11411074	Eye disorders	Astigmatism	01JAN2002		Y
			Myopia	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2017		Y
	C4591001 1141 11411075	Infections and infestations	Otitis media chronic	01JAN1997	31DEC1997	N
			Tonsillitis	01JAN1997	31DEC1997	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Back pain	23FEB2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1997	31DEC1997	N
			Bone operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1141 11411076	Hepatobiliary disorders	Cholelithiasis	01DEC2013	01DEC2013	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2018		Y
			Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN1980	01DEC1985	N
		Surgical and medical procedures	Cholecystectomy	01DEC2013	01DEC2013	N
			Tonsillectomy	01DEC1985	01DEC1985	N
	C4591001 1141 11411077	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01DEC2019		Y
		Nervous system disorders	Headache	01JAN2012		Y
	C4591001 1141 11411078	Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Keratomileusis	01MAR2020	31DEC2020	N
			Tonsillectomy	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411079	Eye disorders	Hypermetropia	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1989	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1997	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1992		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1989	31DEC1989	N
			Caesarean section	23JAN2002	23JAN2002	N
				31MAR2004	31MAR2004	N
			Skin neoplasm excision	01JAN1997	31DEC1997	N
	C4591001 1141 11411080	Investigations	Cardiac murmur	01JAN2012	31DEC2012	N
		Nervous system disorders	Syncope	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1141 11411081	General disorders and administration site conditions	Hernia	01DEC2016	01DEC2016	N
		Immune system disorders	Seasonal allergy	01DEC1998		Y
		Injury, poisoning and procedural complications	Hand fracture	01DEC2016	01DEC2016	N
			Meniscus injury	01DEC2019	01DEC2019	N
			Muscle injury	30JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01DEC2013		Y
		Surgical and medical procedures	Hernia repair	01DEC2016	01DEC2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411082	Immune system disorders	Allergy to arthropod sting	01JAN1977		Y
			Drug hypersensitivity	(b) (6) 1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	23JUL2020	23JUL2020	N
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Depression	01JAN1983		Y
			Post-traumatic stress disorder	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1141 11411084	Congenital, familial and genetic disorders	PTEN gene mutation	01DEC2019		Y
		Endocrine disorders	Thyroid mass	01OCT2019	01OCT2019	N
		Investigations	Vitamin D decreased	15JAN2020		Y
		Surgical and medical procedures	Thyroidectomy	01OCT2019	01OCT2019	N
			Vasectomy	05DEC2019	05DEC2019	N
	C4591001 1141 11411085	Eye disorders	Myopia	01JAN1980		Y
		General disorders and administration site conditions	Pain	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Infections and infestations	Ear infection	01JAN1977	31DEC1984	N
			Tonsillitis	01JAN1978	31DEC1979	N
		Injury, poisoning and procedural complications	Concussion	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1972	31DEC1982	N
				01JAN1987	31DEC1987	N
		Surgical and medical procedures	Nasal septal operation	01JAN1982	31DEC1982	N
				01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1979	31DEC1979	N
			Vasectomy	13JUL2020	13JUL2020	N
	C4591001 1141 11411087	Investigations	Blood cholesterol increased	01OCT2019		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1141 11411088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Open reduction of fracture	01JAN2012	31DEC2012	N
	C4591001 1141 11411089	Musculoskeletal and connective tissue disorders	Back pain	01JAN1996	31DEC2008	N
		Nervous system disorders	Headache	01JAN1996		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
	C4591001 1141 11411090	Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Investigations	Biopsy breast normal	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN1990	31DEC1990	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN1990	31DEC1990	N
			Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1141 11411091	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994		Y
	C4591001 1141 11411092	Eye disorders	Myopia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	27JAN2020		Y
		Nervous system disorders	Tension headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2017		Y
	C4591001 1141 11411093	Eye disorders	Hypermetropia	01JAN1999		Y
			Myopia	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1994	31DEC1995	N
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2007	31DEC2009	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1995	31DEC1995	N
			Nasal septal operation	01JAN2009	31DEC2009	N
	C4591001 1141 11411096	Eye disorders	Myopia	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Investigations	Colonoscopy	01AUG2019	31AUG2019	N
		Nervous system disorders	Hypersomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Large intestinal polypectomy	01AUG2019	31AUG2019	N
			Mammoplasty	01JAN2016	31DEC2016	N
	C4591001 1141 11411097	Cardiac disorders	Supraventricular extrasystoles	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Hepatobiliary disorders	Bile duct stone	01JAN2003	31JAN2003	N
			Cholelithiasis	01AUG1996	31AUG1996	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2000	31JAN2004	N
				01JAN2003	31OCT2003	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
			Osteoarthritis	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	10MAY2017	10MAY2017	N
			Foetal death	10APR2020	10APR2020	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
			Pulmonary embolism	01FEB2003	28FEB2003	N
		Surgical and medical procedures	Caesarean section	21DEC2018	21DEC2018	N
			Cholecystectomy	01AUG1996	31AUG1996	N
			Choledocholithotomy	01JAN2003	31JAN2003	N
			Incisional hernia repair	01JAN2004	31JAN2004	N
				01OCT2003	31OCT2003	N
			Salpingectomy	10MAY2017	10MAY2017	N
			Uterine dilation and curettage	10APR2020	10APR2020	N
	C4591001 1141 11411099	Immune system disorders	Mycotic allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nasal operation	01JAN2007	31DEC2007	N
	C4591001 1141 11411102	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1979	31DEC1983	N
		Eye disorders	Myopia	01JAN1986		Y
		Nervous system disorders	Tension headache	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1141 11411103	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN2016		Y
			Migraine with aura	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1141 11411104	Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1141 11411106	Congenital, familial and genetic disorders	Transitional vertebrae	01JAN1978		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2001	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Spinal disorder	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	01JAN2001	31DEC2001	N
		Psychiatric disorders	Anxiety disorder	01JAN2011		Y
			Sleep disorder	01JAN2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Haemorrhoid operation	01JAN2015	31DEC2015	N
	C4591001 1141 11411107	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2020		Y
		Nervous system disorders	Migraine	01OCT2014		Y
			Tension headache	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2009		Y
			Insomnia	01NOV2019		Y
	C4591001 1141 11411108	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2004	31DEC2004	N
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
	C4591001 1141 11411109	Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1141 11411110	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1141 11411112	Eye disorders	Astigmatism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1998		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Mammoplasty	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1141 11411113	Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1141 11411114	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2017		Y
	C4591001 1141 11411116	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1997		Y
	C4591001 1141 11411118	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Nervous system disorders	Facial paralysis	01SEP2017		Y
	C4591001 1141 11411119	General disorders and administration site conditions	Hernia	01DEC1980	01DEC1980	N
		Infections and infestations	Appendicitis	01DEC2001	01DEC2001	N
		Surgical and medical procedures	Appendicectomy	01DEC2001	01DEC2001	N
			Hernia repair	01DEC1980	01DEC1980	N
			Vasectomy	01AUG2015	01AUG2015	N
	C4591001 1141 11411120	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tenoplasty	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1141 11411121	Psychiatric disorders	Anxiety	01JAN1990		Y
	C4591001 1141 11411122	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Injury	01JAN2017	31DEC2017	N
			Ligament injury	01JAN2013	31DEC2013	N
			Wrist fracture	25DEC2018	25DEC2018	N
		Nervous system disorders	Headache	01JAN2018		Y
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
	C4591001 1141 11411123	Nervous system disorders	Migraine	01JAN2010		Y
			Presyncope	01JAN2016		Y
	C4591001 1141 11411125	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Infections and infestations	Tinea versicolour	01JUL2012		Y
			Tonsillitis	01JAN2003	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2015		Y
			Osteochondrosis	01DEC2006		Y
			Scoliosis	01FEB2016		Y
		Nervous system disorders	Headache	01OCT2006		Y
			Migraine	01SEP2004		Y
		Psychiatric disorders	Anxiety	01SEP2016		Y
			Depression	01SEP2016		Y
			Insomnia	01FEB2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01APR2004	30APR2004	N
	C4591001 1141 11411127	Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
			Major depression	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1141 11411128	Injury, poisoning and procedural complications	Cartilage injury	01DEC2016	31DEC2016	N
			Humerus fracture	01JAN2016	31DEC2016	N
			Joint dislocation	01JAN2016	31DEC2016	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2016		Y
			Major depression	01JAN2016		Y
	C4591001 1141 11411129	Surgical and medical procedures	Rotator cuff repair	01DEC2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1141 11411130	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Nervous system disorders	Migraine	01MAR2020		Y
	C4591001 1141 11411131	Eye disorders	Myopia	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1141 11411132	Surgical and medical procedures	Elbow operation	01JAN2014	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Jaw fracture	01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Jaw operation	01JAN1982	31DEC1982	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1141 11411133	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1141 11411135	Psychiatric disorders	Anxiety	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2011		Y
	C4591001 1141 11411136	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
			Hepatic steatosis	01JUN2020		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2017		Y
		Nervous system disorders	Headache	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Ligament operation	01JAN2005	31DEC2005	N
	C4591001 1141 11411137	Eye disorders	Cataract	01FEB2018		Y
			Glaucoma	01FEB2018	31MAY2018	N
		Infections and infestations	Herpes simplex	10FEB1990		Y
		Investigations	Smear cervix abnormal	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Nervous system disorders	Neuralgia	01FEB2018		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1141 11411139	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011		Y
	C4591001 1141 11411140	Cardiac disorders	Supraventricular tachycardia	01JAN2014		Y
		Eye disorders	Astigmatism	01JAN1995		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1991	31DEC1991	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP2015	30SEP2015	N
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Sleep disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2004	N
			Hysterectomy	01SEP2015	30SEP2015	N
			Ligament operation	01JAN1991	31DEC1991	N
	C4591001 1141 11411142	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1141 11411144	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2012	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
	C4591001 1141 11411146	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1141 11411148	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2007		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1141 11411149	Immune system disorders	Seasonal allergy	15JUL1975		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	15MAR2017		Y
		Psychiatric disorders	Anxiety	15OCT2018		Y
			Attention deficit hyperactivity disorder	15JAN1980		Y
		Skin and subcutaneous tissue disorders	Rosacea	15JUN2005		Y
		Surgical and medical procedures	Hernia repair	05JAN1970	01FEB1970	N
			Skin neoplasm excision	15JUL2015	22JUL2015	N
			Tonsillectomy	05APR1979	12APR1979	N
		Vascular disorders	Hypertension	15JUN2003		Y
	C4591001 1141 11411151	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1975	31DEC1977	N
					31DEC2018	N
		Gastrointestinal disorders	Gingival recession	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2018	N
		Surgical and medical procedures	Femoral derotation osteotomy	01JAN1977	31DEC1977	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gingival graft	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1141 11411152	Eye disorders	Myopia	01JAN1997		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2018		Y
	C4591001 1141 11411153	Injury, poisoning and procedural complications	Post laminectomy syndrome	01OCT2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Scoliosis	01JAN2002		Y
			Spondylolisthesis	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Medical device removal	21JUN2019	21JUN2019	N
			Spinal fusion surgery	01JAN1992	31DEC1992	N
			Spinal nerve stimulator implantation	01OCT2016	31OCT2016	N
				10FEB2017	10FEB2017	N
			Spinal operation	01AUG2004	31AUG2004	N
				01DEC2005	31DEC2005	N
				01JUN1992	30JUN1992	N
				01MAY2010	31MAY2010	N
	C4591001 1141 11411154	Eye disorders	Myopia	01JAN2017		Y
		General disorders and administration site conditions	Hernia	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1998		Y
		Surgical and medical procedures	Hernia repair	01JAN2003	31DEC2003	N
	C4591001 1141 11411156	Infections and infestations	Tonsillitis	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N
			Vasectomy	01NOV2019	30NOV2019	N
	C4591001 1141 11411158	Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Hypermetropia	01JAN2010	31DEC2010	N
			Myopia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2019	31DEC2019	N
			Mastectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1141 11411159	Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1141 11411161	Musculoskeletal and connective tissue disorders	Back pain	01JAN2006	31DEC2020	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	14JUN2020	31DEC2020	N
	C4591001 1141 11411162	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411163	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1141 11411164	Ear and labyrinth disorders	Tinnitus	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
	C4591001 1141 11411165	Eye disorders	Myopia	01JAN1998		Y
		Injury, poisoning and procedural complications	Ligament rupture	01APR2003	30APR2003	N
			Meniscus injury	01SEP2005	30SEP2005	N
		Psychiatric disorders	Perinatal depression	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN2007	31DEC2007	N
			Ligament operation	01APR2003	30APR2003	N
			Meniscus operation	01SEP2005	30SEP2005	N
	C4591001 1141 11411166	Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
		Investigations	Oesophagogastroduodenoscopy	01JAN2018		Y
	C4591001 1141 11411167	Eye disorders	Myopia	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2008	31DEC2008	N
			Rhinoplasty	01JAN2012	31DEC2012	N
	C4591001 1141 11411168	Infections and infestations	Otitis externa	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2013		Y
			Generalised anxiety disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980	31DEC1991	N
	C4591001 1141 11411169	Immune system disorders	Seasonal allergy	01APR2012		Y
	C4591001 1141 11411170	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1994	31DEC1994	N
			Childhood asthma	01JAN1992	31DEC1997	N
		Surgical and medical procedures	Adenoidectomy	01JAN1994	31DEC1994	N
	C4591001 1141 11411171	Investigations	Mycobacterium tuberculosis complex test positive	01JAN1998	31DEC1998	N
	C4591001 1141 11411172	Nervous system disorders	Migraine	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1141 11411173	Injury, poisoning and procedural complications	Suture rupture	01JAN2017	31JAN2017	N
		Investigations	Smear cervix abnormal	01JAN1998	30NOV2016	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JUN2020		Y
		Nervous system disorders	Restless legs syndrome	01MAY2020		Y
			Sciatica	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Bipolar disorder	01JAN2012		Y
			Depression	01JAN1998		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	30NOV2016	30NOV2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vaginal operation	01JAN2017	31JAN2017	N
	C4591001 1141 11411174	Immune system disorders	Seasonal allergy	01JUN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUN2011	01JUN2012	N
	C4591001 1141 11411175	Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2020		Y
	C4591001 1141 11411176	Endocrine disorders	Hypothyroidism	15JAN2012		Y
		Surgical and medical procedures	Caesarean section	14JUN2019	14JUN2019	N
				25OCT2017	25OCT2017	N
	C4591001 1141 11411177	Immune system disorders	Female sterilisation	14JUN2019		Y
			Allergy to animal	20MAY2009		Y
			Seasonal allergy	15NOV1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15SEP2018		Y
		Surgical and medical procedures	Caesarean section	13DEC2004	13DEC2004	N
	C4591001 1141 11411179	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Adenoidectomy	01JAN1996	31DEC1996	N
				01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1141 11411181	Endocrine disorders	Hypothyroidism	24OCT2005		Y
		Metabolism and nutrition disorders	Gout	20OCT2015		Y
		Renal and urinary disorders	Nephrolithiasis	15SEP1995		Y
		Surgical and medical procedures	Enterorrhaphy	10DEC2005	15SEP2006	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	24OCT2005		Y
	C4591001 1141 11411182	Eye disorders	Myopia	(b) (6) 1998	01MAY2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2018		Y
			Depression	01JUN2015		Y
	C4591001 1141 11411184	Surgical and medical procedures	Keratomileusis	01MAY2019	01MAY2019	N
		Blood and lymphatic system disorders	Anaemia	01MAY2010	30SEP2010	N
		Infections and infestations	Herpes simplex	01JAN1977		Y
		Investigations	Biopsy skin	01NOV2019	30NOV2019	N
		Musculoskeletal and connective tissue disorders	Muscle atrophy	01NOV2019	30NOV2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAY2010	30SEP2010	N
		Skin and subcutaneous tissue disorders	Night sweats	01SEP2018		Y
	C4591001 1141 11411185	Surgical and medical procedures	Hysterectomy	01SEP2010	30SEP2010	N
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Jaw operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1141 11411186	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1141 11411188	Infections and infestations	Appendicitis	01DEC2018	31DEC2018	N
		Nervous system disorders	Tension headache	01JAN1989		Y
		Surgical and medical procedures	Appendicectomy	01DEC2018	31DEC2018	N
	C4591001 1141 11411192	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
	C4591001 1141 11411193	Immune system disorders	Seasonal allergy	01JAN2006		Y
	C4591001 1141 11411194	Nervous system disorders	Migraine with aura	01JUL2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01SEP2016	24JAN2020	N
		Surgical and medical procedures	Caesarean section	09OCT2009	09OCT2009	N
				30NOV2006	30NOV2006	N
			Salpingectomy	24JAN2020	24JAN2020	N
	C4591001 1141 11411195	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
	C4591001 1141 11411197	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1141 11411198	Eye disorders	Myopia	01JAN1986		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1141 11411199	Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Infertility	01JAN2011		Y
			Premenstrual dysphoric disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
	C4591001 1141 11411201	Gastrointestinal disorders	Gastrooesophageal reflux disease	15OCT2000		Y
		Immune system disorders	Allergy to animal	15JUN1990		Y
			Seasonal allergy	15JUN1990		Y
		Nervous system disorders	Migraine	20MAY1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15NOV1985		Y
		Surgical and medical procedures	Gastric banding	05FEB2007		Y
			Mammoplasty	25JUL2013	03AUG2013	N
			Skin cosmetic procedure	25JUL2013	03AUG2013	N
			Surgery	20AUG2013	27AUG2013	N
			Urethral dilation procedure	15NOV1987	22NOV1987	N
	C4591001 1141 11411202	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2018	31DEC2018	N
			Ligament rupture	01JAN2019	31DEC2019	N
			Meniscus injury	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013		Y
		Surgical and medical procedures	Ankle operation	01JUL2020	31DEC2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1141 11411203	Infections and infestations	Pharyngitis streptococcal	01JAN2014	31JUL2016	N
		Surgical and medical procedures	Tonsillectomy	01JUL2016	31JUL2016	N
	C4591001 1141 11411204	Injury, poisoning and procedural complications	Ligament rupture	15SEP2015	01OCT2015	N
		Metabolism and nutrition disorders	Lipomatosis	01AUG2014		Y
		Nervous system disorders	Migraine	01SEP2019		Y
		Psychiatric disorders	Anxiety	09AUG2014	01JUN2019	N
			Depression	01AUG2014	01JUN2019	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2012		Y
		Surgical and medical procedures	Ligament operation	01OCT2015	01OCT2015	N
			Lipoma excision	01OCT2014		Y
	C4591001 1141 11411205	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1141 11411206	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1141 11411208	Eye disorders	Myopia	01JAN1991		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1985	31DEC1985	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1991	31DEC1991	N
			Femur fracture	01JAN2005	31DEC2005	N
			Limb injury	01JAN2005	31DEC2005	N
			Meniscus injury	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN1985	31DEC1985	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Tenoplasty	01JAN2005	31DEC2005	N
	C4591001 1141 11411209	Ear and labyrinth disorders	Vertigo	01JAN2020	13AUG2020	N
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Infections and infestations	Sinusitis	01JAN2020	13AUG2020	N
		Psychiatric disorders	Generalised anxiety disorder	01JUN2020		Y
		Surgical and medical procedures	Nasal operation	13AUG2020	13AUG2020	N
			Nasal septal operation	13AUG2020	13AUG2020	N
	C4591001 1141 11411211	Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1141 11411212	Eye disorders	Myopia	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN1988		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN1991	31DEC1993	N
			Anxiety	04NOV2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1141 11411213	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2018		Y
	C4591001 1141 11411214	Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990		Y
	C4591001 1141 11411215	Eye disorders	Myopia	01JAN2005		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1141 11411218	Infections and infestations	Upper respiratory tract infection	01JAN1999	31DEC1999	N
		Psychiatric disorders	Anxiety	01SEP2003		Y
			Attention deficit hyperactivity disorder	01DEC2019		Y
			Eating disorder	01JAN2019		Y
			Insomnia	01DEC2019		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1999	31DEC1999	N
	C4591001 1141 11411219	Psychiatric disorders	Depression	01JAN1996		Y
	C4591001 1141 11411220	Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
	C4591001 1141 11411221	Infections and infestations	Appendicitis	01MAY2012	31MAY2012	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01MAY2012	31MAY2012	N
			Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1141 11411223	Infections and infestations	Appendicitis	01AUG2015	31AUG2015	N
			Pyelonephritis	01AUG2015	31AUG2015	N
		Nervous system disorders	Headache	01JAN2002		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	02AUG2015	02AUG2015	N
				18APR2019	18APR2019	N
				30MAR2017	30MAR2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01AUG2015	31AUG2015	N
			Contraceptive implant	05JUN2019		Y
	C4591001 1141 11411224	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Multiple allergies	01JAN1976		Y
		Infections and infestations	Upper respiratory tract infection	01JAN1973	31DEC1973	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Social circumstances	Postmenopause	01DEC2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1141 11411226	Investigations	Body mass index decreased	01JAN2016		Y
	C4591001 1141 11411227	Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2018		Y
	C4591001 1141 11411228	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1141 11411229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Infections and infestations	Rhinitis	01JAN2005		Y
	C4591001 1141 11411230	Eye disorders	Amblyopia	01JAN1978		Y
			Hypermetropia	01JAN1978		Y
			Myopia	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Impaired gastric emptying	01JAN2016		Y
		Hepatobiliary disorders	Biliary colic	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Injury, poisoning and procedural complications	Maternal drugs affecting foetus	01JAN1974		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Uterine malposition	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1141 11411231	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1141 11411235	Eye disorders	Myopia	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1141 11411236	Infections and infestations	Otitis media chronic	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Ear tube insertion	01JAN1997	31DEC1997	N
	C4591001 1141 11411237	Gastrointestinal disorders	Abdominal hernia	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007	31DEC2017	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2017	31DEC2017	N
			Carpal tunnel decompression	01JAN2000	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1141 11411238	Blood and lymphatic system disorders	Anaemia	30MAY2020	28AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JUN2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	30MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2006		Y
	C4591001 1141 11411239	Congenital, familial and genetic disorders	Deafness congenital	01JAN1998		Y
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1141 11411240	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1141 11411241	Nervous system disorders	Hypersomnia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
	C4591001 1141 11411242	Immune system disorders	Allergy to vaccine	01JAN2000		Y
			Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Floating patella	01JAN2007		Y
		Reproductive system and breast disorders	Polycystic ovaries	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1141 11411243	Infections and infestations	Appendicitis	01OCT2019	01OCT2019	N
			Pharyngitis	01JUN2002	01JUN2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JUN2010		Y
		Surgical and medical procedures	Appendicectomy	01OCT2019	01OCT2019	N
			Tonsillectomy	01JUN2002	01JUN2002	N
	C4591001 1141 11411245	Eye disorders	Myopia	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1141 11411246	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01FEB2001	28FEB2001	N
	C4591001 1141 11411247	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1141 11411248	Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01AUG1997	29APR2002	N
		Reproductive system and breast disorders	Female genital tract fistula	01OCT1997	01OCT1997	N
		Surgical and medical procedures	Caesarean section	29APR2002	29APR2002	N
			Vaginal fistula repair	01OCT1997	01OCT1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411249	Infections and infestations	Helicobacter gastritis	01JAN2017	01MAR2017	N
	C4591001 1141 11411250	Immune system disorders	Food allergy	01APR2012		Y
		Infections and infestations	Gastroenteritis	01NOV2016	30NOV2016	N
		Injury, poisoning and procedural complications	Stress fracture	01DEC2017	31DEC2018	N
				01OCT2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01SEP2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01APR2017	31AUG2017	N
	C4591001 1141 11411251	Eye disorders	Pterygium	01JAN2017	29FEB2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Pseudofolliculitis	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			Pterygium operation	01FEB2020	29FEB2020	N
			Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1141 11411254	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Rubber sensitivity	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Muscle strain	01JAN2018	31DEC2018	N
	C4591001 1141 11411255	Immune system disorders	Upper limb fracture Seasonal allergy	01JAN2014 01JAN2013	31DEC2014	N Y
	C4591001 1141 11411256	Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1141 11411260	Surgical and medical procedures Investigations	Uterine dilation and curettage Cystoscopy	01JAN2015 01JAN2015	31DEC2015 31DEC2015	N N
		Musculoskeletal and connective tissue disorders	Flank pain	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2013	31DEC2015	N
		Surgical and medical procedures	Ureteral stent removal	01JAN2015	31DEC2015	N
	C4591001 1141 11411262	Nervous system disorders	Ureteric operation Migraine	01JUN2015 01JAN2018	31DEC2015	N Y
	C4591001 1141 11411263	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1141 11411264	Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	07JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2013	31DEC2013	N
		Nervous system disorders	Headache	01JAN1993		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	31OCT2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1141 11411265	Eye disorders	Hypermetropia	01JAN2018		Y
			Myopia	01JAN1976		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Seasonal allergy	01JAN2019		Y
		Investigations	Precancerous cells present	01JAN2012	31DEC2014	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1987	31DEC2011	N
		Surgical and medical procedures	Endometrial ablation	01JAN2011	31DEC2011	N
			Hysterectomy	01SEP2014	30SEP2014	N
	C4591001 1141 11411266	Investigations	Biopsy skin	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma	01JAN2013		Y
	C4591001 1141 11411267	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2012	31DEC2012	N
			Gun shot wound	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Surgical and medical procedures	Internal fixation of fracture	01JAN2012	31DEC2012	N
			Jaw operation	01JAN2007	31DEC2010	N
			Open reduction of fracture	01JAN2012	31DEC2012	N
			Tracheostomy	01JAN2007	31DEC2010	N
	C4591001 1141 11411270	Congenital, familial and genetic disorders	Klippel-Feil syndrome	(b) (6) 1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Lisfranc fracture	01OCT2013	11OCT2013	N
			Meniscus injury	01JAN2016	28NOV2016	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	11OCT2013	11OCT2013	N
			Meniscus operation	28NOV2016	28NOV2016	N
			Wisdom teeth removal	01MAY2020	31MAY2020	N
	C4591001 1142 11421002	Immune system disorders	Seasonal allergy	01JAN1977		Y
	C4591001 1142 11421004	Surgical and medical procedures	Adenoidectomy	01JAN1995	31DEC1995	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Gastrectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1142 11421007	Immune system disorders	Drug hypersensitivity	05JAN2018		Y
				24JAN2006		Y
		Infections and infestations	Herpes simplex	22JAN2016		Y
		Surgical and medical procedures	Gastrectomy	01JAN2010	31DEC2010	N
			Gastroplasty	01JAN2000	31DEC2000	N
			Hysterectomy	29JUL2010	29JUL2010	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1142 11421008	Social circumstances	Menopause	24JAN2017		Y
		Surgical and medical procedures	Surgery	01JAN1993	31DEC1993	N
			Tonsillectomy	01JUN1986	30JUN1986	N
	C4591001 1142 11421014	Injury, poisoning and procedural complications	Foot fracture	24JUL2020		Y
	C4591001 1142 11421015	Gastrointestinal disorders	Gastroesophageal reflux disease	12JUN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Hepatic steatosis	02MAY2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1142 11421020	Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1142 11421022	Immune system disorders	Drug hypersensitivity	12DEC2013		Y
		Vascular disorders	Essential hypertension	10OCT2013		Y
	C4591001 1142 11421023	Immune system disorders	Drug hypersensitivity	03AUG2007		Y
	C4591001 1142 11421027	Immune system disorders	Food allergy	05APR2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
	C4591001 1142 11421028	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01NOV2012		Y
	C4591001 1142 11421033	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
	C4591001 1142 11421037	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01MAY2010	31DEC2010	N
	C4591001 1142 11421041	Surgical and medical procedures	Cholecystectomy	01DEC2008	28FEB2009	N
	C4591001 1142 11421043	Immune system disorders	Seasonal allergy	03MAR2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18MAR2013		Y
	C4591001 1142 11421046	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Rubber sensitivity	01JAN2006		Y
	C4591001 1142 11421049	Investigations	Biopsy	29AUG2012	09OCT2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421052	General disorders and administration site conditions	Drug intolerance	06OCT2009		Y
		Surgical and medical procedures	Appendicectomy	19APR2020	19APR2020	N
			Tonsillectomy	15DEC2010	15DEC2010	N
	C4591001 1142 11421056	Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1142 11421058	Immune system disorders	Drug hypersensitivity	31MAR2008		Y
	C4591001 1142 11421060	Endocrine disorders	Hypothyroidism	28FEB2014		Y
		Infections and infestations	Herpes simplex	14OCT2015		Y
		Psychiatric disorders	Depression	28OCT2019		Y
		Surgical and medical procedures	Caesarean section	28AUG2009	28AUG2009	N
	C4591001 1142 11421063	Nervous system disorders	Migraine	04AUG2006		Y
		Surgical and medical procedures	Caesarean section	12DEC2007	12DEC2007	N
				20NOV2003	20NOV2003	N
				26JUL2017	26JUL2017	N
	C4591001 1142 11421066	Immune system disorders	Drug hypersensitivity	11MAR2015		Y
	C4591001 1142 11421067	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	13DEC2019	13DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1142 11421068	Surgical and medical procedures	Caesarean section	30JUL2019	30JUL2019	N
			Mammoplasty	01JAN2011	31DEC2011	N
			Rhinoplasty	01JAN2008	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinus operation	01JAN2008	31DEC2018	N
	C4591001 1142 11421070	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1142 11421078	Gastrointestinal disorders	Colitis ulcerative	01JAN2015		Y
	C4591001 1142 11421079	Surgical and medical procedures	Ankle operation	01JAN1993	31DEC1993	N
			Lithotripsy	01JAN2018	31DEC2018	N
	C4591001 1142 11421082	Surgical and medical procedures	Ureteral stent insertion	01JAN2018	31DEC2018	N
			Caesarean section	22OCT2019	22OCT2019	N
			Spinal laminectomy	09JAN2017	09JAN2017	N
	C4591001 1142 11421084	Psychiatric disorders	Major depression	01JAN2018		Y
			Schizophrenia	01JAN2018		Y
	C4591001 1142 11421085	Immune system disorders	Drug hypersensitivity	11JUN2012		Y
		Surgical and medical procedures	Caesarean section	26JAN2011	26JAN2011	N
				30MAY2017	30MAY2017	N
				31JUL1999	31JUL1999	N
			Hysterosalpingo-oophorectomy	03OCT2019	03OCT2019	N
			Ovarian cystectomy	26JUL2019	26JUL2019	N
	C4591001 1142 11421092	Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1142 11421096	Surgical and medical procedures	Incisional drainage	01MAR2011	31MAR2011	N
			Toe amputation	01JAN1991	31DEC1991	N
	C4591001 1142 11421099	Metabolism and nutrition disorders	Hyperlipidaemia	19SEP2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	29FEB2016		Y
		Vascular disorders	Hypertension	19SEP2011		Y
	C4591001 1142 11421100	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1142 11421101	Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Gastrectomy	01JAN2016	31DEC2016	N
	C4591001 1142 11421107	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
	C4591001 1142 11421112	Surgical and medical procedures	Ankle operation	01JAN2019	31DEC2019	N
			Knee operation	01JAN2010	31DEC2010	N
			Wrist surgery	01JAN2008	31DEC2008	N
	C4591001 1142 11421115	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1142 11421124	Surgical and medical procedures	Fracture treatment	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1142 11421126	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1994		Y
		Surgical and medical procedures	Vascular stent insertion	01JAN2013	31DEC2013	N
		Vascular disorders	May-Thurner syndrome	01JAN2013		Y
	C4591001 1142 11421129	Surgical and medical procedures	Female sterilisation	25SEP2007	25SEP2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421130	Endocrine disorders	Hyperthyroidism	07NOV2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2020	31DEC2020	N
	C4591001 1142 11421131	Surgical and medical procedures	Salpingectomy	10JUN2019	10JUN2019	N
	C4591001 1142 11421138	Immune system disorders	Hypersensitivity	01JAN1989		Y
	C4591001 1142 11421141	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1142 11421142	Skin and subcutaneous tissue disorders	Alopecia areata	01JAN2015		Y
		Surgical and medical procedures	Salpingectomy	01JAN1999	31DEC1999	N
	C4591001 1142 11421149	Surgical and medical procedures	Shoulder operation	01JAN2014	31DEC2014	N
	C4591001 1142 11421150	Surgical and medical procedures	Mammoplasty	01JAN2009	31DEC2009	N
			Synovial cyst removal	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JAN1999	31DEC1999	N
	C4591001 1142 11421153	Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2015	31DEC2015	N
	C4591001 1142 11421155	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
	C4591001 1142 11421157	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1142 11421158	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer stage II	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Colectomy	01JAN2015	31DEC2015	N
	C4591001 1142 11421163	Endocrine disorders	Hyperthyroidism	01JAN2005		Y
	C4591001 1142 11421173	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1142 11421178	Nervous system disorders	Sciatica	10JUL2020		Y
	C4591001 1142 11421181	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Rubber sensitivity	01JAN1966		Y
		Infections and infestations	Influenza	18FEB2020	20FEB2020	N
		Musculoskeletal and connective tissue disorders	Juvenile idiopathic arthritis	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2002	31DEC2002	N
			Anorectal operation	01JAN1990	31DEC1990	N
			Caesarean section	17JAN1999	17JAN1999	N
			Incisional drainage	01JAN1983	31DEC1983	N
			Knee operation	01JAN1984	31DEC1984	N
				01JAN1996	31DEC1996	N
			Uterine polypectomy	16NOV2017	16NOV2017	N
	C4591001 1142 11421182	Surgical and medical procedures	Pleural operation	01JAN2014	31JAN2014	N
	C4591001 1142 11421183	Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
	C4591001 1142 11421187	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Surgical and medical procedures	Elbow operation	01JAN2007	31DEC2007	N
				01JAN2016	31DEC2016	N
			Mammoplasty	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2008	31DEC2008	N
	C4591001 1142 11421188	Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31JAN2016	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1142 11421190	Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1142 11421194	Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N
			Knee operation	01JAN2009	31DEC2009	N
			Nasal septal operation	01JAN2009	31DEC2009	N
	C4591001 1142 11421197	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Immune system disorders	Allergy to vaccine	01JAN1972		Y
			Drug hypersensitivity	01JAN1972		Y
	C4591001 1142 11421198	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Surgical and medical procedures	Oocyte harvest	01JAN2020	31DEC2020	N
	C4591001 1142 11421199	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1142 11421203	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Hernia repair	01JAN2008	31DEC2008	N
			Urethral operation	01JAN2012	31DEC2012	N
	C4591001 1142 11421205	Surgical and medical procedures	Skin lesion removal	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421206	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1142 11421212	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
	C4591001 1142 11421214	Surgical and medical procedures	Limb operation	01JAN1998	31DEC1998	N
	C4591001 1142 11421218	Immune system disorders	Metabolic surgery Drug hypersensitivity	01JAN2019 01JAN1977	31DEC2019	N Y
	C4591001 1142 11421219	Surgical and medical procedures Immune system disorders	Tonsillectomy Drug hypersensitivity	01JAN1983 01JAN1978	31DEC1978	Y N
	C4591001 1142 11421220	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
	C4591001 1142 11421222	Vascular disorders Ear and labyrinth disorders	Hypertension Deafness neurosensory	01JAN2015 01JAN1998		Y Y
	C4591001 1142 11421223	Blood and lymphatic system disorders	Anaemia	01JAN1991		Y
	C4591001 1142 11421229	Endocrine disorders Neoplasms benign, malignant and unspecified (incl cysts and polyps) Surgical and medical procedures Immune system disorders	Autoimmune thyroiditis Melanocytic naevus Tonsillectomy Drug hypersensitivity	01JAN2014 01JAN2007 01JAN2007 01JAN2015	31DEC2007	Y Y N Y
	C4591001 1142 11421231	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Appendectomy Caesarean section	01NOV2008 29FEB2016	30NOV2008 29FEB2016	N N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	29FEB2020	29FEB2020	N
	C4591001 1142 11421233	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1142 11421234	Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN2005	31DEC2005	N
			Gastric bypass	01JAN2017	31DEC2017	N
	C4591001 1142 11421235	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
	C4591001 1142 11421239	Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Knee operation	01JAN2008	31DEC2008	N
				01JAN2013	31DEC2013	N
	C4591001 1142 11421242	Surgical and medical procedures	Diplopia correction	01JAN1982	31DEC1982	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Essential hypertension	01OCT2018		Y
	C4591001 1142 11421244	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Ocular rosacea	01JAN2018		Y
		Surgical and medical procedures	Hip surgery	01DEC2009	31DEC2009	N
			Plastic surgery to the face	01JAN1980	31DEC1980	N
	C4591001 1142 11421245	Surgical and medical procedures	Inguinal hernia repair	01JAN1973	31DEC1973	N
	C4591001 1142 11421250	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2000		Y
				01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Jaw operation	01JAN2005	31DEC2005	N
			Lung operation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1142 11421256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2015		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Essential hypertension	01DEC2009		Y
	C4591001 1142 11421258	Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	31OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1142 11421261	Immune system disorders	Allergy to animal	01JAN2005		Y
			Milk allergy	01JAN2018		Y
			Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Pilonidal sinus repair	01MAR2020	31MAR2020	N
	C4591001 1142 11421262	Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1142 11421264	Immune system disorders	Drug hypersensitivity	01DEC1986		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01OCT1989		Y
		Surgical and medical procedures	Gingival graft	01JAN1994	31DEC1994	N
			Mammoplasty	01SEP2000	30SEP2000	N
			Ovarian cystectomy	01AUG2008	31AUG2008	N
			Tenotomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1984	31DEC1984	N
			Wisdom teeth removal	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421265	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1142 11421269	Psychiatric disorders	Insomnia	01JAN2011		Y
	C4591001 1142 11421271	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Psychiatric disorders	Depression	05OCT2019		Y
		Surgical and medical procedures	Caesarean section	08JUL2019	08JUL2019	N
			Gastrectomy	09FEB2009	09FEB2009	N
			Gastrectomy	01SEP2016	30SEP2016	N
	C4591001 1142 11421274	Surgical and medical procedures	Shoulder operation	01JAN2013	31DEC2013	N
	C4591001 1142 11421277	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAR2020		Y
	C4591001 1142 11421280	Immune system disorders	Rubber sensitivity	01JAN1975		Y
		Surgical and medical procedures	Epididymal operation	01JAN2012	31DEC2012	N
	C4591001 1142 11421282	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1986	31DEC1995	N
	C4591001 1142 11421283	Immune system disorders	Drug hypersensitivity	23DEC2005		Y
		Surgical and medical procedures	Female sterilisation	28OCT2004	28OCT2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421284	Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
			Intra-uterine contraceptive device insertion	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN2017	31DEC2017	N
	C4591001 1142 11421287	Infections and infestations	Latent tuberculosis	16JUL2017	21SEP2018	N
		Investigations	Biopsy breast	31OCT2011	31OCT2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01APR2010	31OCT2011	N
		Social circumstances	Organ donor	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Breast conserving surgery	31OCT2011	31OCT2011	N
	C4591001 1142 11421290	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Infections and infestations	Pneumonia	01MAY2016	31JUL2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1142 11421292	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1142 11421293	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1142 11421295	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1142 11421298	Surgical and medical procedures	Ankle operation	01JAN2012	31DEC2012	N
	C4591001 1142 11421299	Surgical and medical procedures	Cardiac ablation	01JAN2005	31DEC2005	N
	C4591001 1142 11421300	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	28AUG2019	28AUG2019	N
	C4591001 1142 11421303	Surgical and medical procedures	Limb operation	01JAN1998	31DEC1998	N
	C4591001 1142 11421306	Cardiac disorders	Mitral valve prolapse	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
	C4591001 1142 11421307	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Rubber sensitivity	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
	C4591001 1142 11421313	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1142 11421314	Endocrine disorders	Hyperthyroidism	01JUN2020		Y
	C4591001 1142 11421315	Immune system disorders	Allergy to arthropod sting	01JAN2008		Y
	C4591001 1142 11421317	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009	31DEC2015	N
	C4591001 1142 11421322	Immune system disorders	Seasonal allergy	15DEC2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	12OCT2020	12OCT2020	N
		Skin and subcutaneous tissue disorders	Acne	06DEC2017		Y
	C4591001 1142 11421328	Injury, poisoning and procedural complications	Foot fracture	01JAN2017	31DEC2017	N
	C4591001 1142 11421336	Cardiac disorders	Sinus arrhythmia	12JUN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Rubber sensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2007	31JAN2007	N
		Surgical and medical procedures	Adenoidectomy	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1145 11451001	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1145 11451002	Immune system disorders	Allergy to arthropod sting	30JUN1980		Y
			Seasonal allergy	01JAN1980		Y
	C4591001 1145 11451003	Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2012		Y
		Investigations	Blood cholesterol increased	30JUN2012		Y
	C4591001 1145 11451004	Immune system disorders	Drug hypersensitivity	30JUN2000		Y
	C4591001 1145 11451007	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1145 11451011	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1145 11451017	Immune system disorders	Allergy to arthropod sting	01JAN2018		Y
			Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1145 11451019	Surgical and medical procedures	Vaginal ring	01SEP1997		Y
	C4591001 1145 11451020	Skin and subcutaneous tissue disorders	Rash pruritic	01JAN2002		Y
	C4591001 1145 11451021	Immune system disorders	Seasonal allergy	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451022	Immune system disorders	Food allergy	01JAN2006		Y
			Seasonal allergy	01JAN1997		Y
		Infections and infestations	Sepsis syndrome	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001	31DEC2005	N
		Surgical and medical procedures	Prophylaxis against HIV infection	01JAN2016		Y
			Tonsillectomy	01JAN2014	31DEC2014	N
			Vitamin supplementation	01JAN2018		Y
	C4591001 1145 11451025	Eye disorders	Diabetic eye disease	01JAN2017		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2000	31DEC2000	N
			Spinal fracture	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JUN2020		Y
			Lumbar puncture normal	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Intervertebral disc protrusion	14JUL2000		Y
		Nervous system disorders	Migraine	01JAN2018		Y
			Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1145 11451026	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Blood cholesterol increased	12AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	10JUL2020	10JUL2020	N
			Rhinitis allergic	10JUL2020		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2005		Y
	C4591001 1145 11451030	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1995		Y
	C4591001 1145 11451031	Injury, poisoning and procedural complications	Back injury	01JAN2013	28FEB2014	N
		Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Dental implantation	01OCT2018	31OCT2018	N
			Spinal operation	01FEB2014	28FEB2014	N
	C4591001 1145 11451034	Infections and infestations	Ear infection	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Liposuction	01JAN2000	31DEC2000	N
	C4591001 1145 11451036	Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1145 11451037	Metabolism and nutrition disorders	Monogenic diabetes	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	10DEC2018	N
		Surgical and medical procedures	Breast conserving surgery	10DEC2018	10DEC2018	N
			Radiotherapy	01JAN2019	28FEB2019	N
	C4591001 1145 11451039	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1985		Y
		Nervous system disorders	Cerebrovascular accident	01JAN1998	31DEC1998	N
	C4591001 1145 11451042	Blood and lymphatic system disorders	Anaemia	01JAN1990	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Gastrointestinal disorders	Gastric ulcer	01JAN2007	31DEC2014	N	
		Hepatobiliary disorders	Cholecystitis	01JUL1994	31AUG1994	N	
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y	
				01JAN2018		Y	
				Reaction to food additive	01JAN1996		Y
				Seasonal allergy	01MAR2020		Y
			Infections and infestations	Bronchitis	01MAY2011	31MAY2011	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013	31DEC2015	N	
				Obesity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1997		Y	
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2011	31DEC2011	N	
		Surgical and medical procedures	Cholecystectomy	01AUG1994	31AUG1994	N	
				Gastric bypass	01OCT1998	31OCT1998	N
				Loop electrosurgical excision procedure	01NOV2002	30NOV2002	N
				Uterine dilation and curettage	01JAN2010	31DEC2010	N
				Vascular graft	01JAN2015	31JAN2015	N
	C4591001 1145 11451043	Pregnancy, puerperium and perinatal conditions	Delivery	01AUG2019	31AUG2019	N	
					01SEP2015	30SEP2015	N
	C4591001 1145 11451044	Infections and infestations	Influenza	01JAN1980	31DEC1980	N	
	C4591001 1145 11451051	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y	
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y	
	C4591001 1145 11451053	Immune system disorders	Food allergy	01JAN2000		Y	
				Seasonal allergy	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Endoscopy upper gastrointestinal tract	01JAN2015	31DEC2015	N
	C4591001 1145 11451057	Immune system disorders	Food allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
	C4591001 1145 11451059	Hepatobiliary disorders	Gallbladder disorder	01JAN2019	31DEC2019	N
		Infections and infestations	Ear infection	01JAN2018		Y
		Investigations	Cardiac murmur	01JAN2000	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
			Hypermobility syndrome	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1145 11451060	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2015	31JAN2015	N
		Investigations	Cardiac murmur	01JAN1992	31DEC2010	N
		Nervous system disorders	Headache	01JAN1985		Y
	C4591001 1145 11451063	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	10JAN2018	10JAN2018	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2003	31DEC2003	N
	C4591001 1145 11451064	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Foot operation	01JAN2003	31DEC2003	N
			Intervertebral disc operation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
	C4591001 1145 11451067	Surgical and medical procedures	Appendicectomy	01JUL1981	31JUL1981	N
			Nephrectomy	01JUL1981	31JUL1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1145 11451068	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1145 11451071	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Surgical and medical procedures	Fasciotomy	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1145 11451074	Surgical and medical procedures	Pilonidal sinus repair	01JAN1992	31DEC1992	N
	C4591001 1145 11451075	Infections and infestations	Herpes virus infection	01JAN2014		Y
	C4591001 1145 11451077	Nervous system disorders	Hypoaesthesia	01JAN2017	31DEC2017	N
			Nerve compression	01JAN2016	31DEC2016	N
			Thoracic outlet syndrome	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451079	Skin and subcutaneous tissue disorders	Acne	01JAN2008	31DEC2010	N
			Eczema	01JAN2008	31DEC2010	N
	C4591001 1145 11451080	Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01MAR2020	31MAR2020	N
		Injury, poisoning and procedural complications	Ligament rupture	24JUL2020		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1145 11451081	Surgical and medical procedures	Appendicectomy	01MAR2020	31MAR2020	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
	C4591001 1145 11451082	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Cyst removal	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1145 11451085	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970	31DEC1982	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1972		Y
	C4591001 1145 11451086	Immune system disorders	Seasonal allergy	01JAN1976	31DEC1987	N
		Investigations	Colonoscopy	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1145 11451087	Surgical and medical procedures	Polypectomy	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1145 11451088	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	07AUG2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Oophorectomy	01FEB2018	28FEB2018	N
			Uterine dilation and curettage	01JAN2012	31DEC2012	N
	C4591001 1145 11451090	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1987	31DEC1987	N
			Gastroesophageal reflux disease	01JAN2012		Y
		General disorders and administration site conditions	Hyperplasia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Clostridial infection	01JAN2004	31DEC2004	N
			Giardiasis	01JAN2004	31DEC2004	N
			Herpes virus infection	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990	31DEC2020	N
		Surgical and medical procedures	Antiviral prophylaxis	09AUG2020	09AUG2020	N
			Ligament operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2018	31DEC2020	N
	C4591001 1145 11451091	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
	C4591001 1145 11451093	Immune system disorders	Seasonal allergy	01JAN1976		Y
	C4591001 1145 11451094	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1145 11451097	Surgical and medical procedures	Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1145 11451101	Injury, poisoning and procedural complications	Back injury	01JAN2004		Y
	C4591001 1145 11451103	Endocrine disorders	Thyroid mass	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Herpes virus infection	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1986	31DEC1986	N
			Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1145 11451104	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Surgical and medical procedures	Knee operation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451106	Pregnancy, puerperium and perinatal conditions	Delivery	15DEC2014	15DEC2014	N
		Psychiatric disorders	Anxiety	01MAY2018		Y
			Depression	01MAY2018		Y
	C4591001 1145 11451107	Investigations	Blood cholesterol increased	01JAN2018		Y
	C4591001 1145 11451110	Immune system disorders	Drug hypersensitivity	01MAR2019		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
	C4591001 1145 11451112	Skin and subcutaneous tissue disorders	Idiopathic urticaria	01JAN1969	31DEC1980	N
	C4591001 1146 11461002	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2010		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1146 11461004	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1146 11461007	Immune system disorders	Hypersensitivity	02OCT2006		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
	C4591001 1146 11461009	Immune system disorders	Seasonal allergy	01AUG1996		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1146 11461010	Metabolism and nutrition disorders	Hyperglycaemia	01OCT2009		Y
		Psychiatric disorders	Anxiety	06JAN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12JUN2018		Y
	C4591001 1146 11461011	Metabolism and nutrition disorders	Gout	01MAR2019		Y
			Type 2 diabetes mellitus	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461013	Immune system disorders	Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
				01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
	C4591001 1146 11461021	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1146 11461028	Immune system disorders	Seasonal allergy	01SEP1982		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Aortic valve replacement	08MAR2018	08MAR2018	N
		Vascular disorders	Aortic stenosis	01SEP2017	08MAR2018	N
	C4591001 1146 11461030	Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
	C4591001 1146 11461031	Surgical and medical procedures	Spinal fusion surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461034	Gastrointestinal disorders	Gastroesophageal reflux disease	21APR2000		Y
		Psychiatric disorders	Depression	13MAR2020		Y
	C4591001 1146 11461038	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
	C4591001 1146 11461041	Metabolism and nutrition disorders	Hypercholesterolaemia	15JAN2019		Y
	C4591001 1146 11461043	Skin and subcutaneous tissue disorders	Acne	13AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461044	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Surgical and medical procedures	Gastrectomy	01JAN2013	31DEC2013	N
	C4591001 1146 11461049	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y
		Infections and infestations	Acute sinusitis	01JAN2010		Y
			Myringitis	01JAN2004		Y
		Investigations	Cardiac murmur	01JAN1977		Y
		Nervous system disorders	Facial paralysis	28AUG1995		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1146 11461052	Psychiatric disorders	Binge eating	01JUN1990		Y
			Insomnia	08JAN2018		Y
	C4591001 1146 11461053	Cardiac disorders	Coronary artery occlusion	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUL2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461054	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01MAY2015	31MAY2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Surgical and medical procedures	Seizure prophylaxis	01JAN2015		Y
	C4591001 1146 11461055	Immune system disorders	Rubber sensitivity	01JAN2016		Y
		Surgical and medical procedures	Gastric bypass	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461058	Injury, poisoning and procedural complications	Ligament rupture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Ligament operation	01JAN2007	31DEC2007	N
	C4591001 1146 11461059	Cardiac disorders	Cardiac failure	01FEB2020		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN2000	31DEC2000	N
	C4591001 1146 11461061	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
	C4591001 1146 11461070	Social circumstances	Postmenopause	01SEP2017		Y
	C4591001 1146 11461071	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Spinal laminectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461076	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1146 11461077	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1146 11461080	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	16DEC2016	23DEC2016	N
			Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Deep vein thrombosis	01JAN2016	16DEC2016	N
			Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461081	Surgical and medical procedures	Caesarean section	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1146 11461082	Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1146 11461083	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
	C4591001 1146 11461084	Psychiatric disorders	Bipolar II disorder	01SEP2010		Y
	C4591001 1146 11461085	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
	C4591001 1146 11461086	Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2013		Y
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1146 11461090	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2020	17MAR2020	N
		Surgical and medical procedures	Hysterectomy	17MAR2017	17MAR2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461091	Vascular disorders	Hypertension	01NOV2000		Y
	C4591001 1146 11461093	Nervous system disorders	Migraine	01FEB2017		Y
	C4591001 1146 11461094	Vascular disorders	Hypertension	01JUL2015		Y
	C4591001 1146 11461096	Psychiatric disorders	Generalised anxiety disorder	01APR2020		Y
	C4591001 1146 11461100	Endocrine disorders	Hypothyroidism	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Coeliac disease	13AUG2003		Y
	C4591001 1146 11461102	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461103	Injury, poisoning and procedural complications	Ankle fracture	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
			Fracture treatment	01JAN1993	31DEC1993	N
	C4591001 1146 11461104	Gastrointestinal disorders	Coeliac disease	01JUL2015		Y
			Irritable bowel syndrome	01JUL2005		Y
	C4591001 1146 11461108	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
	C4591001 1146 11461113	Nervous system disorders	Migraine	01JAN1997		Y
	C4591001 1146 11461116	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1146 11461119	Psychiatric disorders	Anxiety	01NOV2012		Y
			Bipolar disorder	01APR2014		Y
	C4591001 1146 11461123	Psychiatric disorders	Anxiety	01MAY2010		Y
			Depression	01MAY2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01APR2000		Y
	C4591001 1146 11461124	Psychiatric disorders	Anxiety	01MAY2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461126	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1146 11461129	Blood and lymphatic system disorders	Iron deficiency anaemia	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01SEP2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01SEP2003		Y
	C4591001 1146 11461140	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1146 11461141	Investigations	Blood cholesterol increased	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2005		Y
		Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 1146 11461142	Surgical and medical procedures	Eyelid operation	01OCT2015	31OCT2015	N
	C4591001 1146 11461145	Endocrine disorders	Hypothyroidism	01OCT1992		Y
	C4591001 1146 11461146	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1146 11461147	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1146 11461155	Social circumstances	Postmenopause	01JUN2018		Y
	C4591001 1146 11461157	Investigations	Blood cholesterol increased	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461158	Psychiatric disorders	Attention deficit hyperactivity disorder	01SEP1986		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461159	Endocrine disorders	Hypothyroidism	01FEB2015		Y
		Social circumstances	Postmenopause	01FEB2019		Y
	C4591001 1146 11461160	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Meniscus operation	01JAN2013	31DEC2013	N
	C4591001 1146 11461163	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1146 11461166	Investigations	Blood cholesterol increased	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1146 11461168	Metabolism and nutrition disorders	Obesity	01NOV2007	16NOV2017	N
		Surgical and medical procedures	Gastrectomy	16NOV2017	16NOV2017	N
	C4591001 1146 11461170	Injury, poisoning and procedural complications	Ligament rupture	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
	C4591001 1146 11461172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1146 11461176	Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
	C4591001 1146 11461183	Injury, poisoning and procedural complications	Ligament rupture	01DEC2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ligament operation	01DEC2014	31DEC2014	N
	C4591001 1146 11461184	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1146 11461185	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1146 11461186	Surgical and medical procedures	Umbilical hernia repair	01DEC2019	31DEC2019	N
			Urinary bladder suspension	01JUN2018	30JUN2018	N
	C4591001 1146 11461187	Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	01JAN2018		Y
	C4591001 1146 11461190	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2012		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Perinatal depression	01JAN2020		Y
	C4591001 1146 11461192	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Appendectomy	01JAN2001	31DEC2001	N
			Caesarean section	01JAN2008	31DEC2008	N
	C4591001 1146 11461195	Social circumstances	Menopause	01FEB2018		Y
	C4591001 1146 11461196	Gastrointestinal disorders	Coeliac disease	01APR2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1984	31DEC1984	N
	C4591001 1146 11461197	Infections and infestations	Pneumonia	07JAN2019	14JAN2019	N
	C4591001 1146 11461198	Investigations	Cardiac murmur	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461199	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1146 11461200	Investigations	Blood cholesterol increased	01JAN2003		Y
		Nervous system disorders	Syncope	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1146 11461201	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2015		Y
		Psychiatric disorders	Anxiety	01JUL2015		Y
			Depression	01JUN1990		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1146 11461202	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1146 11461204	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2008		Y
	C4591001 1146 11461205	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	14FEB2003	31MAR2013	N
	C4591001 1146 11461206	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1146 11461207	Blood and lymphatic system disorders	Thrombocytopenia	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Abnormal loss of weight	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1146 11461210	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1146 11461211	Gastrointestinal disorders	Crohn's disease	01SEP2001	31JAN2004	N
		Hepatobiliary disorders	Cholelithiasis	06DEC2011	31DEC2011	N
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	02JAN2012	02JAN2012	N
			Colectomy	04JAN2004	04JAN2004	N
			Ileectomy	04JAN2004	04JAN2004	N
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1146 11461216	Musculoskeletal and connective tissue disorders	Bone cyst	01AUG2009	10MAR2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01SEP1992	08MAY2013	N
		Surgical and medical procedures	Cyst drainage	10MAR2010	10MAR2010	N
			Nasal septal operation	08MAY2013	08MAY2013	N
	C4591001 1146 11461218	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1146 11461219	Psychiatric disorders	Anxiety	01NOV2019		Y
			Bipolar disorder	01JAN2002		Y
	C4591001 1146 11461220	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAY2020		Y
		Immune system disorders	Perennial allergy	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1146 11461221	Investigations	Blood triglycerides increased	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461225	Immune system disorders	Drug hypersensitivity	01FEB1995		Y
		Infections and infestations	Appendicitis	01AUG2004	31AUG2004	N
			Tonsillitis	01JAN1995	31JAN1995	N
		Psychiatric disorders	Postpartum anxiety	01DEC2016	31DEC2017	N
		Surgical and medical procedures	Appendectomy	01AUG2004	31AUG2004	N
			Female sterilisation	20SEP2016	20SEP2016	N
			Tonsillectomy	01JAN1995	31JAN1995	N
	C4591001 1146 11461227	Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
	C4591001 1146 11461229	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1991	31DEC1991	N
			Caesarean section	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461237	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1146 11461238	Gastrointestinal disorders	Abdominal pain	01JUL2020		Y
		Immune system disorders	Food allergy	01JAN2010		Y
	C4591001 1146 11461239	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461240	Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1146 11461241	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1146 11461243	Immune system disorders	Allergy to animal	01JAN2015		Y
		Psychiatric disorders	Depression	01APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2019		Y
	C4591001 1146 11461245	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Appendicectomy	01JAN1991	31DEC1991	N
	C4591001 1146 11461246†	Endocrine disorders	Hypogonadism	01JAN2010		Y
		Investigations	HIV test positive	01JAN2012		Y
	C4591001 1146 11461249	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1146 11461251	Congenital, familial and genetic disorders	Sickle cell anaemia	01JAN1988		Y
		Endocrine disorders	Hyperthyroidism	01JAN1989	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Radiotherapy to thyroid	01JAN2014	31DEC2014	N
	C4591001 1146 11461263	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
		Psychiatric disorders	Schizophrenia	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461265	Injury, poisoning and procedural complications	Meniscus injury	01JAN2018		Y
	C4591001 1146 11461267	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461268	Cardiac disorders	Palpitations	01JAN2003		Y
		Immune system disorders	Dust allergy	01JAN1995		Y
	C4591001 1146 11461269	Social circumstances	Postmenopause	01NOV2017		Y
	C4591001 1146 11461270	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1146 11461271	Eye disorders	Mydriasis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1146 11461272	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1146 11461273	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Renal and urinary disorders	Dysuria	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2016		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461274	Vascular disorders	Deep vein thrombosis	15JUN2020	21AUG2020	N
			Hypertension	01APR2005		Y
	C4591001 1146 11461275	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1146 11461276	Nervous system disorders	Epilepsy	01JAN2013		Y
			Syncope	01JAN2013		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2013	31DEC2013	N
	C4591001 1146 11461277	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Amnesia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1146 11461278	Endocrine disorders	Autoimmune thyroiditis	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461279	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
	C4591001 1146 11461280	Immune system disorders	Food allergy	01JAN1996		Y
			Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Insulin resistant diabetes	01JAN2018		Y
		Psychiatric disorders	Anxiety	01SEP2013		Y
			Depression	01SEP2013		Y
	C4591001 1146 11461281	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Nervous system disorders	Carotid artery dissection	01OCT2011	31OCT2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1146 11461282	Endocrine disorders	Hypothyroidism	01JAN2009		Y
	C4591001 1146 11461283	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN1985		Y
	C4591001 1146 11461285	Gastrointestinal disorders	Coeliac disease	01JAN2005		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1146 11461287	Vascular disorders	Raynaud's phenomenon	01JAN1992		Y
	C4591001 1146 11461288	Immune system disorders	Allergy to animal	01JUN2020		Y
	C4591001 1146 11461289	Congenital, familial and genetic disorders	Tourette's disorder	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Autism spectrum disorder	01JAN2004		Y
			Depression	01JAN2018		Y
	C4591001 1146 11461290	Renal and urinary disorders	Urinary incontinence	01JAN2019		Y
		Social circumstances	Postmenopause	01DEC2018		Y
	C4591001 1146 11461292	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2013		Y
			Generalised anxiety disorder	01JAN2014		Y
	C4591001 1146 11461293	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1971	31DEC1971	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Splenectomy	01JAN1971	31DEC1971	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1146 11461294	Psychiatric disorders	Anxiety	01AUG1986		Y
			Depression	01AUG1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1999		Y
	C4591001 1146 11461295	Immune system disorders	Drug hypersensitivity	01OCT1978		Y
			Dust allergy	01OCT1990		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01SEP2020		Y
	C4591001 1146 11461296	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461297	Vascular disorders	Hypertension	01OCT2008		Y
	C4591001 1146 11461300	Skin and subcutaneous tissue disorders	Acne	01JUL2019		Y
	C4591001 1146 11461301	Investigations	Blood cholesterol increased	01JAN2018		Y
	C4591001 1146 11461302	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1146 11461304	Endocrine disorders	Hypothyroidism	01AUG2000		Y
		Immune system disorders	Drug hypersensitivity	01MAR1993		Y
		Surgical and medical procedures	Appendectomy	01MAR1998	31MAR1998	N
			Gastric banding	01OCT2010	31OCT2010	N
	C4591001 1146 11461307	Congenital, familial and genetic disorders	Factor V deficiency	01OCT2002		Y
	C4591001 1146 11461308	Respiratory, thoracic and mediastinal disorders	Asthma	01OCT1997		Y
	C4591001 1146 11461310	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1146 11461311	Social circumstances	Menopause	01OCT2017		Y
	C4591001 1146 11461312	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Multiple allergies	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1146 11461315	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2020		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1146 11461316	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1146 11461317	Eye disorders	Glaucoma	01OCT2017		Y
	C4591001 1146 11461318	Social circumstances	Postmenopause	01AUG2019		Y
	C4591001 1146 11461322	Endocrine disorders	Basedow's disease	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1994		Y
	C4591001 1146 11461323	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461324	Metabolism and nutrition disorders	Gout	01MAR2018		Y
		Renal and urinary disorders	Nephrolithiasis	19NOV2019	19NOV2019	N
		Skin and subcutaneous tissue disorders	Eczema	01OCT1996	31OCT2003	N
		Surgical and medical procedures	Renal stone removal	29NOV2019	29NOV2019	N
	C4591001 1146 11461325	Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1146 11461326	Surgical and medical procedures	Appendicectomy	01DEC1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	01JAN2006	31DEC2006	N
			Carpal tunnel decompression	01JAN1999	31DEC1999	N
	C4591001 1146 11461328	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1146 11461332	Psychiatric disorders	Anxiety	01AUG2020		Y
			Depression	01AUG2020		Y
	C4591001 1146 11461333	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Turbinectomy	01JAN2010	31DEC2010	N
	C4591001 1146 11461334	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009	31DEC2009	N
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1146 11461335	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1146 11461337	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1146 11461338	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1146 11461340	Metabolism and nutrition disorders	Gout	01JAN2015		Y
	C4591001 1146 11461341	Immune system disorders	Drug hypersensitivity	01OCT2017		Y
		Surgical and medical procedures	Lipoma excision	01JAN1977		Y
				01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1979	31DEC1979	N
	C4591001 1146 11461342	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1146 11461343	Nervous system disorders	Migraine	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2007		Y
	C4591001 1146 11461344	Endocrine disorders	Thyroid mass	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Bile duct stone	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1146 11461346	Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1146 11461349	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Bunion operation	01JAN2013	31DEC2013	N
			Caesarean section	01JAN1995	31DEC1995	N
	C4591001 1146 11461350	Infections and infestations	Lyme disease	01AUG2019	30SEP2019	N
		Psychiatric disorders	Depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461351	Ear and labyrinth disorders	Motion sickness	01JAN2018		Y
		Gastrointestinal disorders	Dry mouth	01OCT2019		Y
			Gastrooesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1146 11461352	Immune system disorders	Seasonal allergy	01OCT2019		Y
		Infections and infestations	Oral herpes	01OCT2017		Y
	C4591001 1146 11461353	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
	C4591001 1146 11461354	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1146 11461357	Gastrointestinal disorders	Haemorrhoids	01JAN2006		Y
		Infections and infestations	Herpes simplex	01JUL2020		Y
	C4591001 1146 11461358	Psychiatric disorders	Anxiety	01FEB2020		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
	C4591001 1146 11461359	Psychiatric disorders	Anxiety	01JAN2002		Y
	C4591001 1146 11461361	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
	C4591001 1146 11461364	Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461365	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1146 11461366	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1146 11461367	Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1146 11461369	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JUN2019	31JUL2019	N
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
			Thyroidectomy	01JUN2019	30JUN2019	N
	C4591001 1146 11461370	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1983	31DEC1983	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2018	29FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Surgical and medical procedures	Meniscus removal	01FEB2020	29FEB2020	N
	C4591001 1146 11461371	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
	C4591001 1146 11461372	Skin and subcutaneous tissue disorders	Rash	01AUG2020		Y
	C4591001 1146 11461373	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2008		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1146 11461375	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2000		Y
	C4591001 1146 11461376	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1146 11461377	Investigations	Blood cholesterol increased	01JAN2019		Y
	C4591001 1146 11461378	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
	C4591001 1146 11461379	Investigations	Blood testosterone decreased	01OCT2008		Y
		Nervous system disorders	Migraine	01OCT2019		Y
		Psychiatric disorders	Anxiety	01OCT2015		Y
	C4591001 1146 11461380	Ear and labyrinth disorders	Tinnitus	01SEP2020	01OCT2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1146 11461381	Immune system disorders	Multiple allergies	01JAN1992		Y
	C4591001 1146 11461382	Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
			Type 2 diabetes mellitus	01OCT2017		Y
	C4591001 1146 11461384	Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Vascular disorders	Deep vein thrombosis	01JAN2020	29FEB2020	N
	C4591001 1146 11461385	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Helicobacter infection	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004	31JUL2020	N
	C4591001 1146 11461386	Vascular disorders	Hypertension	01JAN2015	31DEC2017	N
		Endocrine disorders	Hyperprolactinaemia	01OCT2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01OCT2017		Y
		Immune system disorders	Seasonal allergy	01OCT2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01OCT2015		Y
	C4591001 1146 11461387	Psychiatric disorders	Insomnia	01OCT2019		Y
		Psychiatric disorders	Depression	01OCT1994		Y
		Surgical and medical procedures	Mastectomy	01FEB2018	28FEB2018	N
			Oophorectomy bilateral	28OCT2020	31OCT2020	N
	C4591001 1146 11461388	Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Diabetic foot	01JAN2017	31DEC2019	N
		Surgical and medical procedures	Gastrectomy	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461390	Infections and infestations	Chronic sinusitis	01OCT2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT1990		Y
			Type 2 diabetes mellitus	01OCT2019		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Depression	01OCT2019		Y
		Vascular disorders	Hypertension	01OCT2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461391	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
	C4591001 1146 11461393	Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1146 11461394	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2017	31DEC2017	N
	C4591001 1146 11461395	Surgical and medical procedures	Mastoidectomy	01OCT1980	31OCT1980	N
	C4591001 1146 11461397	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1991		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Neurectomy	01JAN2012	31DEC2012	N
	C4591001 1146 11461399	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
	C4591001 1147 11471001	General disorders and administration site conditions	Asthenia	01OCT2011	31DEC2015	N
			Pain	01DEC2010	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2000	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2010		Y
				01OCT2012		Y
			Back pain	01FEB2013		Y
			Joint range of motion decreased	01SEP2010		Y
			Rotator cuff syndrome	01SEP2010		Y
			Tendonitis	01OCT2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUL2010		Y
			Post-traumatic stress disorder	01JUL2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2013	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2010		Y
		Vascular disorders	Hypertension	01JUL2010	31DEC2017	N
	C4591001 1147 11471003	Blood and lymphatic system disorders	Leukopenia	14SEP2014	31DEC2019	N
		Injury, poisoning and procedural complications	Joint dislocation	01JUN2018	15JUN2018	N
		Investigations	Blood pressure increased	15JAN2020	15JAN2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	14SEP2014	31DEC2019	N
		Surgical and medical procedures	Knee operation	15JUN2018	15JUN2018	N
	C4591001 1147 11471007	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006		Y
		Social circumstances	Menarche	01JAN1996		Y
	C4591001 1147 11471010	Endocrine disorders	Hypothyroidism	27AUG2012		Y
		Eye disorders	Keratitis	01NOV2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	29MAR2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1988		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1147 11471011	Gastrointestinal disorders	Barrett's oesophagus	01JAN2014		Y
			Gastric ulcer	01JUN2014		Y
		General disorders and administration site conditions	Chest pain	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Nervous system disorders	Dizziness	01JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
	C4591001 1147 11471013	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Dry eye	12JUL2014		Y
			Vitreous detachment	12JUN2014		Y
			Vitreous floaters	12JUN2014		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2017		Y
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1147 11471014	Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
			Nicotine dependence	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1998		Y
	C4591001 1147 11471016	Infections and infestations	Herpes simplex	01JAN2009		Y
			Sinusitis	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471017	Cardiac disorders	Palpitations	09JAN2015		Y
			Supraventricular tachycardia	12JAN2015		Y
			Ventricular extrasystoles	12JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	09JAN2006		Y
		Skin and subcutaneous tissue disorders	Alopecia	22NOV2017		Y
	C4591001 1147 11471019	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2015		Y
			Narcolepsy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1147 11471021	Infections and infestations	Herpes simplex	01MAR2015		Y
		Social circumstances	Menarche	01JAN1997		Y
	C4591001 1147 11471025	Congenital, familial and genetic disorders	Type V hyperlipidaemia	20NOV2019		Y
	C4591001 1147 11471027	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01SEP2015		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01SEP2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	21NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
	C4591001 1147 11471031	Gastrointestinal disorders	Pancreatitis	01JAN2008		Y
	C4591001 1147 11471033	Immune system disorders	Seasonal allergy	01JAN1980		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1147 11471035	Metabolism and nutrition disorders	Hyperlipidaemia	25FEB2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01SEP2015		Y
		Nervous system disorders	Headache	22OCT2015		Y
			Sciatica	01JAN2018		Y
	C4591001 1147 11471038	Immune system disorders	Seasonal allergy	01JAN1999		Y
	C4591001 1147 11471039	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1147 11471041	Gastrointestinal disorders	Gastroesophageal reflux disease	08MAY2019		Y
	C4591001 1147 11471045	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN1972		Y
		General disorders and administration site conditions	Pain	01JUL2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2013		Y
			Intervertebral disc degeneration	01MAR2013		Y
			Scoliosis	01MAR2013		Y
			Spinal osteoarthritis	01MAR2013		Y
		Nervous system disorders	Neuritis	01MAR2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
			Rhinitis allergic	01JAN1972		Y
	C4591001 1147 11471046	Cardiac disorders	Diastolic dysfunction	11JUN2020		Y
		Immune system disorders	Food allergy	11JUN2020		Y
		Vascular disorders	Essential hypertension	20SEP2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471047	Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1147 11471048	Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Nervous system disorders	Sciatica	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Nicotine dependence	01JAN1996		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1147 11471049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1147 11471051	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1147 11471053	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Acquired oesophageal web	20JUL2020		Y
			Constipation	25FEB2020		Y
			Dysphagia	25FEB2020		Y
			Gastroesophageal reflux disease	25FEB2020		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471054	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		General disorders and administration site conditions	Hernia	23SEP2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Menopause	01JAN2018		Y
		Vascular disorders	Hypertension	18MAR2010		Y
	C4591001 1147 11471056	Immune system disorders	Multiple allergies	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1147 11471059	Metabolism and nutrition disorders	Hyperlipidaemia	08MAY2017		Y
			Type 2 diabetes mellitus	06JUN2017		Y
		Social circumstances	Postmenopause	21FEB2019		Y
		Vascular disorders	Hypertension	08MAY2017		Y
	C4591001 1147 11471065	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2017		Y
		Nervous system disorders	Hypoaesthesia	01JAN2016		Y
			Lumbar radiculopathy	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2011		Y
			Uterine malposition	01JAN2016		Y
	C4591001 1147 11471066	Metabolism and nutrition disorders	Hyperlipidaemia	05OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471070	Gastrointestinal disorders	Gastroesophageal reflux disease	12NOV2012		Y
		Immune system disorders	Hypersensitivity	29APR2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
			Generalised anxiety disorder	01JAN2003		Y
	C4591001 1147 11471073	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01FEB2001		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1147 11471079	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2008		Y
	C4591001 1147 11471085	Endocrine disorders	Adrenal mass	01JAN2018		Y
		Hepatobiliary disorders	Hepatic mass	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	08MAY2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Surgical and medical procedures	Skin neoplasm excision	04NOV2016	04NOV2016	N
				08SEP2017	08SEP2017	N
			Transurethral prostatectomy	08MAR2017	08MAR2017	N
	C4591001 1147 11471089	Surgical and medical procedures	Hysterectomy	01NOV2018	30NOV2018	N
	C4591001 1147 11471092	Immune system disorders	Seasonal allergy	05DEC2016		Y
		Psychiatric disorders	Anxiety	15MAY2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2020		Y
	C4591001 1147 11471100	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01MAR2019		Y
	C4591001 1147 11471107	Congenital, familial and genetic disorders	Thalassaemia beta	21DEC2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Hepatic steatosis	28DEC2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1147 11471112	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Infections and infestations	Herpes simplex	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1147 11471115	Psychiatric disorders	Anxiety	01JAN1977		Y
			Insomnia	01JAN2018		Y
	C4591001 1147 11471119	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Herpes simplex	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2008		Y
			Tenosynovitis stenosans	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2004		Y
			Migraine	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
			Sleep apnoea syndrome	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471120	Infections and infestations	Rhinitis	20SEP2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	20SEP2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1147 11471121	Congenital, familial and genetic disorders	Marfan's syndrome	01JAN2013		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1147 11471122	Congenital, familial and genetic disorders	Congenital skin disorder	01JAN2019		Y
			Ehlers-Danlos syndrome	01JAN2019		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Hypermobility syndrome	01JAN2019		Y
			Scoliosis	26OCT2018		Y
		Nervous system disorders	Tension headache	01JAN2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
	C4591001 1147 11471123	Infections and infestations	Herpes simplex	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Major depression	01JAN2010		Y
	C4591001 1147 11471129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1988		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	16JAN2020		Y
		Nervous system disorders	Headache	27DEC2019		Y
		Renal and urinary disorders	Nocturia	16JUN2020		Y
			Pollakiuria	27DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1147 11471131	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Congenital, familial and genetic disorders	Haemoglobin C trait	(b) (6) 1981		Y
		Metabolism and nutrition disorders	Iron deficiency	23NOV2013		Y
			Vitamin D deficiency	27NOV2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1981		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2014		Y
	C4591001 1147 11471132	Reproductive system and breast disorders	Erectile dysfunction	26SEP2018		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2016		Y
	C4591001 1147 11471133	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1147 11471134	Gastrointestinal disorders	Constipation	01APR2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	28AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	28AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471135	Gastrointestinal disorders	Dysphagia	30JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	19JUN2002		Y
			Reflux laryngitis	30JUN2020		Y
			Throat clearing	19JUN2020		Y
			Throat irritation	19JUN2020		Y
	C4591001 1147 11471136	Infections and infestations	Genital herpes	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1147 11471140	Renal and urinary disorders	Urinary retention	01AUG2020		Y
	C4591001 1147 11471142	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
	C4591001 1147 11471144	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1147 11471145	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1147 11471147	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1147 11471149	Metabolism and nutrition disorders	Hypercholesterolaemia	09MAY2017		Y
			Hyperlipidaemia	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	28FEB2018		Y
			Sleep disorder	28JAN2019		Y
		Reproductive system and breast disorders	Menopausal symptoms	28JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	07NOV2014		Y
			Pityriasis lichenoides et varioliformis acuta	07NOV2014		Y
			Rosacea	07NOV2014		Y
		Social circumstances	Postmenopause	28JAN2019		Y
		Vascular disorders	Essential hypertension	07NOV2014		Y
	C4591001 1147 11471150	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
	C4591001 1147 11471152	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
			Vitamin D deficiency	01JAN2014		Y
		Vascular disorders	Essential hypertension	01JAN2014		Y
	C4591001 1147 11471153	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1147 11471160	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Social circumstances	Menopause	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1147 11471163	General disorders and administration site conditions	Fatigue	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Generalised anxiety disorder	01JAN2018		Y
			Insomnia	01JAN2018		Y
			Major depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Panic attack	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2018		Y
			Sleep disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1147 11471164	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
			Thyroid mass	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1147 11471165	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Hepatobiliary disorders	Hepatic mass	01JAN2011		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1147 11471166	Eye disorders	Conjunctivitis allergic	01JAN2010		Y
		Immune system disorders	Oral allergy syndrome	05JUN2020		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471168	Endocrine disorders	Hypothyroidism	01JAN2019		Y
	C4591001 1147 11471173	Eye disorders	Myopia	01JAN1986		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1147 11471174	Gastrointestinal disorders	Pancreatitis chronic	01JAN2016		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2016		Y
	C4591001 1147 11471180	Infections and infestations	Genital herpes	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11FEB2017		Y
			Vitamin D deficiency	11FEB2017		Y
		Surgical and medical procedures	Hysterectomy	17JAN2011	17JAN2011	N
	C4591001 1147 11471182	Cardiac disorders	Tachycardia	31JUL2020		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
	C4591001 1147 11471183	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1147 11471186	Congenital, familial and genetic disorders	Sickle cell trait	01JAN1967		Y
	C4591001 1147 11471188	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y
			Joint instability	01JAN2009		Y
		Psychiatric disorders	Affective disorder	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1147 11471189	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471191	Endocrine disorders	Thyroid disorder	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1147 11471194	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
	C4591001 1147 11471195	Psychiatric disorders	Anxiety	15JUN2016		Y
			Depression	15JUN2016		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	04FEB2020		Y
			Seborrhoeic dermatitis	04FEB2020		Y
	C4591001 1147 11471197	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	21JAN2016		Y
			Obsessive-compulsive disorder	01JAN2005		Y
			Sleep disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
			Dyspnoea	01JAN1989		Y
	C4591001 1147 11471201	Eye disorders	Retinal degeneration	01JAN2019		Y
	C4591001 1147 11471204	Immune system disorders	Hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2020		Y
		Social circumstances	Menopause	01MAY2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1147 11471207	Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471209	Immune system disorders	Allergy to animal	19DEC2019		Y
			Iodine allergy	20JAN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	09JUL2020		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2019		Y
	C4591001 1147 11471210	Cardiac disorders	Acute myocardial infarction	18JUL2019	18JUL2019	N
		Eye disorders	Refraction disorder	19APR2018		Y
			Visual impairment	19APR2018		Y
			Vitreous floaters	19APR2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	27JUN2016		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01MAY2015		Y
			Obesity	18FEB2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Temporomandibular joint syndrome	01MAY2015		Y
		Nervous system disorders	Migraine with aura	01MAY2015		Y
			Post-traumatic headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Reproductive system and breast disorders	Infertility male	01JAN2001		Y
		Surgical and medical procedures	Coronary arterial stent insertion	28JUN2015		Y
		Vascular disorders	Essential hypertension	01JAN2015		Y
	C4591001 1147 11471211	Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1147 11471212	Immune system disorders	Drug hypersensitivity	01DEC1994		Y
				01JAN1994		Y
		Nervous system disorders	Migraine	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Generalised anxiety disorder	01JAN2007		Y
	C4591001 1147 11471213	Investigations	Hepatitis B surface antibody positive	22APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Social circumstances	High risk sexual behaviour	01JAN2018		Y
	C4591001 1147 11471217	Musculoskeletal and connective tissue disorders	Back pain	26MAR2020		Y
	C4591001 1147 11471220	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Gastrointestinal disorders	Diarrhoea	01JAN1991		Y
			Gastroesophageal reflux disease	26NOV2012		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	26OCT2012		Y
			Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Migraine	10JUN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1147 11471222	Immune system disorders	Perfume sensitivity	01JAN1995		Y
	C4591001 1147 11471223	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1147 11471226	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471227	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN1986		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
			Generalised anxiety disorder	01JAN2005		Y
			Major depression	01JAN2005		Y
	C4591001 1147 11471231	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1147 11471234	Musculoskeletal and connective tissue disorders	Back pain	19DEC2018		Y
	C4591001 1147 11471235	Congenital, familial and genetic disorders	Cancer gene carrier	25FEB2020		Y
		Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1147 11471236	Immune system disorders	Seasonal allergy	01JAN1985		Y
	C4591001 1147 11471237	Endocrine disorders	Autoimmune thyroiditis	13DEC2019		Y
			Thyroid mass	13DEC2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	15DEC2015		Y
		Psychiatric disorders	Anxiety	16OCT2012		Y
			Insomnia	16DEC2012		Y
		Reproductive system and breast disorders	Infertility	01JAN2012		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1147 11471243	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Nervous system disorders	Headache	27FEB2020		Y
	C4591001 1147 11471245	Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471246	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1147 11471252	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2020		Y
	C4591001 1147 11471253	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1147 11471254	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2018		Y
				01JAN2020		Y
			Seasonal allergy	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1147 11471255	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Food allergy	01JAN2018		Y
	C4591001 1147 11471258	Injury, poisoning and procedural complications	Stress fracture	17NOV2020		Y
	C4591001 1147 11471259	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Infections and infestations	Chronic sinusitis	01JAN2009		Y
	C4591001 1147 11471260	Injury, poisoning and procedural complications	Fibula fracture	16SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471265	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
	C4591001 1147 11471266	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
	C4591001 1147 11471267	Eye disorders	Borderline glaucoma	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2005		Y
	C4591001 1147 11471276	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1149 11491001	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2012	31DEC2012	N
	C4591001 1149 11491007	Psychiatric disorders	Anxiety	01JUN2015		Y
	C4591001 1149 11491012	Immune system disorders	Milk allergy	01JAN2001		Y
	C4591001 1149 11491016	Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2013	31DEC2013	N
	C4591001 1149 11491020	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1149 11491021	Gastrointestinal disorders	Umbilical hernia	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
	C4591001 1149 11491023	Social circumstances	Corrective lens user	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491024	Social circumstances	Corrective lens user	01JAN2004		Y
	C4591001 1149 11491027	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1149 11491029	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1149 11491030	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1149 11491037	Gastrointestinal disorders	Haemorrhoids	01JAN2008		Y
	C4591001 1149 11491040	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1149 11491044	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
	C4591001 1149 11491045	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Crohn's disease	01JAN2002		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491046	Injury, poisoning and procedural complications	Tibia fracture	01JAN2005	31DEC2005	N
	C4591001 1149 11491047	Eye disorders	Hypermetropia	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1149 11491050	Eye disorders	Hypermetropia	01JAN1999		Y
	C4591001 1149 11491051	Eye disorders	Hypermetropia	01JAN1991		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN1989		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
	C4591001 1149 11491054	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2008		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
	C4591001 1149 11491057	Eye disorders	Myopia	01JAN2013		Y
	C4591001 1149 11491059	Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1149 11491061	Reproductive system and breast disorders	Menstrual disorder	01JAN2005		Y
	C4591001 1149 11491062	Surgical and medical procedures	Bone graft	01JAN2019	31DEC2019	N
	C4591001 1149 11491063	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1149 11491065	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Surgical and medical procedures	Knee operation	01JAN2004	31DEC2004	N
				01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
			Sinus operation	01JAN2018	31DEC2018	N
	C4591001 1149 11491066	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2000	31MAR2014	N
		Surgical and medical procedures	Thyroidectomy	01MAR2014	31MAR2014	N
	C4591001 1149 11491067	Eye disorders	Hypermetropia	01JAN2020		Y
	C4591001 1149 11491068	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
	C4591001 1149 11491069	Gastrointestinal disorders	Umbilical hernia	01JAN2005	31DEC2005	N
	C4591001 1149 11491073	Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1996	31DEC1996	N
	C4591001 1149 11491075	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1149 11491076	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Nervous system disorders	Tension headache	01JAN2015		Y
	C4591001 1149 11491077	Immune system disorders	Drug hypersensitivity	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN1986	31DEC1986	N
				01JAN1990	31DEC1990	N
		Surgical and medical procedures	Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1149 11491083	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
	C4591001 1149 11491084	Nervous system disorders	Migraine	01JAN1998		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Knee operation	01JAN1995	31DEC1995	N
				01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
				01JAN2000	31DEC2000	N
	C4591001 1149 11491085	Nervous system disorders	Migraine	01JAN1975		Y
	C4591001 1149 11491086	Psychiatric disorders	Anxiety	01JAN2013		Y
			Depressive symptom	01JAN2019		Y
	C4591001 1149 11491088	Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1149 11491089	Infections and infestations	Oral herpes	01JAN2020		Y
	C4591001 1149 11491093	Surgical and medical procedures	Cholecystectomy	01JAN2007		Y
	C4591001 1149 11491096	Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2015	31DEC2015	N
	C4591001 1149 11491097	Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491099	Social circumstances	Corrective lens user	01JAN1991		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1149 11491110	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993	31DEC1996	N
	C4591001 1149 11491116	Surgical and medical procedures	Umbilical hernia repair	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1149 11491119	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Foot operation	01JAN2013		Y
			Intervertebral disc operation	01JAN2017	31DEC2017	N
	C4591001 1149 11491120	Psychiatric disorders	Anxiety	01JUN2010		Y
			Depression	01JUN2010		Y
	C4591001 1149 11491121	Nervous system disorders	Headache	01MAR2000		Y
	C4591001 1149 11491128	Surgical and medical procedures	Cholecystectomy	01JAN1986	31DEC1986	N
	C4591001 1149 11491129	Infections and infestations	Pneumonia	01JAN1979	31DEC1979	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2001		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1149 11491133	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1149 11491136	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2015		Y
		Vascular disorders	Embolism venous	01JAN2018		Y
	C4591001 1149 11491140	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN1987		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1149 11491141	Cardiac disorders	Supraventricular tachycardia	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Umbilical hernia	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2005		Y
			Spinal osteoarthritis	01JAN1994		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491142	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Anaphylactic reaction	01JAN1992		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1998	31DEC1998	N
			Oral contraception	01APR2020		Y
			Thyroidectomy	01JAN2019	31DEC2019	N
	C4591001 1149 11491146	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Meniscus removal	01FEB2020	31DEC2020	N
	C4591001 1149 11491147	Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1149 11491148	Investigations	Blood cholesterol increased	01JAN2016		Y
		Surgical and medical procedures	Mastectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1149 11491150	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Surgical and medical procedures	Foot operation	01JAN2013	31DEC2013	N
	C4591001 1149 11491154	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2008	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2019	31DEC2019	N
	C4591001 1149 11491155	Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Foot operation	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491156	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2020	31JAN2020	N
	C4591001 1149 11491157	Infections and infestations	Sinusitis	01JAN2005		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1149 11491158	Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2016	31DEC2016	N
	C4591001 1149 11491160	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Social circumstances	Corrective lens user	01JAN1994		Y
		Surgical and medical procedures	Renal surgery	01JAN2016	31DEC2016	N
	C4591001 1149 11491162	Metabolism and nutrition disorders	Lactose intolerance	01JAN1984		Y
			Obesity	01JUN2018		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1149 11491163	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hernia repair	01JAN1982	31DEC1982	N
	C4591001 1149 11491165	Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
	C4591001 1149 11491166	Surgical and medical procedures	Appendicectomy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491169	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
	C4591001 1149 11491172	Nervous system disorders	Headache	01JAN1992		Y
		Surgical and medical procedures	Ligament operation	01JAN2012	31DEC2012	N
	C4591001 1149 11491173	Nervous system disorders	Headache	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
		Surgical and medical procedures	Ligament operation	01JAN2009	31DEC2009	N
			Wound closure	01JAN2014	31DEC2014	N
	C4591001 1149 11491174	Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Pneumonia	01JAN1976	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976	31DEC1999	N
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2002	31DEC2002	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1149 11491175	Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1149 11491176	Surgical and medical procedures	Ankle operation	01JAN2009	31DEC2009	N
				01JAN2019	31DEC2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491178	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN2006		Y
	C4591001 1149 11491179	Psychiatric disorders	Depression	01JUN2017		Y
	C4591001 1149 11491180	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN1998		Y
	C4591001 1149 11491182	Surgical and medical procedures	Mole excision	01JAN1989	31DEC1998	N
	C4591001 1149 11491183	Surgical and medical procedures	Adenoidectomy	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1149 11491186	Nervous system disorders	Migraine	01DEC2000		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Meniscus operation	01JAN1993	31DEC1994	N
			Sinus operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1149 11491187	Surgical and medical procedures	Photorefractive keratectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1149 11491188	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1149 11491191	Immune system disorders	Food allergy	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491194	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Hypersensitivity	01JAN2018		Y
	C4591001 1149 11491198	Surgical and medical procedures	Jaw operation	01JAN2015	31DEC2015	N
	C4591001 1149 11491203	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
	C4591001 1149 11491206	Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Liposuction	01JAN2013	31DEC2013	N
	C4591001 1149 11491207	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2012		Y
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1998	31DEC1998	N
			Cataract operation	01JAN2001	31DEC2001	N
			Cataract operation	01JAN2012		Y
			Thyroidectomy	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1149 11491208	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Paranasal sinus polypectomy	01JAN2018		Y
	C4591001 1149 11491210	Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1149 11491212	Surgical and medical procedures	Knee operation	01JAN2017		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1972		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1984		Y
		Nervous system disorders	Migraine	01JAN1981		Y
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1149 11491215	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2009	N
	C4591001 1149 11491216	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1149 11491217	Ear and labyrinth disorders	Tinnitus	01JAN1990		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2017	31DEC2017	N
		Infections and infestations	Diverticulitis	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Fasciotomy	01JAN2011	31DEC2011	N
			Intestinal resection	01JAN2016	31DEC2016	N
	C4591001 1149 11491218	Blood and lymphatic system disorders	Blood loss anaemia	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2009		Y
	C4591001 1149 11491220	Psychiatric disorders	Depression	01JAN2018		Y
			Persistent depressive disorder	06JAN2018		Y
		Surgical and medical procedures	Meniscus operation	01JAN2000		Y
			Prophylaxis against HIV infection	06JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1149 11491221	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Nervous system disorders	Facial paralysis	01APR2020	31MAY2020	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
	C4591001 1149 11491223	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
	C4591001 1149 11491227	Reproductive system and breast disorders	Varicocele	01JAN2010	31DEC2010	N
	C4591001 1149 11491228	Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
	C4591001 1149 11491230	Injury, poisoning and procedural complications	Limb injury	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491233	Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	01JAN2013		Y
	C4591001 1149 11491238	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Dehydration	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JUL2019		Y
	C4591001 1149 11491241	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN2004	31DEC2004	N
			Abortion spontaneous	01JAN2012	31DEC2012	N
			Abortion spontaneous	01JAN2017	31DEC2017	N
	C4591001 1149 11491242	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
			Rhinoplasty	01JAN2016	31DEC2016	N
	C4591001 1149 11491246	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Infections and infestations	Hepatitis C	01JAN1993	31DEC1994	N
		Surgical and medical procedures	Arthroscopic surgery	01JAN1980	31DEC1992	N
	C4591001 1149 11491247	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Surgical and medical procedures	Ankle operation	01JAN1992	31DEC1992	N
	C4591001 1149 11491248	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Perthes disease	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1149 11491249	Immune system disorders	Food allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1149 11491250	Surgical and medical procedures	Uterine polypectomy	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
	C4591001 1149 11491252	Infections and infestations	Onychomycosis	01AUG2020		Y
	C4591001 1149 11491254	Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1149 11491258	Surgical and medical procedures	Uterine dilation and curettage	01JUN2020	30JUN2020	N
		Eye disorders	Hypermetropia	01JAN1999		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
				01JAN2007	31DEC2007	N
			Meniscus operation	01JAN1995	31DEC1995	N
				01JAN2007	31DEC2007	N
	C4591001 1149 11491259	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N
			Pulmonary resection	01JAN1984	31DEC1984	N
			Tonsillectomy	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491263	Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1149 11491266	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1149 11491268	Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1980		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1149 11491269	Eye disorders	Amblyopia	01JAN1975	31DEC1980	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Surgical and medical procedures	Eye operation	01JAN1975	31DEC1980	N
	C4591001 1149 11491270	Immune system disorders	Food allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Traumatic renal injury	01APR2012	30JUN2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1149 11491271	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
	C4591001 1149 11491273	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491276	Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2020	31JAN2020	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1982		Y
	C4591001 1149 11491277	Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
	C4591001 1149 11491280	Gastrointestinal disorders	Constipation	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1149 11491281	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Human papilloma virus test positive	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Endocervical curettage	01JAN2016	31DEC2016	N
	C4591001 1149 11491282	Skin and subcutaneous tissue disorders	Urticaria	01JAN2007		Y
	C4591001 1149 11491285	Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
	C4591001 1149 11491289	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1976		Y
	C4591001 1149 11491290	Immune system disorders	Hypersensitivity	01JAN2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1996		Y
		Surgical and medical procedures	Caesarean section	01JAN2002		Y
				01JAN2009		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015		Y
			Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1149 11491292	Gastrointestinal disorders	Inguinal hernia	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
	C4591001 1149 11491293	Injury, poisoning and procedural complications	Scar	01JAN2017		Y
	C4591001 1149 11491294	Infections and infestations	Pneumonia	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Reproductive system and breast disorders	Breast mass	01JAN2014	31DEC2014	N
	C4591001 1149 11491295	Injury, poisoning and procedural complications	Scar	01JAN1998		Y
	C4591001 1149 11491302	Immune system disorders	Food allergy	01APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
	C4591001 1149 11491303	Metabolism and nutrition disorders	Lactose intolerance	01JAN2007		Y
	C4591001 1149 11491304	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Investigations	Tuberculin test positive	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
		Surgical and medical procedures	Foot operation	01JAN2017	31DEC2017	N
			Knee operation	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
				01JAN2014	31DEC2014	N
			Shoulder operation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491307	Ear and labyrinth disorders	Hypoacusis	01JAN1992	31DEC1992	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1992	31DEC1993	N
			Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1149 11491308	Eye disorders	Hypermetropia	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN2000	31DEC2000	N
	C4591001 1149 11491310	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Nervous system disorders	Syncope	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1149 11491311	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007	31DEC2008	N
	C4591001 1149 11491314	Gastrointestinal disorders	Dyspepsia	01JAN2002		Y
			Haemorrhoids	01JAN2005		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2005	31DEC2005	N
	C4591001 1149 11491315	Eye disorders	Myopia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1149 11491316	Surgical and medical procedures	Debridement	01JAN2018	31DEC2018	N
	C4591001 1149 11491320	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491321	Nervous system disorders	Migraine	01JAN2014		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2016		Y
	C4591001 1149 11491322	Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Abdominoplasty	01JAN2010	31DEC2010	N
	C4591001 1149 11491324	Social circumstances	Multigravida	01JAN2016	31DEC2016	N
			Multiparous	01JAN2018	31DEC2018	N
			Multiparous	01JAN2016	31DEC2016	N
			Multiparous	01JAN2018	31DEC2018	N
	C4591001 1149 11491327	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
	C4591001 1149 11491328	Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1149 11491329	Infections and infestations	Hepatitis B	01JAN1998	31DEC2015	N
	C4591001 1149 11491331	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2006		Y
		Surgical and medical procedures	Appendectomy	01MAY2020	31MAY2020	N
	C4591001 1149 11491332	Eye disorders	Hypermetropia	01JAN2014		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
	C4591001 1149 11491334†	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Investigations	HIV test positive	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Thyroidectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1149 11491335†	Investigations	HIV test positive	01JAN2017		Y
	C4591001 1149 11491337†	Investigations	HIV test positive	01JAN2008		Y
	C4591001 1149 11491339†	Investigations	HIV test positive	01JAN2015		Y
	C4591001 1149 11491340	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1149 11491341	Gastrointestinal disorders	Femoral hernia	01JAN1992	31DEC1992	N
	C4591001 1149 11491343	Eye disorders	Hypermetropia	01JAN2000		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2019		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
	C4591001 1149 11491344†	Infections and infestations	HIV infection	01FEB2019		Y
	C4591001 1150 11501001	Gastrointestinal disorders	Pancreatitis chronic	01JAN2014		Y
		Infections and infestations	Sinusitis	01JUL2020		Y
	C4591001 1150 11501002	Psychiatric disorders	Generalised anxiety disorder	01AUG2019		Y
	C4591001 1150 11501003	Nervous system disorders	Nerve compression	01DEC2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01SEP2018		Y
		Surgical and medical procedures	Shoulder operation	01FEB2020	29FEB2020	N
	C4591001 1150 11501004	Immune system disorders	Seasonal allergy	01JUN2007		Y
	C4591001 1150 11501005	Gastrointestinal disorders	Oesophageal achalasia	01JAN2008		Y
		Surgical and medical procedures	Pyloromyotomy	01JAN2008	31DEC2008	N
	C4591001 1150 11501006	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1150 11501009	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JUN2020		Y
	C4591001 1150 11501010	Immune system disorders	Drug hypersensitivity	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01APR2020		Y
	C4591001 1150 11501011	Infections and infestations	Oral herpes	01JAN1992		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2015		Y
	C4591001 1150 11501012	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2009		Y
	C4591001 1150 11501014	Surgical and medical procedures	Cholecystectomy	01JAN2020	31JAN2020	N
	C4591001 1150 11501015	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
			Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1150 11501019	Endocrine disorders	Autoimmune thyroiditis	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2008		Y
	C4591001 1150 11501020	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1150 11501021	Gastrointestinal disorders	Colitis ulcerative	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1150 11501022	Metabolism and nutrition disorders	Type 2 diabetes mellitus	31JUL2019		Y
	C4591001 1150 11501023	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Paranasal cyst	01JAN2019		Y
	C4591001 1150 11501025	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1983		Y
	C4591001 1150 11501026	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUN2019		Y
	C4591001 1150 11501027	Surgical and medical procedures	Eye operation	01JUN2019	30JUN2019	N
	C4591001 1150 11501028	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Immune system disorders	Food allergy	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 1150 11501029	Immune system disorders	Food allergy	01JAN2016		Y
	C4591001 1150 11501031	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2018		Y
		Immune system disorders	Allergy to animal	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1150 11501032	Infections and infestations	Urinary tract infection	01JAN1997		Y
	C4591001 1150 11501033	Surgical and medical procedures	Appendectomy	19JUN2020	20JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501035	Infections and infestations	Oral herpes	01JAN2014		Y
	C4591001 1150 11501036	Blood and lymphatic system disorders	Haemolytic anaemia	01JAN2015	31DEC2016	N
		Investigations	Pulmonary function test decreased	01JAN2014	31DEC2015	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN2012	31DEC2013	N
		Reproductive system and breast disorders	Ovarian failure	01JAN2014	31DEC2015	N
	C4591001 1150 11501037	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Food allergy	01JAN2007		Y
			(b) (6) 1979			Y
	C4591001 1150 11501038	Gastrointestinal disorders	Dyspepsia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1150 11501039	Investigations	Blood cholesterol increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1150 11501040	Cardiac disorders	Supraventricular tachycardia	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Surgical and medical procedures	Cardiac ablation	01JUL2019	31JUL2019	N
	C4591001 1150 11501041	Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2018	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501043	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Food allergy	01JAN1986		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1986		Y
	C4591001 1150 11501044	Gastrointestinal disorders	Dyspepsia	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2003		Y
	C4591001 1150 11501045	Infections and infestations	Meningitis	01JAN1985	31DEC1985	N
	C4591001 1150 11501047	Injury, poisoning and procedural complications	Corneal abrasion	01MAR2019		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1150 11501048	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Sinus headache	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1150 11501050	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1150 11501051	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1150 11501052	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501053	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
	C4591001 1150 11501054	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1150 11501055	Immune system disorders	Food allergy	01JAN2005		Y
			Iodine allergy	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
	C4591001 1150 11501056	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
	C4591001 1150 11501059	Immune system disorders	Allergy to animal	01JAN2012		Y
			Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Dandruff	01JAN2010		Y
			Intertrigo	01JAN2020		Y
	C4591001 1150 11501060	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Staphylococcal skin infection	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1150 11501061	Injury, poisoning and procedural complications	Foot fracture	01JAN2020	31DEC2020	N
	C4591001 1150 11501062	Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
	C4591001 1150 11501063	Blood and lymphatic system disorders	Anaemia	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1150 11501064	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Iodine allergy	01JAN2004		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1150 11501065	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1150 11501067	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				27AUG2000		Y
		Investigations	Cardiac murmur	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2016		Y
	C4591001 1150 11501068	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1150 11501069	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1150 11501070	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Psychiatric disorders	Anorexia nervosa	01JAN2014	31DEC2020	N
	C4591001 1150 11501072	Endocrine disorders	Autoimmune thyroiditis	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1150 11501075	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01MAR2003		Y
			Depression	01MAR2003		Y
		Surgical and medical procedures	Gastric bypass	01NOV2016	31DEC2016	N
	C4591001 1150 11501076	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Impetigo	01JAN2007		Y
		Nervous system disorders	Dyslexia	01JAN1996		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
	C4591001 1150 11501078	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1150 11501080	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y
	C4591001 1150 11501081	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes zoster	01APR2020	31MAY2020	N
	C4591001 1150 11501082	Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1150 11501084	Gastrointestinal disorders	Dyspepsia	01JUL2017		Y
			Irritable bowel syndrome	01MAY2017		Y
		Immune system disorders	Seasonal allergy	01AUG2015		Y
	C4591001 1150 11501085	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Food allergy	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1974		Y
	C4591001 1150 11501086	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2016	31DEC2016	N
		Nervous system disorders	Narcolepsy	01JAN2016		Y
			Restless legs syndrome	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1150 11501087	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Reproductive system and breast disorders	Prostatitis	01JAN2013		Y
	C4591001 1150 11501088	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1982		Y
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
	C4591001 1150 11501089	General disorders and administration site conditions	Feeling abnormal	01JAN2019		Y
	C4591001 1150 11501090	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1150 11501091	Immune system disorders	Seasonal allergy	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Incontinence	01JAN2013		Y
			Vesicoureteric reflux	(b) (6) 1976	31DEC1980	N
	C4591001 1150 11501092	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1996		Y
	C4591001 1150 11501093	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1999		Y
	C4591001 1150 11501094	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Fibromyalgia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2000		Y
	C4591001 1150 11501095	Congenital, familial and genetic disorders	Congenital small intestinal atresia	(b) (6) 1986	(b) (6) 1986	N
	C4591001 1150 11501096	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Concussion	01JAN2009	31DEC2009	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1150 11501097	Vascular disorders	Hypertension	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501098	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2010	31DEC2012	N
			Depression	01JAN2010	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1150 11501099	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN1980		Y
	C4591001 1150 11501100	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2014		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2004	31DEC2004	N
	C4591001 1150 11501101	Nervous system disorders	Migraine	01JAN1985		Y
	C4591001 1150 11501102	Immune system disorders	Allergy to chemicals	01JAN1974		Y
			Food allergy	01JAN1974		Y
			Rubber sensitivity	01JAN1974		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1974		Y
	C4591001 1150 11501103	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
	C4591001 1150 11501104	Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501105	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2003		Y
	C4591001 1150 11501106	Endocrine disorders	Hypothyroidism	01SEP2016		Y
		Immune system disorders	Contrast media allergy	01JAN1983		Y
	C4591001 1150 11501110	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1150 11501111	Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01MAR2018		Y
	C4591001 1150 11501112	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1150 11501113	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1150 11501114	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Attention deficit hyperactivity disorder	01JAN2003		Y
			Depression	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1993		Y
	C4591001 1150 11501116	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1150 11501117	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Food allergy	01JAN2003		Y
	C4591001 1150 11501122	Infections and infestations	Herpes dermatitis	01AUG2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstruation irregular	01JAN2018		Y
	C4591001 1150 11501138	Skin and subcutaneous tissue disorders	Acne	01AUG2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2002	31DEC2002	N
	C4591001 1150 11501139	Blood and lymphatic system disorders	Anaemia	01JAN1999		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1150 11501141	Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
	C4591001 1150 11501142	Gastrointestinal disorders	Coeliac disease	27AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2018		Y
			Panic disorder	01JAN2018		Y
	C4591001 1150 11501144	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1150 11501145	Gastrointestinal disorders	Constipation	01JAN2014	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Folliculitis	01JAN2018	31DEC2019	N
	C4591001 1150 11501146	Nervous system disorders	Tremor	01JUN2020	31AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUN2020		Y
	C4591001 1150 11501147	Congenital, familial and genetic disorders	Phimosis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2018		Y
			Nystagmus	01JAN2018		Y
	C4591001 1150 11501148	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2016	31DEC2019	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2019		Y
	C4591001 1150 11501149	Gastrointestinal disorders	Abdominal migraine	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2002		Y
		Psychiatric disorders	Anger	01JAN2015	31DEC2018	N
			Irritability	01JAN2015	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Inadequate diet	01JAN2007		Y
	C4591001 1150 11501151	Metabolism and nutrition disorders	Underweight	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2011	31JUL2020	N
	C4591001 1150 11501152	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2019	31DEC2019	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1150 11501153	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Adjustment disorder	01JAN2018		Y
			Anxiety disorder	01OCT2017		Y
			Major depression	01OCT2017		Y
			Persistent depressive disorder	01JAN2018		Y
	C4591001 1150 11501154	Immune system disorders	Allergy to animal	01JAN2003		Y
		Surgical and medical procedures	Penis frenulectomy	01APR2020	30APR2020	N
	C4591001 1150 11501155	Congenital, familial and genetic disorders	Factor VII deficiency	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2003		Y
		Psychiatric disorders	Anxiety disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Bronchospasm	01JAN2018		Y
			Rhinitis allergic	01JAN2017		Y
	C4591001 1150 11501156	Metabolism and nutrition disorders	Lactose intolerance	01JAN2018		Y
			Vitamin D deficiency	01APR2018	31DEC2020	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018	31DEC2019	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501158	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
	C4591001 1150 11501160	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2014	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1150 11501161	Injury, poisoning and procedural complications	Concussion	01OCT2020	01NOV2020	N
		Nervous system disorders	Dizziness	01JAN2020	31MAR2020	N
	C4591001 1150 11501162	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2018	31DEC2019	N
		Nervous system disorders	Headache	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501163	Metabolism and nutrition disorders	Underweight	01JAN2017		Y
		Surgical and medical procedures	Ligament operation	01JUL2020	31JUL2020	N
	C4591001 1150 11501164	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2020		Y
	C4591001 1150 11501165	Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2020		Y
	C4591001 1150 11501167	Infections and infestations	Lyme disease	01JAN2016	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Tic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1150 11501169	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1150 11501170	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2005		Y
		Injury, poisoning and procedural complications	Stress fracture	01SEP2019	31OCT2019	N
		Investigations	Vitamin D decreased	01SEP2019	31OCT2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1150 11501174	Endocrine disorders	Growth hormone deficiency	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1150 11501175	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2016		Y
	C4591001 1150 11501181	Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1150 11501184	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1150 11501188	Cardiac disorders	Tachycardia	01JAN2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521001	Gastrointestinal disorders	Haemorrhoids	01JAN2013		Y
		Immune system disorders	Perennial allergy	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016		Y
	C4591001 1152 11521002	Surgical and medical procedures	Caesarean section	22APR1994	22APR1994	N
			Female sterilisation	01JAN2012		Y
	C4591001 1152 11521003	Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019	31DEC2019	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Lipoma excision	01JAN2019	31DEC2019	N
			Renal stone removal	01JAN2010	31DEC2010	N
			Synovial cyst removal	01JAN1995	31DEC1995	N
	C4591001 1152 11521005	Immune system disorders	Perennial allergy	01JAN2000		Y
		Investigations	Human papilloma virus test positive	01JAN2000		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2018	31DEC2018	N
	C4591001 1152 11521007	Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Wrist surgery	01JAN1983	31DEC1983	N
	C4591001 1152 11521008	Surgical and medical procedures	Caesarean section	20MAR2012	20MAR2012	N
				23DEC2019	23DEC2019	N
			Female sterilisation	23DEC2019	23DEC2019	N
			Gastric bypass	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1152 11521009	Immune system disorders	Food allergy	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1152 11521012	Gastrointestinal disorders	Constipation	01JAN1996		Y
			Dyspepsia	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2007		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1152 11521014	Infections and infestations	Pneumonia	01APR2019	30APR2019	N
			Pneumonia adenoviral	01APR2019	30APR2019	N
		Investigations	Biopsy lung	01APR2019	30APR2019	N
			Bronchoscopy	01APR2019	30APR2019	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2009	31DEC2009	N
			Uterine dilation and curettage	01JAN2008	31DEC2008	N
			Wisdom teeth removal	01JAN2003	31DEC2003	N
	C4591001 1152 11521015	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	15JUN1999	15JUN1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521017	Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1152 11521019	Surgical and medical procedures	Wisdom teeth removal	01JUN2019	30JUN2019	N
	C4591001 1152 11521020	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	05JUL2011	05JUL2011	N
				13AUG1989	13AUG1989	N
				26NOV1991	26NOV1991	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521029	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1997	31DEC1997	N
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1997		Y
	C4591001 1152 11521030	Hepatobiliary disorders	Cholelithiasis	01SEP2019	30SEP2019	N
		Surgical and medical procedures	Cholecystectomy	01SEP2019	30SEP2019	N
	C4591001 1152 11521031	Nervous system disorders	Sciatica	01JAN2010		Y
	C4591001 1152 11521032	Vascular disorders	Hypertension	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521035	Surgical and medical procedures	Female sterilisation	01JAN2016		Y
	C4591001 1152 11521038	Eye disorders	Myopia	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1152 11521039	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1152 11521044	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2014	31DEC2014	N
	C4591001 1152 11521045	Surgical and medical procedures	Uterine dilation and curettage	01MAY2018	31MAY2018	N
		Vascular disorders	Hypotension	01JAN2008		Y
	C4591001 1152 11521046	Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Gastrectomy	20JAN2020		Y
	C4591001 1152 11521051	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Vascular disorders	Varicose vein	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521052	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
			Cartilage injury	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Ankle operation	01JAN1995	31DEC1995	N
			Appendectomy	01JAN1993	31DEC1993	N
			Chondroplasty	01JAN2008	31DEC2008	N
			Strabismus correction	01JAN1984	31DEC1984	N
			Uterine dilation and curettage	01JAN2015	31DEC2015	N
		Vascular disorders	Varicose vein	01JAN2010		Y
	C4591001 1152 11521053	Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Appendectomy	01JAN2001	31DEC2001	N
	C4591001 1152 11521054	Gastrointestinal disorders	Abdominal hernia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2016	31DEC2016	N
	C4591001 1152 11521056	Infections and infestations	Pneumonia	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Limb operation	01JAN2002		Y
					31DEC2002	N
		Vascular disorders	Varicose vein	01JAN2016		Y
	C4591001 1152 11521058	Infections and infestations	Chlamydial infection	01FEB2020	29FEB2020	N
	C4591001 1152 11521059	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Abdominoplasty	01JAN2010	31DEC2010	N
			Appendicectomy	01JAN1995	31DEC1995	N
			Gastrectomy	01JAN2015		Y
	C4591001 1152 11521060	Infections and infestations	Pneumonia	01JAN2011	31DEC2011	N
		Nervous system disorders	Dizziness	01JAN2008	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
			Ligament operation	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1970	31DEC1970	N
			Wisdom teeth removal	01JAN1997	31DEC1997	N
	C4591001 1152 11521062	Cardiac disorders	Palpitations	01JAN1988		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Sepsis	01AUG2000	31AUG2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31JAN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Human papilloma virus test positive	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2020		Y
		Surgical and medical procedures	Caesarean section	05AUG2000	05AUG2000	N
				28FEB2005	28FEB2005	N
				30SEP2008	30SEP2008	N
			Meniscus operation	01JAN2015	31JAN2015	N
			Spinal laminectomy	01OCT2002	31OCT2002	N
			Thyroidectomy	01SEP2009	30SEP2009	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1152 11521063	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Gastrectomy	01JAN2016		Y
			Ovarian cystectomy	01JAN2013	31DEC2013	N
	C4591001 1152 11521070	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2016		Y
		Surgical and medical procedures	Mole excision	01JAN2018	31DEC2018	N
			Open reduction of fracture	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1152 11521071	Infections and infestations	Sinusitis	01JAN2000	31DEC2012	N
			Tuberculosis	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000	31DEC2005	N
			Depression	01JAN2000	31DEC2005	N
			Insomnia	01JAN2000	31DEC2004	N
		Surgical and medical procedures	Sinus operation	01JAN2012	31DEC2012	N
	C4591001 1152 11521073	Infections and infestations	Sinusitis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Somatic symptom disorder	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1152 11521075	Blood and lymphatic system disorders	Anaemia	01JAN2019	31JAN2020	N
		Gastrointestinal disorders	Food poisoning	01JAN2014	31DEC2014	N
		Psychiatric disorders	Insomnia	01JAN2016	31DEC2017	N
	C4591001 1152 11521076	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01DEC2019		Y
			Perennial allergy	01JAN2000		Y
			Perfume sensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Premature menopause	01JAN2000		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
			Synovial cyst removal	01JAN2013	31DEC2013	N
	C4591001 1152 11521078	Eye disorders	Keratoconus	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Gastric bypass	01JAN2015		Y
	C4591001 1152 11521081	Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
	C4591001 1152 11521084	Immune system disorders	Mite allergy	01JAN1975		Y
			Mycotic allergy	01JAN1975		Y
	C4591001 1152 11521085	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2002	N
				01JAN2017	31DEC2017	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
				01JAN2017	31DEC2017	N
	C4591001 1152 11521086	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1152 11521089	Surgical and medical procedures	Corneal transplant	01JAN1989	31DEC1989	N
	C4591001 1152 11521090	Reproductive system and breast disorders	Premature menopause	01MAR2016		Y
	C4591001 1152 11521098	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Chlamydial infection	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1152 11521100	Gastrointestinal disorders	Diarrhoea	01JAN2010	31DEC2010	N
			Dyspepsia	01JAN2010	31DEC2010	N
			Food poisoning	01JAN1992	31DEC1992	N
		Immune system disorders	Seasonal allergy	01JAN2000	31DEC2013	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521105	Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
			Tendon rupture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2020	17MAR2020	N
			Rotator cuff syndrome	01JAN1992	31DEC1992	N
				01JAN1994	31DEC1994	N
				01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1997		Y
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN1992	31DEC1992	N
				01JAN1994	31DEC1994	N
				01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Spinal fusion surgery	17MAR2020	17MAR2020	N
			Tenoplasty	01JAN2010	31DEC2010	N
	C4591001 1152 11521110	Gastrointestinal disorders	Haemorrhoids	01JAN2009	31DEC2015	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1152 11521112	Hepatobiliary disorders	Cholecystitis	01MAR2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01MAR2016	31MAR2016	N
	C4591001 1152 11521116	Infections and infestations	Hepatitis A	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1152 11521117	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Perennial allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2003	31DEC2008	N
			Depression	01JAN2003	31DEC2008	N
		Surgical and medical procedures	Abdominoplasty	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Varicose vein	01JAN2001		Y
		Eye disorders	Astigmatism	01JAN2005		Y
	C4591001 1152 11521118	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2007	31DEC2007	N
		Nervous system disorders	Headache	01JAN2018	31JAN2020	N
			Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2007	31DEC2007	N
	C4591001 1152 11521120	Eye disorders	Hypermetropia	01JAN1994		Y
	C4591001 1152 11521121	Gastrointestinal disorders	Constipation	01JAN2010		Y
			Dyspepsia	01JAN2010		Y
			Hiatus hernia	01JAN1972	31DEC1972	N
		Immune system disorders	Allergy to animal	01JAN1972		Y
			Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1975		Y
			Seasonal allergy	01JAN1975		Y
		Infections and infestations	Croup infectious	01JAN1982	31DEC1982	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1975		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hernia hiatus repair	01JAN1972	31DEC1972	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521126	Injury, poisoning and procedural complications	Cartilage injury	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1992	31DEC1992	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Chondroplasty	01JAN1993	31DEC1993	N
			Rotator cuff repair	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1981	31DEC1981	N
			Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1152 11521131	Hepatobiliary disorders	Jaundice	01JAN2000	31DEC2000	N
		Investigations	Biopsy liver	01JAN2000	31DEC2000	N
			Liver function test abnormal	01JAN2000	31DEC2000	N
	C4591001 1152 11521137	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2010	31DEC2010	N
	C4591001 1152 11521139	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Bone cyst	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
			Toe amputation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521140	Cardiac disorders	Palpitations	01JAN2019	31JAN2020	N
			Supraventricular tachycardia	01JAN2019	31JAN2020	N
			Ventricular extrasystoles	01JAN2019	31JAN2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2002	31DEC2002	N
			Skin laceration	19AUG2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Bone operation	01JAN2002	31DEC2002	N
			Cardiac ablation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1152 11521143	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1985		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
	C4591001 1152 11521144	Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Oophorectomy	01JAN2000	31DEC2000	N
	C4591001 1152 11521145	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1152 11521146	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Bursa injury	01JAN2000	31DEC2000	N
			Ligament rupture	01JAN2014	31DEC2014	N
		Nervous system disorders	Nerve compression	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Bursal operation	01JAN2000	31DEC2000	N
			Ligament operation	01JAN2014	31DEC2014	N
			Limb operation	01JAN2007	31DEC2007	N
	C4591001 1152 11521148	Injury, poisoning and procedural complications	Meniscus injury	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Meniscus operation	01JAN1992	31DEC1992	N
	C4591001 1152 11521149	Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005	31DEC2013	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1152 11521150	Psychiatric disorders	Anxiety	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1152 11521153	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Perennial allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019		Y
	C4591001 1152 11521154	Infections and infestations	Tuberculosis	01JAN1991	31DEC1991	N
		Investigations	Tuberculin test positive	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1152 11521156	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Nasal septal operation	01JAN2017	31DEC2017	N
			Orchidectomy	01JAN2003	31DEC2003	N
			Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1152 11521157	Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1152 11521158	Immune system disorders	Food allergy	01JAN1997		Y
		Infections and infestations	Gingivitis	01JUN2020	31JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007	31DEC2009	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Gingival graft	01JUL2020	31JUL2020	N
			Wisdom teeth removal	01JUN2020	30JUN2020	N
	C4591001 1152 11521159	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2015	31DEC2015	N
		Investigations	Human papilloma virus test positive	01JAN2019	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2013	31DEC2017	N
			Mental disorder	01JAN2016		Y
		Surgical and medical procedures	Fracture treatment	01JAN2012	31DEC2018	N
	C4591001 1152 11521164	Immune system disorders	Seasonal allergy	01JAN2019	31DEC2019	N
				01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521165	Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1984	31DEC1984	N
	C4591001 1152 11521166	Surgical and medical procedures	Caesarean section	23NOV2013	23NOV2013	N
				28FEB2017	28FEB2017	N
			Female sterilisation	28FEB2017	28FEB2017	N
		Eye disorders	Strabismus	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2018	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2013		Y
			Migraine	01JAN2013		Y
			Sciatica	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2019	N
	Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN2014		Y	
	Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y	
		Urticaria	01JAN2018		Y	
	C4591001 1152 11521168	Surgical and medical procedures	Eye muscle operation	01JAN2018	31DEC2018	N
			Lithotripsy	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Scar	01JAN1999	31DEC2008	N
	Reproductive system and breast disorders	Prostatism	01JAN2008		Y	
		Varicocele	01JAN2005	31DEC2005	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008	31DEC2008	N
		Surgical and medical procedures	Ear operation	01JAN2018	31DEC2018	N
	C4591001 1152 11521173	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
			Pilonidal cyst	01JAN2018	31DEC2018	N
			Syphilis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
			Pilonidal sinus repair	01JAN2018	31DEC2018	N
	C4591001 1152 11521176	Surgical and medical procedures	Caesarean section	17APR2014	17APR2014	N
				21JUL2016	21JUL2016	N
			Female sterilisation	01JAN2016	31DEC2016	N
	C4591001 1152 11521177	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Gonorrhoea	01JAN2019	31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Cold urticaria	01JAN2003		Y
			Psoriasis	01JAN2015		Y
			Urticaria	01JAN2001		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1152 11521180	Immune system disorders	Food allergy	01JAN1991		Y
			Seasonal allergy	01JAN1991		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN1991		Y
			Lactose intolerance	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991	31DEC2014	N
		Surgical and medical procedures	Fracture treatment	01JAN2014	31DEC2014	N
			Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1152 11521182	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Perennial allergy	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31JAN2020	N
			Squamous cell carcinoma of skin	01JAN2010	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2002		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2011	31DEC2011	N
				01JAN2020	31JAN2020	N
			Skin operation	01JAN2020	31JAN2020	N
	C4591001 1152 11521183	Injury, poisoning and procedural complications	Concussion	01DEC2018	31DEC2018	N
			Facial bones fracture	01DEC2018	31DEC2018	N
	C4591001 1152 11521184	Gastrointestinal disorders	Inguinal hernia	01JAN1975	31DEC1975	N
				01JAN2019	31DEC2019	N
				01NOV1966	30NOV1966	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Morton's neuralgia	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2019		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2006		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1975	31DEC1975	N
				01JAN2019	31DEC2019	N
				01NOV1966	30NOV1966	N
			Neurectomy	01JAN2014	31DEC2014	N
	C4591001 1152 11521185	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1978	31DEC1978	N
	C4591001 1152 11521186	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Genital herpes	01JAN1999	31DEC2019	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Tenoplasty	01JAN2000	31DEC2000	N
	C4591001 1152 11521188	Ear and labyrinth disorders	Deafness	01JAN2010		Y
	C4591001 1152 11521189	Psychiatric disorders	Obsessive-compulsive disorder	01JAN2008		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31JAN2019	N
	C4591001 1152 11521192	Psychiatric disorders	Anxiety	01JAN2001		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N
			Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1152 11521195	Gastrointestinal disorders	Constipation	01MAR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2014		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1982	31DEC1982	N
	C4591001 1152 11521196	Infections and infestations	Pneumonia	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1152 11521197	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Bladder prolapse	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Premature menopause	01JAN1998		Y
		Surgical and medical procedures	Bladder repair	01JAN1995	31DEC1995	N
	C4591001 1152 11521199	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Perennial allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Spinal column injury	01JAN2016	31DEC2016	N
		Nervous system disorders	Sciatica	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
	C4591001 1152 11521204	Eye disorders	Myopia	01JAN1999		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521206	Surgical and medical procedures	Fracture treatment	01JAN1998	31DEC1998	N
		Endocrine disorders	Thyroid disorder	01JAN2012	31DEC2014	N
	C4591001 1152 11521208	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Bile duct stent insertion	01DEC2018	31DEC2018	N
			Cholecystectomy	01DEC2018	31DEC2018	N
			Wisdom teeth removal	01MAR2005	31MAR2005	N
		Eye disorders	Astigmatism	01JAN2000		Y
			Strabismus	01JAN1996		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
			Meniscus injury	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Adenoidectomy	01JAN2018	31DEC2018	N
	C4591001 1152 11521211		Ligament operation	01JAN2011	31DEC2011	N
			Meniscus operation	01JAN2010	31DEC2010	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1152 11521212	Endocrine disorders	Thyroid disorder	01JAN2014	31DEC2017	N
	C4591001 1152 11521213	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Immune system disorders	Milk allergy	01JAN1983		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1993	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521214	Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1152 11521215	Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
			Caesarean section	16MAR2007	16MAR2007	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Female sterilisation	01JAN2008	31DEC2008	N
			Liposuction	01JAN2014	31DEC2014	N
	C4591001 1152 11521216	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Myomectomy	01JAN2019	31DEC2019	N
	C4591001 1152 11521218	Gastrointestinal disorders	Haemorrhoids	01JAN2018	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN2010	31DEC2015	N
		Infections and infestations	Urinary tract infection	01JAN2018	31JAN2020	N
	C4591001 1152 11521219	Immune system disorders	Food allergy	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Rhinoplasty	01JAN2005	31DEC2005	N
	C4591001 1152 11521220	Congenital, familial and genetic disorders	Cryptorchism	01JAN2000	31DEC2000	N
		Infections and infestations	Pharyngitis	01JAN2007		Y
		Surgical and medical procedures	Orchidopexy	01JAN2000	31DEC2000	N
	C4591001 1152 11521221	Ear and labyrinth disorders	Vertigo	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN2018		Y
		Injury, poisoning and procedural complications	Skin laceration	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1152 11521222	Injury, poisoning and procedural complications	Ankle fracture	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Clavicle fracture	01JAN2012	31DEC2012	N
			Ankle operation	01JAN2011	31DEC2011	N
			Bone operation	01JAN2012	31DEC2012	N
	C4591001 1152 11521223	Eye disorders	Strabismus	01JAN1975		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN1980	31DEC2013	N
		Surgical and medical procedures	Ligament operation	01JAN2007	31DEC2007	N
			Strabismus correction	01JAN1980	31DEC1980	N
	C4591001 1152 11521224	Eye disorders	Myopia	01JAN2007		Y
	C4591001 1152 11521225	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1969		Y
		Surgical and medical procedures	Keratomileusis	01JAN2013	31DEC2013	N
	C4591001 1152 11521226	Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Pneumonia	01JAN1986	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1152 11521228	Surgical and medical procedures	Knee arthroplasty	01JUN2020	30JUN2020	N
	C4591001 1152 11521229	Skin and subcutaneous tissue disorders	Urticaria	01JAN1984		Y
	C4591001 1152 11521231	Infections and infestations	Genital herpes	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN2003	31DEC2003	N
	C4591001 1152 11521235	Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2009	N
			Tendon rupture	01JAN1998	31DEC1998	N
				01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Joint dislocation reduction	01JAN1998	31DEC1998	N
			Lithotripsy	01JAN2015	31DEC2015	N
			Meniscus operation	01JAN2009	31DEC2009	N
			Shoulder operation	01JAN2008	31DEC2008	N
			Tenoplasty	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1976	31DEC1976	N
			Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521236	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521239	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
			Tibia fracture	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
			Bone operation	01JAN2000	31DEC2000	N
			Keratomileusis	01JAN2015	31DEC2015	N
	C4591001 1152 11521240	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Genital herpes	01JAN2007		Y
		Surgical and medical procedures	Keratomileusis	01JAN2019	31DEC2019	N
			Mammoplasty	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1152 11521248	Injury, poisoning and procedural complications	Back injury	01JAN1990	31DEC1990	N
			Patella fracture	01JAN1997	31DEC1997	N
		Nervous system disorders	Sciatica	01JAN1990		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1990	31DEC1990	N
			Knee operation	01JAN1997	31DEC1997	N
			Spinal laminectomy	01JAN1990	31DEC1990	N
	C4591001 1152 11521249	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2006	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2019	N
			Depression	01JAN2017	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521253	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2004	31DEC2004	N
	C4591001 1152 11521254	Immune system disorders	Perennial allergy	01JAN1996		Y
		Surgical and medical procedures	Wisdom teeth removal	13FEB2020	13FEB2020	N
	C4591001 1152 11521255	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2000	31DEC2000	N
	C4591001 1152 11521256	Eye disorders	Diabetic retinopathy	01JAN2016		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
		Infections and infestations	Scrotal infection	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Diabetes mellitus inadequate control	01JAN2008	31DEC2008	N
			Hypercholesterolaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Gastric banding	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1152 11521261	Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2009	31DEC2009	N
	C4591001 1152 11521263	Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1152 11521264	Gastrointestinal disorders	Malocclusion	01JAN1990	31DEC2008	N
		Infections and infestations	Pilonidal cyst	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Jaw operation	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN2011	31DEC2011	N
			Wisdom teeth removal	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521269	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1980	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
	C4591001 1152 11521270	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1971	31DEC1995	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
	C4591001 1152 11521271	Gastrointestinal disorders	Constipation	01JAN2009		Y
		Immune system disorders	Perennial allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	01JAN2004	31DEC2010	N
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Nervous system disorders	Sciatica	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1152 11521274	Eye disorders	Myopia	01JAN1993		Y
	C4591001 1152 11521275	Infections and infestations	Chronic sinusitis	01JAN2000	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Sinus operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1152 11521276	Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521277	Surgical and medical procedures	Tonsillectomy	01JAN1987	31DEC1987	N
			Wisdom teeth removal	01JAN1995	31DEC1995	N
	C4591001 1152 11521282	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Caesarean section	23JAN2004	23JAN2004	N
				27FEB2006	27FEB2006	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1152 11521283	Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	20FEB2012	20FEB2012	N
			Tonsillectomy	01JAN1986	31DEC1986	N
	C4591001 1152 11521284	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Social circumstances	Menopause	30DEC2014		Y
	C4591001 1152 11521285	Immune system disorders	Perennial allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1992	31DEC1992	N
		Psychiatric disorders	Bipolar disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Meniscus operation	01JAN2017	31DEC2017	N
			Nasal polypectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521286	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1152 11521291	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Dengue fever	01JAN2002	31DEC2002	N
	C4591001 1152 11521295	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	21AUG2020	21AUG2020	N
		Surgical and medical procedures	Skin neoplasm excision	21AUG2020	21AUG2020	N
	C4591001 1152 11521296	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1152 11521297	Injury, poisoning and procedural complications	Ligament rupture	01JAN1997	31DEC1997	N
				01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Knee operation	01JAN1997	31DEC1997	N
				01JAN2005	31DEC2005	N
	C4591001 1152 11521298	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2010	31DEC2017	N
			Depression	01JAN2010	31DEC2017	N
		Surgical and medical procedures	Knee operation	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2010	31DEC2010	N
			Wisdom teeth removal	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521302	Psychiatric disorders	Insomnia	01JAN1988		Y
	C4591001 1152 11521308	Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2013	N
		Surgical and medical procedures	Appendectomy	01JAN2017	31DEC2017	N
	C4591001 1152 11521309	Gastrointestinal disorders	Diarrhoea	01JAN2008		Y
			Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2001		Y
			Urticaria	01JAN2001		Y
	C4591001 1152 11521312	Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2006		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1152 11521316	Immune system disorders	Food allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1989	31DEC1989	N
				01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Rotator cuff repair	01JAN1989	31DEC1989	N
				01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Vasectomy	01JAN1987	31DEC1987	N
			Vasectomy reversal	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521318	Cardiac disorders	Palpitations	01JAN1984		Y
		Eye disorders	Myopia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1984		Y
		Surgical and medical procedures	Liposuction	01JAN2005	31DEC2005	N
	C4591001 1152 11521319	Ear and labyrinth disorders	Exostosis of external ear canal	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Ligament injury	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Bone lesion excision	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
			Ligament operation	01JAN1989	31DEC1989	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1152 11521322	Immune system disorders	Food allergy	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
	C4591001 1152 11521323	Blood and lymphatic system disorders	Anaemia	01JAN2002	31DEC2003	N
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Haemorrhoids	01JAN2005	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Perennial allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1992	31DEC1992	N
			Osteoarthritis	01JAN2008	31DEC2009	N
			Rheumatoid arthritis	01JAN1999	31DEC2003	N
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Bunion operation	01JAN1992	31DEC1992	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
	C4591001 1152 11521327	Blood and lymphatic system disorders	Anaemia	01JAN2008	31DEC2008	N
		Cardiac disorders	Palpitations	01JAN2014		Y
		Congenital, familial and genetic disorders	Congenital jaw malformation	(b) (6) 1982	31DEC1996	N
			Ehlers-Danlos syndrome	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
			Haemorrhoids	01JAN2014	31DEC2017	N
		Immune system disorders	Perennial allergy	01JAN2005		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
			Latent tuberculosis	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Paranasal sinus haemorrhage	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Jaw operation	01JAN1996	31DEC1996	N
			Myomectomy	01JAN2008	31DEC2008	N
			Sinus operation	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521328	Cardiac disorders	Palpitations	01JAN2008		Y
		Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Dyspepsia	01JAN1992		Y
			Impaired gastric emptying	01JAN1992		Y
		General disorders and administration site conditions	Fatigue	01JAN1992		Y
		Immune system disorders	Allergy to animal	01JAN1992		Y
			Drug hypersensitivity	01JAN2004		Y
				01JAN2010		Y
			Food allergy	01JAN2000		Y
			Perennial allergy	01JAN1992		Y
			Rubber sensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament injury	01DEC2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2005	31DEC2005	N
				01JAN2013	31DEC2013	N
		Nervous system disorders	Dizziness	01JAN2008		Y
			Epilepsy	(b) (6) 1982		Y
			Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1985		Y
			Insomnia	01JAN1992		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2018	31JAN2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urticaria	01JAN1986		Y
		Surgical and medical procedures	Caesarean section	16JAN2015	16JAN2015	N
			Female sterilisation	16JAN2015	16JAN2015	N
			Hysterectomy	31JAN2018	31JAN2018	N
			Ligament operation	01DEC2017	31DEC2017	N
			Neurectomy	01JAN2005	31DEC2005	N
				01JAN2013	31DEC2013	N
		Vascular disorders	Hypotension	01JAN2008		Y
	C4591001 1152 11521329	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1152 11521332	Eye disorders	Astigmatism	01JAN1986		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2006	31DEC2006	N
			Skull fractured base	01JAN2006	31DEC2006	N
			Subarachnoid haematoma	01JAN2006	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Breast operation	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2009	31DEC2009	N
			Mole excision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1152 11521333	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01MAY2019	31MAY2019	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Facial operation	01MAY2019	31MAY2019	N
	C4591001 1152 11521335	Congenital, familial and genetic disorders	Cataract congenital	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Borderline glaucoma	01JAN1968		Y
			Eyelid ptosis	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
			Retinal detachment	01JAN1998	31DEC1998	N
			Strabismus	01JAN1972	31DEC1972	N
				01JAN1978	31DEC1978	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Infections and infestations	Sinusitis fungal	01JAN2018	29FEB2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
			Caesarean section	01JAN2000	31DEC2000	N
			Cataract operation	01JAN1970	31DEC1970	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Retinopexy	01JAN1998	31DEC1998	N
			Sinus operation	01FEB2020	29FEB2020	N
			Strabismus correction	01JAN1972	31DEC1972	N
				01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521336	Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC2000	N
		Immune system disorders	Food allergy	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
	C4591001 1152 11521338	Eye disorders	Retinal detachment	01JUL2018	31JUL2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Biopsy cervix abnormal	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Abortion induced	01JAN2015	31DEC2015	N
			Cervix cryotherapy	01JAN1994	31DEC1994	N
			Retinopexy	01JUL2018	31JUL2018	N
		Nervous system disorders	Migraine	01JAN2006		Y
	C4591001 1152 11521339					
	C4591001 1152 11521340	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2012		Y
		Reproductive system and breast disorders	Prostatism	01JAN2018		Y
	C4591001 1152 11521344	Eye disorders	Myopia	01JAN1995		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1152 11521345	Congenital, familial and genetic disorders	Pectus excavatum	01JAN1988	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Surgical and medical procedures	Thoracoplasty	01JAN2003	31DEC2003	N
	C4591001 1152 11521346	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Perennial allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
	C4591001 1152 11521347	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Infections and infestations	Otitis media	01JAN1975	31DEC1985	N
		Injury, poisoning and procedural complications	Concussion	01JAN1985	31DEC1985	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Renal stone removal	01JAN1987	31DEC1987	N
	C4591001 1152 11521348	Gastrointestinal disorders	Abdominal pain	01AUG2010	31AUG2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
	C4591001 1152 11521352	Surgical and medical procedures	Appendicectomy	01AUG2010	31AUG2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN1992		Y
		Infections and infestations	Ear infection	01JAN1986	31DEC2018	N
			Genital herpes	01JAN2009		Y
			Pneumonia	01AUG2011	31AUG2011	N
				01FEB2020	29FEB2020	N
				01JUL2019	31JUL2019	N
				01SEP2018	30SEP2018	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1996		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
			Wisdom teeth removal	01JAN2003	31DEC2003	N
	C4591001 1152 11521353	Eye disorders	Myopia	01JAN2009		Y
	C4591001 1152 11521354	Gastrointestinal disorders	Haemorrhoids	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1152 11521355	Injury, poisoning and procedural complications	Ligament sprain	27AUG2020		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1152 11521356	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521357	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2014	31DEC2019	N
	C4591001 1152 11521361	Congenital, familial and genetic disorders	Deafness congenital	(b) (6) 1965		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2014	31DEC2016	N
	C4591001 1152 11521362	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1152 11521363	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1152 11521365	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Immune system disorders	Allergy to animal	01JAN2005		Y
			Allergy to arthropod sting	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2012	31DEC2012	N
			Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2009	31DEC2009	N
		Nervous system disorders	Migraine	01JAN1981	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2001	31DEC2001	N
			Appendicectomy	01JAN1990	31DEC1990	N
			Gastric bypass	14FEB2000	14FEB2000	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2001	31DEC2001	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin cosmetic procedure	01JAN2002	31DEC2002	N
			Spinal operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
			Varicose vein	01JAN2010		Y
	C4591001 1152 11521367	Eye disorders	Myopia	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Pneumonia	01DEC1984	31DEC1984	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987	31DEC1990	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1152 11521372	Immune system disorders	Perennial allergy	01JAN1991		Y
		Infections and infestations	Ear infection	01JAN1991	31DEC2015	N
		Investigations	Human papilloma virus test positive	01JAN2017	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997	31DEC2005	N
		Surgical and medical procedures	Ear tube insertion	01JAN1996	31DEC1996	N
			Mole excision	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
			Otoplasty	01JAN2004	31DEC2004	N
			Wisdom teeth removal	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521373	Immune system disorders	Food allergy	01JAN1976		Y
		Surgical and medical procedures	Keratomileusis	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1152 11521374	Gastrointestinal disorders	Dyspepsia	01JAN2000	31DEC2013	N
		Immune system disorders	Perennial allergy	01JAN1995		Y
		Nervous system disorders	Epilepsy	01JAN1980	31DEC1985	N
		Psychiatric disorders	Anxiety	01JAN2017	31DEC2017	N
			Insomnia	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1988		Y
		Surgical and medical procedures	Breast operation	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2008	31DEC2008	N
			Keratomileusis	01JAN2009	31DEC2009	N
	C4591001 1152 11521376	Nervous system disorders	Headache	01JAN1999		Y
			Monoplegia	01JAN2011		Y
		Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
	C4591001 1152 11521377	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
	C4591001 1152 11521378	Immune system disorders	Perennial allergy	01JAN1995		Y
		Investigations	Human papilloma virus test positive	01JAN1995	31DEC2000	N
		Surgical and medical procedures	Keratomileusis	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN2011	31DEC2011	N
	C4591001 1152 11521379	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1977	31DEC1977	N
		Immune system disorders	Allergy to animal	01JAN1984		Y
		Infections and infestations	Influenza	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pneumonia	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1994	31DEC1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984	31DEC2019	N
		Surgical and medical procedures	Pharyngeal polyp	01JAN1996	31DEC1996	N
			Micrographic skin surgery	01JAN2019	31DEC2019	N
			Pharyngeal operation	01JAN1996	31DEC1996	N
			Pylorus dilation procedure	01JAN1977	31DEC1977	N
			Wisdom teeth removal	01JAN2000	31DEC2000	N
	C4591001 1152 11521381	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2002	31DEC2015	N
		Surgical and medical procedures	Lithotripsy	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1152 11521383	Eye disorders	Dry eye	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1152 11521384	Infections and infestations	Chlamydial infection	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31JAN2019	N
	C4591001 1152 11521390	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Infections and infestations	Bronchitis	01JAN1994	31DEC1994	N
			Typhus	01JAN2002	31DEC2002	N
		Skin and subcutaneous tissue disorders	Keloid scar	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Scar excision	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1152 11521391	Psychiatric disorders	Insomnia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1152 11521393	Eye disorders	Myopia	01JAN2000		Y
	C4591001 1152 11521394	Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
	C4591001 1152 11521396	Gastrointestinal disorders	Umbilical hernia	01JAN2011	31DEC2011	N
				01JUN2020	30JUN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2011	31DEC2011	N
				01JUN2020	30JUN2020	N
	C4591001 1152 11521397	Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01MAR2020		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1152 11521399	Eye disorders	Keratoconus	01JAN1993		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1986	31DEC1986	N
				01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Corneal transplant	01JAN2018	31DEC2018	N
			Elbow operation	01JAN1986	31DEC1986	N
				01JAN1987	31DEC1987	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1152 11521400	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
		Immune system disorders	Perennial allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2015	31DEC2015	N
	C4591001 1152 11521401	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1978	31DEC1978	N
		Nervous system disorders	Headache	01MAR2020		Y
			Migraine	01JAN1994		Y
	C4591001 1152 11521402	Infections and infestations	Cellulitis orbital	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1152 11521403	Congenital, familial and genetic disorders	Anomaly of external ear congenital	01JAN1995		Y
			Congenital neoplasm	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Surgical failure	01DEC2011	31DEC2011	N
		Vascular disorders	Hypotension	01JAN2010	31DEC2014	N
	C4591001 1152 11521404	Blood and lymphatic system disorders	Anaemia	01JAN2017	31DEC2018	N
		Hepatobiliary disorders	Cholecystitis	01JAN1999	31DEC1999	N
		Immune system disorders	Food allergy	01JAN2017		Y
			Seasonal allergy	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
			Endometrial ablation	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2014	31DEC2014	N
	C4591001 1152 11521405	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1982		Y
		Surgical and medical procedures	Circumcision	01JAN1997	31DEC1997	N
			Orchidectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Varicose vein	01FEB2020		Y
	C4591001 1152 11521406	Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Bone lesion	01JAN2019	17JAN2020	N
		Surgical and medical procedures	Ankle operation	17JAN2020	17JAN2020	N
			Meniscus removal	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521407	Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
	C4591001 1152 11521408	Surgical and medical procedures	Circumcision	01JUN2020	30JUN2020	N
	C4591001 1152 11521409	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2016	31DEC2016	N
	C4591001 1152 11521412	Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Food allergy	01JAN1984		Y
			Seasonal allergy	01JAN1982		Y
	C4591001 1152 11521413	Hepatobiliary disorders	Cholelithiasis	01JAN2019		Y
	C4591001 1152 11521415	Immune system disorders	Perennial allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2015	31DEC2015	N
		Investigations	Cardiac murmur	09SEP2020		Y
	C4591001 1152 11521419	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
			Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Urinary tract infection	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Ectopic pregnancy termination	01JAN2005	31DEC2005	N
	C4591001 1152 11521421	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2008		Y
		Infections and infestations	Pneumonia	01JAN1980	31DEC1995	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Lactation puerperal increased	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980	31DEC1995	N
			Sinus polyp	01JAN2008	31DEC2008	N
				01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
			Paranasal sinus polypectomy	01JAN2008	31DEC2008	N
				01JAN2012	31DEC2012	N
		Vascular disorders	Deep vein thrombosis	01JAN2016	31DEC2016	N
	C4591001 1152 11521422	Gastrointestinal disorders	Inguinal hernia	01JAN1978	31DEC1978	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Iodine allergy	01JAN2005		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Genital herpes	01JAN2005		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2003	31DEC2003	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1978	31DEC1978	N
			Meniscus operation	01JAN1999	31DEC1999	N
				01JAN2003	31DEC2003	N
	C4591001 1152 11521423	Gastrointestinal disorders	Dyspepsia	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN1992	31DEC2019	N
			Depression	01JAN1992	31DEC2019	N
			Insomnia	01JAN1992		Y
	C4591001 1152 11521424	Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1152 11521426	Eye disorders	Myopia	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1152 11521427	Gastrointestinal disorders	Umbilical hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Dust allergy	01JAN1990		Y
			Mycotic allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
	C4591001 1152 11521429	Gastrointestinal disorders	Rectal haemorrhage	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1996	31DEC1998	N
			Insomnia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972	31DEC1992	N
	C4591001 1152 11521430	Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Eye disorders	Myopia	01JAN1979		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Immune system disorders	Allergy to arthropod sting	01JAN1986		Y
			Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521431	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Knee operation	01JAN1974	31DEC1974	N
	C4591001 1152 11521432	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN2002		Y
		Infections and infestations	Pelvic infection	01JAN1996	31DEC1996	N
			Urinary tract infection	01JAN1988	31DEC1998	N
		Investigations	Biopsy breast	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2001		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sciatica	01JAN2017	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1152 11521433	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1987	31DEC1987	N
			Meniscus injury	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Ligament operation	01JAN1987	31DEC1987	N
			Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1152 11521434	Eye disorders	Myopia	01JAN1983		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
		Vascular disorders	Varicose vein	01JAN2016		Y
	C4591001 1152 11521435	Eye disorders	Myopia	01JAN1992		Y
		Surgical and medical procedures	Keratomileusis	01JAN2008	31DEC2008	N
	C4591001 1152 11521436	Congenital, familial and genetic disorders	Congenital foot malformation	(b) (6) 1994	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2013	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1152 11521437	Surgical and medical procedures	Foot operation	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Tendonitis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Epiphysiodesis	01JAN1981	31DEC1981	N
				01JAN1983	31DEC1983	N
			Tonsillectomy	01JAN1970	31DEC1970	N
			Wrist surgery	01JAN2018	31DEC2018	N
	C4591001 1152 11521439	Gastrointestinal disorders	Haemorrhoids	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2012		Y
			Perennial allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1152 11521440	Gastrointestinal disorders	Colitis ulcerative	01JAN2017		Y
			Rectal haemorrhage	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2014		Y
			Milk allergy	01JAN2017		Y
		Investigations	Biopsy breast	01NOV2014	30NOV2014	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01DEC2006	31DEC2006	N
				01MAY2007	31MAY2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01DEC2016	28FEB2017	N
		Nervous system disorders	Migraine	01JAN1999	31DEC2019	N
		Pregnancy, puerperium and perinatal conditions	Premature labour	01FEB2001	28FEB2001	N
				01JUN1998	30JUN1998	N
		Renal and urinary disorders	Cystitis interstitial	01JAN2005		Y
			Nephrolithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Bunion operation	01DEC2006	31DEC2006	N
				01DEC2007	31DEC2007	N
				01MAY2007	31MAY2007	N
			Mammoplasty	01JUL1989	31JUL1989	N
			Renal stone removal	01OCT2009	31OCT2009	N
			Rhinoplasty	01JUL1989	31JUL1989	N
			Skin neoplasm excision	01FEB2017	28FEB2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521441	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2007	31DEC2019	N
			Depression	01JAN2007	31DEC2017	N
		Surgical and medical procedures	Osteotomy	01JAN2008	31DEC2008	N
	C4591001 1152 11521443	Eye disorders	Myopia	01JAN1999		Y
	C4591001 1152 11521444	Ear and labyrinth disorders	Meniere's disease	01JAN2016		Y
		Eye disorders	Retinal tear	01JAN2015		Y
		Nervous system disorders	Dizziness	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1152 11521445	Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Dust allergy	01JAN1985		Y
	C4591001 1152 11521446	Surgical and medical procedures	Umbilical hernia repair	01JAN2010	31DEC2010	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2005		Y
		Investigations	Biopsy liver	01FEB2019	28FEB2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	02SEP2020		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Vascular disorders	Hypertension	02SEP2020		Y
	C4591001 1152 11521449	Eye disorders	Hypermetropia	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1152 11521450	Gastrointestinal disorders	Diarrhoea	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Cough	01MAR2019		Y
	C4591001 1152 11521451	Eye disorders	Myopia	01JAN2006		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Suicide attempt	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Urge incontinence	01JAN2019		Y
	C4591001 1152 11521452	Eye disorders	Myopia	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Keratomileusis	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1152 11521453	Ear and labyrinth disorders	Exostosis of external ear canal	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2017		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Vascular disorders	Hypotension	01JAN1980		Y
	C4591001 1152 11521454	Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
			Ligament operation	01JAN2006	31DEC2006	N
			Ovarian cystectomy	01JAN2005	31DEC2005	N
	C4591001 1152 11521455	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1152 11521456	Immune system disorders	Allergy to animal	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2008		Y
	C4591001 1152 11521457	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521459	Blood and lymphatic system disorders	Anaemia	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Investigations	Cardiac murmur	01JAN1968		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1152 11521460	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009	31DEC2016	N
	C4591001 1152 11521461	Skin and subcutaneous tissue disorders	Urticaria	01JAN2009		Y
	C4591001 1152 11521462	Eye disorders	Dry eye	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	24JUL2010	24JUL2010	N
	C4591001 1152 11521465	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1152 11521467	Eye disorders	Myopia	01JAN2015		Y
		Infections and infestations	Genital herpes	01JAN2003		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1152 11521468	Gastrointestinal disorders	Haemorrhoids	01JAN2009		Y
		Infections and infestations	Genital herpes	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN1998		Y
	C4591001 1152 11521472	Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
	C4591001 1152 11521474	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1152 11521475	Cardiac disorders	Tachycardia	01JAN2005	31DEC2007	N
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
			Genital herpes	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Cardiac ablation	01JAN2007	31DEC2007	N
	C4591001 1152 11521477	Gastrointestinal disorders	Dyspepsia	01JAN2018	31JAN2020	N
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Nervous system disorders	Epilepsy	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN1980		Y
	C4591001 1152 11521478	Injury, poisoning and procedural complications	Forearm fracture	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Open reduction of fracture	01JAN2003	31DEC2003	N
	C4591001 1152 11521479	Immune system disorders	Allergy to chemicals	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1152 11521482	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Dyspepsia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Dyspnoea	01JAN2017		Y
			Sinus disorder	01JAN2010		Y
		Surgical and medical procedures	Cholelithotomy	01JAN1987	31DEC1987	N
	C4591001 1152 11521489	Infections and infestations	Respiratory syncytial virus infection	01JAN2000	31DEC2000	N
					31DEC2002	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1152 11521490	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	30APR2020	N
		Surgical and medical procedures	Caesarean section	10JAN2000	10JAN2000	N
			Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1152 11521492	Eye disorders	Myopia	01JAN1977		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1152 11521493	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Food allergy	01JUN2020		Y
	C4591001 1152 11521496	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	31DEC2017	N
			Rotator cuff syndrome	01AUG2019	31AUG2019	N
		Surgical and medical procedures	Joint manipulation	01AUG2019	31DEC2019	N
			Mammoplasty	01JAN2017	31DEC2017	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1152 11521498	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1152 11521499	Blood and lymphatic system disorders	Anaemia	01JAN2011		Y
		Immune system disorders	Perennial allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Surgical and medical procedures	Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1152 11521500	Gastrointestinal disorders	Food poisoning	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1152 11521501	Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypotension	01JAN2000		Y
	C4591001 1152 11521504	Endocrine disorders	Hypothyroidism	01JAN2002		Y
			Thyroid mass	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Thyroidectomy	01JAN2002	31DEC2002	N
	C4591001 1152 11521505	Immune system disorders	Mite allergy	01JAN1999		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1152 11521506	Cardiac disorders	Palpitations	01JAN2000		Y
			Tachycardia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521509	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Food poisoning	01JAN2018	31DEC2018	N
		Immune system disorders	Perennial allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521512	Ear and labyrinth disorders	Meniere's disease	01JAN2015		Y
		Eye disorders	Cataract	01JUL2020		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
			Urinary bladder suspension	01JAN2003	31DEC2003	N
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1152 11521515	Immune system disorders	Food allergy	01JAN1972		Y
			Milk allergy	01JAN1972		Y
			Perennial allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013		Y
			Melanocytic naevus	01JAN2014	31DEC2014	N
			Squamous cell carcinoma of skin	01JAN2013		Y
		Nervous system disorders	Sciatica	01JAN1983	31DEC1984	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Mole excision	01JAN2014	31DEC2014	N
			Skin neoplasm excision	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
	C4591001 1152 11521517	Injury, poisoning and procedural complications	Cartilage injury	01JAN1984	31DEC1984	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Premature menopause	01APR2015		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2015	31DEC2015	N
			Knee operation	01JAN1984	31DEC1984	N
			Mammoplasty	01JAN2015	31DEC2015	N
			Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1152 11521519	Immune system disorders	Food allergy	01JAN2014		Y
			Perennial allergy	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Staphylococcal infection	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2014	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y	
			Ingrowing nail	01JAN2014	31DEC2014	N	
				Urticaria	01JAN2016	31DEC2016	N
					01JAN2012		Y
		Surgical and medical procedures	Nail operation	01JAN2014	31DEC2014	N	
				01JAN2016	31DEC2016	N	
				Wisdom teeth removal	01JAN2017	31DEC2017	N
	C4591001 1152 11521520	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N	
		Psychiatric disorders	Anxiety	01JAN2020		Y	
				Depression	01JAN2020		Y
				Insomnia	01MAR2020		Y
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N	
				01JAN2009	31DEC2009	N	
				Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1152 11521521	Immune system disorders	Food allergy	01JAN1988		Y	
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1987		Y	
		Nervous system disorders	Migraine	01JAN1987		Y	
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN2017	31DEC2017	N	
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N	
				Gastric bypass	01JAN2006	31DEC2006	N
		Vascular disorders	Varicose vein	01JAN1990		Y	
	C4591001 1152 11521522	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N	
		Immune system disorders	Seasonal allergy	01JAN2018		Y	
		Infections and infestations	Diverticulitis	01JAN2014	31DEC2014	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
			Cholecystectomy	01JAN2007	31DEC2007	N
	C4591001 1152 11521529	Blood and lymphatic system disorders	Anaemia	01JAN2019	29FEB2020	N
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Perennial allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
			Meniscus injury	01JAN2007	31DEC2007	N
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN1990		Y
			Sciatica	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
			Meniscus operation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1152 11521534	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Facial paralysis	01JAN2008	31DEC2008	N
			Headache	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Eye operation	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521537	Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2011	N
	C4591001 1152 11521549	Congenital, familial and genetic disorders	Cleft palate	(b) (6) 1980	31DEC1985	N
		Surgical and medical procedures	Cleft palate repair	01JAN1985	31DEC1985	N
	C4591001 1152 11521551	Gastrointestinal disorders	Femoral hernia	01JAN2011	31DEC2011	N
			Inguinal hernia	01JAN2017	31DEC2017	N
		Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2008	31DEC2008	N
		Investigations	Cardiac murmur	21OCT2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2018	31DEC2018	N
			Thyroid cancer	01JAN2010	31DEC2010	N
			Uterine leiomyoma	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
			Femoral hernia repair	01JAN2011	31DEC2011	N
			Incisional hernia repair	01JAN2008	31DEC2008	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
			Mammary ductectomy	01JAN2018	31DEC2018	N
			Myomectomy	01JAN2004	31DEC2004	N
			Rhinoplasty	01JAN1998	31DEC1998	N
			Thyroidectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521552	Gastrointestinal disorders	Constipation	01JAN2019	31JUL2020	N
		Infections and infestations	Pneumonia	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2010		Y
	C4591001 1152 11521557	Injury, poisoning and procedural complications	Joint dislocation	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Gastric bypass	01JAN2013	31DEC2013	N
			Knee operation	01JAN2005	31DEC2005	N
			Liposuction	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2007	31DEC2007	N
		Vascular disorders	Varicose vein	01JAN2002		Y
	C4591001 1152 11521560	Eye disorders	Macular degeneration	01JAN2017		Y
		Immune system disorders	Perennial allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521566	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2000		Y
			Sciatica	01JAN2019		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1152 11521568	Eye disorders	Myopia	01JAN2019	30SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Inguinal hernia	01JAN1978	31DEC1978	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2000	31DEC2000	N
				01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN1989	31DEC1989	N
			Ear operation	01JAN2000	31DEC2000	N
				01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN1978	31DEC1978	N
			Photorefractive keratectomy	01SEP2020	30SEP2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521569	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1152 11521571	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2005	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
	C4591001 1152 11521577	Eye disorders	Blepharitis	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1999	31DEC1999	N
	C4591001 1152 11521583	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019	30NOV2019	N
		Surgical and medical procedures	Joint arthroplasty	01NOV2019	30NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521584	Infections and infestations	Syphilis	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
	C4591001 1152 11521588	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1152 11521590	Eye disorders	Myopia	01JAN2015		Y
	C4591001 1152 11521591	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
			Insomnia	01JAN2018	29FEB2020	N
		Surgical and medical procedures	Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1152 11521598	Immune system disorders	Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
	C4591001 1152 11521600	Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
	C4591001 1152 11521601	Infections and infestations	Respiratory syncytial virus infection	01JAN2003	31DEC2003	N
	C4591001 1152 11521602	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1152 11521603	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2018		Y
			Mental disorder	01FEB2020	29FEB2020	N
	C4591001 1152 11521606	Infections and infestations	Ear infection	01JAN2004	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ear tube insertion	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
	C4591001 1152 11521609	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004	31DEC2006	N
	C4591001 1152 11521610	Immune system disorders	Mite allergy	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1152 11521618	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1152 11521620	Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1152 11521621	Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1152 11521622	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Pneumonia	01JAN2014	31DEC2014	N
	C4591001 1152 11521623	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1152 11521624	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Surgical and medical procedures	Wisdom teeth removal	01AUG2020	31AUG2020	N	
	C4591001 1152 11521627	Immune system disorders	Seasonal allergy	01JAN2004		Y	
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y	
	C4591001 1152 11521631	Skin and subcutaneous tissue disorders Injury, poisoning and procedural complications	Eczema Clavicle fracture	01JAN2019	31DEC2019	Y N	
	C4591001 1152 11521632	Surgical and medical procedures Immune system disorders	Bone operation Seasonal allergy	01JAN2019	31DEC2019	N Y	
		Reproductive system and breast disorders	Testicular torsion	01JAN2013	31DEC2013	N	
	C4591001 1152 11521634	Surgical and medical procedures Immune system disorders	Testicular operation Seasonal allergy	01JAN2013	31DEC2013	N Y	
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N	
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y	
	C4591001 1152 11521643	Surgical and medical procedures Immune system disorders	Appendicectomy Drug hypersensitivity	01JAN2006	31DEC2006	N Y	
		Investigations	Thyroid function test abnormal	02OCT2020		Y	
	C4591001 1156 11561002	Psychiatric disorders	Aggression	28FEB2019	28FEB2019	N	
	C4591001 1156 11561003	Metabolism and nutrition disorders	Schizophrenia Hyperlipidaemia	28FEB2019	03MAY2018	Y Y	
	C4591001 1156 11561004	Skin and subcutaneous tissue disorders Gastrointestinal disorders	Dermatitis atopic Inguinal hernia	04JUN2018	01JAN2000	31DEC2000	Y N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Back pain	02AUG2019		Y
		Psychiatric disorders	Anxiety disorder	02AUG2019		Y
		Social circumstances	Tobacco user	01JAN1998		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
				01JAN2002	31DEC2002	N
	C4591001 1156 11561005	Infections and infestations	Chlamydial infection	27MAY2020	30MAY2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	28MAY2020		Y
	C4591001 1156 11561006	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG2014		Y
	C4591001 1156 11561007	Metabolism and nutrition disorders	Obesity	06JUN2019		Y
		Reproductive system and breast disorders	Menorrhagia	03JAN2020	20JAN2020	N
		Surgical and medical procedures	Caesarean section	16MAY2019	16MAY2019	N
	C4591001 1156 11561009	Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2018	31DEC2018	N
	C4591001 1156 11561010	Eye disorders	Keratoconus	20AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1156 11561012	Cardiac disorders	Tachycardia	20JAN2016		Y
		Immune system disorders	Iodine allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	02AUG2020		Y
	C4591001 1156 11561013	Eye disorders	Glaucoma	30MAY2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Peripheral nerve lesion	20APR2020		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	03MAR1990	03MAR1990	N
			Female sterilisation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1156 11561014	Gastrointestinal disorders	Umbilical hernia	01JUN2020	30JUN2020	N
		Surgical and medical procedures	Caesarean section	07MAY2015	07MAY2015	N
				23AUG2009	23AUG2009	N
				23SEP2018	23SEP2018	N
				30MAR2016	30MAR2016	N
			Female sterilisation	23SEP2018	23SEP2018	N
			Umbilical hernia repair	01JUN2020	30JUN2020	N
	C4591001 1156 11561015	Immune system disorders	Food allergy	01JAN2010		Y
	C4591001 1156 11561016	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
			Microcytic anaemia	23SEP2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	23SEP2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	21JUL2017		Y
		Reproductive system and breast disorders	Menorrhagia	18MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	21FEB2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis	28FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	04MAY1998	04MAY1998	N
			Female sterilisation	01JAN2003	31DEC2003	N
		Vascular disorders	Deep vein thrombosis	13OCT2017	11DEC2017	N
			Hypertension	12MAY2017		Y
			Peripheral arterial occlusive disease	23SEP2019		Y
	C4591001 1156 11561018	Hepatobiliary disorders	Cholelithiasis	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JUL2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	10OCT2006	10OCT2006	N
				22NOV2002	22NOV2002	N
			Eye laser surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Essential hypertension	01JAN2016		Y
	C4591001 1156 11561019	Surgical and medical procedures	Caesarean section	05MAY2016	05MAY2016	N
	C4591001 1156 11561021	Musculoskeletal and connective tissue disorders	Neck pain	08MAR2019		Y
		Nervous system disorders	Carpal tunnel syndrome	06FEB2019		Y
			Headache	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2015	31MAR2020	N
		Surgical and medical procedures	Hysterectomy	31MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01OCT2017		Y
	C4591001 1156 11561023	Metabolism and nutrition disorders	Obesity	17APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	24OCT2019		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561026	Metabolism and nutrition disorders	Metabolic syndrome	06JUL2020		Y
			Obesity	06JUL2020		Y
		Reproductive system and breast disorders	Amenorrhoea	06JUL2020		Y
			Breast pain	06JUL2020		Y
			Cervical cyst	06JUL2020		Y
			Infertility female	21JUL2020		Y
			Polycystic ovaries	06JUL2020		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	06JUL2020		Y
			Hirsutism	06JUL2020		Y
		Vascular disorders	Hypertension	06JUL2020		Y
	C4591001 1156 11561028	Congenital, familial and genetic disorders	Ectopic kidney	(b) (6) 1987		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29DEC2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	06NOV2018		Y
		Nervous system disorders	Sciatica	06NOV2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	17MAY2017		Y
	C4591001 1156 11561029	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
			Thrombocytopenia	01JAN2016		Y
		Eye disorders	Keratoconus	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	10MAY2010	10MAY2010	N
				14MAY2015	14MAY2015	N
				30AUG2011	30AUG2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Corneal transplant	01JAN2012	31DEC2012	N
	C4591001 1156 11561030	Blood and lymphatic system disorders	Anaemia	02MAR2017		Y
		Surgical and medical procedures	Caesarean section	04OCT2017	04OCT2017	N
				08JUL2006	08JUL2006	N
				14AUG2018	14AUG2018	N
			Hysterectomy	14AUG2018	14AUG2018	N
	C4591001 1156 11561031	Immune system disorders	Drug hypersensitivity	22DEC2017		Y
		Injury, poisoning and procedural complications	Meniscus injury	14MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	14MAY2020		Y
	C4591001 1156 11561032	Investigations	Aortic bruit	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Aortic valve repair	01JAN1988	31DEC1988	N
		Vascular disorders	Aortic disorder	(b) (6) 1988	31DEC1988	N
	C4591001 1156 11561033	Gastrointestinal disorders	Gastritis	18APR2019		Y
			Gastroesophageal reflux disease	18APR2019		Y
			Haemorrhoids	18APR2019		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	28NOV2018		Y
		Investigations	Vitamin D abnormal	21FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
			Spondylitis	01JAN2003		Y
			Tenosynovitis	01JAN2017	24JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	26JUN2016		Y
		Psychiatric disorders	Anxiety	04JUN2010		Y
			Insomnia	16JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	06APR2020		Y
		Social circumstances	Tobacco user	01JAN1978		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2003	31DEC2003	N
			Carpal tunnel decompression	24JUN2020	24JUN2020	N
			Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2019		Y
			Hypertension	01JAN1985		Y
	C4591001 1156 11561034	Infections and infestations	Salpingitis	01JAN2004	31DEC2004	N
		Investigations	Liver function test increased	10APR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2000		Y
		Surgical and medical procedures	Salpingectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Peripheral venous disease	10APR2019		Y
	C4591001 1156 11561036	Musculoskeletal and connective tissue disorders	Plantar fasciitis	06APR2018	21AUG2018	N
		Renal and urinary disorders	Nephrolithiasis	21NOV2018		Y
		Surgical and medical procedures	Fascia release	21AUG2018	21AUG2018	N
	C4591001 1156 11561039	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Surgical and medical procedures	Liposuction	01JAN2015	31JAN2015	N
	C4591001 1156 11561040	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1156 11561041	Metabolism and nutrition disorders	Hypertriglyceridaemia	13JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	10JAN2019		Y
		Reproductive system and breast disorders	Infertility male	10JAN2019		Y
	C4591001 1156 11561042	Gastrointestinal disorders	Diarrhoea	01JAN2015		Y
			Gastrooesophageal reflux disease	06JUL2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	14JUL2020		Y
		Vascular disorders	Hypertension	06JUL2020		Y
	C4591001 1156 11561043	Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Investigations	Hepatic enzyme abnormal	18MAR2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	06JUN2019		Y
			Glucose tolerance impaired	18MAR2020		Y
			Obesity	01JAN1998		Y
			Vitamin D deficiency	18MAR2020		Y
		Nervous system disorders	Migraine	01JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JUN2019		Y
			Sleep apnoea syndrome	05JUN2019		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Appendicectomy	01JAN1982	31DEC1982	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Salpingectomy	26FEB1988	26FEB1988	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1156 11561045	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	08JUN2019		Y
			Overweight	01JAN2012		Y
			Vitamin D deficiency	08JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	06JUN2019		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1156 11561046	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996	31DEC2001	N
	C4591001 1156 11561049	Blood and lymphatic system disorders	Leukopenia	29APR2020		Y
			Neutropenia	29APR2020		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2020		Y
			Hypocholesterolaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2020		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
			Post-traumatic epilepsy	01JAN2017		Y
	C4591001 1156 11561050	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	03MAR2005	03MAR2005	N
				15DEC1999	15DEC1999	N
		Reproductive system and breast disorders	Ovarian cyst	01FEB2019	28FEB2019	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN1989	31DEC1989	N
			Tonsillar hypertrophy	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenoidectomy	01JAN1989	31DEC1989	N
			Caesarean section	03MAR2005	03MAR2005	N
				15DEC1999	15DEC1999	N
			Oophorectomy	01FEB2019	28FEB2019	N
			Tonsillectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1999		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1156 11561053	Hepatobiliary disorders	Hepatic steatosis	18JUN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	05JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	07FEB2018		Y
			Osteoarthritis	10AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	22DEC2017		Y
	C4591001 1156 11561055	Blood and lymphatic system disorders	Iron deficiency anaemia	14MAY2020		Y
		Cardiac disorders	Sinus tachycardia	12JUN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	14MAY2020		Y
			Glucose tolerance impaired	14MAY2020		Y
			Overweight	13MAR2020		Y
		Reproductive system and breast disorders	Menstrual disorder	12MAY2020		Y
			Metrorrhagia	12MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13MAR2020		Y
		Vascular disorders	Hypertension	12JUN2019		Y
	C4591001 1156 11561056	Infections and infestations	Rhinitis	13JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	05MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16DEC2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	13SEP2011		Y
	C4591001 1156 11561057	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2015		Y
	C4591001 1156 11561058	Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	04JUN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Raynaud's phenomenon	02APR2018		Y
			Varicose vein	31OCT2015		Y
	C4591001 1156 11561060	Metabolism and nutrition disorders	Vitamin D deficiency	12JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12JUN2020		Y
	C4591001 1156 11561061	Infections and infestations	Appendicitis	13JAN2020	13JAN2020	N
		Surgical and medical procedures	Appendicectomy	13JAN2020	13JAN2020	N
	C4591001 1156 11561064	Infections and infestations	Tonsillitis	01JAN2010	31DEC2012	N
		Injury, poisoning and procedural complications	Head injury	08AUG2020	11AUG2020	N
			Neck injury	08AUG2020	11AUG2020	N
		Surgical and medical procedures	Caesarean section	24SEP2019	24SEP2019	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1156 11561065	Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1156 11561072	Metabolism and nutrition disorders	Hyperlipidaemia	15AUG2019		Y
			Obesity	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	29AUG2017	31DEC2019	N
	C4591001 1156 11561073	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	16JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16JUL2019		Y
		Surgical and medical procedures	Caesarean section	31MAR2006	31MAR2006	N
			Salpingectomy	31MAR2006	31MAR2006	N
	C4591001 1156 11561074	Gastrointestinal disorders	Gastroesophageal reflux disease	20AUG2019		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperglycaemia	21AUG2019		Y
			Hyperlipidaemia	20AUG2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
	C4591001 1156 11561075	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Food allergy	01JAN2018		Y
	C4591001 1156 11561076	Pregnancy, puerperium and perinatal conditions	Delivery	22DEC2015	22DEC2015	N
		Surgical and medical procedures	Caesarean section	22DEC2015	22DEC2015	N
	C4591001 1156 11561077	Psychiatric disorders	Depression	08APR2019		Y
			Panic attack	08APR2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2020		Y
	C4591001 1156 11561078	Infections and infestations	Rhinitis	08NOV2019		Y
	C4591001 1156 11561082	Metabolism and nutrition disorders	Vitamin D deficiency	02NOV2019		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561085	Gastrointestinal disorders	Chronic gastritis	01JAN1998		Y
		Hepatobiliary disorders	Hepatic steatosis	22MAY2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	17JAN2017		Y
			Vitamin D deficiency	17JAN2017	21SEP2018	N
		Nervous system disorders	Lumbar radiculopathy	01JAN1995		Y
		Psychiatric disorders	Major depression	10JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Substance use	01JAN2017	31DEC2019	N
			Tobacco user	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1156 11561086	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1156 11561087	Gastrointestinal disorders	Diverticulum intestinal	01JAN2018		Y
		Investigations	High density lipoprotein decreased	11FEB2020		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	11FEB2020		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1156 11561089	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
	C4591001 1156 11561090	Gastrointestinal disorders	Gastroesophageal reflux disease	13DEC2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561093	Metabolism and nutrition disorders	Underweight	01JAN2000		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
	C4591001 1156 11561097	Endocrine disorders	Thyroid cyst	26DEC2019		Y
		Investigations	Antinuclear antibody positive	20DEC2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y
	C4591001 1156 11561105	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Dyslipidaemia	30OCT2019		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
			Schizophrenia	01JAN2010		Y
		Social circumstances	Postmenopause	01SEP2018		Y
			Tobacco user	01JAN2005		Y
		Surgical and medical procedures	Metabolic surgery	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1156 11561107	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1156 11561108	Social circumstances	Tobacco user	01JAN2008		Y
	C4591001 1156 11561109	Endocrine disorders	Testicular failure	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Gynaecomastia	01JAN2012	31DEC2012	N
	C4591001 1156 11561111	Surgical and medical procedures	Mastectomy	01JAN2012	31DEC2012	N
		Blood and lymphatic system disorders	Anaemia	15MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Food allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	15MAY2020		Y
			Vitamin D deficiency	27MAY2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	02NOV2017	02NOV2017	N
				12DEC2015	12DEC2015	N
		Reproductive system and breast disorders	Amenorrhoea	15MAR2020		Y
		Surgical and medical procedures	Caesarean section	02NOV2017	02NOV2017	N
				12DEC2015	12DEC2015	N
			Salpingectomy	02NOV2017	02NOV2017	N
			Sterilisation	02NOV2017	02NOV2017	N
	C4591001 1156 11561115	Hepatobiliary disorders	Cholecystitis	06MAR2013	06MAR2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
			Endocarditis	21JAN2014	29APR2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	31MAR2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Spinal pain	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2013	21MAY2013	N
			Pituitary tumour benign	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine leiomyoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Sciatica	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2013		Y
			Major depression	01JAN2013		Y
			Panic attack	01JAN2013		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2011	31DEC2011	N
			Appendectomy	01JAN1992	31DEC1992	N
			Axillary lymphadenectomy	01JUL2013	31JUL2013	N
			Breast operation	01MAR2013	31MAR2013	N
			Breast reconstruction	16SEP2016	16SEP2016	N
			Central venous catheterisation	23AUG2013	07MAY2014	N
			Cholecystectomy	06MAR2013	06MAR2013	N
			Gastric bypass	01MAR2012	31MAR2012	N
			Hysterectomy	01JAN2011	31JAN2011	N
			Mammoplasty	03OCT2014	03OCT2014	N
			Mastectomy	03OCT2014	03OCT2014	N
				21MAY2013	21MAY2013	N
			Oophorectomy bilateral	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1156 11561119	Immune system disorders	Food allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561120	Infections and infestations	Adenoiditis	01JAN2006	31DEC2006	N
			Tonsillitis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN2006	31DEC2006	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561123	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN2019		Y
		Infections and infestations	Adenoiditis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Tendonitis	21NOV2019	31MAR2020	N
		Reproductive system and breast disorders	Varicocele	01JAN2014	31DEC2016	N
		Surgical and medical procedures	Adenoidectomy	01JAN2000	31DEC2000	N
			Varicocele repair	01JAN2016	31DEC2016	N
	C4591001 1156 11561124	Psychiatric disorders	Anxiety	01NOV2018		Y
	C4591001 1156 11561126	Hepatobiliary disorders	Cholelithiasis	30JUN2019	12AUG2019	N
		Investigations	Blood thyroid stimulating hormone decreased	21JAN2019	28MAR2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	21JAN2019	28MAR2020	N
			Obesity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002	31DEC2010	N
			Sleep apnoea syndrome	18JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	12AUG2019	12AUG2019	N
	C4591001 1156 11561128	Surgical and medical procedures	Liposuction	01JAN2016	31DEC2016	N
	C4591001 1156 11561129	Endocrine disorders	Thyroid mass	23NOV2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Tobacco user	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	05JUL2008	05JUL2008	N
				13JUL2005	13JUL2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1156 11561131	Injury, poisoning and procedural complications	Limb injury	17SEP2016	17SEP2016	N
		Surgical and medical procedures	Soft tissue flap operation	17SEP2016	17SEP2016	N
	C4591001 1156 11561132	Eye disorders	Visual acuity reduced	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
	C4591001 1156 11561134	Surgical and medical procedures	Caesarean section	04JAN2015	04JAN2015	N
			Salpingectomy	04JAN2015	04JAN2015	N
			Sterilisation	04JAN2015		Y
	C4591001 1156 11561135	Injury, poisoning and procedural complications	Muscle strain	11SEP2020		Y
			Road traffic accident	01MAY2020	31MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2015	N
		Social circumstances	Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	04SEP2019	04SEP2019	N
				29JUL2015	29JUL2015	N
	C4591001 1156 11561136	Hepatobiliary disorders	Hepatic steatosis	03AUG2020		Y
	C4591001 1156 11561137	Surgical and medical procedures	Hysterectomy	17MAR2020	17MAR2020	N
			Inguinal hernia repair	01JAN1996	31DEC1996	N
	C4591001 1156 11561145	Surgical and medical procedures	Caesarean section	05FEB2020	05FEB2020	N
				25JUL2017	25JUL2017	N
				26SEP2014	26SEP2014	N
	C4591001 1156 11561146	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN1996		Y
	C4591001 1156 11561148	Hepatobiliary disorders	Hepatic function abnormal	12JUL2018		Y
			Hepatic steatosis	13JUL2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
	C4591001 1156 11561154	Metabolism and nutrition disorders	Hyperlipidaemia	23JUL2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	14NOV2002	14NOV2002	N
		Surgical and medical procedures	Caesarean section	14NOV2002	14NOV2002	N
			Salpingectomy	14NOV2002	14NOV2002	N
			Sterilisation	14NOV2002		Y
	C4591001 1156 11561158	Metabolism and nutrition disorders	Lactose intolerance	01JAN1978		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1156 11561159	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2014		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Gastritis	01JAN2014		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1994	31DEC1994	N
			Road traffic accident	01JAN1993	31DEC1993	N
				01JAN1994	31DEC1994	N
		Nervous system disorders	Hemiparesis	01JAN1994		Y
			Migraine	01JAN1994		Y
		Psychiatric disorders	Major depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Surgical and medical procedures	Ankle operation	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561161	Infections and infestations	Latent tuberculosis	01JAN2020		Y
	C4591001 1156 11561162	Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2014	26DEC2019	N
		Psychiatric disorders	Insomnia	22SEP2020		Y
		Surgical and medical procedures	Knee operation	26DEC2019	26DEC2019	N
			Meniscus removal	26DEC2019	26DEC2019	N
	C4591001 1156 11561164	Metabolism and nutrition disorders	Overweight	29OCT2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	29OCT2013		Y
	C4591001 1156 11561166	Cardiac disorders	Mitral valve prolapse	01JAN1998		Y
			Sinus tachycardia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Tonsillectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1156 11561170	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1156 11561172	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2019		Y
			Obesity	05APR2019		Y
		Psychiatric disorders	Depression	16MAY2019		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1156 11561174	Blood and lymphatic system disorders	Anaemia	27MAY2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	27MAY2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
	C4591001 1156 11561175	Endocrine disorders	Goitre	01JAN2019		Y
		Reproductive system and breast disorders	Menstruation irregular	18JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1156 11561176	Surgical and medical procedures	Caesarean section	11FEB2011	11FEB2011	N
			Carpal tunnel decompression	27FEB2020	27FEB2020	N
				28FEB2020	28FEB2020	N
	C4591001 1156 11561178	Immune system disorders	Rubber sensitivity	08APR2020		Y
		Vascular disorders	Hypertension	01NOV1998		Y
	C4591001 1156 11561179	Injury, poisoning and procedural complications	Road traffic accident	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Caesarean section	21NOV2012	21NOV2012	N
			Female sterilisation	01JAN2013	31DEC2013	N
			Fracture treatment	01JAN2002	31DEC2002	N
	C4591001 1156 11561185	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1156 11561189	Gastrointestinal disorders	Gastritis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Ex-tobacco user	01JAN1998	31DEC2014	N
	C4591001 1156 11561190	Gastrointestinal disorders	Gastritis	01MAR2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety disorder	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	13JUL2020	13JUL2020	N
			Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1156 11561196	Infections and infestations	Onychomycosis	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1156 11561198	Cardiac disorders	Mitral valve incompetence	01APR2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2019		Y
			Sciatica	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	27FEB1990	27FEB1990	N
			Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	23APR2019		Y
	C4591001 1156 11561199	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
			Vitamin D deficiency	01MAY2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	19DEC2011	19DEC2011	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	19DEC2011	19DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salpingectomy	01JAN2018	31DEC2018	N
			Sterilisation	01JAN2018		Y
	C4591001 1156 11561200	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
		Nervous system disorders	Cervical radiculopathy	01FEB2020		Y
			Lumbar radiculopathy	01JAN2020		Y
		Vascular disorders	Hypertension	05MAR2020		Y
	C4591001 1156 11561201	Surgical and medical procedures	Caesarean section	07JUL2011	07JUL2011	N
	C4591001 1156 11561203	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2007	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2007	31DEC2007	N
	C4591001 1156 11561205	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992	31DEC2017	N
		Surgical and medical procedures	Salpingectomy	11AUG2013	11AUG2013	N
			Sterilisation	11AUG2013		Y
	C4591001 1156 11561206	Blood and lymphatic system disorders	Iron deficiency anaemia	01OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1156 11561208	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Adenoiditis	01JAN1998	31DEC1998	N
		Investigations	Blood triglycerides increased	01FEB2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc protrusion	26FEB2020		Y
		Psychiatric disorders	Anxiety disorder	01JAN2019		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	04APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1998	31DEC1998	N
			Caesarean section	04APR2018	04APR2018	N
				25MAY2009	25MAY2009	N
				26SEP2012	26SEP2012	N
			Salpingectomy	04APR2018	04APR2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1156 11561209	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1156 11561210	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
			Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2014	31DEC2014	N
	C4591001 1156 11561213	Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561214	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JUL2011	31JUL2011	N
	C4591001 1156 11561226	Infections and infestations	Adenoiditis	01JAN2013	31DEC2014	N
		Nervous system disorders	Seizure	01JAN2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2014	31DEC2014	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1156 11561227	Gastrointestinal disorders	Gastritis	14JAN2013		Y
		Investigations	Human papilloma virus test positive	14JAN2013		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
	C4591001 1156 11561229	Nervous system disorders	Headache	19DEC2019		Y
	C4591001 1156 11561230	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
			Oppositional defiant disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1156 11561231	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
		Nervous system disorders	Migraine	28MAR2017		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Salpingectomy	02JUN2019	02JUN2019	N
			Sterilisation	02JUN2019		Y
	C4591001 1156 11561234	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1156 11561235	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	30NOV1992	30NOV1992	N
			Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1156 11561251	Endocrine disorders	Thyroid mass	16DEC2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	08MAR2018		Y
		Renal and urinary disorders	Nephrolithiasis	16DEC2016		Y
	C4591001 1156 11561268	Skin and subcutaneous tissue disorders	Acne	23SEP2020		Y
	C4591001 1156 11561272	Reproductive system and breast disorders	Ovarian cyst	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
			Ovarian cystectomy	01JAN2011	31DEC2011	N
	C4591001 1156 11561274	Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
			Pilonidal cyst	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	06AUG2020		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2019		Y
		Surgical and medical procedures	Colectomy	01JAN2015	31DEC2015	N
			Pilonidal sinus repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	05MAR2018		Y
	C4591001 1156 11561275	Metabolism and nutrition disorders	Obesity	18FEB2019		Y
			Type 2 diabetes mellitus	18FEB2019		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	18MAR2019		Y
	C4591001 1156 11561276	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1156 11561277	Surgical and medical procedures	Caesarean section	03OCT2013	03OCT2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				07APR2018	07APR2018	N
			Salpingectomy	07APR2018	07APR2018	N
	C4591001 1156 11561281	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	27FEB2020		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2009	31DEC2009	N
			Back pain	01JAN2006		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Breast cyst excision	01JAN2009	31DEC2009	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Salpingectomy	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2009	31DEC2009	N
			Sterilisation	01JAN2018		Y
			Tonsillectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1156 11561283	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1156 11561286	Metabolism and nutrition disorders	Obesity	06MAY2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	27DEC2018	27DEC2018	N
			Ectopic pregnancy	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Caesarean section	27DEC2018	27DEC2018	N
			Salpingostomy	01JAN2016	31DEC2016	N
	C4591001 1156 11561287	Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	25NOV2019		Y
	C4591001 1156 11561288	Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1156 11561289	Gastrointestinal disorders	Lumbar hernia	30JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	30JAN2017		Y
		Nervous system disorders	Sciatica	30JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN2002		Y
	C4591001 1156 11561290	Gastrointestinal disorders	Gastroesophageal reflux disease	17OCT2020		Y
		Immune system disorders	Food allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	09AUG2017		Y
			Obesity	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	12FEB2011	12FEB2011	N
				13JUN2004	13JUN2004	N
				17MAY2019	17MAY2019	N
				24JAN2006	24JAN2006	N
		Surgical and medical procedures	Caesarean section	12FEB2011	12FEB2011	N
				13JUN2004	13JUN2004	N
				17MAY2019	17MAY2019	N
				24JAN2006	24JAN2006	N
			Salpingectomy	17MAY2019	17MAY2019	N
			Sterilisation	17MAY2019		Y
	C4591001 1156 11561291	Metabolism and nutrition disorders	Obesity	09MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	09JAN2020		Y
	C4591001 1156 11561294	Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1156 11561295	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1156 11561298	Injury, poisoning and procedural complications	Injury to brachial plexus due to birth trauma	(b) (6) 2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	04SEP2019		Y
		Surgical and medical procedures	Peripheral nerve operation	01JAN2005	31DEC2005	N
	C4591001 1156 11561299	Reproductive system and breast disorders	Dysmenorrhoea	18JUL2017		Y
			Menorrhagia	18JUL2017		Y
	C4591001 1156 11561300	Immune system disorders	Food allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2010	N
		Surgical and medical procedures	Tenotomy	01JAN2010	31DEC2010	N
	C4591001 1156 11561302	Metabolism and nutrition disorders	Obesity	08FEB2017	19NOV2020	N
	C4591001 1156 11561315	Infections and infestations	Oral herpes	20NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
			Rhinitis allergic	20NOV2018		Y
	C4591001 1156 11561329	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1157 11571003	Hepatobiliary disorders	Cholecystitis	01JAN2006	31DEC2006	N
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1157 11571004	Blood and lymphatic system disorders	Pernicious anaemia	01JAN2004		Y
		Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
			Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN1992		Y
		Surgical and medical procedures	Gastric bypass	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1157 11571006	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Hypersensitivity	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Mastectomy	01JAN2014	31DEC2014	N
			Oophorectomy bilateral	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571010	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1157 11571013	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1157 11571015	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1157 11571017	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571019	Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1157 11571020	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1157 11571026	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1157 11571034	Reproductive system and breast disorders	Menstruation irregular	02JUL2020		Y
	C4591001 1157 11571040	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1157 11571042	Congenital, familial and genetic disorders	Myotonic dystrophy	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1157 11571054	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1157 11571057	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1157 11571070	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018		Y
	C4591001 1157 11571081	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
	C4591001 1157 11571082	Surgical and medical procedures	Salpingectomy	01JAN2014	31DEC2014	N
	C4591001 1157 11571083	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01APR2018	31JUL2018	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2013	N
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2013	31DEC2013	N
			Mastectomy	01JUL2018	31JUL2018	N
	C4591001 1157 11571092	Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571103	Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1157 11571108	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Spinal fusion surgery	12DEC2019	12DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571111	Surgical and medical procedures	Salpingectomy	01JAN2009		Y
	C4591001 1157 11571112	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1998	31DEC1998	N
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Oophorectomy	01JAN1998	31DEC1998	N
	C4591001 1157 11571113	Psychiatric disorders	Depression	01JAN2019		Y
			Generalised anxiety disorder	01JAN2019		Y
	C4591001 1157 11571115	Cardiac disorders	Ventricular extrasystoles	01JAN2018		Y
		Psychiatric disorders	Anxiety	01MAR2018		Y
	C4591001 1157 11571117	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571118	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1157 11571125	Psychiatric disorders	Anxiety	01JAN2008		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
	C4591001 1157 11571126	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1157 11571127	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Drug dependence	01JAN2015		Y
			Insomnia	01JAN2016		Y
		Surgical and medical procedures	Salpingectomy	01JAN2003	31DEC2003	N
	C4591001 1157 11571130	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1157 11571135	Surgical and medical procedures	Keratomileusis	01JAN2004	31DEC2004	N
	C4591001 1157 11571136	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2019	31DEC2019	N
	C4591001 1157 11571137	Cardiac disorders	Supraventricular tachycardia	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2012	31DEC2012	N
	C4591001 1157 11571140	Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571141	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Infections and infestations	Genital herpes	01JAN1996		Y
	C4591001 1157 11571166	Gastrointestinal disorders	Hiatus hernia	01JAN2009		Y
			Nausea	01JAN2009		Y
		Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1157 11571168	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Pancreatitis chronic	01JAN2004		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2011	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1157 11571169	Immune system disorders	Seasonal allergy	01MAY2020		Y
		Surgical and medical procedures	Salpingectomy	01MAY2007	31MAY2007	N
	C4591001 1157 11571170	Cardiac disorders	Mitral valve prolapse	01JAN1999		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y
	C4591001 1157 11571174	Cardiac disorders	Cardiac failure congestive	01JAN2018		Y
		Surgical and medical procedures	Salpingectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1157 11571176	Immune system disorders	Seasonal allergy	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1161 11611001	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1161 11611002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1161 11611005	Reproductive system and breast disorders	Menorrhagia	01JAN2017	18JUN2020	N
		Surgical and medical procedures	Hysterectomy	18JUN2020	18JUN2020	N
	C4591001 1161 11611007	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1161 11611009	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1161 11611010	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1161 11611011	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1161 11611014	Social circumstances	Tobacco user	01JAN2001	31MAR2020	N
	C4591001 1161 11611015	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2004		Y
		Social circumstances	Tobacco user	01JAN2015		Y
	C4591001 1161 11611016	Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1161 11611017	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1161 11611019	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1161 11611020	Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Nervous system disorders	Radiculopathy	12MAR2020		Y
	C4591001 1161 11611023	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01OCT2019		Y
			Panic attack	01JAN2018		Y
	C4591001 1161 11611027	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Congenital, familial and genetic disorders	Ventricular septal defect	01JAN1978	31DEC1978	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2020		Y
		Surgical and medical procedures	Female sterilisation	03JUN1997	03JUN1997	N
	C4591001 1161 11611028	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1161 11611032	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2009		Y
		Nervous system disorders	Febrile convulsion	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Vasectomy	01JAN2018	31JAN2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1161 11611034	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1162 11621001	Psychiatric disorders	Obsessive-compulsive disorder	01FEB2018		Y
	C4591001 1162 11621010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Blood testosterone decreased	01FEB2019		Y
	C4591001 1162 11621018	Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01MAY2017		Y
		Surgical and medical procedures	Caesarean section	16MAY1992	16MAY1992	N
				25AUG1996	25AUG1996	N
			Rhinoplasty	01JAN2008	31DEC2008	N
	C4591001 1162 11621019	Psychiatric disorders	Anxiety	01SEP2019		Y
			Attention deficit hyperactivity disorder	01MAY2019		Y
			Depression	01JAN2019		Y
			Insomnia	01FEB2020		Y
		Surgical and medical procedures	Rhinoplasty	01JUN2018	30JUN2018	N
	C4591001 1162 11621021	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1162 11621023	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Surgical and medical procedures	Mass excision	01JAN1998	31DEC1998	N
	C4591001 1162 11621024	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01FEB2019		Y
			Attention deficit hyperactivity disorder	01DEC2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
	C4591001 1162 11621025	Eye disorders	Myopia	01JAN1988		Y
	C4591001 1162 11621026	Immune system disorders	Food allergy	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JUN2016		Y
		Surgical and medical procedures	Caesarean section	11JUN2014	11JUN2014	N
				31MAY2016	31MAY2016	N
			Knee operation	01JAN2017	31DEC2017	N
	C4591001 1162 11621028	Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621031	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Oophorectomy	01JAN1990	31DEC1990	N
	C4591001 1162 11621033	Blood and lymphatic system disorders	Anaemia	01JAN1995		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621034	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1162 11621035	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Suture insertion	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1162 11621037	Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
	C4591001 1162 11621039	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN1980		Y
		Eye disorders	Myopia	01JAN1989		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1972	31DEC1983	N
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2004	31DEC2004	N
	C4591001 1162 11621041	Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	31MAR2014	31MAR2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1162 11621042	Metabolism and nutrition disorders	Obesity	01AUG2006		Y
	C4591001 1162 11621043	Gastrointestinal disorders	Hiatus hernia	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Heart rate irregular	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Obsessive-compulsive disorder	01JAN2017		Y
			Suicidal ideation	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2016	31DEC2016	N
			Nasal septum deviation	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2016	31DEC2016	N
			Cardiac operation	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
	C4591001 1162 11621051	Congenital, familial and genetic disorders	Haemoglobinopathy	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Social circumstances	Corrective lens user	01FEB2020		Y
	C4591001 1162 11621054	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Food allergy	01JAN2007		Y
	C4591001 1162 11621055	Injury, poisoning and procedural complications	Fibula fracture	01JAN2010	31DEC2010	N
	C4591001 1162 11621056	Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Strabismus correction	01JAN2000	31DEC2000	N
	C4591001 1162 11621061	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621062	Surgical and medical procedures	Skin graft	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621064	Eye disorders	Myopia	01JAN1983	31DEC2005	N
		Surgical and medical procedures	Keratomileusis	01JAN2005	31DEC2005	N
	C4591001 1162 11621066	Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Mammoplasty	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1162 11621067	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1162 11621070	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Myopia	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	01JAN1987		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
			Thyroidectomy	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
	C4591001 1162 11621075	Nervous system disorders	Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	04OCT2017	04OCT2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				23FEB2014	23FEB2014	N
			Female sterilisation	04OCT2017	04OCT2017	N
	C4591001 1162 11621077	Immune system disorders	Mite allergy	01JAN1990		Y
			Smoke sensitivity	01JAN1983		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2013	31DEC2013	N
	C4591001 1162 11621080	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1162 11621081	Surgical and medical procedures	Ear operation	01JAN2005	31DEC2005	N
	C4591001 1162 11621083	Psychiatric disorders	Schizophrenia	01JAN1986		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1162 11621085	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Psychiatric disorders	Depression	01MAR2020		Y
	C4591001 1162 11621091	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Rhinoplasty	01JAN1979	31DEC1979	N
	C4591001 1162 11621093	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621094	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621096	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2015		Y
	C4591001 1162 11621097	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
			Colectomy	01JAN2019	31DEC2019	N
	C4591001 1162 11621098	Eye disorders	Astigmatism	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Surgical and medical procedures	Skin graft	01JAN2006	31DEC2006	N
	C4591001 1162 11621100	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1162 11621103	Surgical and medical procedures	Caesarean section	13JAN2007	13JAN2007	N
				15JUN2013	15JUN2013	N
				18JUN2016	18JUN2016	N
	C4591001 1162 11621104	Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	24SEP2008	24SEP2008	N
			Rhinoplasty	01JAN1989	31DEC1989	N
	C4591001 1162 11621106	Surgical and medical procedures	Caesarean section	07AUG2015	07AUG2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621108	Eye disorders	Myopia	01JAN1990	31DEC2015	N
		Surgical and medical procedures	Keratomileusis	01JAN2015	31DEC2015	N
	C4591001 1162 11621110	Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1162 11621111	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Schizophrenia	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	27AUG2007	27AUG2007	N
			Mammoplasty	01JAN2009	31DEC2009	N
	C4591001 1162 11621112	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1162 11621114	Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
	C4591001 1162 11621115	Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	11NOV2005	11NOV2005	N
				13APR2007	13APR2007	N
			Tonsillectomy	01JAN1982	31DEC1982	N
	C4591001 1162 11621120	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1162 11621121	Immune system disorders	Food allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1162 11621124	Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		General disorders and administration site conditions	Cyst	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Infections and infestations	Infected cyst	01JAN2004	31DEC2004	N
			Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cyst removal	01JAN2004		Y
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1162 11621128	Injury, poisoning and procedural complications	Gun shot wound	01MAY2016	31MAY2016	N
		Surgical and medical procedures	Abdominal exploration	01JAN2016	31DEC2016	N
	C4591001 1162 11621130	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Adenoidectomy	01JUN2009	30JUN2009	N
	C4591001 1162 11621131	Surgical and medical procedures	Fracture treatment	01JAN2012	31DEC2012	N
	C4591001 1162 11621132	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1162 11621133	Endocrine disorders	Hyperthyroidism	01NOV2019		Y
		Infections and infestations	Herpes simplex	01NOV2019		Y
		Social circumstances	Corrective lens user	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	18MAR2017	18MAR2017	N
	C4591001 1162 11621135	Infections and infestations	Diverticulitis	01JAN2009	31DEC2009	N
		Psychiatric disorders	Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Colectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621137	Ear and labyrinth disorders	Deafness neurosensory	01SEP2019		Y
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1162 11621140	Eye disorders	Myopia	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Fibula fracture	01DEC2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01APR2020		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Breech presentation	17OCT2017	17OCT2017	N
			Pregnancy	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2005		Y
				01JAN2018		Y
		Surgical and medical procedures	Caesarean section	17OCT2017	17OCT2017	N
			Female sterilisation	17OCT2017	17OCT2017	N
			Tonsillectomy	01JAN2008	31DEC2008	N
	C4591001 1162 11621141	Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2010		Y
	C4591001 1162 11621142	Gastrointestinal disorders	Gastric haemorrhage	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Gastrectomy	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1162 11621144	Injury, poisoning and procedural complications	Ankle fracture	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Fracture treatment	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621145	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1162 11621146	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood testosterone decreased	01MAY2020		Y
	C4591001 1162 11621150	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Immune system disorders	Food allergy	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1162 11621151	Surgical and medical procedures	Ligament operation	01JAN2008	31DEC2008	N
	C4591001 1162 11621152	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN2006		Y
			Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621153	Gastrointestinal disorders	Intestinal cyst	01JAN2018	31DEC2018	N
		Investigations	Human papilloma virus test positive	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Large intestine operation	01JAN2018	31DEC2018	N
			Papilloma excision	01JAN2014	31DEC2014	N
	C4591001 1162 11621155	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Caesarean section	07SEP2010	07SEP2010	N
	C4591001 1162 11621156	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1162 11621158	Immune system disorders	Sarcoidosis	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Lesion excision	01JAN2010	31DEC2010	N
	C4591001 1162 11621159	Gastrointestinal disorders	Oesophageal stenosis	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
		Surgical and medical procedures	Oesophagocardiomyotomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621162	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN2015	31DEC2015	N
			Shoulder operation	01JAN2002	31DEC2002	N
	C4591001 1162 11621166	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
			Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
	C4591001 1162 11621168	Surgical and medical procedures	Cholecystectomy	01OCT2018	31OCT2018	N
		Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1162 11621169	Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Tonsillitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1162 11621170	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977	31DEC1995	N
		Surgical and medical procedures	Tenoplasty	02JAN2018	02JAN2018	N
	C4591001 1162 11621171	Eye disorders	Hypermetropia	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
	C4591001 1162 11621172	Blood and lymphatic system disorders	Thrombocytopenia	01JAN2019	31DEC2020	N
		Cardiac disorders	Cardiac arrest	22MAY2019	22MAY2019	N
		Eye disorders	Myopia	01JAN1977	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2016		Y
			Hyperlipidaemia	01JAN2006		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Depression	01OCT2019		Y
			Insomnia	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Respiratory disorder	20MAY2019	01JUN2019	N
		Surgical and medical procedures	Aortic valve replacement	31JUL2019	31JUL2019	N
			Keratomileusis	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1162 11621175	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1162 11621177	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1162 11621180	Eye disorders	Hypermetropia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Rubber sensitivity	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
			Insomnia	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN1991		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Myomectomy	01JAN2008	31DEC2008	N
	C4591001 1162 11621181	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2001	31DEC2001	N
	C4591001 1162 11621182	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
	C4591001 1162 11621183	Reproductive system and breast disorders	Uterine prolapse	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
	C4591001 1162 11621187	Eye disorders	Astigmatism	01JAN2010		Y
			Myopia	01JAN2010		Y
	C4591001 1162 11621188	Eye disorders	Hypermetropia	01JAN1990		Y
			Myopia	01JAN1990		Y
		Immune system disorders	Allergic oedema	01JAN1999		Y
			Hypersensitivity	01JAN1999		Y
		Surgical and medical procedures	Keratomileusis	01JAN2001	31DEC2001	N
			Tenoplasty	01JAN1999	31DEC1999	N
	C4591001 1162 11621190	Skin and subcutaneous tissue disorders	Rash	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621193	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1992	31DEC1992	N
		Renal and urinary disorders	Bladder malposition acquired	01JAN1999	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Ankle operation	01JAN1992	31DEC1992	N
			Urinary bladder suspension	01JAN2002	31DEC2002	N
	C4591001 1162 11621195	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2019		Y
			Myopia	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Keratomileusis	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1162 11621202	Ear and labyrinth disorders	Ear pain	01JAN2018		Y
			Ear pruritus	01JAN2018		Y
			Tinnitus	01JAN2018		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2018		Y
		Immune system disorders	Allergy to metals	01JAN1978		Y
			Drug hypersensitivity	01JAN1992		Y
			Food allergy	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Bronchitis	01JAN2018	31DEC2018	N
			Tonsillitis	01JAN1972	31DEC1973	N
			Urinary tract infection	01JAN1992	31DEC2017	N
		Investigations	Heart rate irregular	01JAN1991		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN2013		Y
			Obesity	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1996		Y
			Migraine	01JAN1996		Y
			Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Suicidal ideation	01JAN1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Epistaxis	01JAN1976	31DEC2000	N
			Pulmonary hypertension	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980	31DEC1991	N
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	21JAN1999	21JAN1999	N
			Loop electrosurgical excision procedure	01JAN1996	31DEC1996	N
			Skin cyst excision	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621203	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1972		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
			Sinusitis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2008	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
			Nasal congestion	01JAN2000		Y
			Nasal septum deviation	01JAN2000		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
			Cholelithotomy	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Ovarian cystectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621204	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2019	N
		Immune system disorders	Hypersensitivity	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JUL2019	31JUL2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
	C4591001 1162 11621205	Gastrointestinal disorders	Tooth impacted	01JAN2011	31DEC2011	N
		Immune system disorders	Food allergy	01JAN1993		Y
			Seasonal allergy	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Wisdom teeth removal	01JAN2011	31DEC2011	N
	C4591001 1162 11621206	Congenital, familial and genetic disorders	Sebaceous naevus	01JAN1995	31DEC1995	N
		Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Eye disorders	Myopia	01JAN1988		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1162 11621207	Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Gastrointestinal disorders	Swollen tongue	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Infections and infestations	Mastitis	01JAN2007	31JAN2011	N
		Investigations	Blood oestrogen	01JAN2017		Y
			Blood testosterone	01JAN2017		Y
			Blood triglycerides increased	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
			Insomnia	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Pruritus	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621208	Infections and infestations	Tonsillitis	01JAN2000	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1985		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Keratomileusis	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1162 11621210	Eye disorders	Cataract	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Crohn's disease	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1980	N
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621216	Ear and labyrinth disorders	Deafness	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01JAN1995	31DEC1999	N
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN1980		Y
			Insomnia	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1972		Y
		Surgical and medical procedures	Ear operation	01JAN1999	31DEC1999	N
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1162 11621217	Eye disorders	Hypermetropia	(b) (6) 1996		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sneezing	01JAN2010		Y
			Upper-airway cough syndrome	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Eye operation	01JAN1998	31DEC1998	N
	C4591001 1162 11621219	Ear and labyrinth disorders	Deafness	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1989		Y
		Surgical and medical procedures	Ear operation	01JAN2007	31DEC2007	N
	C4591001 1162 11621220	Congenital, familial and genetic disorders	Haemoglobinopathy	01JAN1997		Y
		Eye disorders	Myopia	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Obesity	01JAN1978		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Gastric bypass	01JAN2004	31DEC2004	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621222	Eye disorders	Myopia	01JAN1981		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	10SEP2004	10SEP2004	N
		Vascular disorders	Thrombosis	01JAN1997	31DEC1997	N
	C4591001 1162 11621223	Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Testes exploration	01JAN2015	31DEC2015	N
	C4591001 1162 11621224	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1162 11621226	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1162 11621227	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Infections and infestations	Sinusitis	01JAN2017		Y
		Surgical and medical procedures	Limb operation	01JAN2003	31DEC2003	N
			Muscle operation	01JAN2001	31DEC2001	N
	C4591001 1162 11621234	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	13NOV2012	13NOV2012	N
				17SEP2002	17SEP2002	N
			Female sterilisation	13NOV2012	13NOV2012	N
	C4591001 1162 11621235	Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1162 11621239	Immune system disorders	Food allergy	01JAN1976		Y
	C4591001 1162 11621243	Metabolism and nutrition disorders	Obesity	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621244	Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2002		Y
	C4591001 1162 11621245	Metabolism and nutrition disorders	Obesity	31AUG2015		Y
	C4591001 1162 11621247	Eye disorders	Myopia	01JAN2017		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1162 11621249	Gastrointestinal disorders	Umbilical hernia	01JAN1999	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2013	31DEC2017	N
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2013	31DEC2017	N
	C4591001 1162 11621251	Surgical and medical procedures	Caesarean section	26JUN2020	26JUN2020	N
	C4591001 1162 11621252	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Social circumstances	Corrective lens user	01JAN2020		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2001	31DEC2001	N
	C4591001 1162 11621254	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Myopia	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1162 11621255	Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Infections and infestations	Oral herpes	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1996		Y
		Surgical and medical procedures	Ligament operation	01JAN1994	31DEC1994	N
				01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1162 11621256	Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
	C4591001 1162 11621259	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Eye disorders	Myopia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
	C4591001 1162 11621260	Eye disorders	Myopia	01JAN2012		Y
		Immune system disorders	Food allergy	01JAN1985		Y
			Seasonal allergy	01JAN1969		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2010		Y
		Nervous system disorders	Intracranial aneurysm	01JAN2014	31DEC2014	N
				01MAR2014	31OCT2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1162 11621268	Eye disorders	Myopia	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01FEB2017		Y
		Investigations	Heart rate irregular	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01FEB2017		Y
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
	C4591001 1162 11621269	Immune system disorders	Milk allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1986		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN1976	31DEC1976	N
	C4591001 1162 11621273	Eye disorders	Myopia	01JAN1979	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986		Y
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
			Knee operation	01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
				01JAN1996	31DEC1996	N
				01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621274	Blood and lymphatic system disorders	Anaemia	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2019	31MAY2019	N
		Reproductive system and breast disorders	Ovarian cyst	01SEP2008	30APR2009	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Wrist surgery	01MAY2019	31MAY2019	N
	C4591001 1162 11621275	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Oral cavity neoplasm surgery	01JAN2010	31DEC2010	N
	C4591001 1162 11621279	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Eye disorder	01JAN1991	31DEC1996	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Bipolar disorder	01JAN2005		Y
			Depression	01JAN2005		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2006		Y
			Nasal septum deviation	(b) (6) 1991	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1991		Y
		Surgical and medical procedures	Eye operation	01JAN1996	31DEC1996	N
			Rhinoplasty	01JAN2012	31DEC2012	N
	C4591001 1162 11621282	Investigations	Blood triglycerides increased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Surgical and medical procedures	Toe operation	01JAN1989	31DEC1989	N
	C4591001 1162 11621283	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1162 11621284	Metabolism and nutrition disorders	Overweight	01JAN2001		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Surgical and medical procedures	Spinal operation	01JAN2017	31DEC2017	N
	C4591001 1162 11621285	Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
		Surgical and medical procedures	Hair transplant	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621286	Eye disorders	Myopia	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Herpes zoster	01JAN2004	31DEC2006	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2010		Y
	C4591001 1162 11621287	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Anaphylactic reaction	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2004		Y
	C4591001 1162 11621289	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1162 11621290	Eye disorders	Myopia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN1994		Y
	C4591001 1162 11621291	Surgical and medical procedures	Anorectal operation	01JAN2001	31DEC2001	N
			Skin operation	01JAN2017	31DEC2017	N
	C4591001 1162 11621294	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
	C4591001 1162 11621295	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Rhinitis allergic	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
			Ovarian cystectomy	01JAN2019	31MAR2019	N
			Salpingectomy	08MAR2019	08MAR2019	N
	C4591001 1162 11621296	Investigations	Blood triglycerides increased	01MAR2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621302	Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Renal stone removal	01JAN2008	31DEC2008	N
	C4591001 1162 11621304	Eye disorders	Hypermetropia	01JAN1971		Y
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
	C4591001 1162 11621308	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Shoulder operation	01JAN2001	31DEC2001	N
	C4591001 1162 11621310	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1162 11621311	Eye disorders	Myopia	01JAN1983		Y
		Surgical and medical procedures	Fracture treatment	01DEC2008	31DEC2008	N
	C4591001 1162 11621313	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
		Eye disorders	Blindness unilateral	01JAN2010		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2013		Y
		Immune system disorders	Food allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
		Surgical and medical procedures	Renal stone removal	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1162 11621314	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Schizophrenia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621315	Eye disorders	Myopia	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Schizophrenia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1162 11621316	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
				01JAN1990	31DEC1990	N
				14AUG1991	14AUG1991	N
			Female sterilisation	14AUG1991	14AUG1991	N
			Laparotomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621320	Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Mental disorder	01JAN2018	31DEC2018	N
			Nightmare	01JAN2010		Y
	C4591001 1162 11621321	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Tenoplasty	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1162 11621322	Eye disorders	Cataract	01JAN2016		Y
			Glaucoma	01JAN2016		Y
		Infections and infestations	Sinusitis	01JAN2019		Y
			Tonsillitis	01JAN1993	31DEC1993	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Abdominal operation	01JAN1978	31DEC1978	N
			Abdominoplasty	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1162 11621324	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2019	30JUN2019	N
		Surgical and medical procedures	Caesarean section	01JUN2016	30JUN2016	N
			Spinal operation	01JUN2009	30JUN2009	N
				01SEP2010	30SEP2010	N
	C4591001 1162 11621325	Metabolism and nutrition disorders	Obesity	04JAN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01JAN2005		Y
			Mental disorder	01JAN2011	31DEC2011	N
			Suicidal ideation	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013	01JAN2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2020		Y
	C4591001 1162 11621326	Eye disorders	Myopia	01JAN1981		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Food allergy	01JAN1996		Y
			Rubber sensitivity	01JAN2017		Y
		Investigations	Liver function test increased	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2015		Y
			Obesity	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2019		Y
			Migraine	01JAN1985	31DEC1996	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Bipolar disorder	01JAN1997		Y
			Suicidal behaviour	01JAN2010	31DEC2010	N
			Suicidal ideation	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N
		Surgical and medical procedures	Bone cyst excision	01JAN1997	31DEC1997	N
			Tooth extraction	01JAN1990	31DEC1990	N
	C4591001 1162 11621328	Eye disorders	Astigmatism	01JAN1990		Y
		Immune system disorders	Food allergy	01JAN1977		Y
	C4591001 1162 11621331	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Blindness	01JUN2008	30JUN2008	N
			Hypermetropia	01JAN2010		Y
			Optic ischaemic neuropathy	01JUN2008	01JUN2008	N
		Infections and infestations	Genital herpes	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Thyroidectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Varicose vein	01JAN1980		Y
	C4591001 1162 11621334	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1162 11621335	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	02SEP2011	02SEP2011	N
				08MAR2009	08MAR2009	N
			Mammoplasty	01MAR2015	31MAR2015	N
			Salpingectomy	02SEP2011	02SEP2011	N
	C4591001 1162 11621336	Investigations	Blood triglycerides increased	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2017	31DEC2017	N
			Appendicectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621338	Blood and lymphatic system disorders	Lymphadenitis	01JAN1980	31DEC1980	N
		Endocrine disorders	Primary hypogonadism	01JAN2004		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Genital herpes	01JAN2002		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1987	31DEC1987	N
		Social circumstances	Corrective lens user	01JAN1980		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinus operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1162 11621339	Eye disorders	Astigmatism	01JAN2010		Y
			Myopia	01JAN2010		Y
		Gastrointestinal disorders	Gastric ulcer	01MAR2018	31MAR2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1162 11621340	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Gastric bypass	01FEB2020	29FEB2020	N
	C4591001 1162 11621344	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1162 11621346	Metabolism and nutrition disorders	Obesity	01JAN1992		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN2006	31DEC2006	N
	C4591001 1162 11621350	Eye disorders	Myopia	01JAN1992		Y
		Gastrointestinal disorders	Stomatitis	13SEP2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1162 11621351	Gastrointestinal disorders	Dyspepsia	01JAN2003		Y
			Hiatus hernia	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	14SEP2020		Y
			Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Fibromyalgia	01JAN2015		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	01DEC2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621352	Endocrine disorders	Hypothyroidism	08JAN2020		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2012	31DEC2012	N
	C4591001 1162 11621354	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Myopia correction	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1162 11621358	Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JUL2018		Y
		Surgical and medical procedures	Tenoplasty	01SEP2019	30SEP2019	N
	C4591001 1162 11621360	Eye disorders	Myopia	01DEC2011		Y
		Immune system disorders	Food allergy	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01MAR2020	31MAR2020	N
			Ear tube insertion	01JAN2006	31DEC2006	N
	C4591001 1162 11621361	Eye disorders	Myopia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621362	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1162 11621363	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Social circumstances	Corrective lens user	31DEC2019		Y
	C4591001 1162 11621366	Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Psychiatric disorders	Anxiety	01DEC1986		Y
			Bipolar disorder	01JAN1986		Y
	C4591001 1162 11621367	Infections and infestations	Herpes ophthalmic	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1162 11621370	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2018		Y
	C4591001 1162 11621372	Eye disorders	Astigmatism	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01DEC2012		Y
	C4591001 1162 11621374	Nervous system disorders	Headache	14SEP2020		Y
			Multiple sclerosis	19MAY2017		Y
		Psychiatric disorders	Anxiety	01MAR2000		Y
			Autism spectrum disorder	01JAN2000		Y
			Mental disorder	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	11JAN2000		Y
			Nasal septum deviation	15JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01FEB2000		Y
	C4591001 1162 11621375	Eye disorders	Keratoconus	01JAN2006		Y
		Metabolism and nutrition disorders	Gout	01JAN1999		Y
			Obesity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1996	31DEC1996	N
			Renal stone removal	01JAN1992	31DEC1992	N
			Sinus operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621376	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
			Nasal congestion	01JAN1991		Y
			Rhinitis allergic	01JAN1991		Y
	C4591001 1162 11621377	Eye disorders	Vision blurred	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
			Schizophrenia	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1984		Y
		Social circumstances	Corrective lens user	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1162 11621378	Ear and labyrinth disorders	Deafness	01JAN1972		Y
		Metabolism and nutrition disorders	Obesity	13SEP2020		Y
			Type 2 diabetes mellitus	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Nervous system disorders	Cerebrovascular accident	01JAN1995	31DEC1995	N
			Headache	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
		Surgical and medical procedures	Limb operation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1162 11621379	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Gallbladder operation	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1162 11621381	Musculoskeletal and connective tissue disorders	Back pain	14SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	23SEP2019	23SEP2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621382	Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1162 11621383	Immune system disorders	Drug hypersensitivity	01JUL1987		Y
			Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ear neoplasm malignant	01DEC2019	31JAN2020	N
		Psychiatric disorders	Anxiety	01JUL2019		Y
		Social circumstances	Corrective lens user	01JAN1992		Y
		Vascular disorders	Hypertension	01SEP2002		Y
	C4591001 1162 11621384	Eye disorders	Myopia	17SEP2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2001	31DEC2001	N
			Seizure	01JAN2001	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001		Y
			Insomnia	01JAN2001		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621386	Eye disorders	Myopia	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Wisdom teeth removal	01JAN2011	31DEC2011	N
	C4591001 1162 11621387	Psychiatric disorders	Insomnia	01FEB2020		Y
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
			Uterine dilation and curettage	01JAN2000	31DEC2020	N
	C4591001 1162 11621388	Congenital, familial and genetic disorders	Thalassaemia beta	(b) (6) 1996		Y
		Ear and labyrinth disorders	Deafness	01JUN2018		Y
	C4591001 1162 11621389	Eye disorders	Hypermetropia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
	C4591001 1162 11621391	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1162 11621392	Eye disorders	Myopia	01JAN1986		Y
		Infections and infestations	Sinusitis	01JAN1990		Y
		Nervous system disorders	Arachnoid cyst	01JAN1973		Y
			Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1990	31DEC2011	N
	C4591001 1162 11621393	Surgical and medical procedures	Limb operation	01APR2020	30APR2020	N
	C4591001 1162 11621394	Psychiatric disorders	Schizophrenia	01JAN2001		Y
		Surgical and medical procedures	Removal of foreign body	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621396	Investigations	Blood triglycerides increased	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
	C4591001 1162 11621401	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Corrective lens user	01JUN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1162 11621404	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997	31DEC2003	N
	C4591001 1162 11621405	Psychiatric disorders	Anxiety	01AUG2020		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01AUG2020		Y
	C4591001 1162 11621406	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Surgical and medical procedures	Finger amputation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
			Raynaud's phenomenon	01JAN2019		Y
	C4591001 1162 11621408	Eye disorders	Myopia	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Sarcoidosis	01AUG2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01NOV2012	30NOV2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Skin neoplasm excision	01NOV2012	30NOV2012	N
			Thoracic outlet surgery	01FEB2020	29FEB2020	N
	C4591001 1162 11621413	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Stomatitis	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	17SEP2020		Y
		Surgical and medical procedures	Shoulder operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1976	31DEC1976	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1162 11621414	Immune system disorders	Food allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	10JAN2019		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1981		Y
		Nervous system disorders	Cerebrovascular accident	18DEC2017	22DEC2017	N
		Reproductive system and breast disorders	Endometriosis	01JAN2012	13FEB2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Hysterectomy	13FEB2014	13FEB2014	N
			Limb operation	18APR2018	18APR2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621416	Eye disorders	Hypermetropia	01JAN2013		Y
			Myopia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Bipolar disorder	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Panic attack	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621417	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2016		Y
		Psychiatric disorders	Schizophrenia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621421	Immune system disorders	Food allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1162 11621422	Infections and infestations	Tonsillitis	01JAN1986		Y
		Investigations	Heart rate irregular	01JAN1984		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1162 11621423	Eye disorders	Hypermetropia	01JAN1995		Y
			Myopia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Infections and infestations	Herpes zoster	01SEP2013	30SEP2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1162 11621434	Eye disorders	Myopia	01JAN2006		Y
		Psychiatric disorders	Anxiety	31DEC2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2006		Y
	C4591001 1162 11621435	Eye disorders	Myopia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1162 11621437	Ear and labyrinth disorders	Tinnitus	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01DEC2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Bipolar disorder	01JAN1990		Y
			Depression	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621439	Psychiatric disorders	Anxiety	01JAN2016		Y
			Bipolar disorder	01JAN2016		Y
	C4591001 1162 11621442	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1162 11621443	Eye disorders	Vision blurred	01JAN2018		Y
		Investigations	Heart rate irregular	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Psychiatric disorders	Bipolar disorder	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621446	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Surgical and medical procedures	Abdominoplasty	10JUL2020	10JUL2020	N
			Gastrectomy	03OCT2018	03OCT2018	N
			Mammoplasty	01SEP2019	30SEP2019	N
	C4591001 1162 11621450	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621451	Surgical and medical procedures	Splenectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621452	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1989	31DEC1989	N
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1162 11621454	Eye disorders	Hypermetropia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN1995		Y
		Investigations	Laparoscopy	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1992		Y
		Surgical and medical procedures	Caesarean section	10APR1991	10APR1991	N
				15SEP1995	15SEP1995	N
				26NOV1984	26NOV1984	N
	C4591001 1162 11621456	Eye disorders	Myopia	01JAN2010		Y
	C4591001 1162 11621457	Eye disorders	Myopia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2013		Y
	C4591001 1162 11621460	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1162 11621463	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
	C4591001 1162 11621464	Surgical and medical procedures Metabolism and nutrition disorders	Appendectomy Obesity	01JAN2016 01JAN2010	31DEC2016	N Y
		Psychiatric disorders	Schizophrenia	01JAN2006		Y
	C4591001 1162 11621466	Surgical and medical procedures Gastrointestinal disorders	Limb operation Dyspepsia	01JAN2018 20JUN2018	31DEC2018	N Y
		Immune system disorders	Food allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	11SEP2019		Y
		Nervous system disorders	Headache	13SEP2018		Y
			Migraine	20JAN2017		Y
		Psychiatric disorders	Anxiety	29APR2017		Y
			Depression	29APR2017		Y
			Insomnia	29APR2017		Y
	C4591001 1162 11621467	Surgical and medical procedures Metabolism and nutrition disorders	Bunion operation Obesity	01JAN2014 01JAN2010	31DEC2014	N Y
	C4591001 1162 11621468	Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Endocrine disorders	Hyperthyroidism	01JAN2006	31DEC2006	N
		Eye disorders	Myopia	01JAN2012		Y
			Vision blurred	01JAN2012		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2006		Y
			Irritable bowel syndrome	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Chest pain	01JAN2006		Y
		Infections and infestations	Osteomyelitis	01NOV2019	31DEC2019	N
			Tonsillitis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
			Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2012		Y
			Nasal congestion	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUL2020		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN1999		Y
			Varicose vein	01JAN2006		Y
	C4591001 1162 11621469	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
	C4591001 1162 11621472	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621479	Renal and urinary disorders	Chronic kidney disease	01JAN1998	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621480	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Bipolar disorder	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1162 11621483	Eye disorders	Vision blurred	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1162 11621484	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621486	Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN1991		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621488	Immune system disorders	Food allergy	01JAN1996		Y
		Psychiatric disorders	Schizophrenia	01JAN2012		Y
	C4591001 1162 11621489	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Bone operation	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1162 11621490	Congenital, familial and genetic disorders	Haemoglobinopathy	01JAN2019		Y
		Infections and infestations	Sinusitis	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Bipolar disorder	01JAN1995		Y
			Post-traumatic stress disorder	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
	C4591001 1162 11621491	Musculoskeletal and connective tissue disorders	Back pain	27OCT2004		Y
			Pain in extremity	27OCT2004		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Limb operation	27OCT2007	27OCT2007	N
	C4591001 1162 11621492	Eye disorders	Hypermetropia	01JAN2016		Y
			Myopia	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1162 11621496	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
	C4591001 1162 11621499	Injury, poisoning and procedural complications	Penetrating abdominal trauma	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Wound closure	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621500	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621502	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	20MAY2019	30AUG2020	N
		Surgical and medical procedures	Limb operation	01AUG2020	31AUG2020	N
				01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1162 11621504	Immune system disorders	Mycotic allergy	01JUL2013		Y
		Metabolism and nutrition disorders	Obesity	01JUN2017		Y
		Psychiatric disorders	Schizoaffective disorder	01MAY2015		Y
		Surgical and medical procedures	Caesarean section	24APR2002	24APR2002	N
	C4591001 1162 11621505	Immune system disorders	Food allergy	01JAN2012		Y
				01JAN2015		Y
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Laparotomy	01JAN1995	31DEC1995	N
	C4591001 1162 11621510	Eye disorders	Myopia	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621513	Eye disorders	Hypermetropia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	04OCT2019	04OCT2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
	C4591001 1162 11621514	Eye disorders	Myopia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2003	31DEC2004	N
		Surgical and medical procedures	Laminoplasty	01JAN2004	31DEC2004	N
	C4591001 1162 11621515	Endocrine disorders	Autoimmune thyroiditis	01JAN1998		Y
		Nervous system disorders	Headache	01JAN1992		Y
			Migraine	12OCT2020	13OCT2020	N
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	03MAR2008	03MAR2008	N
			Hysterectomy	01SEP2017	30SEP2017	N
	C4591001 1162 11621518	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1162 11621520	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621522	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1162 11621526	Immune system disorders	Food allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
			Nephrolithiasis	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Fracture treatment	01JAN1989	31DEC1989	N
			Urostomy	01JAN1976	31DEC1976	N
	C4591001 1162 11621530	Eye disorders	Blindness unilateral	01JAN2009		Y
			Glaucoma	01JAN2009		Y
			Myopia	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Varicose vein	01JAN1991		Y
	C4591001 1162 11621532	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
	C4591001 1162 11621534	Metabolism and nutrition disorders	Obesity	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1162 11621535	Renal and urinary disorders	Chronic kidney disease	25AUG2017		Y
		Surgical and medical procedures	Nephrostomy	01JAN2017		Y
					31DEC2017	N
			Renal surgery	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621537	Immune system disorders	Drug hypersensitivity	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621538	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621540	Endocrine disorders	Hyperthyroidism	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
			Thyroidectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621541	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1162 11621545	Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
	C4591001 1162 11621548	Eye disorders	Myopia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1162 11621551	Eye disorders	Myopia	01JAN2006		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
	C4591001 1162 11621553	Eye disorders	Myopia	01JAN1988	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Eye operation	01JAN2017	31DEC2017	N
	C4591001 1162 11621554	Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Laparoscopy	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Infertility	01JAN2003	31DEC2005	N
	C4591001 1162 11621559	Immune system disorders	Rubber sensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Ear tube insertion	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
				01JAN1991	31DEC1991	N
			Tenoplasty	01JAN2001	31DEC2001	N
	C4591001 1162 11621563	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621566	Investigations	Heart rate irregular	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621569	Blood and lymphatic system disorders	Anaemia	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
			Depression	01JAN1994		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1997		Y
			Eczema	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	05NOV2010	05NOV2010	N
				14JAN2005	14JAN2005	N
				17OCT2008	17OCT2008	N
	C4591001 1162 11621571	Eye disorders	Myopia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Tonsillitis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
			Nasal congestion	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1989		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621572	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621573	Eye disorders	Hypermetropia	01JAN1996		Y
	C4591001 1162 11621574	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Investigations	Heart rate irregular	01JUL2010		Y
		Surgical and medical procedures	Caesarean section	16MAR2012	16MAR2012	N
			Cyst removal	01JAN1994	31DEC1994	N
			Female sterilisation	16MAR2012	16MAR2012	N
	C4591001 1162 11621576	Eye disorders	Myopia	01JAN2019		Y
	C4591001 1162 11621579	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Bipolar disorder	01JAN1978		Y
			Depression	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Social circumstances	Postmenopause	01MAY2019		Y
	C4591001 1162 11621582	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Myopia	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621583	Congenital, familial and genetic disorders	Colour blindness	01JAN2016		Y
		Eye disorders	Myopia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621587	Eye disorders	Myopia	01JUL2017		Y
	C4591001 1162 11621589	Surgical and medical procedures	Umbilical hernia repair	01JAN2004	31DEC2010	N
	C4591001 1163 11631004	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	31JUL2020		Y
		Vascular disorders	Hot flush	01MAY2017		Y
	C4591001 1163 11631006	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1163 11631023	Metabolism and nutrition disorders	Obesity	01AUG2008		Y
	C4591001 1163 11631028	Respiratory, thoracic and mediastinal disorders	Asthma	31JAN1991		Y
	C4591001 1163 11631029	Surgical and medical procedures	Female sterilisation	01JAN2003		Y
		Vascular disorders	Hypertension	31OCT2016		Y
	C4591001 1163 11631036	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2012		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	17FEB2017		Y
	C4591001 1163 11631040	Metabolism and nutrition disorders	Obesity	01DEC2011		Y
		Surgical and medical procedures	Hysterectomy	17DEC2015	17DEC2015	N
	C4591001 1163 11631048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003	31JAN2011	N
		Psychiatric disorders	Anxiety	31JAN2015		Y
			Depression	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1999	31JAN2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1163 11631049	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
	C4591001 1163 11631050	Musculoskeletal and connective tissue disorders	Back pain	01MAR2020		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1163 11631060	Psychiatric disorders	Anxiety	01AUG2005		Y
		Social circumstances	Postmenopause	05JUN2018		Y
		Vascular disorders	Hot flush	01JUL2020		Y
	C4591001 1163 11631061	Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Insomnia	01JAN2018		Y
	C4591001 1163 11631064	Surgical and medical procedures	Hysterectomy	01JUN2020	30JUN2020	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1163 11631066	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01AUG2007	31AUG2007	N
	C4591001 1163 11631069	Psychiatric disorders	Alcohol abuse	01AUG2020		Y
	C4591001 1163 11631074	Surgical and medical procedures	Contraceptive implant	01FEB2017	28FEB2017	N
	C4591001 1163 11631075	Infections and infestations	Appendicitis	01JUN1996	30JUN1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAY2007	31MAY2007	N
		Surgical and medical procedures	Appendicectomy	01JUN1996	30JUN1996	N
			Hysterectomy	01MAY2007	31MAY2007	N
	C4591001 1163 11631076	Psychiatric disorders	Depression	01JUN2019		Y
	C4591001 1163 11631081	Psychiatric disorders	Depression	01JAN1995		Y
	C4591001 1163 11631087	Psychiatric disorders	Anxiety	05MAY2020		Y
		Social circumstances	Tobacco user	01JAN2003	31JAN2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1163 11631088	Metabolism and nutrition disorders	Obesity	01MAR2000		Y
		Surgical and medical procedures	Female sterilisation	01AUG2008	31AUG2008	N
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1163 11631093	Nervous system disorders	Migraine	01JUL2015		Y
	C4591001 1163 11631096	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1986		Y
			Food allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31JAN2014	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1163 11631104	Psychiatric disorders	Anxiety	30JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Surgical and medical procedures	Thyroidectomy	01NOV2007	30NOV2007	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1163 11631106	Immune system disorders	Food allergy	01JAN2013		Y
			Seasonal allergy	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1163 11631107	Psychiatric disorders	Depression	31JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1163 11631110	Psychiatric disorders	Bipolar disorder	01AUG2003		Y
		Social circumstances	Postmenopause	08AUG2019		Y
		Surgical and medical procedures	Carotid endarterectomy	01MAR2000	31MAR2000	N
	C4591001 1163 11631112	Surgical and medical procedures	Female sterilisation	18DEC2007	18DEC2007	N
	C4591001 1163 11631117	Endocrine disorders	Hypothyroidism	17JUL1998		Y
		Nervous system disorders	Migraine	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	10FEB2020		Y
			Obsessive-compulsive disorder	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Urticaria	11JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	01JAN2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1163 11631121	Psychiatric disorders	Anxiety	01JUL2019		Y
	C4591001 1163 11631124	Surgical and medical procedures	Female sterilisation	21OCT2014	21OCT2014	N
	C4591001 1163 11631127	Surgical and medical procedures	Hysterectomy	01JAN2014	31JAN2014	N
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1163 11631135	Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1166 11661002	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Febrile convulsion	01JAN1968	31DEC1969	N
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1166 11661003	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1166 11661004	Eye disorders	Myopia	01JAN2001		Y
		Gastrointestinal disorders	Nausea	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JUL2018		Y
		Surgical and medical procedures	Shoulder operation	01JAN2019	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01DEC2019	31DEC2019	N
	C4591001 1166 11661005	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN1990		Y
	C4591001 1166 11661008	Nervous system disorders	Cluster headache	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01APR2020		Y
	C4591001 1166 11661009	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Reduction of increased intracranial pressure	01JAN1984	31DEC1984	N
	C4591001 1166 11661011	Surgical and medical procedures	Hysterectomy	17JUL2017	17JUL2017	N
			Oophorectomy	17JUL2017	17JUL2017	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1166 11661014	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Social circumstances	Menopause	01FEB2018		Y
	C4591001 1166 11661016	Nervous system disorders	Migraine	01JAN1988		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1166 11661017	Eye disorders	Myopia	01JAN1993		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1166 11661019	Eye disorders	Myopia	01JAN2001		Y
	C4591001 1166 11661022	Eye disorders	Myopia	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1166 11661023	Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1166 11661024	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Injury, poisoning and procedural complications	Muscle strain	06JUL2020	10JUL2020	N
	C4591001 1166 11661025	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
		Surgical and medical procedures	Appendectomy	01JAN1999	01JAN1999	N
			Fracture treatment	01JAN2012	01JAN2012	N
	C4591001 1166 11661028	Psychiatric disorders	Insomnia	01JAN2019		Y
		Social circumstances	Menopause	01MAY2019		Y
	C4591001 1166 11661030	Endocrine disorders	Thyroid mass	01JAN2005		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Cluster headache	01JAN2015		Y
			Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2013		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2019	31OCT2019	N
			Uterine mass	01JAN2019	31OCT2019	N
		Surgical and medical procedures	Hysterectomy	01OCT2019	31OCT2019	N
			Oophorectomy	01OCT2019	31OCT2019	N
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1166 11661032	Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2016		Y
		Surgical and medical procedures	Tenoplasty	01JUL2019	01JUL2019	N
				01MAR2020	01MAR2020	N
	C4591001 1166 11661033	Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
	C4591001 1166 11661035	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1166 11661036	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Gastric bypass	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1166 11661037	Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
	C4591001 1166 11661039	Psychiatric disorders	Depression	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01OCT2019	31OCT2019	N
	C4591001 1166 11661041	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1166 11661042	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1166 11661046	Eye disorders	Myopia	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2013	01JAN2013	N
	C4591001 1166 11661047	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1980		Y
			Scoliosis	01JAN1980		Y
		Social circumstances	Tobacco user	01JAN1988		Y
		Surgical and medical procedures	Arterial repair	01JAN2011	31DEC2011	N
	C4591001 1166 11661049	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Post-traumatic stress disorder	01MAR2020		Y
	C4591001 1166 11661051	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2011		Y
			Seasonal allergy	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01JAN2007	31DEC2007	N
				01JAN2011	31DEC2011	N
			Keratomileusis	01JAN2009	31DEC2009	N
			Uterine dilation and curettage	01JAN2007	31DEC2007	N
	C4591001 1166 11661052	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Nervous system disorders	Sciatica	01JAN2008	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Intraocular lens implant	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1166 11661055	Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1166 11661056	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1166 11661060	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1166 11661061	Social circumstances	Corrective lens user	01JAN2002		Y
	C4591001 1166 11661062	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1166 11661063	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1166 11661064	Eye disorders	Hypermetropia	01JAN2018		Y
			Presbyopia	01JAN1973	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N
			Muscle operation	01OCT2017	31OCT2017	N
			Tendon sheath incision	01AUG2018	31AUG2018	N
				01FEB2019	28FEB2019	N
	C4591001 1166 11661066	Psychiatric disorders	Perinatal depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2004		Y
		Surgical and medical procedures	Abscess drainage	01JAN2003	31DEC2003	N
			Photorefractive keratectomy	01JAN2017	31DEC2017	N
	C4591001 1166 11661068	Immune system disorders	Food allergy	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2020	N
		Surgical and medical procedures	Hysterectomy	01JAN2020	31JAN2020	N
			Keratomileusis	01JAN2008	31DEC2008	N
	C4591001 1166 11661070	Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1996		Y
	C4591001 1166 11661071	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	15JAN2019	N
		Surgical and medical procedures	Hip arthroplasty	15JAN2019	15JAN2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1166 11661072	Eye disorders	Hypermetropia	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN2013		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN2006		Y
	C4591001 1166 11661073	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1166 11661076	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2020		Y
	C4591001 1166 11661078	Surgical and medical procedures	Caesarean section	15APR2020	15APR2020	N
	C4591001 1166 11661079	Eye disorders	Presbyopia	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007	31DEC2020	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN2012	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Tobacco user	01JAN1989	31DEC2018	N
		Surgical and medical procedures	Gastric bypass	13JUL2020	13JUL2020	N
			Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1166 11661080	Gastrointestinal disorders	Coeliac disease	01JAN2019		Y
		Immune system disorders	Allergy to animal	01JAN1994		Y
			Food allergy	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2015	31DEC2015	N
	C4591001 1166 11661081	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1166 11661082	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Surgical and medical procedures	Hernia repair	01JAN2014	31DEC2014	N
			Meniscus operation	01JAN2016	31DEC2016	N
	C4591001 1166 11661083	Surgical and medical procedures	Contraception	01JAN2017		Y
			Keratomileusis	24AUG2020	24AUG2020	N
	C4591001 1166 11661084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1986		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1166 11661085	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1999	31DEC1999	N
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2018	31DEC2018	N
			Lymphadenectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1166 11661086	Eye disorders	Astigmatism	01JAN2004		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Medical device removal	01JAN2011	31DEC2011	N
			Pituitary tumour removal	01MAR2018	31MAR2018	N
			Spinal operation	01JAN2007	31DEC2007	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1166 11661087	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2013	N
		Surgical and medical procedures	Hip surgery	01JAN2013	31DEC2013	N
	C4591001 1166 11661088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Hip surgery	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1166 11661090	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Investigations	Blood cholesterol increased	01JAN1994		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
			Hand dermatitis	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
	C4591001 1166 11661091	Eye disorders	Myopia	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN1984		Y
	C4591001 1166 11661094	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1166 11661095	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1166 11661096	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Surgical and medical procedures	Ligament operation	01JAN2008	31DEC2008	N
	C4591001 1166 11661099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
	C4591001 1166 11661103	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1166 11661104	Immune system disorders	Seasonal allergy	01JAN1978		Y
	C4591001 1166 11661106	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1166 11661109	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1166 11661110	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
	C4591001 1166 11661112	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01MAY2019		Y
		Surgical and medical procedures	Appendicectomy	01AUG2011	31AUG2011	N
			Meniscus operation	01JAN2006	31DEC2006	N
	C4591001 1167 11671004	Gastrointestinal disorders	Gastroesophageal reflux disease	16SEP2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	09MAY2013		Y
		Vascular disorders	Hypertension	31AUG2015		Y
	C4591001 1167 11671005	Metabolism and nutrition disorders	Vitamin B12 deficiency	27JUN2017		Y
			Vitamin D deficiency	28JUN2017		Y
	C4591001 1167 11671007	Blood and lymphatic system disorders	Iron deficiency anaemia	13JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01OCT2014		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Psychiatric disorders	Bipolar II disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
			Reflux laryngitis	21OCT2019		Y
	C4591001 1167 11671009	Endocrine disorders	Hypothyroidism	01APR2011		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	09JUL2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Panic attack	24JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	07JUN2016		Y
		Surgical and medical procedures	Gastrectomy	10MAY2018	10MAY2018	N
			Hysterectomy	31JAN2020	31JAN2020	N
	C4591001 1167 11671010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN1995		Y
			Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	09SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1167 11671011	Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671017	Endocrine disorders	Hyperthyroidism	29JUN2018		Y
			Thyroid mass	16MAY2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	12APR2017		Y
		Investigations	Anti-thyroid antibody positive	06MAY2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17MAY2017		Y
	C4591001 1167 11671019	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1167 11671021	Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Depression	01JUN2019		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	27JAN2012	31DEC2016	N
		Social circumstances	Menopause	01JUN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1167 11671023	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31JAN2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1167 11671025	Nervous system disorders	Migraine	01AUG1999		Y
		Psychiatric disorders	Perinatal depression	01SEP2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1167 11671026	Blood and lymphatic system disorders	Iron deficiency anaemia	29JUL2019		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Oral herpes	25JUN2009		Y
	C4591001 1167 11671029	Nervous system disorders	Periodic limb movement disorder	01JAN2015		Y
	C4591001 1167 11671030	General disorders and administration site conditions	Oedema	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	22MAY2012	22MAY2012	N
	C4591001 1167 11671032	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUL1984		Y
	C4591001 1167 11671034	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1167 11671035	Investigations	Electrocardiogram abnormal	04OCT2011		Y
		Nervous system disorders	Sciatica	12OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2004		Y
	C4591001 1167 11671036	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	28JAN2016		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Nasal turbinate hypertrophy	28DEC2006		Y
			Sleep apnoea syndrome	11JUL2005		Y
	C4591001 1167 11671038	Surgical and medical procedures	Hysterectomy	01JAN2014	31JAN2014	N
	C4591001 1167 11671039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Enuresis	01JAN2018		Y
		Social circumstances	Alcohol use	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1167 11671040	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1167 11671045	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1167 11671046	Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2019		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1167 11671053	Blood and lymphatic system disorders	Anaemia	01JAN2003		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2017		Y
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
			Hypertension	01JAN2019		Y
	C4591001 1167 11671054	Surgical and medical procedures	Hysterectomy	17FEB2015	17FEB2015	N
		Vascular disorders	Hypertension	06SEP1996		Y
	C4591001 1167 11671057	Investigations	Apolipoprotein E	01JAN2019		Y
	C4591001 1167 11671058	Metabolism and nutrition disorders	Obesity	23AUG2019		Y
	C4591001 1167 11671061	Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	22JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	02JUL2019		Y
			Insomnia	02JUL2019		Y
	C4591001 1167 11671065	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1996		Y
	C4591001 1167 11671066	Nervous system disorders	Migraine	22FEB2017		Y
		Psychiatric disorders	Anxiety	09MAR2018		Y
			Insomnia	09MAR2018		Y
	C4591001 1167 11671070	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1167 11671073	General disorders and administration site conditions	Oedema	01JUL2019		Y
		Infections and infestations	Herpes simplex	01AUG2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Vitamin D deficiency	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
		Nervous system disorders	Migraine with aura	01JAN2003		Y
		Psychiatric disorders	Anxiety	01MAY2016		Y
			Major depression	01MAY2016		Y
		Vascular disorders	Essential hypertension	01JUL2018		Y
	C4591001 1167 11671082	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	28JUN2007	28JUN2007	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1167 11671083	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1167 11671086	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01OCT2017		Y
	C4591001 1167 11671089	Endocrine disorders	Hypothyroidism	28OCT2015		Y
		Gastrointestinal disorders	Celiac disease	01JAN2019		Y
			Diarrhoea	01JAN2019		Y
		General disorders and administration site conditions	Fatigue	01JAN2013		Y
		Infections and infestations	Chronic sinusitis	01MAY2013		Y
			Folliculitis	11SEP2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	28JAN2019		Y
		Nervous system disorders	Epilepsy	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
			Depression	09JUN2016		Y
			Insomnia	01JAN2006		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2017		Y
			Polycystic ovaries	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1167 11671092	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1167 11671095	Endocrine disorders	Hypogonadism	01JUN2019		Y
		Psychiatric disorders	Bipolar disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
	C4591001 1167 11671097	Psychiatric disorders	Anxiety	01JAN2000		Y
			Major depression	01JAN2000		Y
			Post-traumatic stress disorder	01JAN2000		Y
	C4591001 1167 11671099	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	14JUN2019	16SEP2019	N
			Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Gastric bypass	01DEC2002	31DEC2002	N
	C4591001 1167 11671103	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1167 11671105	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1167 11671106	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1167 11671113	Nervous system disorders	Migraine	01MAR1989		Y
		Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1167 11671114	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1167 11671118	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01AUG2020		Y
	C4591001 1167 11671119	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
	C4591001 1167 11671120	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1167 11671124	Injury, poisoning and procedural complications	Post procedural diarrhoea	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671128	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1167 11671129	Psychiatric disorders	Attention deficit hyperactivity disorder	14JAN2014		Y
	C4591001 1167 11671130	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1997		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01MAR2017		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Anxiety	17JUL2018		Y
			Depression	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1167 11671132	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	29AUG2020		Y
	C4591001 1167 11671134	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671140	Cardiac disorders	Palpitations	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Autism spectrum disorder	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2019		Y
	C4591001 1167 11671142	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1167 11671144	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	16JUL2018	16JUL2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1167 11671149	Metabolism and nutrition disorders	Hyperlipidaemia	07NOV2017		Y
		Psychiatric disorders	Anxiety	07DEC2011		Y
			Insomnia	31MAY2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	24JUL2017		Y
	C4591001 1167 11671150	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Vascular disorders	Essential hypertension	01JAN2005		Y
	C4591001 1167 11671152	Nervous system disorders	Multiple sclerosis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
	C4591001 1167 11671160	Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1167 11671162	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2014		Y
			Gastrooesophageal reflux disease	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
	C4591001 1167 11671164	Gastrointestinal disorders	Gastrooesophageal reflux disease	30MAY2018		Y
		Immune system disorders	Seasonal allergy	08SEP2009		Y
		Vascular disorders	Hypertension	24SEP2018		Y
	C4591001 1167 11671166	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	23FEB2016		Y
	C4591001 1167 11671167	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1167 11671170	Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1167 11671174	Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1167 11671175	Blood and lymphatic system disorders	Polycythaemia	14MAY2020		Y
		Endocrine disorders	Hypogonadism male	15NOV2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Neck pain	18SEP2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	10MAR2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Social circumstances	Tobacco user	01JAN1990		Y
	C4591001 1167 11671178	Psychiatric disorders	Attention deficit hyperactivity disorder	25JUL2020		Y
	C4591001 1167 11671179	Immune system disorders	Seasonal allergy	01JAN1977		Y
	C4591001 1167 11671181	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1167 11671185	Cardiac disorders	Ventricular extrasystoles	13SEP2011		Y
		Injury, poisoning and procedural complications	Iliotibial band syndrome	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Bursitis	22SEP2015		Y
			Fibromyalgia	28OCT2019		Y
		Nervous system disorders	Migraine	01JAN2005		Y
			Narcolepsy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2019	31DEC2019	N
	C4591001 1167 11671187	Gastrointestinal disorders	Diverticulum	01JUN2020		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1167 11671188	Gastrointestinal disorders	Abdominal hernia	09JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dysphagia	26FEB2019		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	24JUL2018		Y
		Metabolism and nutrition disorders	Haemochromatosis	18MAR2019		Y
	C4591001 1167 11671189	Ear and labyrinth disorders	Deafness bilateral	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1999		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
			Stress urinary incontinence	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1167 11671191	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1167 11671194	Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2016		Y
		Vascular disorders	Essential hypertension	01JAN2017		Y
	C4591001 1167 11671195	Gastrointestinal disorders	Gastroesophageal reflux disease	20JAN2020		Y
			Irritable bowel syndrome	18OCT2019		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21JAN2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1167 11671199	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
	C4591001 1167 11671200	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671201	Hepatobiliary disorders	Hepatic steatosis	01APR2020		Y
		Nervous system disorders	Narcolepsy	01JAN2018		Y
		Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 1167 11671202	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1167 11671205	Nervous system disorders	Migraine	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2019		Y
	C4591001 1167 11671206	Musculoskeletal and connective tissue disorders	Neck pain	06DEC2018		Y
	C4591001 1167 11671210	Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JUN2016	30JUN2016	N
	C4591001 1167 11671211	Psychiatric disorders	Depression	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1167 11671212	Immune system disorders	Seasonal allergy	03MAR2016		Y
	C4591001 1167 11671213	Investigations	Cardiac murmur	01JAN2019		Y
	C4591001 1167 11671216	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1167 11671217	Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
	C4591001 1167 11671219	Nervous system disorders	Migraine	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671230	Immune system disorders	Allergy to arthropod sting	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	20AUG2020	20AUG2020	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	27SEP2018		Y
		Surgical and medical procedures	Skin lesion removal	20AUG2020	20AUG2020	N
	C4591001 1167 11671231	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1168 11681001	Blood and lymphatic system disorders	Increased tendency to bruise	01JAN2014		Y
		Endocrine disorders	Hyperthyroidism	01JAN2003		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1168 11681002	Eye disorders	Hypermetropia	01JAN2011		Y
			Myopia	01JAN1987		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1991	31DEC1991	N
		Investigations	Human papilloma virus test positive	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1168 11681003	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2016		Y
	C4591001 1168 11681004	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Premature ejaculation	01JAN2015		Y
		Surgical and medical procedures	Meniscus operation	01JAN2018	31DEC2018	N
	C4591001 1168 11681006	Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
	C4591001 1168 11681007	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Female sterilisation	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681008	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1168 11681009	Infections and infestations	Appendicitis	01DEC2019	31DEC2019	N
			Tonsillitis	01JAN2001	31DEC2001	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2011	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01DEC2019	31DEC2019	N
			Endometrial ablation	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2001	31DEC2011	N
	C4591001 1168 11681011	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1168 11681014	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1168 11681016	Infections and infestations	Ophthalmic herpes simplex	01JAN2013		Y
		Nervous system disorders	Tension headache	01DEC2019		Y
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N
	C4591001 1168 11681018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1986	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ligament operation	01JAN2004	31DEC2004	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1168 11681019	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Insomnia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1168 11681020	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Nausea	01JAN2011		Y
		General disorders and administration site conditions	Pain	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN1998		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2011		Y
			Osteoarthritis	01JAN2011		Y
			Spinal osteoarthritis	01JAN2011		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
			Tension headache	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2011		Y
		Surgical and medical procedures	Arthrodesis	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
	C4591001 1168 11681022	Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1168 11681023	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Osteoarthritis	01JUL2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Neuralgia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000		Y
	C4591001 1168 11681024	General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01OCT2015		Y
			Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Anxiety	01MAY2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Knee arthroplasty	01FEB2019	28FEB2019	N
				01NOV2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1168 11681025	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Cataract	01FEB2019	28FEB2019	N
		Gastrointestinal disorders	Constipation	01JAN2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Nervous system disorders	Tension headache	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2010		Y
			Insomnia	(b) (6) 1969		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2019	31DEC2019	N
			Hernia repair	01JAN1974	31DEC1974	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1168 11681026	Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1168 11681027	Endocrine disorders	Hypothyroidism	01MAR2004		Y
		Eye disorders	Amblyopia	(b) (6) 1982		Y
		Immune system disorders	Hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Oral herpes	01JAN2015		Y
		Psychiatric disorders	Anxiety	01APR2001		Y
			Depression	01APR2001		Y
	C4591001 1168 11681028	Eye disorders	Cataract	01JAN1999		Y
			Myopia	01SEP2017		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Nervous system disorders	Headache	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681030	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Tension headache	01JAN1994		Y
		Psychiatric disorders	Bipolar disorder	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
	C4591001 1168 11681031	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Iodine allergy	01JAN1998		Y
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1168 11681032	Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1964		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1168 11681033	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2018	31DEC2018	N
		Nervous system disorders	Sinus headache	01JAN2000		Y
		Surgical and medical procedures	Chondroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681034	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2001		Y
		Surgical and medical procedures	Appendectomy	01JAN2019	31DEC2019	N
	C4591001 1168 11681035	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Tension headache	01JAN2015		Y
	C4591001 1168 11681036	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1168 11681038	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01FEB2020	29FEB2020	N
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bowen's disease	01JAN2001	31DEC2001	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Headache	01JAN1985		Y
		Surgical and medical procedures	Cancer surgery	01JAN2001	31DEC2001	N
			Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Chondroplasty	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1168 11681039	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1168 11681040	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1168 11681042	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
				01JAN2007		Y
			Seasonal allergy	01JAN1986		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Obsessive-compulsive disorder	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1168 11681045	Blood and lymphatic system disorders	Anaemia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Tonsillitis	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Surgical and medical procedures	Ovarian cystectomy	01AUG2017		Y
	C4591001 1168 11681046	Nervous system disorders	Tension headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
	C4591001 1168 11681047	Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1168 11681048	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Depression	01JAN2003		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681050	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
			Toothache	14AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1168 11681052	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2004		Y
	C4591001 1168 11681053	Gastrointestinal disorders	Inguinal hernia	01JAN1968	31DEC1968	N
				01JAN1972	31DEC1972	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Surgical and medical procedures	Osteotomy	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1168 11681054	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1168 11681058	Surgical and medical procedures	Sesamoidectomy	01JAN2013	31DEC2013	N
	C4591001 1168 11681059	Ear and labyrinth disorders	Tinnitus	01JAN1975		Y
		Eye disorders	Blindness unilateral	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1988	31DEC1988	N
	C4591001 1168 11681060	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Keratosi pilaris	01JAN1990		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1168 11681063	Ear and labyrinth disorders	Tinnitus	01JAN2008		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01NOV2019	31DEC2019	N
	C4591001 1168 11681064	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
	C4591001 1168 11681065	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN2017		Y
			Rubber sensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1994		Y
	C4591001 1168 11681068	Gastrointestinal disorders	Dyspepsia	01MAR2020		Y
			Umbilical hernia	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1168 11681069	Eye disorders	Hypermetropia	01JAN1999		Y
			Myopia	01JAN1999		Y
		Nervous system disorders	Headache	01JAN2007		Y
	C4591001 1168 11681070	Immune system disorders	Seasonal allergy	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1168 11681071	Eye disorders	Myopia	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1168 11681072	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Headache	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01JUN2020	30JUN2020	N
	C4591001 1168 11681073	Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1168 11681074	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Urinary tract infection	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1997		Y
	C4591001 1168 11681077	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
			Irritable bowel syndrome	01JAN2005		Y
			Nausea	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
	C4591001 1168 11681078	Infections and infestations	Tonsillitis	01JUL2019	31JUL2019	N
		Nervous system disorders	Headache	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JUL2019	31JUL2019	N
	C4591001 1168 11681079	Injury, poisoning and procedural complications	Tendon rupture	01APR2020	30APR2020	N
		Investigations	Blood testosterone decreased	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Surgical and medical procedures	Tenoplasty	01JAN2009		Y
	C4591001 1168 11681080	Gastrointestinal disorders	Dyspepsia	01APR2020	30APR2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008	31DEC2008	N
		Psychiatric disorders	Restlessness	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2011		Y
	C4591001 1168 11681081	Hepatobiliary disorders	Hysterectomy	01JAN2019	31DEC2019	N
		Immune system disorders	Gallbladder disorder	01AUG2011	01AUG2011	N
		Musculoskeletal and connective tissue disorders	Drug hypersensitivity	01JAN2011	31DEC2011	N
		Nervous system disorders	Seasonal allergy	01JAN1987		Y
		Surgical and medical procedures	Arthralgia	01JAN2010		Y
		Surgical and medical procedures	Headache	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1168 11681084	Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
			Vasectomy	01JAN1979	31DEC1979	N
				01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681085	Eye disorders	Hypermetropia	01JAN2018		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1999	31DEC1999	N
		Nervous system disorders	Headache	01JAN1976		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Bipolar disorder	01JAN2016		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1998		Y
		Surgical and medical procedures	Bone graft	01JAN1999	31DEC1999	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N
	C4591001 1168 11681086	Ear and labyrinth disorders	Deafness bilateral	01JAN1998		Y
			Tinnitus	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1168 11681087	Infections and infestations	Herpes zoster	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01FEB2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681088	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
			Dermatitis contact	01OCT2017		Y
		Surgical and medical procedures	Bursal operation	01OCT2017	31OCT2017	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1168 11681089	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1168 11681090	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Surgical and medical procedures	Gastric operation	01JAN2012	31DEC2012	N
	C4591001 1168 11681093	Hepatobiliary disorders	Gallbladder disorder	01JAN2006	31DEC2006	N
		Infections and infestations	Tonsillitis	01DEC2019	31DEC2019	N
		Nervous system disorders	Tension headache	01JAN2003		Y
		Renal and urinary disorders	Nephropathy	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01DEC2019	31DEC2019	N
	C4591001 1168 11681094	Surgical and medical procedures	Tonsillectomy	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681095	Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
			Urinary tract infection	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01NOV2016	30NOV2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01NOV2016	30NOV2016	N
	C4591001 1168 11681096	Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2014		Y
	C4591001 1168 11681097	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Nervous system disorders	Tension headache	01JAN1997		Y
		Psychiatric disorders	Anxiety	01MAY2019		Y
			Attention deficit hyperactivity disorder	01MAY2019		Y
			Depression	01MAY2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1992		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
	C4591001 1168 11681098	Eye disorders	Myopia	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1168 11681100	Cardiac disorders	Myocardial infarction	01MAY2019	31MAY2019	N
		Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Tonsillitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1168 11681101	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1168 11681102	General disorders and administration site conditions	Hernia	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hernia repair	01JAN2015	31DEC2015	N
	C4591001 1168 11681103	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2014	31DEC2017	N
		Surgical and medical procedures	Scoliosis surgery	01JAN2017	31DEC2017	N
	C4591001 1168 11681104	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1168 11681105	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN1988		Y
	C4591001 1168 11681107	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Nervous system disorders	Tension headache	01JAN1971		Y
		Surgical and medical procedures	Chondroplasty	01JAN2008	31DEC2008	N
			Ligament operation	01JAN2000	31DEC2000	N
			Meniscus operation	01JAN2005	31DEC2005	N
	C4591001 1168 11681109	Eye disorders	Myopia	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
	C4591001 1168 11681112	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1168 11681114	Eye disorders	Myopia	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN1979		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2016	31DEC2016	N
	C4591001 1168 11681115	Ear and labyrinth disorders	Deafness bilateral	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Infections and infestations	Pneumonia	01JAN1981	31DEC1981	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Cardiac murmur	(b) (6) 1970		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2019		Y
			Pain in extremity	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N
			Knee operation	01JAN1982	31DEC1982	N
	C4591001 1168 11681116	Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1168 11681117	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2015	31DEC2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y
		Psychiatric disorders	Dysphemia	01JAN1983		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Brain operation	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1168 11681118	Eye disorders	Hypermetropia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681121	Eye disorders	Hypermetropia	01JAN2004		Y
			Myopia	01JAN2016		Y
		Nervous system disorders	Headache	01JAN1981		Y
			Migraine	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Post-traumatic stress disorder	01JAN1991		Y
	C4591001 1168 11681127	Ear and labyrinth disorders	Deafness bilateral	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01MAR2019		Y
			Seasonal allergy	01JAN1987		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Surgical and medical procedures	Meniscus removal	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
	C4591001 1168 11681128	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Rubber sensitivity	01JAN1989		Y
			Seasonal allergy	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987	31DEC2007	N
		Vascular disorders	Thrombosis	01JAN2009	31DEC2009	N
	C4591001 1168 11681130	Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1168 11681132	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Neck pain	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1168 11681134	Eye disorders	Diabetic retinopathy	01JAN2005	31DEC2005	N
			Glaucoma	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01FEB2019		Y
				01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2015		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Nervous system disorders	Neuropathy peripheral	01FEB2019		Y
		Skin and subcutaneous tissue disorders	Diabetic foot	01NOV2019	01MAR2020	N
			Skin hyperpigmentation	01MAY2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1168 11681135	Cardiac disorders	Tachycardia	01JAN2020		Y
		Endocrine disorders	Hyperthyroidism	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	31MAY2019	31MAY2019	N
			Tonsillitis	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Post-traumatic stress disorder	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	31MAY2019	31MAY2019	N
			Tonsillectomy	01JAN2003	31DEC2003	N
	C4591001 1168 11681136	Ear and labyrinth disorders	Hypoacusis	01JAN1988		Y
		Gastrointestinal disorders	Tooth loss	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1168 11681137	Ear and labyrinth disorders	Vertigo	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1168 11681138	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681141	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1168 11681142	Eye disorders	Hypermetropia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Herpes virus infection	01JAN1999		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1988		Y
		Psychiatric disorders	Anxiety	01SEP2018		Y
	C4591001 1168 11681143	Eye disorders	Myopia	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1967		Y
		Infections and infestations	Dengue fever	01JAN2008	31DEC2008	N
			Herpes virus infection	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1168 11681145	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1168 11681146	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN1992		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
	C4591001 1168 11681148	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1168 11681153	Infections and infestations	Diverticulitis	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1168 11681154	Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2011		Y
			Tension headache	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
	C4591001 1168 11681157	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1168 11681158	Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1168 11681159	Blood and lymphatic system disorders	Anaemia	01JAN2002		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1168 11681160	Immune system disorders	Allergy to metals	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1168 11681163	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Surgical and medical procedures	Gastrectomy	01APR2019	30APR2019	N
	C4591001 1168 11681164	Eye disorders	Myopia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2016		Y
	C4591001 1168 11681166	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
	C4591001 1168 11681167	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
	C4591001 1168 11681168	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1168 11681169	Ear and labyrinth disorders	Deafness bilateral	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005		Y
	C4591001 1168 11681175	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUL2019		Y
	C4591001 1168 11681176	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
	C4591001 1168 11681177	Congenital, familial and genetic disorders	Cleft palate	01JAN1995		Y
		Eye disorders	Myopia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1168 11681178	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1168 11681182	Eye disorders	Hypermetropia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Chondroplasty	01JAN2008	31DEC2008	N
			Tenoplasty	01JAN2019	31JAN2019	N
	C4591001 1168 11681184	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2013		Y
	C4591001 1168 11681185	Eye disorders	Hypermetropia	01JAN1990		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1998	31DEC1998	N
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1990		Y
			Hyposmia	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681186	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1168 11681187	Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1168 11681188	Eye disorders	Astigmatism	01JAN1990		Y
			Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
		Surgical and medical procedures	Fracture treatment	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1168 11681192	Psychiatric disorders	Depression	01NOV2017		Y
			Insomnia	01NOV2017		Y
	C4591001 1168 11681193	Eye disorders	Myopia	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Ovarian cystectomy	01JAN2006	31DEC2006	N
			Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1168 11681194	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1168 11681195	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Migraine	01SEP2018		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Autism spectrum disorder	01JAN2016		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2020		Y
	C4591001 1168 11681197	Congenital, familial and genetic disorders	Diverticulitis Meckel's	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1168 11681198	Ear and labyrinth disorders	Tinnitus	01JAN2013		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2016	31DEC2016	N
		Nervous system disorders	Sinus headache	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681202	Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1168 11681203	Eye disorders	Hypermetropia	01JAN1978		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2006		Y
		Surgical and medical procedures	Ankle operation	01JAN2002	31DEC2002	N
			Appendectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1168 11681206	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Irritable bowel syndrome	01JAN2005		Y
			Nausea	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2014		Y
			Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2014	31DEC2014	N
	C4591001 1168 11681207	Gastrointestinal disorders	Coeliac disease	01MAR2020		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN1994		Y
				01JAN2001		Y
			Seasonal allergy	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Persistent depressive disorder	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681210	Eye disorders	Myopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
	C4591001 1168 11681212	Eye disorders	Myopia	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1168 11681213	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Tenoplasty	01JAN2016	31DEC2016	N
	C4591001 1168 11681215	Immune system disorders	Seasonal allergy	01MAR2011		Y
	C4591001 1168 11681216	Blood and lymphatic system disorders	Anaemia	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Synovial cyst	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Chondroplasty	01JAN2013	31DEC2013	N
			Synovial cyst removal	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1168 11681217	Blood and lymphatic system disorders	Anaemia	01JAN1998		Y
		Cardiac disorders	Angina pectoris	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Dry mouth	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1974		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
		Investigations	Cardiac murmur	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
			Insomnia	01JAN1999		Y
			Post-traumatic stress disorder	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1168 11681218	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681219	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2019		Y
	C4591001 1168 11681220	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1168 11681221	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1168 11681222	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Apnoea	01APR2020		Y
	C4591001 1168 11681223	Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Female sterilisation	13APR2001	13APR2001	N
	C4591001 1168 11681224	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1168 11681226	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1168 11681228	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Infections and infestations	Tonsillitis	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1168 11681229	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Iodine allergy	01JAN1995		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1168 11681234	Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1168 11681239	Surgical and medical procedures	Ligament operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681241	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2006		Y
			Migraine	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAY2000	31DEC2012	N
	C4591001 1169 11691001	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	29SEP2015	29SEP2015	N
	C4591001 1169 11691002	Infections and infestations	Oral herpes	07DEC2014		Y
		Investigations	Biopsy skin	25MAR2020	25MAR2020	N
		Metabolism and nutrition disorders	Hyperglycaemia	19DEC2014		Y
			Obesity	07DEC2014		Y
		Nervous system disorders	Migraine	14DEC2014		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	07DEC2014		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01OCT2018		Y
			Premenstrual dysphoric disorder	19DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	07DEC2014		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	19DEC2014		Y
	C4591001 1169 11691010	Psychiatric disorders	Anxiety	20APR2018		Y
	C4591001 1169 11691011	Metabolism and nutrition disorders	Obesity	03DEC2015		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1169 11691012	Injury, poisoning and procedural complications	Jaw fracture	01JAN1997	31DEC1997	N
	C4591001 1169 11691014	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01OCT2016	07OCT2016	N
		Surgical and medical procedures	Thyroidectomy	07OCT2016	07OCT2016	N
	C4591001 1169 11691017	Immune system disorders	Seasonal allergy	18DEC2013		Y
	C4591001 1169 11691018	Infections and infestations	Genital herpes	30SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	14DEC2019		Y
		Nervous system disorders	Lumbar radiculopathy	26DEC2018		Y
			Migraine	01JUN2020		Y
		Psychiatric disorders	Anxiety disorder	14DEC2019		Y
			Insomnia	25FEB2018		Y
			Major depression	19DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	19OCT2018		Y
	C4591001 1169 11691020	Metabolism and nutrition disorders	Hypercholesterolaemia	28JAN2014		Y
			Type 2 diabetes mellitus	28JAN2014		Y
			Vitamin D deficiency	01APR2019	04AUG2020	N
		Nervous system disorders	Carotid artery dissection	01JAN2012	10MAY2014	N
			Cerebrovascular accident	10MAY2012	10MAY2012	N
		Reproductive system and breast disorders	Erectile dysfunction	28JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	28JAN2014		Y
			Sleep apnoea syndrome	28JAN2014		Y
		Vascular disorders	Hypertension	28JAN2014		Y
	C4591001 1169 11691023	Gastrointestinal disorders	Dysphagia	19DEC2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	19JUL2016		Y
		Vascular disorders	Raynaud's phenomenon	09JAN2015		Y
	C4591001 1169 11691024	Vascular disorders	Hypertension	30JAN2018		Y
	C4591001 1169 11691025	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	14NOV2017		Y
		Psychiatric disorders	Anxiety	01NOV2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01NOV2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1169 11691026	Gastrointestinal disorders	Gastroesophageal reflux disease	22DEC2014		Y
			Irritable bowel syndrome	05JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22DEC2014		Y
			Vitamin D deficiency	20JUN2020		Y
		Nervous system disorders	Migraine	30JAN2018		Y
		Psychiatric disorders	Insomnia	22DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	22DEC2014		Y
	C4591001 1169 11691027	Congenital, familial and genetic disorders	Gilbert's syndrome	25SEP2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	25FEB2019		Y
	C4591001 1169 11691030	Endocrine disorders	Autoimmune thyroiditis	21DEC2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	08AUG2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	21DEC2014		Y
	C4591001 1169 11691031	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
		Psychiatric disorders	Anxiety	19MAY2020		Y
			Attention deficit hyperactivity disorder	19MAY2020		Y
			Major depression	19MAY2020		Y
	C4591001 1169 11691033	Cardiac disorders	Postural orthostatic tachycardia syndrome	11JAN2019		Y
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	25SEP2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	26NOV2019		Y
		Immune system disorders	Seasonal allergy	18OCT2018		Y
		Nervous system disorders	Migraine	03OCT2019		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1169 11691034	Psychiatric disorders	Panic disorder	26JUN2019		Y
		Social circumstances	Trans-sexualism	05FEB2015		Y
	C4591001 1169 11691036	Endocrine disorders	Hypothyroidism	09MAY2012		Y
		Metabolism and nutrition disorders	Obesity	21DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	17APR2018		Y
		Skin and subcutaneous tissue disorders	Vitiligo	09SEP2020		Y
		Vascular disorders	Hypertension	21DEC2014		Y
	C4591001 1169 11691038	Hepatobiliary disorders	Non-alcoholic steatohepatitis	19JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	16APR2015		Y
		Skin and subcutaneous tissue disorders	Eczema	02JUN2016		Y
	C4591001 1169 11691039	Metabolism and nutrition disorders	Obesity	02JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	21DEC2014		Y
			Bipolar disorder	21DEC2014		Y
			Depression	21DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	06AUG2018		Y
		Skin and subcutaneous tissue disorders	Acne	10JAN2013		Y
	C4591001 1169 11691040	Endocrine disorders	Hyperthyroidism	06DEC2016		Y
			Hypothyroidism	23DEC2014		Y
		Gastrointestinal disorders	Constipation	05JUN2019		Y
			Gastrooesophageal reflux disease	23DEC2014		Y
		Immune system disorders	Drug hypersensitivity	21SEP2012		Y
			Food allergy	21DEC2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tinea versicolour	24JAN2020		Y
		Investigations	Mammogram abnormal	20OCT2017		Y
			Smear cervix abnormal	13MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10OCT2018		Y
			Impaired fasting glucose	02AUG2020		Y
			Obesity	30JUN2020		Y
			Vitamin D deficiency	21SEP2012		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	24JAN2020		Y
		Nervous system disorders	Carotid artery stenosis	02AUG2020		Y
			Migraine	23DEC2014		Y
		Psychiatric disorders	Insomnia	23DEC2014		Y
		Renal and urinary disorders	Nephrolithiasis	23JUL2019	23JUL2019	N
		Reproductive system and breast disorders	Menopausal symptoms	07APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23DEC2014		Y
			Sleep apnoea syndrome	23JUL2019		Y
		Social circumstances	Tobacco user	23DEC2014		Y
	C4591001 1169 11691041	Gastrointestinal disorders	Gastroesophageal reflux disease	16OCT2019		Y
		Psychiatric disorders	Generalised anxiety disorder	09SEP2019		Y
			Major depression	09SEP2019	16OCT2019	N
	C4591001 1169 11691043	Cardiac disorders	Mitral valve incompetence	16NOV2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	05JAN2018		Y
	C4591001 1169 11691044	Musculoskeletal and connective tissue disorders	Back pain	30JUN2020		Y
		Nervous system disorders	Sciatica	30JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1169 11691046	Gastrointestinal disorders	Gastroesophageal reflux disease	30AUG2017		Y
		Skin and subcutaneous tissue disorders	Urticaria chronic	30AUG2017		Y
	C4591001 1169 11691047	Endocrine disorders	Hypothyroidism	28JAN2016		Y
		Metabolism and nutrition disorders	Obesity	17DEC2015		Y
		Surgical and medical procedures	Hysterectomy	01MAY2019	31MAY2019	N
	C4591001 1169 11691048	Psychiatric disorders	Social anxiety disorder	04NOV2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	04NOV2015		Y
		Vascular disorders	Hypertension	18DEC2014		Y
	C4591001 1169 11691049	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1169 11691053	Gastrointestinal disorders	Gastroesophageal reflux disease	20OCT2015		Y
		Immune system disorders	Seasonal allergy	03SEP2015		Y
		Metabolism and nutrition disorders	Obesity	03SEP2015		Y
		Psychiatric disorders	Anxiety	03SEP2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	03SEP2015		Y
		Social circumstances	Menopause	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	03SEP2015		Y
	C4591001 1169 11691054	Metabolism and nutrition disorders	Obesity	03JAN2013		Y
	C4591001 1169 11691055	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	21MAY2015		Y
		Metabolism and nutrition disorders	Obesity	21DEC2014		Y
		Psychiatric disorders	Anxiety	01DEC2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1169 11691056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Urinary tract infection	13SEP2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2019		Y
		Psychiatric disorders	Anxiety	01APR2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Vascular disorders	Essential hypertension	01AUG2018		Y
	C4591001 1169 11691058	Gastrointestinal disorders	Gastroesophageal reflux disease	22OCT2019		Y
		Psychiatric disorders	Anxiety	11OCT2019		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1169 11691059	Endocrine disorders	Hypothyroidism	02JUL2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	09MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	24MAY2013		Y
		Surgical and medical procedures	Metabolic surgery	29AUG2017	29AUG2017	N
	C4591001 1169 11691060	Psychiatric disorders	Anxiety	23MAY2018		Y
			Depression	23MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	11APR2019		Y
	C4591001 1169 11691062	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	29JUL2020		Y
		Psychiatric disorders	Depression	14NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	16JUN2020		Y
		Reproductive system and breast disorders	Uterine prolapse	31AUG2020		Y
	C4591001 1169 11691063	Psychiatric disorders	Bipolar disorder	24JAN2018		Y
	C4591001 1169 11691064	Psychiatric disorders	Depression	01JUL2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	05JUN2015		Y
	C4591001 1169 11691065	Endocrine disorders	Thyroid mass	06MAR2019	29MAY2019	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	06MAR2019		Y
			Obesity	28FEB2019		Y
		Surgical and medical procedures	Thyroidectomy	29MAY2019	29MAY2019	N
	C4591001 1169 11691067	Metabolism and nutrition disorders	Vitamin D deficiency	25JUN2020		Y
		Nervous system disorders	Migraine with aura	25JUN2020		Y
		Renal and urinary disorders	Pollakiuria	10DEC2018		Y
		Reproductive system and breast disorders	Menopausal symptoms	10DEC2018		Y
	C4591001 1169 11691069	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	11DEC2015		Y
	C4591001 1169 11691072	Cardiac disorders	Acute myocardial infarction	23AUG2019	23AUG2019	N
			Cardiac arrest	26JUN2019	26JUN2019	N
			Coronary artery disease	08JUN2020		Y
	C4591001 1169 11691073†	Gastrointestinal disorders	Gastroesophageal reflux disease	06JUL2016		Y
		Infections and infestations	HIV infection	25MAY2012		Y
		Metabolism and nutrition disorders	Lactose intolerance	06JUL2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	06JUL2016		Y
		Social circumstances	Tobacco user	01JAN2000		Y
	C4591001 1169 11691075†	Endocrine disorders	Hypothyroidism	21DEC2014		Y
		Infections and infestations	HIV infection	01MAY2007		Y
		Metabolism and nutrition disorders	Obesity	21DEC2014		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	21DEC2014		Y
		Psychiatric disorders	Bipolar disorder	21DEC2014		Y
		Renal and urinary disorders	Chronic kidney disease	27NOV2019		Y
		Vascular disorders	Hypertension	11NOV2014		Y
	C4591001 1170 11701001	Nervous system disorders	Cerebral venous sinus thrombosis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1170 11701002	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701006	Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1170 11701009	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1170 11701011	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1170 11701012	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
	C4591001 1170 11701015	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
	C4591001 1170 11701016	Surgical and medical procedures	Vasectomy	01JAN2014		Y
	C4591001 1170 11701018	Gastrointestinal disorders	Colitis ulcerative	26APR2020		Y
		Immune system disorders	Multiple allergies	01JAN1992		Y
		Nervous system disorders	Headache	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1170 11701020	Psychiatric disorders	Bipolar disorder	01JAN1988		Y
	C4591001 1170 11701021	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
	C4591001 1170 11701022	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2015		Y
	C4591001 1170 11701024	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1170 11701025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1170 11701026	Vascular disorders	Hypertension	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1170 11701031	Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
	C4591001 1170 11701034	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1170 11701035	Psychiatric disorders	Generalised anxiety disorder	01JAN2010		Y
	C4591001 1170 11701038	Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1170 11701041	Skin and subcutaneous tissue disorders	Chloasma	01JAN2010		Y
	C4591001 1170 11701043	Hepatobiliary disorders	Hepatic steatosis	01JAN2019	31MAY2020	N
		Infections and infestations	Folliculitis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1170 11701044	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
	C4591001 1170 11701045	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
	C4591001 1170 11701048	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1170 11701052	Cardiac disorders	Coronary artery disease	01JAN2020		Y
	C4591001 1170 11701060	Nervous system disorders	Hypersomnia	01AUG2015		Y
			Narcolepsy	01AUG2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701063	Endocrine disorders	Hypothyroidism	01JAN2007		Y
	C4591001 1170 11701064	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1170 11701073	Cardiac disorders	Cardiac failure congestive	01JAN2018	31DEC2018	N
			Coronary artery disease	01JAN2018		Y
	C4591001 1170 11701074	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2018	31DEC2018	N
	C4591001 1170 11701075	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
	C4591001 1170 11701076	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1170 11701077	Psychiatric disorders	Bipolar disorder	01JAN1994		Y
	C4591001 1170 11701081	Gastrointestinal disorders	Peptic ulcer	01JUN2020		Y
	C4591001 1170 11701087	Investigations	Blood cholesterol increased	01JAN1987		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1977		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1170 11701091	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701093	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1170 11701095	Immune system disorders	Seasonal allergy	01JAN1999		Y
	C4591001 1170 11701096	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
	C4591001 1170 11701097	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1170 11701099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1170 11701100	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1170 11701101	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1170 11701102	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1170 11701103	Endocrine disorders	Hypothyroidism	01JAN2019		Y
	C4591001 1170 11701104	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998	31DEC2000	N
	C4591001 1170 11701105	Immune system disorders	Seasonal allergy	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01DEC2003	31DEC2003	N
	C4591001 1170 11701106	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701110	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1170 11701111	Metabolism and nutrition disorders	Lactose intolerance	01AUG2019		Y
			Obesity	01JAN2005		Y
	C4591001 1170 11701112	General disorders and administration site conditions	Face oedema	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701115	Immune system disorders	Seasonal allergy	01JAN1984		Y
	C4591001 1170 11701116	Immune system disorders	Seasonal allergy	01JAN1998		Y
	C4591001 1170 11701119	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01APR2008	30APR2008	N
	C4591001 1170 11701120	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1170 11701122	Immune system disorders	Seasonal allergy	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
	C4591001 1170 11701123	Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Muscle spasms	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1170 11701125	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1170 11701127	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1170 11701128	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1980		Y
	C4591001 1170 11701129	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiomyolipoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nephrectomy	01JAN2010	31DEC2010	N
	C4591001 1170 11701137	Social circumstances	Postmenopause	01JAN2016	31DEC2016	N
	C4591001 1170 11701139	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1992		Y
	C4591001 1170 11701144	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1170 11701145	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2002	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701150	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Investigations	Blood uric acid increased	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1170 11701151	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701152	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Nervous system disorders	Migraine	01JAN1987		Y
	C4591001 1170 11701153	Immune system disorders	Seasonal allergy	01JAN2019	31JAN2019	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1170 11701156	Gastrointestinal disorders	Gastric ulcer	01JAN2018		Y
		Surgical and medical procedures	Spinal operation	01JAN1999	31DEC1999	N
	C4591001 1170 11701158	Cardiac disorders	Right atrial enlargement	01AUG2020		Y
	C4591001 1170 11701163	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN1987		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701164	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Autism spectrum disorder	01JAN2005		Y
			Obsessive-compulsive disorder	01JAN2005		Y
	C4591001 1170 11701165	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701166	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1170 11701167	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1170 11701171	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1170 11701174	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1170 11701181	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
			Rhinitis allergic	01JAN1988		Y
	C4591001 1170 11701182	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1170 11701183	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Multiple allergies	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1170 11701184	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2005		Y
	C4591001 1170 11701185	Reproductive system and breast disorders	Amenorrhoea	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1170 11701190	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN1994		Y
				01JAN2016		Y
			Seasonal allergy	01JAN1988		Y
	C4591001 1170 11701191	Psychiatric disorders	Anxiety disorder	01JAN2020		Y
	C4591001 1170 11701192	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1982		Y
	C4591001 1170 11701195	Social circumstances	Postmenopause	01JAN2020		Y
	C4591001 1170 11701204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701205	Gastrointestinal disorders	Gastroesophageal reflux disease	27AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Nervous system disorders	Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
	C4591001 1170 11701206	Congenital, familial and genetic disorders	Factor VIII deficiency	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2002		Y
	C4591001 1170 11701208	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1170 11701209	Gastrointestinal disorders	Gastritis	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
	C4591001 1170 11701210	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701211	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1170 11701212	Immune system disorders	Seasonal allergy	01JAN2002		Y
	C4591001 1170 11701213	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701215	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701221	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1991		Y
	C4591001 1170 11701222	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dysplastic naevus	01JAN2008		Y
		Renal and urinary disorders	Haematuria	01JAN1986		Y
	C4591001 1170 11701223	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701225	Immune system disorders	Seasonal allergy	01JAN1967		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1170 11701226	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
	C4591001 1170 11701227	Psychiatric disorders	Anxiety	01JAN2001		Y
	C4591001 1170 11701228	Ear and labyrinth disorders	Tinnitus	01AUG2015		Y
		Immune system disorders	Seasonal allergy	01FEB2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1984		Y
	C4591001 1170 11701229	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1170 11701230	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701233	Immune system disorders	Hypersensitivity	01JAN2007		Y
		Psychiatric disorders	Anxiety	01AUG2007		Y
			Depression	01AUG2007		Y
		Social circumstances	Postmenopause	01JAN2020	31DEC2020	N
	C4591001 1170 11701235	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
	C4591001 1170 11701237	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1170 11701241	Immune system disorders	Hypersensitivity	01JAN2018		Y
	C4591001 1170 11701243	Immune system disorders	Seasonal allergy	01APR2011		Y
	C4591001 1170 11701244	Immune system disorders	Hypersensitivity	01JAN2010		Y
	C4591001 1170 11701245	Immune system disorders	Hypersensitivity	01JAN2012		Y
	C4591001 1170 11701249	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701250	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1170 11701252	Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701255	Blood and lymphatic system disorders	Mastocytosis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 1170 11701256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701257	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
	C4591001 1170 11701258	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1170 11701259	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1170 11701261	Immune system disorders	Hypersensitivity	01FEB2019		Y
	C4591001 1170 11701262	Immune system disorders	Seasonal allergy	01JAN1991		Y
	C4591001 1170 11701263	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1170 11701264	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1170 11701269	Immune system disorders	Seasonal allergy	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01OCT2000		Y
	C4591001 1170 11701271	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1170 11701274	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1170 11701279	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1170 11701280	Immune system disorders	Seasonal allergy	01OCT2009		Y
	C4591001 1170 11701281	Immune system disorders	Seasonal allergy	01OCT2000		Y
	C4591001 1170 11701283	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1170 11701284	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	01JAN2018	31DEC2018	N
	C4591001 1170 11701285	Gastrointestinal disorders	Impaired gastric emptying	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01MAR2001		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Depression	01JAN2001		Y
	C4591001 1170 11701286	Immune system disorders	Seasonal allergy	01MAR2013		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701287	Endocrine disorders	Hypothyroidism	13FEB2019		Y
		Immune system disorders	Seasonal allergy	01MAR2012		Y
		Reproductive system and breast disorders	Polycystic ovaries	14OCT2019		Y
	C4591001 1170 11701288	Immune system disorders	Seasonal allergy	01APR2015		Y
	C4591001 1170 11701290	Immune system disorders	Seasonal allergy	01MAR2008		Y
	C4591001 1170 11701291	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1170 11701292	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1170 11701293	Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Polymorphic light eruption	01JAN2011		Y
	C4591001 1170 11701297	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1170 11701298	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1170 11701300	Social circumstances	Postmenopause	01JAN2020	31DEC2020	N
	C4591001 1170 11701302	Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1170 11701303	Psychiatric disorders	Depression	01FEB2018		Y
	C4591001 1170 11701304	Psychiatric disorders	Depression	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701306	Psychiatric disorders	Anxiety	01FEB2020		Y
	C4591001 1170 11701307	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1170 11701308	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1170 11701310	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2019		Y
	C4591001 1170 11701311	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1170 11701312	Immune system disorders	Allergy to plants	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
	C4591001 1170 11701313	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701315	Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701317	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
			Chronic obstructive pulmonary disease	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701318	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1170 11701320	Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Juvenile myoclonic epilepsy	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1170 11701321	Psychiatric disorders	Insomnia	01JAN2005		Y
	C4591001 1170 11701322	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1992		Y
	C4591001 1170 11701323	Social circumstances	Postmenopause	01JAN2018	31DEC2018	N
	C4591001 1170 11701325†	Infections and infestations	Hepatitis B	01JAN1999		Y
		Investigations	HIV test positive	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1170 11701326†	Investigations	HIV test positive	01JAN2006		Y
	C4591001 1170 11701334†	Endocrine disorders	Testicular failure	27JUL2016		Y
		Investigations	HIV test positive	01JAN1991		Y
			Hepatitis C core antibody negative	01JAN1995	31DEC2009	N
		Psychiatric disorders	Anxiety	13DEC2015		Y
			Depression	13DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	11APR2011		Y
	C4591001 1170 11701340	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1170 11701341	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1170 11701343	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1170 11701344†	Investigations	HIV test positive	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701348	Gastrointestinal disorders	Gastritis	01MAR2019		Y
	C4591001 1170 11701349	Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1170 11701352†	Immune system disorders	Seasonal allergy	01FEB2018		Y
		Investigations	HIV test positive	01JAN2004		Y
	C4591001 1170 11701355†	Investigations	HIV test positive	01OCT2014		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	04SEP2010		Y
	C4591001 1170 11701358	Blood and lymphatic system disorders	Anaemia	01JAN1999		Y
		Congenital, familial and genetic disorders	Factor XII deficiency	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1170 11701359	Endocrine disorders	Autoimmune thyroiditis	01JAN2006		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Coeliac disease	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1984		Y
	C4591001 1170 11701360	Ear and labyrinth disorders	Tinnitus	03MAY2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	23MAY2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701364	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1170 11701365	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Biliary dyskinesia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2014	31DEC2014	N
		Psychiatric disorders	Perinatal depression	01AUG2019	30SEP2019	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Lipoma excision	01JAN2014	31DEC2014	N
	C4591001 1170 11701370	Endocrine disorders	Hypogonadism	02SEP2020		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1170 11701372	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701373	Immune system disorders	Seasonal allergy	01OCT2008		Y
	C4591001 1170 11701374	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1170 11701376	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 1 diabetes mellitus	01JAN1984		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
	C4591001 1170 11701377	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1170 11701378	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01JAN2010		Y
	C4591001 1170 11701379	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1170 11701381	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1170 11701382	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
	C4591001 1170 11701383	Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1170 11701385†	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN1998		Y
		Investigations	HIV test positive	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701386	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1170 11701388	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
		Vascular disorders	Essential hypertension	01JAN2017		Y
	C4591001 1170 11701389	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1170 11701390	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1170 11701394†	Investigations	HIV test positive	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2019		Y
			Alopecia	01FEB2015		Y
	C4591001 1170 11701395	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701396	Injury, poisoning and procedural complications	Ligament sprain	18OCT2020	18OCT2020	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1975		Y
	C4591001 1170 11701397	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
	C4591001 1170 11701398	Immune system disorders	Seasonal allergy	01JAN1985		Y
	C4591001 1170 11701399	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
	C4591001 1170 11701400	Immune system disorders	Seasonal allergy	01JAN1977		Y
	C4591001 1170 11701402	Gastrointestinal disorders	Constipation	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2000		Y
	C4591001 1170 11701403	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1170 11701405	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1170 11701406	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701407	Endocrine disorders	Hypothyroidism	01AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2010		Y
	C4591001 1170 11701408†	Infections and infestations	Genital herpes	01JAN1997		Y
		Investigations	HIV test positive	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1170 11701410	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2019		Y
	C4591001 1170 11701412	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1170 11701413	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701414	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1170 11701416	Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
			Nasal polyps	01JAN1992		Y
	C4591001 1170 11701417	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2020	31DEC2020	N
	C4591001 1170 11701418	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701419	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1170 11701420	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1170 11701421	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Oral herpes	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1170 11701422†	Investigations	HIV test positive	01JAN2017		Y
	C4591001 1170 11701423	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01APR2020		Y
			Depression	01APR2019		Y
	C4591001 1170 11701424	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	14OCT2020		Y
	C4591001 1170 11701425	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701427†	Infections and infestations	Hepatitis B	01JAN2003		Y
		Investigations	HIV test positive	01JAN2003		Y
		Psychiatric disorders	Insomnia	01JAN1983		Y
	C4591001 1170 11701428	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Hyperlipidaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1170 11701429	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1170 11701430	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y
	C4591001 1170 11701431	Immune system disorders	Seasonal allergy	01JAN1987		Y
	C4591001 1170 11701432	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1170 11701433	Psychiatric disorders	Anxiety	20APR2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1170 11701434	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Psychiatric disorders	Anxiety	02FEB2015		Y
		Vascular disorders	Hypertension	03APR2006		Y
	C4591001 1170 11701436	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1170 11701437	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1170 11701438	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
	C4591001 1170 11701440	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1170 11701441	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1170 11701442	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1992		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JUL2020		Y
	C4591001 1170 11701443	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1170 11701444	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
	C4591001 1170 11701446	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1170 11701449	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1170 11701450	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
	C4591001 1170 11701451	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2007		Y
	C4591001 1170 11701452	Cardiac disorders	Atrial fibrillation	01JUN2020		Y
			Tachycardia	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Crohn's disease	01JAN2013		Y
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1170 11701453	Immune system disorders	Seasonal allergy	01JAN1984		Y
	C4591001 1170 11701455	Immune system disorders	Seasonal allergy	01JAN1985		Y
	C4591001 1170 11701456†	Investigations	HIV test positive	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1170 11701457†	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Investigations	HIV test positive	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
	C4591001 1170 11701458	Infections and infestations	Herpes simplex	01JUL2020		Y
			Tinea versicolour	01JAN2010		Y
	C4591001 1170 11701459	Psychiatric disorders	Anxiety	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
	C4591001 1170 11701460	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1170 11701461	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Endocrine disorders	Hypogonadism	01JAN2019		Y
			Hypothyroidism	01JAN2019		Y
	C4591001 1170 11701462	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701463†	Cardiac disorders	Palpitations	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Gastrointestinal disorders	Abdominal pain upper	01APR2020		Y
		Investigations	HIV test positive	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2018	31DEC2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1170 11701464	Ear and labyrinth disorders	Vertigo	01FEB2020		Y
	C4591001 1170 11701465	Psychiatric disorders	Bipolar disorder	01JAN2006		Y
			Insomnia	01JAN2015		Y
	C4591001 1170 11701466	Skin and subcutaneous tissue disorders	Alopecia	01DEC2019		Y
	C4591001 1170 11701467	Psychiatric disorders	Depression	01SEP2020		Y
	C4591001 1170 11701469	Skin and subcutaneous tissue disorders	Alopecia	01MAR2020		Y
	C4591001 1170 11701471	Cardiac disorders	Palpitations	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1998		Y
	C4591001 1170 11701472	Vascular disorders	Giant cell arteritis	01JAN2012		Y
	C4591001 1170 11701474†	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Infections and infestations	Herpes simplex	01NOV2019		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
			HIV test positive	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN1977		Y
			Depression	01JAN2000		Y
	C4591001 1170 11701475	Skin and subcutaneous tissue disorders	Alopecia	01SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701478	Gastrointestinal disorders	Large intestine polyp	01JAN2001		Y
	C4591001 1170 11701482	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1170 11701484	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1170 11701485	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1170 11701487	Congenital, familial and genetic disorders	Renal fusion anomaly	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2018		Y
	C4591001 1170 11701488	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1170 11701490	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1170 11701493	Metabolism and nutrition disorders	Haemochromatosis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
	C4591001 1170 11701495	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1170 11701496	Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1170 11701497†	Investigations	HIV test positive	01NOV2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701498	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Chronic sinusitis	01JAN2013		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
	C4591001 1170 11701499	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1170 11701500	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
	C4591001 1170 11701501	Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1171 11711001	Surgical and medical procedures	Vasectomy	30JAN2020	30JAN2020	N
	C4591001 1171 11711002	Investigations	Arthroscopy	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JUN2019		Y
		Surgical and medical procedures	Tenoplasty	01JAN2006	31DEC2006	N
			Vasectomy	01OCT2016	31OCT2016	N
	C4591001 1171 11711003	Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Female sterilisation	01JAN1996	31DEC1996	N
	C4591001 1171 11711004	Immune system disorders	Seasonal allergy	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01DEC2014	31DEC2014	N
			Female sterilisation	01DEC2019	31DEC2019	N
			Hot flush	21MAY2009	21MAY2009	N
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1171 11711005	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	05MAY2020	05MAY2020	N
	C4591001 1171 11711006	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1171 11711008	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1171 11711009	Endocrine disorders	Hypothyroidism	01FEB2016		Y
		Reproductive system and breast disorders	Polycystic ovaries	01FEB2016		Y
	C4591001 1171 11711010	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1171 11711011	Hepatobiliary disorders	Cholecystitis	01JAN1998	31DEC1998	N
			Nonalcoholic fatty liver disease	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
	C4591001 1171 11711012	Ear and labyrinth disorders	Deafness	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y
	C4591001 1171 11711013	Gastrointestinal disorders	Umbilical hernia	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Hernia repair	01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01OCT2018		Y
	C4591001 1171 11711014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Bone operation	01JAN1999	31DEC1999	N
			Cholecystectomy	01OCT2016	31OCT2016	N
			Knee operation	01JAN1998	31DEC1998	N
	C4591001 1171 11711020	Gastrointestinal disorders	Haemorrhoids	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1171 11711021	Infections and infestations	Appendicitis	01MAR2020	31MAR2020	N
		Skin and subcutaneous tissue disorders	Eczema	01MAY2020		Y
		Surgical and medical procedures	Appendicectomy	01MAR2020	31MAR2020	N
	C4591001 1171 11711023	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01FEB1998	31AUG1998	N
		Surgical and medical procedures	Chemotherapy	01APR1998	30APR1998	N
			Hernia repair	01JAN2012	31DEC2012	N
			Laparoscopic surgery	01JAN2018	31DEC2018	N
			Orchidectomy	01MAR1998	31MAR1998	N
			Toe operation	01JAN2000	31DEC2000	N
			Hypertension	01JAN2015		Y
	C4591001 1171 11711024	Vascular disorders				
	C4591001 1171 11711026	Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1171 11711027	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN2006	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1171 11711028	Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1171 11711029	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2005	N
			Wrist fracture	01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1998		Y
	C4591001 1171 11711030	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Sciatica	01APR2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1171 11711031	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016	31DEC2016	N
			Foot deformity	01JAN1996	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN1991		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1996		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2016	31DEC2016	N
			Bunion operation	01JAN2001	31DEC2001	N
			Dental implantation	01JAN2007	31DEC2019	N
	C4591001 1171 11711033	Hepatobiliary disorders	Cholecystitis	01APR2017	31OCT2017	N
		Surgical and medical procedures	Cholecystectomy	01OCT2017	31OCT2017	N
	C4591001 1171 11711034	Ear and labyrinth disorders	Tinnitus	01JAN1991		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Bipolar disorder	01JAN2007		Y
			Insomnia	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2012	31DEC2012	N
			Toe operation	01JAN2008	31DEC2008	N
			Uterine dilation and curettage	01JAN2006	31DEC2006	N
	C4591001 1171 11711036	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Latent tuberculosis	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2002	31DEC2002	N
			Intervertebral disc protrusion	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Bunion operation	01JAN2002	31DEC2002	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
	C4591001 1171 11711037	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711039	Injury, poisoning and procedural complications	Radius fracture	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2014	31DEC2014	N
			Depression	01JAN1995		Y
	C4591001 1171 11711043	Cardiac disorders	Bradycardia	01OCT2017	31OCT2017	N
		Infections and infestations	Meningitis viral	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01OCT2017		Y
			Vasectomy	01OCT2010	31OCT2010	N
	C4591001 1171 11711044	Psychiatric disorders	Anxiety	27JUL2013		Y
	C4591001 1171 11711046	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
	C4591001 1171 11711047	Psychiatric disorders	Insomnia	01NOV2019		Y
		Surgical and medical procedures	Pilonidal sinus repair	01DEC1987	31DEC1987	N
	C4591001 1171 11711050	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1171 11711052	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Nervous system disorders	Migraine without aura	01JAN2009		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1171 11711053	Metabolism and nutrition disorders	Hyperlipidaemia	01APR2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711055	Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1171 11711056	Endocrine disorders	Hypothyroidism	01JAN2012		Y
	C4591001 1171 11711058	Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
	C4591001 1171 11711060	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1983		Y
	C4591001 1171 11711062	Hepatobiliary disorders	Cholecystitis	01FEB2005	31MAR2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2019		Y
		Surgical and medical procedures	Cholecystectomy	01MAR2005	31MAR2005	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1171 11711065	Endocrine disorders	Hypothyroidism	14JAN2020		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1996		Y
	C4591001 1171 11711066	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Inguinal hernia	01AUG2016	31AUG2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Inguinal hernia repair	01AUG2016	31AUG2016	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1171 11711067	Immune system disorders	Drug hypersensitivity	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01MAR2019	31MAR2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1171 11711070	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1171 11711072	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711073	Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 1171 11711076	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01FEB2017	28FEB2017	N
	C4591001 1171 11711077	Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Female sterilisation	09NOV1998	09NOV1998	N
	C4591001 1171 11711079	Cardiac disorders	Atrial tachycardia	01APR2018	03JUL2018	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	02JAN2014	N
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
	C4591001 1171 11711080	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711081	Endocrine disorders	Goitre	01JAN2014	31DEC2015	N
		Gastrointestinal disorders	Aphthous ulcer	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
				01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2015	31DEC2015	N
	C4591001 1171 11711082	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JUN2000		Y
		Vascular disorders	Hot flush	01JAN2019		Y
	C4591001 1171 11711084	Blood and lymphatic system disorders	Anaemia	01JAN2013	31DEC2013	N
		Immune system disorders	Rubber sensitivity	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1171 11711087	Congenital, familial and genetic disorders	Cerebral palsy	(b) (6) 1985		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Arthrodesis	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
			Radiculotomy	01JAN1989	31DEC1989	N
	C4591001 1171 11711088	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1171 11711089	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
	C4591001 1171 11711091	Endocrine disorders	Hypothyroidism	01JUN2017		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711092	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2005	31DEC2005	N
	C4591001 1171 11711093	Psychiatric disorders	Attention deficit hyperactivity disorder	(b) (6) 1979		Y
	C4591001 1171 11711095	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1171 11711096	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1171 11711100	Psychiatric disorders	Anxiety	15JUL2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
	C4591001 1171 11711103	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
			Benign breast neoplasm	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN1980		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N
			Micrographic skin surgery	01JAN2012	31DEC2012	N
	C4591001 1171 11711104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN1986		Y
		Nervous system disorders	Carpal tunnel syndrome	01APR2013	30APR2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1171 11711106	Injury, poisoning and procedural complications	Cartilage injury	01JAN2003	31DEC2003	N
		Investigations	Arthroscopy	01JAN2003	31DEC2003	N
	C4591001 1171 11711109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
	C4591001 1171 11711110	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1171 11711111	Eye disorders	Myopia	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1171 11711112	Gastrointestinal disorders	Inguinal hernia	01JAN1997	31DEC1997	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN1997	31DEC1997	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1171 11711113	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Hyperuricaemia	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1171 11711114	Congenital, familial and genetic disorders	Congenital ureteric anomaly	01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Rubber sensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Surgical and medical procedures	Abdominal operation	01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Gastric bypass	01JAN2006	31DEC2006	N
	C4591001 1171 11711115	Metabolism and nutrition disorders	Obesity	01DEC2017		Y
	C4591001 1171 11711118	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01MAY2019	31MAY2019	N
	C4591001 1171 11711119	Metabolism and nutrition disorders	Hyperlipidaemia	02JUL2020		Y
	C4591001 1171 11711121	Gastrointestinal disorders	Large intestine polyp	01APR2019	30APR2019	N
		Investigations	Colonoscopy	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Large intestinal polypectomy	01APR2019	30APR2019	N
	C4591001 1171 11711122	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2006	31DEC2010	N
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
	C4591001 1171 11711124	Surgical and medical procedures	Shoulder operation	01JAN2008	31DEC2008	N
	C4591001 1171 11711125	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711126	Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
			Sleep apnoea syndrome	01JAN2010	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
			Uvulectomy	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1171 11711127	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Social circumstances	Menopause	01FEB2014		Y
	C4591001 1171 11711128	Congenital, familial and genetic disorders	Atrial septal defect	01JAN1975	31DEC1975	N
			Ventricular septal defect	01JAN1975	31DEC1975	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2003		Y
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
			Otitis media	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Atrial septal defect repair	01JAN1975	31DEC1975	N
			Hysterectomy	17JUN2020	17JUN2020	N
			Myringotomy	01JAN1975	31DEC1975	N
			Ventricular septal defect repair	01JAN1975	31DEC1975	N
	C4591001 1171 11711129	Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1171 11711130	Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
	C4591001 1171 11711131	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01APR2020	09JUL2020	N
		Surgical and medical procedures	Rotator cuff repair	09JUL2020	09JUL2020	N
	C4591001 1171 11711133	Surgical and medical procedures	Gastrectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JUN2018		Y
	C4591001 1171 11711134	Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
	C4591001 1171 11711135	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2009		Y
			Obesity	01JAN2019		Y
	C4591001 1171 11711136	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin D deficiency	01JAN2019		Y
	C4591001 1171 11711139	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2014		Y
	C4591001 1171 11711141	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1171 11711142	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1171 11711144	Nervous system disorders	Migraine without aura	01JAN2005		Y
	C4591001 1171 11711145	Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JUN1995	30JUN1995	N
		Renal and urinary disorders	Hypertonic bladder	10NOV2008	31DEC2009	N
		Surgical and medical procedures	Tonsillectomy	01JUN1995	30JUN1995	N
			Urinary bladder suspension	01DEC2009	31DEC2009	N
	C4591001 1171 11711146	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN1983		Y
	C4591001 1171 11711147	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2019	31MAR2019	N
		Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
			Mastectomy	01JAN2019	31DEC2019	N
	C4591001 1171 11711151	Surgical and medical procedures	Caesarean section	01DEC2002	31DEC2002	N
	C4591001 1171 11711153	Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
	C4591001 1171 11711154	Metabolism and nutrition disorders	Obesity	01JAN2016	31JUL2019	N
		Surgical and medical procedures	Gastrectomy	01JUL2019	31JUL2019	N
	C4591001 1171 11711156	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Cholesterosis	01JUL2005	31JUL2005	N
			Hypercholesterolaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2005	31JUL2005	N
			Coronary artery bypass	01SEP2013	30SEP2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1171 11711158	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1977		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
			Hernia repair	01JAN2012	31DEC2012	N
	C4591001 1171 11711159	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
			Depression	01SEP2018		Y
	C4591001 1171 11711163	Endocrine disorders	Hypogonadism	01JAN2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
			Tonsillitis	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Transient ischaemic attack	01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711164	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Migraine with aura	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1171 11711167	Endocrine disorders	Hypothyroidism	01FEB2019		Y
		Surgical and medical procedures	Inguinal hernia repair	06JUN1982	06JUN1982	N
	C4591001 1171 11711169	Musculoskeletal and connective tissue disorders	Back pain	01JUL2009		Y
			Spondylolisthesis	01JUL2009	31JUL2009	N
	C4591001 1171 11711171	Ear and labyrinth disorders	Tinnitus	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Ear operation	01JAN2017	31DEC2017	N
	C4591001 1171 11711172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Hand fracture	01FEB2020		Y
			Lumbar vertebral fracture	01JAN1990	23FEB2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
			Neck pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Spinal fusion surgery	23FEB2017	23FEB2017	N
			Wrist surgery	01MAR2020	31MAR2020	N
	C4591001 1171 11711174	Gastrointestinal disorders	Irritable bowel syndrome	01FEB2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Hirsutism	01JAN2015		Y
	C4591001 1171 11711175	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2005	31DEC2019	N
		Surgical and medical procedures	Mastectomy	01JAN2001	31DEC2001	N
			Synovial cyst removal	01JAN2019	31DEC2019	N
	C4591001 1171 11711176	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN1984	31DEC1985	N
			Malignant melanoma	01JUL2010	31JUL2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Chemotherapy	01JAN1984	31DEC1985	N
			Skin neoplasm excision	01JUL2010	31JUL2010	N
	C4591001 1171 11711177	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1171 11711181	Surgical and medical procedures	Adenoidectomy	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1171 11711183	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Gastric bypass	01JAN2019	31DEC2019	N
			Gastric stapling	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1171 11711184	Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
	C4591001 1171 11711185	Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Depression	01OCT2019		Y
	C4591001 1171 11711187	Immune system disorders	Drug hypersensitivity	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
	C4591001 1171 11711189	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1171 11711191	Cardiac disorders	Atrial fibrillation	01OCT2018		Y
		Surgical and medical procedures	Gastric bypass	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1171 11711192	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
	C4591001 1171 11711194	Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
	C4591001 1171 11711195	Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN1978		Y
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Endometrial ablation	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1171 11711196	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
	C4591001 1171 11711198	Nervous system disorders	Migraine	01JAN2008		Y
		Surgical and medical procedures	Mammoplasty	05MAY2018	05MAY2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711203	Ear and labyrinth disorders	Deafness unilateral	(b) (6) 1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Adenoidectomy	01JAN1999	31DEC1999	N
			Ear tube insertion	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1171 11711206	Surgical and medical procedures	Mammoplasty	30JUN2005	30JUN2005	N
	C4591001 1171 11711207	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1171 11711209	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1171 11711210	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
	C4591001 1171 11711211	Gastrointestinal disorders	Gastroesophageal reflux disease	07JUL2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017	06JUL2020	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Gastrectomy	06JUL2020	06JUL2020	N
	C4591001 1171 11711213	Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1171 11711214	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
	C4591001 1171 11711216	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1991	31DEC1991	N
		Nervous system disorders	Headache	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1991	31DEC1991	N
	C4591001 1171 11711219	Ear and labyrinth disorders	Tinnitus	01JAN2007		Y
	C4591001 1171 11711221	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
			Haemorrhoids	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
	C4591001 1171 11711223	Congenital, familial and genetic disorders	Gilbert's syndrome	01JUN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1171 11711225	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711226	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1171 11711231	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1171 11711234	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Neuralgia	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1171 11711236	Eye disorders	Eyelid ptosis	(b) (6) 1992		Y
		Infections and infestations	Appendicitis	01MAY2012	31MAY2012	N
		Surgical and medical procedures	Appendicectomy	01MAY2012	31MAY2012	N
	C4591001 1171 11711239	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1171 11711241	Infections and infestations	Appendicitis	01JAN2009	28FEB2009	N
		Injury, poisoning and procedural complications	Ligament injury	01MAY2014	31MAY2014	N
		Psychiatric disorders	Bipolar disorder	01NOV2016		Y
		Surgical and medical procedures	Appendicectomy	01FEB2009	28FEB2009	N
			Ligament operation	01JUN2014	30JUN2014	N
	C4591001 1171 11711246	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711247	Psychiatric disorders	Post-traumatic stress disorder	01JAN2010	31DEC2018	N
	C4591001 1171 11711248	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1171 11711250	Eye disorders	Eyelid cyst	01JAN2018	30APR2018	N
		Surgical and medical procedures	Eyelid cyst removal	01APR2018	30APR2018	N
	C4591001 1171 11711251	Infections and infestations	Onychomycosis	01JAN2018		Y
	C4591001 1171 11711252	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2001		Y
	C4591001 1171 11711256	Endocrine disorders	Hypothyroidism	01JAN2011		Y
	C4591001 1171 11711258	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998		Y
	C4591001 1171 11711261	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Herpes simplex	01JAN2011		Y
		Investigations	Arthroscopy	01JAN2014	31JAN2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2017	17AUG2020	N
		Surgical and medical procedures	Mammoplasty	01MAY2010	31MAY2010	N
			Sebaceous cyst excision	17AUG2020	17AUG2020	N
	C4591001 1171 11711262	Blood and lymphatic system disorders	Anaemia	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01AUG1987		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018	31DEC2018	N
		Nervous system disorders	Colloid brain cyst	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cerebral cyst excision	01OCT2009	31OCT2009	N
			Hip arthroplasty	01AUG2018	31AUG2018	N
			Tenoplasty	01MAR2006	31MAR2006	N
	C4591001 1171 11711265	Eye disorders	Strabismus	01JAN2001	09AUG2006	N
		Surgical and medical procedures	Strabismus correction	09AUG2006	09AUG2006	N
	C4591001 1171 11711266	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1171 11711267	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2018	31OCT2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN1991	31DEC1991	N
		Skin and subcutaneous tissue disorders	Lichenoid keratosis	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01OCT2018	31OCT2018	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1171 11711271	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JUN2020		Y
		Surgical and medical procedures	Bladder repair	01JUN2008	30JUN2008	N
			Joint surgery	01JUN2008	30JUN2008	N
	C4591001 1171 11711273	Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1171 11711274	Immune system disorders	Food allergy	01JAN1973		Y
			Seasonal allergy	01JAN1973		Y
		Infections and infestations	Genital herpes	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
	C4591001 1171 11711278	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Infections and infestations	Tonsillitis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
	C4591001 1171 11711287	Renal and urinary disorders	Micturition urgency	01JUL2020	06AUG2020	N
	C4591001 1171 11711288	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1171 11711289	Infections and infestations	Oral herpes	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	03APR2018	03APR2018	N
		Nervous system disorders	Migraine	01JAN1976		Y
		Reproductive system and breast disorders	Erectile dysfunction	03APR2018		Y
		Surgical and medical procedures	Prostatectomy	03APR2018	03APR2018	N
			Vasectomy	03APR2018	03APR2018	N
	C4591001 1171 11711290	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711292	Metabolism and nutrition disorders	Obesity	01JAN2006		Y
	C4591001 1171 11711293	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	23JUL2007	23JUL2007	N
				29OCT2009	29OCT2009	N
	C4591001 1171 11711294	Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1970		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1171 11711298	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1171 11711301	Infections and infestations	Appendicitis	01JUN2014	30JUN2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JUN2014	30JUN2014	N
			Gastric bypass	01NOV2018	30NOV2018	N
	C4591001 1171 11711303	Infections and infestations	Herpes simplex	01JAN2005		Y
		Injury, poisoning and procedural complications	Spinal cord injury cervical	01JAN1999	31DEC1999	N
		Nervous system disorders	Headache	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal fusion surgery	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1171 11711305	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Depression	01OCT2019		Y
	C4591001 1171 11711306	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1174 11741003	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Tooth impacted	01JAN1982	31DEC1982	N
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Investigations	Colonoscopy	01JAN2019	31JAN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN1988	31DEC1988	N
	C4591001 1174 11741004	Infections and infestations	Pyelonephritis	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
		Nervous system disorders	Narcolepsy	01JAN1999		Y
			Restless legs syndrome	01JAN2009		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1979	31DEC1979	N
			Gastric bypass	01JAN2003	31DEC2003	N
			Sinus operation	01JAN1986	31DEC1986	N
				01JAN1992	31DEC1992	N
				01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1988	31DEC1988	N
			Wrist surgery	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1174 11741005	Immune system disorders	Food allergy	01JAN2016		Y
			Hypersensitivity	01JAN2020		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1174 11741006	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Infections and infestations	Toxic shock syndrome	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Chondroplasty	01AUG2015	31DEC2015	N
				01JAN2018	31DEC2018	N
				01OCT2015	31OCT2015	N
	C4591001 1174 11741008	Surgical and medical procedures	Caesarean section	01JUL2015	01JUL2015	N
				02JUL2017	02JUL2017	N
				12OCT2011	12OCT2011	N
	C4591001 1174 11741011	Cardiac disorders	Sinus tachycardia	01JAN2015		Y
		Ear and labyrinth disorders	Sudden hearing loss	01JAN2002	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Facet joint syndrome	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
		Surgical and medical procedures	Myringotomy	01JAN2002	31DEC2002	N
	C4591001 1174 11741013	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dairy intolerance	(b) (6) 1972		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gluten sensitivity	01JAN2006		Y
			Hypercholesterolaemia	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Perinatal depression	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1972		Y
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
			Nasal septal operation	01JAN1994	31DEC1994	N
			Synovial cyst removal	01JAN1984	31DEC1984	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1174 11741015	Immune system disorders	Drug hypersensitivity	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1174 11741020	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1174 11741023	Surgical and medical procedures	Abdominal wall operation	01JAN2016	31DEC2016	N
			Caesarean section	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2012	31DEC2012	N
			Hernia repair	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N
	C4591001 1174 11741024	Immune system disorders	Food allergy	01JAN2016		Y
			Seasonal allergy	01JAN1992		Y
		Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
			Ligament operation	01JAN2011	31DEC2011	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1174 11741026	Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
	C4591001 1174 11741027	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Herpes zoster	01JAN1980		Y
				01JAN2004	31DEC2004	N
				01JAN2014	31DEC2014	N
			Infectious mononucleosis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1980	31DEC1980	N
			Inguinal hernia repair	01JAN1976	31DEC1976	N
			Wisdom teeth removal	01JAN1990	31DEC1990	N
	C4591001 1174 11741030	Infections and infestations	Papilloma viral infection	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1174 11741031	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1174 11741032	Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1174 11741034	Endocrine disorders	Thyroid mass	01MAY1988		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2013	31DEC2013	N
			Hand fracture	01JAN2013	31DEC2013	N
		Nervous system disorders	Epilepsy	01NOV2017		Y
			Generalised tonic-clonic seizure	28NOV2017	28NOV2017	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
		Surgical and medical procedures	Bunion operation	27DEC2019	27DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1174 11741038	Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Tonsillectomy	01JAN1977	31DEC1977	N
			Wisdom teeth removal	01JAN2004	31DEC2004	N
	C4591001 1174 11741045	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
	C4591001 1174 11741046	Injury, poisoning and procedural complications	Femur fracture	01JAN1975	31DEC1975	N
		Psychiatric disorders	Tibia fracture	01JAN1988	31DEC1988	N
			Depression	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Wisdom teeth removal	01JAN1988	31DEC1988	N
	C4591001 1174 11741049	Injury, poisoning and procedural complications	Forearm fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
	C4591001 1174 11741050	Injury, poisoning and procedural complications	Clavicle fracture	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Hernia repair	01JAN1982	31DEC1982	N
	C4591001 1174 11741051	Blood and lymphatic system disorders	Anaemia	01MAR2020		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Caesarean section	01JAN2010	31DEC2010	N
			Wisdom teeth removal	01JAN1994	31DEC1994	N
	C4591001 1174 11741053	Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1174 11741055	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1174 11741056	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Myringotomy	01JAN1994	31DEC1994	N
			Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1174 11741057	Eye disorders	Chorioretinopathy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2019	31JUL2020	N
			Sleep apnoea syndrome	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1989		Y
		Surgical and medical procedures	Anorectal operation	01JAN2013	31DEC2013	N
			Hernia repair	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Nasal septal operation	01JUL2020	31JUL2020	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1174 11741058	Immune system disorders	Hypersensitivity	01JAN1996		Y
	C4591001 1174 11741060	Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Surgical and medical procedures	Myringotomy	01JAN1990	31DEC1990	N
	C4591001 1174 11741061	Psychiatric disorders	Autism spectrum disorder	01JAN2006		Y
			Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Myringotomy	01JAN1995	31DEC1995	N
	C4591001 1174 11741063	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Surgical and medical procedures	Salpingectomy	01NOV2017	30NOV2017	N
			Uterine dilation and curettage	01JAN1992	31DEC1992	N
	C4591001 1174 11741065	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JUL2017	31JUL2017	N
	C4591001 1174 11741066†	Endocrine disorders	Testicular failure	09MAY2014		Y
		Investigations	HIV test positive	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Depression	01JAN1988		Y
		Renal and urinary disorders	Hypertonic bladder	09MAY2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
	C4591001 1174 11741071	Congenital, familial and genetic disorders	Alpha-1 antitrypsin deficiency	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
				01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2001	31DEC2001	N
			Tendon transfer	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1174 11741072	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Surgical and medical procedures	Bone marrow donation	01JAN2010	31DEC2010	N
	C4591001 1177 11771001	Investigations	Biopsy breast	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Uterine polyp	01JAN2017	21SEP2017	N
		Surgical and medical procedures	Uterine polypectomy	21SEP2017	21SEP2017	N
	C4591001 1177 11771003	Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1177 11771004	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771005	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05MAY2016		Y
			Type 1 diabetes mellitus	01JAN2003		Y
		Reproductive system and breast disorders	Infertility	01JAN2017		Y
	C4591001 1177 11771007	Reproductive system and breast disorders	Ovarian cyst	01JAN2004	21SEP2012	N
		Surgical and medical procedures	Caesarean section	21SEP2012	21SEP2012	N
				29MAR2011	29MAR2011	N
				30AUG2014	30AUG2014	N
	C4591001 1177 11771013	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 1 diabetes mellitus	01JAN1999		Y
		Surgical and medical procedures	Wrist surgery	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771014	Eye disorders	Myopia	01JAN1976	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2014		Y
		Infections and infestations	Chronic sinusitis	01JAN1995	29FEB2016	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2009	24JUN2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005	14FEB2013	N
			Jaw disorder	01JAN1966	07DEC2004	N
			Spinal pain	01DEC2014		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	16SEP2015	N
					30DEC2015	N
			Headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2015	30JUN2020	N
			Depression	01JAN2015	30JUN2020	N
			Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Infertility	03FEB2016		Y
			Polycystic ovaries	01JAN2000	31DEC2015	N
		Surgical and medical procedures	Adenoidectomy	01JAN1969	31DEC1969	N
			Carpal tunnel decompression	16SEP2015	16SEP2015	N
				30DEC2015	30DEC2015	N
			Chondroplasty	24JUN2010	24JUN2010	N
			Functional endoscopic sinus surgery	01JAN1997	31DEC1997	N
				29FEB2016	29FEB2016	N
			Hysterectomy	03FEB2015	03FEB2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc operation	14FEB2013	14FEB2013	N
			Keratotomy	01JAN1995	31DEC1995	N
			Oophorectomy bilateral	03FEB2015	03FEB2015	N
			Orthognathic surgery	07DEC2004	07DEC2004	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1177 11771017	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2019	31JAN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Tendon sheath incision	01JUN2019	30JUN2019	N
	C4591001 1177 11771018	Immune system disorders	Mite allergy	01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2010		Y
		Surgical and medical procedures	Functional endoscopic sinus surgery	12MAR2020	12MAR2020	N
	C4591001 1177 11771021	Psychiatric disorders	Anxiety	01JUN2019		Y
			Insomnia	01JUN2019		Y
	C4591001 1177 11771022	Endocrine disorders	Goitre	01JAN2013	31DEC2013	N
			Thyroid cyst	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01NOV2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Infertility	01NOV2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Hysterectomy	01NOV2018	30NOV2018	N
			Thyroid nodule removal	01JAN2008	31DEC2008	N
			Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1177 11771023	Eye disorders	Pterygium	01JAN2020		Y
					15JUL2020	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2020		Y
	C4591001 1177 11771025	Immune system disorders	Rubber sensitivity	01JAN2011		Y
		Injury, poisoning and procedural complications	Ankle fracture	01AUG1988	31AUG1988	N
			Ligament rupture	01OCT2016	31OCT2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01DEC2019	29FEB2020	N
	C4591001 1177 11771026	Gastrointestinal disorders	Gastric disorder	01JUL2018		Y
		Surgical and medical procedures	Gingival graft	01JAN2018	31DEC2018	N
	C4591001 1177 11771027	Immune system disorders	Allergy to vaccine	01NOV2018		Y
			Dust allergy	01JAN1979		Y
			Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN1979		Y
				01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01SEP2006	30SEP2006	N
		Nervous system disorders	Headache	01JAN2006		Y
		Surgical and medical procedures	Nephrectomy	01SEP2006	30SEP2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771028	General disorders and administration site conditions	Pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1177 11771030	Eye disorders	Glaucoma	01JAN2012		Y
		Immune system disorders	Allergy to plants	01JAN1997		Y
			Dust allergy	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2018		Y
	C4591001 1177 11771032	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
	C4591001 1177 11771038	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1992	31DEC2011	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
			Ovarian cystectomy	01JAN2011	31DEC2011	N
			Ovariocentesis	01JAN1992	31DEC1992	N
				01JAN2004	31DEC2004	N
	C4591001 1177 11771039	Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1177 11771047	Cardiac disorders	Ventricular extrasystoles	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Renal and urinary disorders	Stress urinary incontinence	01FEB2018	08AUG2020	N
		Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
			Urinary bladder suspension	08AUG2020	08AUG2020	N
	C4591001 1177 11771048	Eye disorders	Diabetic retinopathy	01JUL2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01DEC2014	01DEC2014	N
				05JUN2017	05JUN2017	N
	C4591001 1177 11771049	Eye disorders	Maculopathy	01JAN2016		Y
		Gastrointestinal disorders	Anal fistula	01JAN2010	31DEC2013	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2007	31JUL2012	N
			Ligament injury	01JAN1989	31DEC2007	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01MAY2018		Y
		Surgical and medical procedures	Fistula repair	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
			Joint dislocation reduction	01JUL2012	31JUL2012	N
			Ligament operation	01DEC2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771050	General disorders and administration site conditions	Pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1177 11771051	Gastrointestinal disorders	Diverticulum	01NOV2016		Y
			Large intestine polyp	01NOV2016	30NOV2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Surgical and medical procedures	Large intestinal polypectomy	01NOV2016	30NOV2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771054	Musculoskeletal and connective tissue disorders	Jaw disorder	01JAN2003	31DEC2006	N
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
			Orthognathic surgery	01JAN2006	31DEC2006	N
	C4591001 1177 11771056	Respiratory, thoracic and mediastinal disorders	Asthma	23JAN1998		Y
	C4591001 1177 11771057	Infections and infestations	Otitis media chronic	01JAN1988	31DEC1989	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
			Obesity	01JAN2018		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1989	31DEC1989	N
	C4591001 1177 11771058	Eye disorders	Cataract	01JAN2009	31DEC2010	N
					31DEC2011	N
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771066	Immune system disorders	Dust allergy	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1979	31DEC1979	N
	C4591001 1177 11771070	Immune system disorders	Food allergy	01JAN2005		Y
		Investigations	Blood cholinesterase decreased	(b) (6) 1969		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1177 11771075	Social circumstances	Postmenopause	01JUL2019		Y
		Surgical and medical procedures	Peripheral nerve decompression	01JAN2009	31DEC2009	N
	C4591001 1177 11771078	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Lactose intolerance	(b) (6) 1973		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	(b) (6) 1973		Y
		Surgical and medical procedures	Otoplasty	01JAN2003	31DEC2003	N
	C4591001 1177 11771079	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01MAR2015		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01FEB2018		Y
	C4591001 1177 11771080	Injury, poisoning and procedural complications	Ligament rupture	01DEC2017	23MAR2018	N
		Surgical and medical procedures	Ligament operation	23MAR2018	23MAR2018	N
	C4591001 1177 11771086	Immune system disorders	Food allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Suicidal ideation	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
	C4591001 1177 11771087	Injury, poisoning and procedural complications	Ligament rupture	01DEC2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Ligament operation	01DEC2007	31DEC2007	N
	C4591001 1177 11771088	Surgical and medical procedures	Limb operation	01JAN1995	31DEC1995	N
			Uterine polypectomy	01JAN2015	31DEC2015	N
	C4591001 1177 11771090	Investigations	Blood cholesterol increased	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Vulval cancer	01JAN2016	29FEB2016	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Vulvectomy	01FEB2016	29FEB2016	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1177 11771092	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1177 11771093	Injury, poisoning and procedural complications	Joint injury	01JAN1996	31DEC1996	N
	C4591001 1177 11771095	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771097	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
			Urinary tract infection	01AUG2020	04AUG2020	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1177 11771101	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Contraception	01JAN2017		Y
	C4591001 1177 11771103	General disorders and administration site conditions	Drug intolerance	01JAN1982		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
			Prolactin-producing pituitary tumour	01JAN2005	31DEC2006	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Nasal septal operation	01JAN1994	31DEC1994	N
			Rhinoplasty	01JAN2004	31DEC2004	N
	C4591001 1177 11771105	Psychiatric disorders	Depression	01JAN2003		Y
	C4591001 1177 11771113	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1177 11771114	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771116	Immune system disorders	Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
		Surgical and medical procedures	Meniscus operation	01NOV2018	30NOV2018	N
	C4591001 1177 11771117	Reproductive system and breast disorders	Adenomyosis	01MAR2012	31MAR2012	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01MAR2012	31MAR2012	N
	C4591001 1177 11771118	Eye disorders	Myopia	01JAN2004	13AUG2020	N
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
				01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Perinatal depression	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	11MAR2019	11MAR2019	N
			Keratomileusis	13AUG2020	13AUG2020	N
	C4591001 1177 11771119	Immune system disorders	Allergy to animal	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	14JUN2014	14JUN2014	N
		Surgical and medical procedures	Caesarean section	15JUN2014	15JUN2014	N
			Wisdom teeth removal	01FEB2005	28FEB2005	N
	C4591001 1177 11771128	Endocrine disorders	Hypothyroidism	01OCT2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Drug intolerance	01JUL2018		Y
		Infections and infestations	Abscess neck	01JUL2018	31JUL2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2003		Y
	C4591001 1177 11771134	Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN1979		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
				01JAN2020	24AUG2020	N
		Psychiatric disorders	Anxiety	01JAN1987		Y
			Depression	01JAN1987		Y
		Social circumstances	Postmenopause	01APR2019		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31DEC2017	N
				24AUG2020	24AUG2020	N
			Meniscus operation	01JAN2012	31DEC2012	N
			Spinal laminectomy	01JAN1981	31DEC1981	N
				01JAN2001	31DEC2001	N
				01JAN2017	31DEC2017	N
	C4591001 1177 11771135	Endocrine disorders	Goitre	01JAN2013		Y
		Gastrointestinal disorders	Toothache	01JUN2020	15JUL2020	N
		Nervous system disorders	Headache	01JUL2020	10AUG2020	N
		Surgical and medical procedures	Tooth extraction	15JUL2020	15JUL2020	N
	C4591001 1177 11771137	Endocrine disorders	Hypothyroidism	01AUG2020		Y
		Eye disorders	Glaucoma	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Skeletal injury	01JAN1984	31DEC1984	N
			Osteoarthritis	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01SEP1999	30SEP1999	N
		Surgical and medical procedures	Ectopic pregnancy termination	01SEP1999	30SEP1999	N
			Knee operation	01JAN1984	31DEC1984	N
				01JAN1990	31DEC1990	N
			Meniscus operation	01JAN2000	31DEC2000	N
	C4591001 1177 11771138	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01MAR2019		Y
		Surgical and medical procedures	Appendectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1177 11771145	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2007	31JUL2007	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Joint dislocation reduction	01JUL2007	31JUL2007	N
	C4591001 1177 11771153	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1177 11771154	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Compartment syndrome	01JAN2008	30APR2010	N
		Nervous system disorders	Headache	01AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Attention deficit hyperactivity disorder	14OCT2016		Y
			Depression	01JAN1997		Y
			Insomnia	01MAY2020		Y
			Post-traumatic stress disorder	01JAN1996		Y
			Suicide attempt	21OCT2017	21OCT2017	N
		Surgical and medical procedures	Fasciotomy	01APR2010	30APR2010	N
	C4591001 1177 11771155	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1177 11771156	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01FEB2002		Y
		Injury, poisoning and procedural complications	Joint dislocation	01OCT2014	31OCT2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01MAY2020		Y
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Implantable defibrillator insertion	01JUN2016	30JUN2016	N
	C4591001 1177 11771157	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	24JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intervertebral disc operation	24JUL2020	24JUL2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771159	General disorders and administration site conditions	Pain	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01MAR2020		Y
			Gout	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	29FEB2016	N
		Surgical and medical procedures	Knee arthroplasty	01FEB2016	29FEB2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1177 11771160	Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Infections and infestations	Root canal infection	01FEB2020	19FEB2020	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	24JUN2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Apicectomy	19FEB2020	19FEB2020	N
			Meniscus operation	24JUN2015	24JUN2015	N
			Vasectomy	16JUN2016	16JUN2016	N
	C4591001 1177 11771161	Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Bone cyst	01JAN2019	19AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Bone cyst excision	19AUG2020	19AUG2020	N
		Vascular disorders	Hypertension	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771162	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010	30APR2020	N
			Depression	01JAN2010	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2009	31DEC2009	N
			Rhinitis allergic	01JAN2009		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Nasal polypectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1177 11771163	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01JAN2010	31DEC2010	N
	C4591001 1177 11771166	Investigations	Cardiac murmur	01JAN1990		Y
	C4591001 1177 11771167	Injury, poisoning and procedural complications	Hand fracture	01JUN2018	25JUN2018	N
		Surgical and medical procedures	Bone operation	25JUN2018	25JUN2018	N
	C4591001 1177 11771170	Immune system disorders	Allergy to animal	01AUG2018		Y
	C4591001 1177 11771171	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
	C4591001 1177 11771172	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Food allergy	01JAN1977		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
				01JAN1979		Y
		Investigations	Cardiac murmur	01JAN1984		Y
			Precancerous cells present	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Cervical conisation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771173	Eye disorders	Retinal detachment	01JAN2019	20JAN2019	N
		Surgical and medical procedures	Retinopexy	20JAN2019	20JAN2019	N
	C4591001 1177 11771174	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Stent placement	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1177 11771176	Immune system disorders	Dust allergy	01JAN2010		Y
			Mycotic allergy	01JAN2010		Y
	C4591001 1177 11771177	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1177 11771179	General disorders and administration site conditions	Drug intolerance	01JAN2015		Y
		Investigations	Laparoscopy	11SEP2001	11SEP2001	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JUL2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	11SEP2001	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	16JUL2013	16JUL2013	N
				21APR2015	21APR2015	N
	C4591001 1177 11771181	Injury, poisoning and procedural complications	Patella fracture	01JUL1992	31JUL1992	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JUN2012		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01DEC1993	31DEC1993	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	15JUL2020		Y
		Surgical and medical procedures	Knee arthroplasty	01JUL1992	31JUL1992	N
			Scoliosis surgery	01DEC1993	31DEC1993	N
	C4591001 1177 11771182	Hepatobiliary disorders	Cholecystitis	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
	C4591001 1177 11771183	Congenital, familial and genetic disorders	Ventricular septal defect	01JAN1979		Y
	C4591001 1177 11771184	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
	C4591001 1177 11771185	Immune system disorders	Allergy to animal	01JAN2000		Y
			Allergy to plants	01JAN2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2015	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Chondroplasty	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septal operation	01JAN2017	31DEC2017	N
			Rhinitis allergic	01JAN2012	31DEC2012	N
	C4591001 1177 11771186	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1177 11771187	Musculoskeletal and connective tissue disorders	Chondromalacia	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Osteotomy	01JAN1995	31DEC1995	N
	C4591001 1177 11771192	Cardiac disorders	Bundle branch block right	01JAN2010		Y
	C4591001 1177 11771194	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1990		Y
			Food allergy	01JAN1996		Y
			Mycotic allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2008	01JAN2009	N
		Metabolism and nutrition disorders	Gout	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Ligament operation	01JAN2009	01JAN2009	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1177 11771196	Immune system disorders	Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Hand fracture	04APR2020	04APR2020	N
			Ulna fracture	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Internal fixation of fracture	04APR2020	04APR2020	N
			Open reduction of fracture	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771197	Injury, poisoning and procedural complications	Cartilage injury	21JUN2019	21JUN2019	N
		Surgical and medical procedures	Chondroplasty	21JUN2019	21JUN2019	N
	C4591001 1177 11771200	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Meniscus removal	01JAN1999	31DEC1999	N
	C4591001 1177 11771207	Immune system disorders	Dust allergy	01JAN2017		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Joint instability	01JAN2015	28FEB2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Ligament operation	01FEB2017	28FEB2017	N
	C4591001 1177 11771209	Gastrointestinal disorders	Umbilical hernia	01JAN1978	31DEC1978	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1978	31DEC1978	N
	C4591001 1177 11771210	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
	C4591001 1177 11771212	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
			Uterine leiomyoma	01JAN2016	31AUG2016	N
		Surgical and medical procedures	Breast conserving surgery	01DEC2012	31DEC2012	N
			Hysterectomy	01AUG2016	31AUG2016	N
	C4591001 1177 11771216	General disorders and administration site conditions	Drug intolerance	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1177 11771218	Injury, poisoning and procedural complications	Meniscus injury	01SEP2019	30SEP2019	N
			Tendon rupture	01OCT2018	31OCT2018	N
		Investigations	Blood testosterone decreased	01JUN2019		Y
		Surgical and medical procedures	Meniscus operation	01SEP2019	30SEP2019	N
			Tenoplasty	01OCT2018	31OCT2018	N
	C4591001 1177 11771219	Infections and infestations	Sinusitis	01JAN2010	31DEC2014	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2014		Y
		Surgical and medical procedures	Meniscus operation	01JAN2003	31DEC2003	N
			Sinus operation	01JAN2014	31DEC2014	N
	C4591001 1177 11771221	Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
			Diverticulitis	01JAN1993	31DEC1993	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2018	31DEC2018	N
			Ligament rupture	01JAN2015	31DEC2015	N
			Meniscus injury	01JAN1992	31DEC1992	N
				01JAN2015	31DEC2015	N
			Sciatic nerve injury	01JUL2017		Y
			Tendon rupture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Carpal tunnel decompression	01JAN2001	31DEC2001	N
			Chondroplasty	01JAN2018	31DEC2018	N
			Intestinal resection	01JAN1993	31DEC1993	N
			Keratomileusis	01JAN2003	31DEC2003	N
			Ligament operation	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN2001	31DEC2001	N
			Meniscus operation	01JAN1992	31DEC1992	N
				01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
			Tenoplasty	01JAN2018	31DEC2018	N
			Therapeutic nerve ablation	01FEB2020	29FEB2020	N
				01JAN2017	31DEC2017	N
				01OCT2019	31OCT2019	N
	C4591001 1177 11771222	Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	30JUN2020	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Nasal septum deviation	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Bunion operation	01DEC2019	31DEC2019	N
				01JUN2020	30JUN2020	N
			Caesarean section	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2007	31DEC2007	N
			Nasal septal operation	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1177 11771223	Injury, poisoning and procedural complications	Cartilage injury	01JAN2016	31OCT2016	N
		Surgical and medical procedures	Shoulder arthroplasty	01OCT2016	31OCT2016	N
	C4591001 1177 11771224	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
	C4591001 1177 11771225	Endocrine disorders	Goitre	01JAN2018	31DEC2018	N
			Hypothyroidism	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2016		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2018	31DEC2018	N
	C4591001 1177 11771228	Immune system disorders	Mite allergy	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2001	31DEC2001	N
			Rhinitis allergic	01JAN1998		Y
		Surgical and medical procedures	Therapeutic aspiration	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771234	Eye disorders	Astigmatism	29JUN2017		Y
			Myopia	29JUN2017		Y
		Immune system disorders	Dust allergy	01JAN2010		Y
		Infections and infestations	Rhinitis	19MAY2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	10AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	07NOV2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2016		Y
			Insomnia	01AUG2019		Y
			Obsessive-compulsive disorder	07NOV2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1177 11771235	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2008	31DEC2008	N
	C4591001 1177 11771236	Metabolism and nutrition disorders	Insulin resistance	01JAN2017		Y
			Type 1 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2004		Y
		Reproductive system and breast disorders	Oligomenorrhoea	01JAN2016	31DEC2019	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2005	31DEC2005	N
	C4591001 1177 11771241	Reproductive system and breast disorders	Endometriosis	01JAN2012		Y
	C4591001 1177 11771242	General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1177 11771245	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN1988	31DEC1988	N
	C4591001 1177 11771246	Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1177 11771248	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01MAY2017	31JUL2018	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Bone lesion excision	01JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1177 11771251	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2019		Y
			Obesity	01JAN2016		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1177 11771254	Injury, poisoning and procedural complications	Gun shot wound	01NOV1992	31DEC1992	N
			Limb injury	01JAN2009	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1993	31DEC1994	N
		Surgical and medical procedures	Bone lesion excision	01JAN1994	31DEC1994	N
			Chondroplasty	01JAN2010	31DEC2010	N
			Removal of foreign body	01NOV1992	30NOV1992	N
	C4591001 1177 11771257	Injury, poisoning and procedural complications	Procedural pain	26AUG2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Gender dysphoria	01JAN2018		Y
		Surgical and medical procedures	Bilateral orchidectomy	26AUG2020	26AUG2020	N
	C4591001 1177 11771258	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007	31DEC2017	N
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771260	Immune system disorders	Allergy to animal	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1177 11771261	Gastrointestinal disorders	Malocclusion	01JAN2007	31MAY2010	N
		Surgical and medical procedures	Orthognathic surgery	01MAY2010	31MAY2010	N
			Tooth extraction	01JAN2013	31DEC2013	N
			Wisdom teeth removal	01JAN2011	31DEC2011	N
	C4591001 1177 11771266	Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
			Tonsillitis	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Meniscus injury	01JUL2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Infertility	18AUG2018		Y
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
			Caesarean section	01JAN2016	31DEC2016	N
				18AUG2018	18AUG2018	N
			Salpingectomy	18AUG2018	18AUG2018	N
			Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1177 11771267	Ear and labyrinth disorders	Meniere's disease	01MAY2020		Y
		Hepatobiliary disorders	Cholelithiasis	01OCT2017	31OCT2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2016		Y
				01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01OCT2017	31OCT2017	N
			Mammoplasty	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771270	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1177 11771271	Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
				01JAN2011	31DEC2011	N
	C4591001 1177 11771278	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771281	Endocrine disorders	Hypothyroidism	01DEC2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Nasal septal operation	01JAN2008	31DEC2008	N
	C4591001 1177 11771282	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2014	31DEC2014	N
			Intervertebral disc protrusion	01JAN2001	31DEC2001	N
				01JAN2014	31DEC2014	N
		Surgical and medical procedures	Bone lesion excision	01JAN2014	31DEC2014	N
			Intervertebral disc operation	01JAN2001	31DEC2001	N
				01JAN2014	31DEC2014	N
	C4591001 1177 11771283	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Food allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Pilonidal cyst	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1995	31DEC1995	N
			Shoulder operation	01JAN2013	31DEC2013	N
	C4591001 1177 11771284	Immune system disorders	Allergy to animal	01JAN1992		Y
			Allergy to plants	01JAN1992		Y
			Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Joint injury	01AUG2008	31AUG2008	N
		Investigations	Arthroscopy	01AUG2008	31AUG2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01FEB2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771285	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2010	31DEC2010	N
	C4591001 1177 11771289	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN1998		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771292	Eye disorders	Myopia	01JAN1997	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Pain in extremity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Keratomileusis	01JAN2007	31DEC2007	N
	C4591001 1177 11771296	Eye disorders	Amblyopia	01JAN2001	31DEC2001	N
		Immune system disorders	Food allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Surgical and medical procedures	Strabismus correction	01JAN2001	31DEC2001	N
	C4591001 1177 11771297	Cardiac disorders	Mitral valve prolapse	01JAN1986		Y
			Palpitations	01JAN2006		Y
		Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Gastrointestinal disorders	Constipation	01JAN2020		Y
			Irritable bowel syndrome	01JAN2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2010		Y
				01JAN2013		Y
			Food allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2007	31DEC2007	N
			Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1997	31DEC1997	N
			Radioactive iodine therapy	01JAN2007	31DEC2007	N
			Rhinoplasty	01JAN1977	31DEC1977	N
			Thyroidectomy	01JAN2007	31DEC2007	N
	C4591001 1177 11771300	Gastrointestinal disorders	Peptic ulcer	01JAN2018	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1177 11771302	Injury, poisoning and procedural complications	Clavicle fracture	01MAY2019	31MAY2019	N
		Nervous system disorders	Headache	01JAN2012		Y
		Surgical and medical procedures	Fracture treatment	01MAY2019	31MAY2019	N
	C4591001 1177 11771303	Eye disorders	Myopia	01JAN1991	31DEC2010	N
		Immune system disorders	Food allergy	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Appendectomy	01JAN2007	31DEC2007	N
			Keratomileusis	01JAN2010	31DEC2010	N
	C4591001 1177 11771304	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1177 11771306	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Food allergy	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
	C4591001 1177 11771307	Congenital, familial and genetic disorders	Congenital aortic stenosis	01JAN1991		Y
	C4591001 1177 11771309	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Surgical and medical procedures	Caesarean section	05JUN2009	05JUN2009	N
				14MAY1996	14MAY1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				22JUL1999	22JUL1999	N
			Female sterilisation	05JUN2009	05JUN2009	N
	C4591001 1177 11771310	Immune system disorders	Allergy to chemicals	01JAN1992		Y
			Milk allergy	01JAN1992		Y
	C4591001 1177 11771312	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
	C4591001 1177 11771313	Eye disorders	Myopia	01JAN2001	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Binge eating	01JAN2003		Y
			Depression	01JAN2003		Y
			Insomnia	01JAN2003		Y
	C4591001 1177 11771315	Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Tenoplasty	01JAN2008	31DEC2008	N
	C4591001 1177 11771319	General disorders and administration site conditions	Pain	01JAN2000		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Vertebral osteophyte	01JAN2005		Y
		Nervous system disorders	Neuralgia	01JAN2005		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1988	31DEC1988	N
	C4591001 1177 11771321	Immune system disorders	Drug hypersensitivity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
			Food allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771322	Congenital, familial and genetic disorders	Congenital foot malformation	01JAN2002	31DEC2002	N
		Injury, poisoning and procedural complications	Hand fracture	01MAR2013	31MAR2013	N
		Musculoskeletal and connective tissue disorders	Ankle impingement	01MAR2017	31MAR2017	N
			Intervertebral disc degeneration	01FEB2019		Y
		Surgical and medical procedures	Finger repair operation	01MAR2013	31MAR2013	N
			Foot operation	01JAN2002	31DEC2002	N
			Joint debridement	01MAR2017	31MAR2017	N
	C4591001 1177 11771324	Immune system disorders	Food allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
			Meniscus injury	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Ligament operation	01JAN1998	31DEC1998	N
			Meniscus operation	01JAN1998	31DEC1998	N
	C4591001 1177 11771331	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2006	31DEC2006	N
			Obesity	01JAN2000	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Gastrectomy	01JAN2011	31DEC2011	N
			Gastric banding	01JAN2006	31DEC2006	N
			Gastric banding reversal	01JAN2011	31DEC2011	N
	C4591001 1177 11771332	Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
			Wisdom teeth removal	01JUN2019	30JUN2019	N
	C4591001 1177 11771333	Injury, poisoning and procedural complications	Hand fracture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
			Mammoplasty	01DEC2018	31DEC2018	N
	C4591001 1177 11771334	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1997	31DEC1998	N
		Surgical and medical procedures	Knee operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2005		Y
	C4591001 1177 11771335	Immune system disorders	Food allergy	01JAN2001		Y
	C4591001 1177 11771342	Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1177 11771345	Immune system disorders	Allergy to chemicals	01JAN2018		Y
	C4591001 1177 11771347	Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
	C4591001 1177 11771348	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771351	Eye disorders	Dacryostenosis acquired	01JAN2010	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Surgical and medical procedures	Lacrimal duct procedure	01JAN2012	31DEC2012	N
	C4591001 1177 11771354	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1177 11771357	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
			Meniscus injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN2017	31DEC2017	N
			Parathyroid tumour benign	01JAN2020	30JUN2020	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN2016	31DEC2016	N
			Mastectomy	01JAN2017	31DEC2017	N
			Thyroidectomy	01JUN2020	30JUN2020	N
	C4591001 1177 11771360	Endocrine disorders	Autoimmune thyroiditis	01JAN2014		Y
		Infections and infestations	Appendicitis	01SEP2018	19SEP2018	N
		Surgical and medical procedures	Appendicectomy	19SEP2018	19SEP2018	N
			Intestinal resection	19SEP2018	19SEP2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771361	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Investigations	Bronchoscopy	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
		Surgical and medical procedures	Keratomileusis	01JAN2007	31DEC2007	N
	C4591001 1177 11771367	General disorders and administration site conditions	Drug intolerance	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
	C4591001 1177 11771368	Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N
	C4591001 1177 11771369	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1177 11771371	Gastrointestinal disorders	Inguinal hernia	01JAN1979	31DEC1979	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Inguinal hernia repair	01JAN1979	31DEC1979	N
	C4591001 1177 11771374	Immune system disorders	Food allergy	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1177 11771375	Immune system disorders	Allergy to animal	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01DEC2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1177 11771377	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01SEP1995	30SEP1995	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01MAR2020		Y
	C4591001 1177 11771383	Surgical and medical procedures	Shoulder operation	01SEP1995	30SEP1995	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2013	14FEB2013	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Gout	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
	C4591001 1177 11771385	Surgical and medical procedures	Inguinal hernia repair	14JAN2013	14FEB2013	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2019	31DEC2019	N
			Ligament rupture	01JAN2010	31DEC2010	N
			Meniscus injury	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Fracture treatment	01JAN2019	31DEC2019	N
			Ligament operation	01JAN2010	31DEC2010	N
			Meniscus operation	01JAN2010	31DEC2010	N
			Meniscus removal	01JAN2013	31DEC2013	N
	C4591001 1177 11771386	Immune system disorders	Food allergy	01JAN2002		Y
				01JAN2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1177 11771389	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Malignant melanoma stage I	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
				01MAR2020	31MAR2020	N
	C4591001 1177 11771392	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Dust allergy	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999	31DEC1999	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Myomectomy	01JAN2008	31DEC2008	N
			Spinal fusion surgery	01JAN1999	31DEC1999	N
	C4591001 1177 11771393	Gastrointestinal disorders	Hyperaesthesia teeth	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1177 11771394	Gastrointestinal disorders	Anal fistula	01JAN2010	16JUN2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Surgical and medical procedures	Anal fistula repair	16JUN2010	16JUN2010	N
	C4591001 1177 11771397	Immune system disorders	Dust allergy	01JAN1994		Y
			Mycotic allergy	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2014		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771400	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1177 11771401	Endocrine disorders	Autoimmune thyroiditis	01JAN2008		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01DEC2019		Y
		Reproductive system and breast disorders	Uterine polyp	01JUL2018	31JUL2018	N
		Surgical and medical procedures	Uterine polypectomy	01JUL2018	31JUL2018	N
	C4591001 1177 11771402	Injury, poisoning and procedural complications	Joint injury	01JAN2005	31DEC2005	N
				01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
			Ligament operation	01JAN2005	31DEC2005	N
			Meniscus operation	01JAN2016	31DEC2016	N
	C4591001 1177 11771403	Immune system disorders	Allergy to animal	01JAN1990		Y
			Food allergy	01JAN1990		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Impaired fasting glucose	01SEP2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign hydatidiform mole	01JAN2010	31DEC2010	N
			Papillary thyroid cancer	01JAN2000	31MAR2000	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Thyroidectomy	01MAR2000	31MAR2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine dilation and curettage	01JAN2010	31DEC2010	N
	C4591001 1177 11771404	Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1177 11771405	Infections and infestations	Appendicitis	01FEB1978	28FEB1978	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Caesarean section	25OCT1995	25OCT1995	N
	C4591001 1177 11771411	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
	C4591001 1177 11771415	Blood and lymphatic system disorders	Anaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	03SEP2020		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Social circumstances	Postmenopause	01APR2019		Y
		Surgical and medical procedures	Caesarean section	26OCT2005	26OCT2005	N
				31MAR2008	31MAR2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771416	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1996	31DEC2000	N
		Investigations	Arthroscopy	01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771420	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2017		Y
	C4591001 1177 11771423	Injury, poisoning and procedural complications	Cartilage injury	01NOV2009	30NOV2009	N
		Surgical and medical procedures	Chondroplasty	01NOV2009	30NOV2009	N
	C4591001 1177 11771424	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Dust allergy	(b) (6) 1991		Y
			Food allergy	01JAN1998		Y
			Rubber sensitivity	(b) (6) 1991		Y
			Seasonal allergy	(b) (6) 1991		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	(b) (6) 1991		Y
		Skin and subcutaneous tissue disorders	Eczema	(b) (6) 1991		Y
	C4591001 1177 11771428	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2009		Y
		Surgical and medical procedures	Wisdom teeth removal	01APR2017	30APR2017	N
	C4591001 1177 11771432	Injury, poisoning and procedural complications	Subdural haematoma	01JAN2011	31DEC2011	N
			Upper limb fracture	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N
	C4591001 1177 11771433	Gastrointestinal disorders	Umbilical hernia	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Fracture treatment	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771434	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Nasal septal operation	01JAN2008	31DEC2008	N
	C4591001 1177 11771435	Immune system disorders	Allergy to animal	01JAN2010		Y
			Mite allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Peripheral nerve injury	15MAY2019	15MAY2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Peripheral nerve operation	15MAY2019	15MAY2019	N
	C4591001 1177 11771438	General disorders and administration site conditions	Drug intolerance	01JAN2011		Y
	C4591001 1177 11771439	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1177 11771440	Psychiatric disorders	Depression	01MAR2020		Y
			Drug dependence	01JAN2000		Y
	C4591001 1177 11771441	Eye disorders	Retinal vein occlusion	01SEP2018	31MAY2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Depression	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
			Nasal polyps	01JAN1996	31DEC1996	N
			Nasal septum deviation	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Caesarean section	03SEP2000	03SEP2000	N
				13OCT2003	13OCT2003	N
			Knee operation	01JAN1995	31DEC1995	N
			Nasal polypectomy	01JAN1996	31DEC1996	N
			Nasal septal operation	01JAN1989	31DEC1989	N
	C4591001 1177 11771442	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1177 11771443	Immune system disorders	Food allergy	01JAN2005		Y
		Infections and infestations	Ear infection	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Myringotomy	01JAN2004	31DEC2004	N
	C4591001 1177 11771444	Gastrointestinal disorders	Inguinal hernia	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Glucose tolerance impaired	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2010		Y
	C4591001 1177 11771446	Surgical and medical procedures	Inguinal hernia repair	01JAN1979	31DEC1979	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
	C4591001 1177 11771450	Surgical and medical procedures	Appendectomy	01JAN1993	31DEC1993	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
			Seasonal allergy	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Bipolar II disorder	01JAN2012		Y
			Depression	01JAN2006		Y
			Insomnia	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
	C4591001 1177 11771452	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
	C4591001 1177 11771453	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Food allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771454	Infections and infestations	Genital herpes	01APR2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2011	31DEC2014	N
	C4591001 1177 11771455	Infections and infestations	Latent tuberculosis	01JAN2007	31DEC2007	N
	C4591001 1177 11771456	Infections and infestations	Latent tuberculosis	07JAN2005	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01NOV2009	30NOV2009	N
		Surgical and medical procedures	Eyelid operation	01NOV2009	30NOV2009	N
			Micrographic skin surgery	01NOV2009	30NOV2009	N
	C4591001 1177 11771458	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Tinea versicolour	01AUG2019		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1998		Y
	C4591001 1177 11771463	Injury, poisoning and procedural complications	Ligament rupture	01JUL2013	31JUL2013	N
			Meniscus injury	01JUL2013	31JUL2013	N
		Surgical and medical procedures	Ligament operation	01JUL2013	31JUL2013	N
			Meniscus operation	01JUL2013	31JUL2013	N
	C4591001 1177 11771465	Congenital, familial and genetic disorders	Cerebral palsy	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1985	31DEC1987	N
		Surgical and medical procedures	Bunion operation	01JAN1987	31DEC1987	N
			Tendon transfer	01JAN1976	31DEC1976	N
			Tenotomy	01JAN1973	31DEC1973	N
	C4591001 1177 11771466	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771472	Immune system disorders	Allergy to animal	01JAN1998		Y
			Dust allergy	01JAN1998		Y
			Seasonal allergy	01JAN1998		Y
	C4591001 1177 11771473	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Appendicitis	01SEP2014	30SEP2014	N
		Surgical and medical procedures	Appendicectomy	01SEP2014	30SEP2014	N
	C4591001 1177 11771475	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2006	31DEC2006	N
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2014		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Infertility	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN1980	31DEC1990	N
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2006	31DEC2006	N
			Breast reconstruction	01JAN2018	31DEC2018	N
			Hysterosalpingo-oophorectomy	01JAN2017	31DEC2017	N
			Mastectomy	01JAN2017	31DEC2017	N
			Rhinoplasty	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771478	General disorders and administration site conditions	Fatigue	01JAN2015		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01JAN2017		Y
	C4591001 1177 11771479	General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Infections and infestations	Adenoiditis	01JAN2011	31DEC2011	N
			Tonsillitis	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Adenoidectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1177 11771482	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2013	31DEC2015	N
		Reproductive system and breast disorders	Uterine haemorrhage	01SEP2017	30SEP2017	N
		Surgical and medical procedures	Bone cyst excision	01JUN2018	30JUN2018	N
			Uterine cystectomy	01SEP2017	30SEP2017	N
	C4591001 1177 11771485	Gastrointestinal disorders	Inguinal hernia	01JAN1999	15OCT1999	N
		Immune system disorders	Allergy to arthropod sting	01JAN1977		Y
		Surgical and medical procedures	Hernia repair	15OCT1999	15OCT1999	N
		Vascular disorders	Hypertension	25APR2002		Y
	C4591001 1177 11771488	Gastrointestinal disorders	Gingival recession	01JAN2017	30APR2017	N
		Infections and infestations	Urinary tract infection	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Gingival graft	01APR2017	30APR2017	N
			Wisdom teeth removal	01APR2018	30APR2018	N
	C4591001 1177 11771490	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1177 11771491	Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Salpingostomy	01JAN2008	31DEC2008	N
	C4591001 1177 11771493	Eye disorders	Myopia	01JAN2009	31OCT2014	N
		Immune system disorders	Allergy to animal	01JAN1993		Y
			Mite allergy	01JAN1993		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01OCT2019		Y
		Surgical and medical procedures	Keratomileusis	01OCT2014	31OCT2014	N
			Mastectomy	01DEC2016	31DEC2016	N
	C4591001 1177 11771494	Psychiatric disorders	Anxiety	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Laryngeal polyp	01JAN2019	31JUL2019	N
		Surgical and medical procedures	Laryngeal polypectomy	01JUL2019	31JUL2019	N
	C4591001 1177 11771496	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
	C4591001 1177 11771497	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1177 11771499	Congenital, familial and genetic disorders	Scimitar syndrome	(b) (6) 1970		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01AUG2011		Y
		Surgical and medical procedures	Gastric bypass	01AUG2011	31AUG2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771500	Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
	C4591001 1177 11771501	Investigations	Blood testosterone decreased	01OCT2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014		Y
	C4591001 1177 11771502	Injury, poisoning and procedural complications	Clavicle fracture	22AUG2020		Y
			Femur fracture	01JAN2011	31DEC2013	N
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
	C4591001 1177 11771503	Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y
			Gastrooesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1177 11771504	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN1997		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN1995	31DEC1995	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Elbow operation	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771509	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Diagnostic aspiration	27AUG2018	27AUG2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2016	27DEC2016	N
		Nervous system disorders	Cervical radiculopathy	01JAN2008		Y
			Tremor	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Surgical and medical procedures	Neck dissection	27DEC2016	27DEC2016	N
			Thyroidectomy	27DEC2016	27DEC2016	N
	C4591001 1177 11771510	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Glucose tolerance impaired	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771511	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2001	31DEC2001	N
		Nervous system disorders	Headache	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN2001	31DEC2001	N
	C4591001 1177 11771513	Gastrointestinal disorders	Coeliac disease	01AUG2018		Y
			Malocclusion	01JUN2008	30JUN2008	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Sinusitis	01DEC2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01SEP2011	30SEP2011	N
			Scoliosis	01JUN2006	30JUN2006	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2008		Y
		Surgical and medical procedures	Intervertebral disc operation	01SEP2011	30SEP2011	N
			Orthognathic surgery	01JUN2008	30JUN2008	N
			Spinal fusion surgery	01JUN2006	30JUN2006	N
			Turbinoplasty	01DEC2019	31DEC2019	N
	C4591001 1177 11771514	Infections and infestations	Infected cyst	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Cyst removal	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1177 11771515	Immune system disorders	Food allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
	C4591001 1177 11771516	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771517	Immune system disorders	Allergy to animal	01JAN1992		Y
	C4591001 1177 11771520	Blood and lymphatic system disorders	Lymphadenopathy	01JUL2020		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1987		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1991	31DEC1991	N
	C4591001 1177 11771521	Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771524	Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1177 11771525	Congenital, familial and genetic disorders	Vitello-intestinal duct remnant	01MAR2020	14MAR2020	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
		Surgical and medical procedures	Diverticulectomy	14MAR2020	14MAR2020	N
	C4591001 1177 11771528	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Investigations	Arthroscopy	01DEC2017	31DEC2017	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2015		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Ankle operation	01AUG2015	31AUG2015	N
			Hip arthroplasty	01SEP2015	30SEP2015	N
			Shoulder arthroplasty	01JUN2017	30JUN2017	N
			Synovectomy	01JUN2018	30JUN2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771529	Immune system disorders	Food allergy	01JAN2001		Y
	C4591001 1177 11771531	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01SEP2018		Y
			Food allergy	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2006	31OCT2006	N
		Nervous system disorders	Migraine	01JAN2009		Y
		Surgical and medical procedures	Elbow operation	01OCT2006	31OCT2006	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01AUG2015	31AUG2015	N
	C4591001 1177 11771532	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma stage I	01JAN2003		Y
	C4591001 1177 11771533	Injury, poisoning and procedural complications	Tibia fracture	01JAN1992	31DEC1992	N
		Investigations	Cardiac murmur	(b) (6) 1965		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
			Pain in jaw	01JAN2017		Y
		Psychiatric disorders	Perinatal depression	02FEB1996		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN1992	31DEC1992	N
	C4591001 1177 11771534	General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1995		Y
			Food allergy	01JAN2005		Y
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013	30NOV2013	N
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2017	30NOV2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Intervertebral disc operation	01NOV2013	30NOV2013	N
			Uterine polypectomy	01NOV2017	30NOV2017	N
	C4591001 1177 11771537	Gastrointestinal disorders	Inguinal hernia	01JAN1979	31DEC1980	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771539	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	(b) (6) 1998		Y
	C4591001 1177 11771540	Infections and infestations	Otitis media	01JAN2005	31DEC2005	N
		Investigations	Cardiac murmur	01JAN2014		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2005	31DEC2005	N
	C4591001 1177 11771543	Injury, poisoning and procedural complications	Upper limb fracture	01MAR2011	31MAR2011	N
		Metabolism and nutrition disorders	Dyslipidaemia	01MAY2016		Y
			Glucose tolerance impaired	01JUN2020		Y
			Gout	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01MAR2011	31MAR2011	N
		Vascular disorders	Hypertension	01MAY2016		Y
	C4591001 1177 11771544	Infections and infestations	Diverticulitis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Colectomy	01JAN1985	31DEC1985	N
	C4591001 1177 11771548	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Endometriosis	01JAN1988	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1177 11771549	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Fracture treatment	01JAN2012	31DEC2012	N
	C4591001 1177 11771550	Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2016		Y
	C4591001 1177 11771551	Injury, poisoning and procedural complications	Tendon rupture	01NOV2016	30NOV2016	N
		Surgical and medical procedures	Tendon transfer	01NOV2016	30NOV2016	N
	C4591001 1177 11771554	Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
	C4591001 1177 11771557	Nervous system disorders	Headache	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	19APR2007	19APR2007	N
	C4591001 1177 11771562	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Hernia	01JAN2009	31DEC2009	N
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1998	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2009	31DEC2009	N
			Bunion operation	01JAN2000	31DEC2000	N
			Hernia repair	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1177 11771563	Blood and lymphatic system disorders	Anaemia	01JAN1974		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Food allergy	01JAN1998		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1177 11771565	Immune system disorders	Dust allergy	01JAN2014		Y
			Food allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1178 11781001	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781010	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1178 11781014	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN2006		Y
	C4591001 1178 11781030	Cardiac disorders	Coronary artery disease	01DEC2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01DEC2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781036	Immune system disorders	Seasonal allergy	01JAN2016		Y
	C4591001 1178 11781040	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JUL2018		Y
			Depression	01JUL2018		Y
		Surgical and medical procedures	Gastric bypass	01SEP2008	30SEP2008	N
	C4591001 1178 11781041	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1178 11781043	Cardiac disorders	Supraventricular tachycardia	01JAN2012	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2016		Y
		Nervous system disorders	Tension headache	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1178 11781044	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Nervous system disorders	Restless legs syndrome	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1178 11781050	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1178 11781051	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1178 11781052	Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1178 11781053	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Seasonal allergy	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	30JUN2000	N
		Surgical and medical procedures	Hysterectomy	01JUN2000	30JUN2000	N
	C4591001 1178 11781054	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1178 11781055	Immune system disorders	Seasonal allergy	01JAN1984		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Nervous system disorders	Headache	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2014		Y
	C4591001 1178 11781058	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
	C4591001 1178 11781061	Injury, poisoning and procedural complications	Cartilage injury	01MAR2020	18MAY2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Chondroplasty	18MAY2020	18MAY2020	N
	C4591001 1178 11781065	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781067	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01NOV2019		Y
		Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1178 11781069	Gastrointestinal disorders	Coeliac disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2002		Y
	C4591001 1178 11781072	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1178 11781073	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1178 11781074	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1178 11781079	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2002		Y
			Panic attack	01JAN2002		Y
	C4591001 1178 11781082	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1178 11781084	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1178 11781087	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1178 11781089	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Food allergy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1178 11781092	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1178 11781095	Blood and lymphatic system disorders	Pernicious anaemia	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1178 11781096	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1178 11781097	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip and/or oral cavity cancer	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
			Rosacea	01JAN2005		Y
	C4591001 1178 11781098	Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1178 11781100	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
	C4591001 1178 11781107	Ear and labyrinth disorders	Vertigo positional	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2005	N
		Nervous system disorders	Sinus headache	01JAN1977		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2003	31DEC2005	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
	C4591001 1178 11781110	Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1178 11781113	Nervous system disorders	Headache	01JAN2000		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781114	Investigations	Blood testosterone decreased	01JAN2010		Y
	C4591001 1178 11781120	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1178 11781121	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	07SEP2020		Y
		Nervous system disorders	Sinus headache	01JAN1995		Y
			Tension headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Panic attack	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
	C4591001 1178 11781127	Endocrine disorders	Basedow's disease	01JAN1986		Y
			Hypothyroidism	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31AUG2004	N
		Surgical and medical procedures	Hysterectomy	01AUG2004	31AUG2004	N
	C4591001 1178 11781128	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2005		Y
			Seasonal allergy	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1178 11781129	Gastrointestinal disorders	Abdominal pain upper	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1178 11781130	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
	C4591001 1178 11781131	Immune system disorders	Rubber sensitivity	01JAN2010		Y
	C4591001 1178 11781135	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1178 11781137	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1178 11781144	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Hypersomnia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
	C4591001 1178 11781145	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1178 11781149	Infections and infestations	Hand-foot-and-mouth disease	01JAN2017	31DEC2017	N
			Herpes zoster	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1178 11781150	Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1178 11781153	Immune system disorders	Drug hypersensitivity	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JUL2020		Y
		Psychiatric disorders	Drug dependence	01JAN2007		Y
			Insomnia	01JUL2020		Y
	C4591001 1178 11781154	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1178 11781155	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1178 11781156	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1178 11781161	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1178 11781162	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Oral herpes	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781163	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1178 11781168	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma stage 0	01JAN2015	31DEC2015	N
			Squamous cell carcinoma	01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Cancer surgery	01JAN2009	31DEC2009	N
				01JAN2015	31DEC2015	N
	C4591001 1178 11781170	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
	C4591001 1178 11781171	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1178 11781175	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1178 11781179	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
	C4591001 1178 11781182	Surgical and medical procedures	Vasectomy	01JAN2008		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2010		Y
	C4591001 1178 11781183	Psychiatric disorders	Insomnia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1178 11781185	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN1990		Y
			Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Tension headache	01AUG2020		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
	C4591001 1178 11781186	Immune system disorders	Seasonal allergy	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781188	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1178 11781189	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Weight decreased	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01APR2018		Y
	C4591001 1178 11781190	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1178 11781194	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUL2003	31JUL2003	N
		Surgical and medical procedures	Breast conserving surgery	01JUL2003	31JUL2003	N
	C4591001 1178 11781197	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2004		Y
	C4591001 1178 11781198	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781208	Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1178 11781210	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
	C4591001 1178 11781211	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1178 11781213	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1178 11781214	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Dental caries	01AUG2020		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1997		Y
			Iodine allergy	01JAN1988		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2020		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1178 11781216	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
	C4591001 1178 11781217	Metabolism and nutrition disorders	Vitamin D deficiency	15SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781218	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Traumatic arthritis	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN1994		Y
	C4591001 1178 11781221	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN2010		Y
			Hiatus hernia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Infections and infestations	Genital herpes	01JUN2019		Y
		Investigations	Blood triglycerides increased	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1178 11781222	Congenital, familial and genetic disorders	BRCA2 gene mutation	01JAN2015		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Oophorectomy bilateral	01JAN2015	31DEC2015	N
	C4591001 1178 11781223	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781224	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1988		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781226	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781230	Immune system disorders	Hypersensitivity	01JAN1977		Y
		Nervous system disorders	Migraine	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1178 11781233	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Nervous system disorders	Migraine	01JAN1998		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1178 11781234	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01NOV2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007		Y
	C4591001 1178 11781239	Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
	C4591001 1178 11781245	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Liver disorder	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1178 11781247	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
	C4591001 1178 11781248	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN1972		Y
				01JAN1988		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1178 11781249	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1178 11781251	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1178 11781253	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1178 11781258	Nervous system disorders	Facial paralysis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1178 11781263	Infections and infestations	Genital herpes	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1178 11781268	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1178 11781269	Immune system disorders	Allergy to plants	01JAN2000		Y
			Seasonal allergy	01JAN1998		Y
				01JAN2000		Y
		Infections and infestations	Otitis media chronic	01JAN1981		Y
	C4591001 1178 11781270	Surgical and medical procedures	Ear tube insertion	01JAN1982	31DEC1982	N
		Immune system disorders	Seasonal allergy	01JAN1989		Y
	C4591001 1178 11781271	Gastrointestinal disorders	Pancreatitis	01MAY2019	31JAN2020	N
		Psychiatric disorders	Anxiety disorder	01JAN2004		Y
			Bipolar disorder	01JAN2004		Y
	C4591001 1178 11781275	Immune system disorders	Seasonal allergy	01JAN1994		Y
	C4591001 1178 11781277	Endocrine disorders	Autoimmune thyroiditis	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
	C4591001 1178 11781279	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1178 11781284	Endocrine disorders	Basedow's disease	01JUL2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01DEC2014		Y
	C4591001 1178 11781285	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Investigations	Laparoscopy	01JAN2018	31DEC2018	N
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
			Eating disorder	01JAN2002		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
	C4591001 1178 11781286	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1178 11781288	Ear and labyrinth disorders	Tinnitus	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01AUG1999	31AUG1999	N
	C4591001 1178 11781290	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1178 11781291	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Rash	29SEP2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781295	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1993		Y
			Type 1 diabetes mellitus	01JAN1993		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
			Post-traumatic stress disorder	01JUL2020		Y
		Renal and urinary disorders	Urinary retention	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1178 11781296	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2002		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
	C4591001 1178 11781298	Skin and subcutaneous tissue disorders	Eczema	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1178 11781300	Congenital, familial and genetic disorders	Factor II deficiency	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JUL2020		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Salpingectomy	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
	C4591001 1178 11781309	Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1178 11781311	Nervous system disorders	Migraine	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1178 11781312	Surgical and medical procedures	Nasal septal operation	01JAN1998	31DEC2016	N
					31DEC2017	N
	C4591001 1178 11781314	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2004		Y
	C4591001 1178 11781316	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1179 11791002	Immune system disorders	Allergy to animal	01MAR1987	11MAY2010	N
	C4591001 1179 11791008	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Sarcoidosis	01JAN2014	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1179 11791009	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791010	Surgical and medical procedures	Intrauterine contraception	01AUG2019		Y
	C4591001 1179 11791023	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
	C4591001 1179 11791030	Surgical and medical procedures	Contraceptive implant	01JAN2019		Y
	C4591001 1179 11791033	Surgical and medical procedures	Female sterilisation	01JAN2008		Y
	C4591001 1179 11791050	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1179 11791054	Surgical and medical procedures	Intrauterine contraception	01JAN2014		Y
	C4591001 1179 11791058	Surgical and medical procedures	Hernia repair	01JAN1991	31DEC1991	N
	C4591001 1179 11791061	Infections and infestations	Tinea versicolour	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
		Surgical and medical procedures	Salpingectomy	01JAN2010		Y
	C4591001 1179 11791066	Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1179 11791067	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1179 11791069	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
	C4591001 1179 11791075	Psychiatric disorders	Affective disorder	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Autism spectrum disorder	01JAN2000		Y
	C4591001 1179 11791076	Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1179 11791079	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
	C4591001 1179 11791081	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013	31DEC2015	N
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1179 11791082	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1179 11791083	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Nervous system disorders	Migraine	01MAR2020		Y
	C4591001 1179 11791086	Investigations	Vitamin D decreased	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1179 11791087	Congenital, familial and genetic disorders	Hereditary spherocytosis	(b) (6) 1998		Y
	C4591001 1179 11791090	Psychiatric disorders	Bipolar II disorder	01JAN1990		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1179 11791093	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1179 11791098	Infections and infestations	Chlamydial infection	01JAN2020	29FEB2020	N
	C4591001 1179 11791100	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791101	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1179 11791104	Surgical and medical procedures	Knee operation	01JAN2015	31DEC2015	N
	C4591001 1179 11791106	Infections and infestations	Sinusitis	01JAN2000		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1179 11791117	Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
	C4591001 1179 11791122	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
	C4591001 1179 11791123	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1179 11791125	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Vascular disorders	Prehypertension	01JAN2015		Y
	C4591001 1179 11791126	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1179 11791130	Eye disorders	Keratoconus	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1179 11791131	Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995		Y
	C4591001 1179 11791133	Surgical and medical procedures	Female sterilisation	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791137	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Rhinitis allergic	01JAN1991		Y
	C4591001 1179 11791138	Cardiac disorders	Pericarditis	01JAN2015	31DEC2016	N
	C4591001 1179 11791146	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1179 11791149	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983	31DEC1993	N
	C4591001 1179 11791150	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1179 11791153	Vascular disorders	Hypertension	01JAN2010	31DEC2015	N
	C4591001 1179 11791154	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1179 11791158	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Salpingectomy	01JAN2005		Y
	C4591001 1179 11791159	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1179 11791160	Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
	C4591001 1179 11791161	Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1179 11791162	Surgical and medical procedures	Tonsillectomy	01JAN1967		Y
	C4591001 1179 11791165	Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791166	Surgical and medical procedures	Colectomy	01JAN2005	31DEC2006	N
	C4591001 1179 11791167	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1179 11791170	Investigations	HLA-B*27 positive	(b) (6) 1982		Y
	C4591001 1179 11791173	Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1179 11791174	Immune system disorders	Multiple allergies	01JAN1971		Y
	C4591001 1185 11851002	Infections and infestations	Folliculitis	01JAN2000		Y
	C4591001 1185 11851005	Social circumstances	Celibacy	01OCT2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Thyroidectomy	01JAN2003	31DEC2003	N
	C4591001 1185 11851008	Social circumstances	Celibacy	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1185 11851009	Social circumstances	Celibacy	01SEP2020		Y
	C4591001 1185 11851011	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1185 11851017	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1185 11851018	Social circumstances	Celibacy	01OCT2020		Y
	C4591001 1185 11851021	Immune system disorders	Drug hypersensitivity	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1185 11851022†	Investigations	HIV test positive	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1185 11851023	Social circumstances	Celibacy	01JAN2020		Y
	C4591001 1185 11851025	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Social circumstances	Celibacy	01JAN2020		Y
	C4591001 1185 11851028	Social circumstances	Celibacy	01JAN2020		Y
	C4591001 1185 11851030	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Celibacy	01OCT2020		Y
	C4591001 1185 11851032	Cardiac disorders	Bundle branch block left	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2020	31DEC2020	N
	C4591001 1185 11851033	Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1185 11851040	Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1185 11851050	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Social circumstances	Celibacy	01OCT2020		Y
	C4591001 1185 11851052	Psychiatric disorders	Autism spectrum disorder	01JAN2017		Y
	C4591001 1185 11851053	Endocrine disorders	Hypothyroidism	01APR2017		Y
		Musculoskeletal and connective tissue disorders	Morphoea	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Rosacea	01APR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1185 11851055	Infections and infestations	Salpingitis	01OCT2014	10OCT2014	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	06SEP2014	06SEP2014	N
		Surgical and medical procedures	Abscess drainage	07OCT2014	07OCT2014	N
			Tonsillectomy	20DEC2001	20DEC2001	N
	C4591001 1185 11851059	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1185 11851060	Investigations	Human papilloma virus test positive	01MAR2020		Y
		Social circumstances	Celibacy	01JAN2020		Y
	C4591001 1194 11941003	Endocrine disorders	Hypothyroidism	01AUG2015		Y
	C4591001 1194 11941010	Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1194 11941012	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1194 11941016	Congenital, familial and genetic disorders	Cystic fibrosis	(b) (6) 1991		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1194 11941019	Endocrine disorders	Autoimmune thyroiditis	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1194 11941020	Eye disorders	Conjunctivitis allergic	01JAN1970		Y
		Investigations	Blood creatine phosphokinase increased	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1194 11941023	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1194 11941024	Cardiac disorders	Bundle branch block right	01JAN2016		Y
		Congenital, familial and genetic disorders	Cystic fibrosis	(b) (6) 1988		Y
		Eye disorders	Conjunctivitis allergic	01JAN1996		Y
	C4591001 1194 11941025	Eye disorders	Cataract	01JAN2005		Y
			Conjunctivitis allergic	01JAN1975		Y
			Glaucoma	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1194 11941026	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
	C4591001 1194 11941030	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1194 11941031	Infections and infestations	Osteomyelitis	01JAN1995	31DEC1996	N
	C4591001 1194 11941032	Immune system disorders	Hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1194 11941033	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1194 11941034	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1194 11941041	Ear and labyrinth disorders	Hypoacusis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983		Y
	C4591001 1194 11941046	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1194 11941048	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1194 11941052	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1194 11941053	Cardiac disorders	Myocardial infarction	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1194 11941054	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2013	31DEC2014	N
	C4591001 1194 11941056	Psychiatric disorders	Post-traumatic stress disorder	01JAN2014		Y
	C4591001 1194 11941058	Cardiac disorders	Supraventricular tachycardia	01JUN2011	31JUL2011	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31AUG2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia areata	01MAR2017		Y
		Social circumstances	Postmenopause	01MAR2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1194 11941061	Infections and infestations	Chronic sinusitis	01JAN1999	31DEC2001	N
			Pertussis	01JAN2020	31MAR2020	N
	C4591001 1194 11941066	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Nervous system disorders	Sciatica	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1194 11941067	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1997		Y
	C4591001 1194 11941071	Eye disorders	Conjunctivitis allergic	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1194 11941072	Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1194 11941080	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1194 11941082	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1194 11941083	Immune system disorders	Mite allergy	01JAN1978		Y
	C4591001 1194 11941086	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1194 11941087	Eye disorders	Conjunctivitis allergic	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2018	31MAR2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1194 11941088	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1194 11941089	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1194 11941093	Gastrointestinal disorders	Crohn's disease	01JAN2006		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1998	31DEC1998	N
	C4591001 1194 11941096	Gastrointestinal disorders	Abdominal pain upper	01JAN2015		Y
		Psychiatric disorders	Depression	01SEP2019		Y
	C4591001 1194 11941097	Immune system disorders	Food allergy	01JAN1992		Y
	C4591001 1194 11941098	Surgical and medical procedures	Hysterectomy	01JAN2017		Y
	C4591001 1194 11941100	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
	C4591001 1194 11941103	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1194 11941106	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1195 11951002	Immune system disorders	Sarcoidosis	01JAN2012		Y
	C4591001 1195 11951003	Endocrine disorders	Autoimmune thyroiditis	01JAN2017		Y
	C4591001 1195 11951004	Surgical and medical procedures Congenital, familial and genetic disorders	Hysterectomy Osteogenesis imperfecta	01JAN2001 (b) (6) 1981	31DEC2001	N Y
	C4591001 1195 11951005	Psychiatric disorders Injury, poisoning and procedural complications	Depression Epicondylitis	28JAN2020 01APR2020		Y Y
	C4591001 1195 11951008	Vascular disorders Endocrine disorders	Hypertension Goitre	01JAN2018 24APR2012		Y Y
	C4591001 1195 11951009	Gastrointestinal disorders Metabolism and nutrition disorders	Haemorrhoids Hypercholesterolaemia Type 2 diabetes mellitus	01JAN1999 15APR2010 03JAN2020		Y Y Y
	C4591001 1195 11951013	Psychiatric disorders Surgical and medical procedures Vascular disorders Cardiac disorders	Depression Female sterilisation Arteriosclerosis Coronary artery disease	01FEB2020 01JAN2005 28APR2010 16APR2018	31DEC2005	Y N Y Y
	C4591001 1195 11951017	Metabolism and nutrition disorders Vascular disorders Hepatobiliary disorders	Hypercholesterolaemia Hypertension Hepatic steatosis	15APR2010 24APR2018 23OCT2018		Y Y Y
	C4591001 1195 11951017	Psychiatric disorders Immune system disorders	Depression Seasonal allergy	01JAN2018 01JAN2016		Y Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	29AUG2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Arteriosclerosis	07MAY2009		Y
	C4591001 1195 11951018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Vascular disorders	Hypertension	05MAR2013		Y
	C4591001 1195 11951019	Blood and lymphatic system disorders	Iron deficiency anaemia	01FEB2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	16JAN2015		Y
	C4591001 1195 11951020	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	31JAN2019		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1195 11951021	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1195 11951023	Gastrointestinal disorders	Irritable bowel syndrome	24AUG2010		Y
		Hepatobiliary disorders	Hepatic steatosis	21NOV2014		Y
		Immune system disorders	Seasonal allergy	01JUL2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2002		Y
			Intervertebral disc protrusion	05OCT2020		Y
			Osteochondrosis	03APR2001		Y
			Spinal disorder	13OCT2014		Y
		Psychiatric disorders	Anxiety disorder	01MAY2001		Y
			Depression	01JAN2004		Y
	C4591001 1195 11951026	Immune system disorders	Seasonal allergy	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	03JUL2019		Y
	C4591001 1195 11951027	Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2000		Y
	C4591001 1195 11951030	Nervous system disorders	Sciatica	12OCT2020	15OCT2020	N
	C4591001 1195 11951032	Endocrine disorders	Goitre	15MAY2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2019		Y
			Osteochondrosis	25JAN2018		Y
			Spinal disorder	07FEB2018		Y
		Psychiatric disorders	Depression	10SEP2013		Y
	C4591001 1195 11951040	Metabolism and nutrition disorders	Haemochromatosis	01JAN2018		Y
		Vascular disorders	Hypertension	20JAN2018		Y
	C4591001 1195 11951041	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1195 11951042	Metabolism and nutrition disorders	Lipoedema	01JAN2007		Y
	C4591001 1195 11951043	Immune system disorders	Atopy	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	29NOV2012		Y
		Surgical and medical procedures	Hip arthroplasty	23JUN2017	23JUN2017	N
			Shoulder operation	13OCT2020	13OCT2020	N
	C4591001 1195 11951047	Gastrointestinal disorders	Irritable bowel syndrome	08AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2003		Y
	C4591001 1195 11951053	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1195 11951054	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1195 11951055	Metabolism and nutrition disorders	Obesity	01JUL1993		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	12OCT2010		Y
			Limb asymmetry	01JUL1993		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	31MAY2013		Y
	C4591001 1195 11951061	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1195 11951067	Endocrine disorders	Hypothyroidism	28OCT2015		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01SEP2015	30SEP2015	N
	C4591001 1195 11951068	Metabolism and nutrition disorders	Hypercholesterolaemia	22AUG2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	06NOV2007		Y
		Vascular disorders	Varicose vein	11NOV2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1195 11951070	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31JAN2018	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1195 11951071	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1195 11951073	Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1195 11951075	Metabolism and nutrition disorders	Iron metabolism disorder	12FEB2014		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	16MAY2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	10SEP2003		Y
	C4591001 1195 11951076	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1993		Y
			Intervertebral disc protrusion	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	09NOV2001		Y
	C4591001 1195 11951077	Musculoskeletal and connective tissue disorders	Spinal disorder	18APR2016		Y
	C4591001 1195 11951080	Psychiatric disorders	Bulimia nervosa	15OCT2010		Y
	C4591001 1195 11951081	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Headache	08OCT2010	11OCT2010	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1195 11951082	Ear and labyrinth disorders	Tinnitus	14OCT2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	21DEC2016		Y
			Osteochondrosis	17MAR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal disorder	24SEP2015		Y
		Nervous system disorders	Migraine	15JUL2011		Y
		Psychiatric disorders	Depression	11JAN2010		Y
	C4591001 1195 11951085	Renal and urinary disorders	Urinary incontinence	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1195 11951089	Immune system disorders	Drug hypersensitivity	10MAR2008		Y
			Food allergy	07JUN2001		Y
			Seasonal allergy	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Diffuse alopecia	01JAN2001		Y
	C4591001 1195 11951090	Metabolism and nutrition disorders	Hyperuricaemia	07SEP2005		Y
	C4591001 1195 11951091	Nervous system disorders	Carpal tunnel syndrome	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JUN2020		Y
	C4591001 1195 11951098	Gastrointestinal disorders	Crohn's disease	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1195 11951099	Cardiac disorders	Coronary artery disease	01JAN2008		Y
			Myocardial infarction	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1195 11951100	Endocrine disorders	Hypothyroidism	01JUL2020		Y
	C4591001 1195 11951104	Nervous system disorders	Migraine	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1195 11951105	Musculoskeletal and connective tissue disorders	Spinal disorder	06OCT2020	10OCT2020	N
		Skin and subcutaneous tissue disorders	Rosacea	10DEC2014		Y
			Urticaria	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	21MAR2017	21MAR2017	N
	C4591001 1195 11951113	Gastrointestinal disorders	Crohn's disease	01JAN2015		Y
	C4591001 1195 11951114	Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1195 11951119	Endocrine disorders	Goitre	08NOV2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	08NOV2004		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	23MAR2009		Y
		Nervous system disorders	Migraine	26NOV2004		Y
		Vascular disorders	Hypertension	16MAY2017		Y
	C4591001 1195 11951120	Metabolism and nutrition disorders	Hypercholesterolaemia	25OCT2004		Y
		Nervous system disorders	Migraine	25OCT2004		Y
		Psychiatric disorders	Sleep disorder	07OCT2019		Y
	C4591001 1195 11951134	Immune system disorders	Seasonal allergy	27OCT2011		Y
		Psychiatric disorders	Depression	30NOV2009		Y
		Surgical and medical procedures	Thyroidectomy	01JUN2008	30JUN2008	N
	C4591001 1195 11951135	Cardiac disorders	Tachycardia paroxysmal	29OCT2018		Y
	C4591001 1195 11951137	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
	C4591001 1195 11951138	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	31AUG2011		Y
			Type 2 diabetes mellitus	22JAN2008		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	25APR2005		Y
			Tendon pain	29JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
			Sleep apnoea syndrome	26AUG2009		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	25APR2005		Y
	C4591001 1195 11951139	Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2007		Y
	C4591001 1195 11951140	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1195 11951141	Immune system disorders	Seasonal allergy	01APR1999		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	14OCT2020	19OCT2020	N
	C4591001 1195 11951146	Immune system disorders	Seasonal allergy	18MAY2015		Y
		Metabolism and nutrition disorders	Obesity	27MAY2003		Y
		Nervous system disorders	Cervicobrachial syndrome	20JAN2015		Y
	C4591001 1195 11951148	Metabolism and nutrition disorders	Obesity	20OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	31JAN2017		Y
	C4591001 1195 11951153	Respiratory, thoracic and mediastinal disorders	Asthma	12AUG2020		Y
	C4591001 1195 11951154	Endocrine disorders	Goitre	01JAN2009		Y
			Hypothyroidism	16AUG2012		Y
		Gastrointestinal disorders	Gastritis	14OCT2011		Y
			Gastrooesophageal reflux disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Exostosis	14OCT2020		Y
			Foot deformity	15OCT2020		Y
			Spinal disorder	18MAY2010		Y
		Nervous system disorders	Carpal tunnel syndrome	07JAN2015		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1195 11951155	General disorders and administration site conditions	Chest pain	14OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12JUN2020		Y
	C4591001 1195 11951157	Endocrine disorders	Hypothyroidism	01AUG2019		Y
	C4591001 1197 11971001	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
	C4591001 1197 11971003	Gastrointestinal disorders	Gastritis	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rash	15SEP2020		Y
	C4591001 1197 11971005	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	20MAR2020	20MAR2020	N
		Surgical and medical procedures	Salpingectomy	01JUN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971007	Endocrine disorders	Goitre	19OCT2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000		Y
	C4591001 1197 11971014	Nervous system disorders	Carotid arteriosclerosis	14MAY2018		Y
		Vascular disorders	Hypertension	27SEP2018		Y
	C4591001 1197 11971015	Metabolism and nutrition disorders	Hypercholesterolaemia	30APR2014		Y
			Type 2 diabetes mellitus	30APR2020		Y
		Musculoskeletal and connective tissue disorders	Tendon pain	31AUG2020		Y
		Vascular disorders	Hypertension	28FEB2011		Y
	C4591001 1197 11971017	Metabolism and nutrition disorders	Hypercholesterolaemia	23JUL2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	07MAY2015	23DEC2015	N
		Renal and urinary disorders	Renal failure	20DEC2019		Y
	C4591001 1197 11971018	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2014		Y
		Surgical and medical procedures	Uterine operation	01JAN2014	31DEC2014	N
	C4591001 1197 11971019	Metabolism and nutrition disorders	Hypercholesterolaemia	30JUL2020		Y
			Obesity	30JUL2020		Y
		Vascular disorders	Hypertension	11JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971020	Gastrointestinal disorders	Gastritis	04AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	14AUG2019		Y
	C4591001 1197 11971026	Gastrointestinal disorders	Chronic gastritis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Bunion operation	18JUN2020	18JUN2020	N
	C4591001 1197 11971028	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1197 11971029	Eye disorders	Amblyopia	09JAN2019	28FEB2019	N
	C4591001 1197 11971035	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
			Type 2 diabetes mellitus	12FEB2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Vascular disorders	Hypertension	23JAN2018		Y
	C4591001 1197 11971039	Cardiac disorders	Coronary artery disease	04NOV2018		Y
			Myocardial infarction	04NOV2018	04NOV2018	N
		Endocrine disorders	Hypothyroidism	23FEB2017		Y
		Gastrointestinal disorders	Chronic gastritis	12JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	28JUL2016		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	04OCT2017		Y
		Vascular disorders	Hypertension	04NOV2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1197 11971040	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Vascular disorders	Hypertension	29DEC2017		Y
	C4591001 1197 11971041	Musculoskeletal and connective tissue disorders	Osteochondrosis	21JUN2018		Y
		Psychiatric disorders	Depression	21MAR2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12APR2016		Y
			Rhinitis allergic	12APR2016		Y
	C4591001 1197 11971042	Cardiac disorders	Palpitations	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1197 11971045	Endocrine disorders	Hypothyroidism	22MAY2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	24APR2018		Y
		Vascular disorders	Hypertension	11MAY2017		Y
			Varicose vein	29AUG2016		Y
	C4591001 1197 11971053	Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2015		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2010		Y
		Vascular disorders	Hypertension	07JUN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971058	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	21AUG2020		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1197 11971060	Gastrointestinal disorders	Abdominal pain	01SEP2020		Y
			Oesophagitis	01OCT2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01AUG2014		Y
		Nervous system disorders	Carotid arteriosclerosis	25JUL2019		Y
		Vascular disorders	Hypertension	01NOV2014		Y
	C4591001 1197 11971064	Gastrointestinal disorders	Gastritis	02SEP2020	04OCT2020	N
	C4591001 1197 11971068	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	15NOV2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2015		Y
	C4591001 1197 11971069	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1197 11971077	Injury, poisoning and procedural complications	Epicondylitis	07SEP2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
		Renal and urinary disorders	Renal failure	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1197 11971079	Endocrine disorders	Autoimmune thyroiditis	01JAN2008		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1197 11971088	Metabolism and nutrition disorders	Hypercholesterolaemia	20JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14JUN1994		Y
	C4591001 1197 11971092	Surgical and medical procedures	Meniscus removal	17JUN2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1197 11971094	Cardiac disorders	Aortic valve incompetence	27SEP2019		Y
			Coronary artery disease	02AUG2019		Y
			Myocardial infarction	02AUG2019	02AUG2019	N
		Hepatobiliary disorders	Hepatic steatosis	21JUL2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	02AUG2019		Y
			Type 2 diabetes mellitus	19JUL2016		Y
		Surgical and medical procedures	Coronary arterial stent insertion	02AUG2019	02AUG2019	N
	C4591001 1197 11971096	Cardiac disorders	Coronary artery disease	01FEB2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2015		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Vascular disorders	Hypertension	01FEB2015		Y
	C4591001 1202 12021007	Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1202 12021009	Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1202 12021011	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1203 12031001	Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1203 12031004	Immune system disorders	Allergy to animal	01JAN2002		Y
			Mite allergy	01JAN2002		Y
			Seasonal allergy	01JAN2002		Y
	C4591001 1203 12031005	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Nervous system disorders	Headache	01JAN1998		Y
	C4591001 1203 12031008	Surgical and medical procedures	Shoulder operation	01JAN2018	31DEC2018	N
	C4591001 1203 12031010	Surgical and medical procedures	Hysterectomy	01APR2011	30APR2011	N
	C4591001 1203 12031020	Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1203 12031021	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2019		Y
		Surgical and medical procedures	Gastrectomy	01AUG2020	31AUG2020	N
			Thyroidectomy	01JAN1993	31DEC1993	N
	C4591001 1203 12031032	Immune system disorders	Allergy to animal	01AUG2020		Y
			Seasonal allergy	01JAN1980		Y
	C4591001 1203 12031033	Congenital, familial and genetic disorders	Anomalous pulmonary venous connection	(b) (6) 1986	31DEC1991	N
			Atrial septal defect	(b) (6) 1986	31DEC1991	N
				01JAN1991		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Medical device removal	01JAN2016	31DEC2016	N
			Scar excision	01JAN2016	31DEC2016	N
	C4591001 1203 12031034	Cardiac disorders	Atrioventricular block complete	01JAN2010	31DEC2010	N
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
				01JAN2000		Y
		Psychiatric disorders	Gambling disorder	01JAN2017	31DEC2018	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2019		Y
		Social circumstances	Menopause	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2010		Y
			Cardiac pacemaker replacement	01AUG2020	31AUG2020	N
				01MAR2020	31MAR2020	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Psychotherapy	01JAN2017	31DEC2018	N
	C4591001 1203 12031041	Surgical and medical procedures	Female sterilisation	01FEB2017	28FEB2017	N
	C4591001 1203 12031042	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1203 12031044	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Histamine intolerance	01FEB2020		Y
	C4591001 1203 12031048	Nervous system disorders	Transient ischaemic attack	03OCT2020	03OCT2020	N
	C4591001 1203 12031051	Immune system disorders	Allergy to plants	01JAN1990		Y
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Immune tolerance induction	01JAN2006	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1203 12031056	Immune system disorders	Seasonal allergy	23OCT2008		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1203 12031058	Immune system disorders	Allergy to animal	01JAN1999		Y
			Seasonal allergy	01JAN1999		Y
	C4591001 1203 12031059	Gastrointestinal disorders	Gastritis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1203 12031060	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1203 12031063	Immune system disorders	Drug hypersensitivity	(b) (6) 1983		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	01JAN2009		Y
	C4591001 1203 12031064	Immune system disorders	Food allergy	01JAN2010		Y
			Mite allergy	01JAN1990		Y
			Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
	C4591001 1203 12031067	Infections and infestations	Herpes zoster	01JAN2010	01JAN2010	N
		Surgical and medical procedures	Caesarean section	27JAN2019	27JAN2019	N
	C4591001 1203 12031069	Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Adjustment disorder	01JAN2017		Y
	C4591001 1204 12041001	Endocrine disorders	Hypothyroidism	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2015	01NOV2015	N
		Nervous system disorders	Headache	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1204 12041004	Metabolism and nutrition disorders	Vitamin B12 deficiency	24AUG2010		Y
	C4591001 1204 12041005	Immune system disorders	Seasonal allergy	09OCT1986		Y
		Surgical and medical procedures	Knee operation	16JUN2020	16JUN2020	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	25AUG2010		Y
	C4591001 1204 12041008	Cardiac disorders	Arrhythmia	25AUG2003	25AUG2004	N
		Infections and infestations	Helicobacter infection	25AUG2007	25SEP2007	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	25JAN2005	31AUG2005	N
	C4591001 1204 12041010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1204 12041011	Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1204 12041012	Psychiatric disorders	Depression	28AUG2016		Y
	C4591001 1204 12041015	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2012		Y
	C4591001 1204 12041017	Immune system disorders	Multiple allergies	01JAN2015		Y
		Infections and infestations	Urosepsis	01DEC2017	01DEC2017	N
		Nervous system disorders	Migraine	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1204 12041018	Surgical and medical procedures	Phlebectomy	01JUL2012	31JUL2012	N
		Vascular disorders	Varicose vein	01JUN2012	31JUL2012	N
	C4591001 1204 12041019	Vascular disorders	Aortic aneurysm	01JAN2010		Y
			Hypertension	01JAN2010		Y
	C4591001 1204 12041020	Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Anxiety	01APR2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1204 12041021	Infections and infestations	Kidney infection	01JAN1978	31DEC1997	N
		Surgical and medical procedures	Nephrectomy	01JAN1997	31DEC1997	N
			Renal cyst excision	01APR2001	01APR2001	N
	C4591001 1204 12041026	Musculoskeletal and connective tissue disorders	Back pain	18AUG2020	01SEP2020	N
	C4591001 1204 12041030	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01JAN2013		Y
	C4591001 1204 12041034	Reproductive system and breast disorders	Uterine polyp	01JAN2017	31DEC2017	N
	C4591001 1204 12041039	Psychiatric disorders	Anxiety	01MAR2020		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Surgical and medical procedures	Circumcision	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041040	Skin and subcutaneous tissue disorders	Acne	01JAN2009		Y
		Surgical and medical procedures	Bone operation	01JUN2015	30JUN2015	N
			Fracture treatment	01JUN2011	30JUN2011	N
				01OCT2009	31OCT2009	N
			Joint surgery	01JUL2010	31JUL2010	N
				01JUN2010	30JUN2010	N
			Rhinoplasty	01JAN2001	31DEC2001	N
	C4591001 1204 12041041	Psychiatric disorders	Anxiety	01AUG2019		Y
			Attention deficit hyperactivity disorder	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
	C4591001 1204 12041043	Blood and lymphatic system disorders	Thrombocytopenia	01JUL2015		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1204 12041044	Surgical and medical procedures	Tenoplasty	01JAN2013	31DEC2013	N
	C4591001 1204 12041046	Psychiatric disorders	Anxiety	01JUL2011		Y
	C4591001 1204 12041052	Investigations	Blood cholesterol increased	08AUG2020		Y
			HLA marker study	(b) (6) 1991		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Ear tube insertion	01JAN2005	31DEC2005	N
			Eye operation	01JAN1996	31DEC1996	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
			Tooth extraction	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	08SEP2015		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1204 12041055	Endocrine disorders	Hypothyroidism	08SEP2013		Y
	C4591001 1204 12041058	Metabolism and nutrition disorders	Hyperglycaemia	01JAN2009		Y
		Surgical and medical procedures	Ligament operation	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Sinus operation	01JAN2007	31DEC2007	N
				01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2013	31DEC2013	N
	C4591001 1204 12041059	Gastrointestinal disorders	Dyspepsia	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2006		Y
	C4591001 1204 12041060	Surgical and medical procedures	Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1204 12041061	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Surgical and medical procedures	Chondroplasty	01JAN2013	31DEC2013	N
			Wrist surgery	01JAN2014	31DEC2014	N
	C4591001 1204 12041062	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1204 12041063	Infections and infestations	Herpes simplex	09SEP2005	31DEC2010	N
	C4591001 1204 12041064	Nervous system disorders	Migraine	01OCT2013		Y
		Surgical and medical procedures	Chondroplasty	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
	C4591001 1204 12041065	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	12SEP2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1204 12041067	Vascular disorders	Hypertension	09SEP2015		Y
	C4591001 1204 12041071	Surgical and medical procedures	Nasal septal operation	09SEP2015	09SEP2015	N
	C4591001 1204 12041073	Endocrine disorders	Hypothyroidism	09SEP2013		Y
		Psychiatric disorders	Alcoholism	09SEP2002	09SEP2019	N
			Depression	09SEP2004		Y
	C4591001 1204 12041074	Metabolism and nutrition disorders	Gout	01APR2019		Y
	C4591001 1204 12041075	Skin and subcutaneous tissue disorders	Acne	09JAN2020		Y
			Eczema	09SEP2019		Y
			Skin discolouration	09JUL2020		Y
	C4591001 1204 12041076	Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	09FEB2017	09APR2017	N
		Surgical and medical procedures	Thyroidectomy	01APR2017	30APR2017	N
	C4591001 1204 12041077	Surgical and medical procedures	Shoulder operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1204 12041078	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01OCT2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1204 12041079	Psychiatric disorders	Bipolar II disorder	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV2019		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2012	31DEC2012	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1204 12041080	Investigations	Blood cholesterol increased	10SEP2018		Y
	C4591001 1204 12041082	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Nasal septal operation	31OCT2017	31OCT2017	N
			Sinus operation	31OCT2017	31OCT2017	N
	C4591001 1204 12041084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Surgical and medical procedures	Ovarian cystectomy	01MAY2017	31MAY2017	N
			Salpingectomy	01MAY2017	31MAY2017	N
	C4591001 1204 12041089	Immune system disorders	Seasonal allergy	01APR1990		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1990	31DEC1990	N
			Fracture treatment	01JAN2013	31DEC2013	N
			Mastectomy	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1204 12041090	Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2007		Y
		Surgical and medical procedures	Fracture treatment	01FEB2020	31DEC2020	N
				01JAN2007	31DEC2007	N
	C4591001 1204 12041092	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2018		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Surgical and medical procedures	Ostectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041093	Injury, poisoning and procedural complications	Scar	01JUL2017	01JUL2017	N
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2012	31DEC2012	N
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1204 12041094	Gastrointestinal disorders	Irritable bowel syndrome	11SEP2019		Y
	C4591001 1204 12041096	Surgical and medical procedures	Fracture treatment	01JAN2004	31DEC2004	N
			Mole excision	01JAN2007	31DEC2007	N
			Toe operation	01JAN2019	31DEC2019	N
	C4591001 1204 12041097	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01OCT2019		Y
	C4591001 1204 12041098	Investigations	Cardiac murmur	11SEP2012		Y
	C4591001 1204 12041099	Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1204 12041101	Skin and subcutaneous tissue disorders	Eczema	01JAN2020	01MAR2020	N
		Surgical and medical procedures	Papilloma excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1204 12041102	Immune system disorders	Seasonal allergy	01APR1993		Y
		Nervous system disorders	Migraine	01JUL2002		Y
		Surgical and medical procedures	Mammoplasty	01JAN1995	31DEC1995	N
			Meniscus operation	18DEC2019	18DEC2019	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041103	Surgical and medical procedures	Inguinal hernia repair	01JAN1971	31DEC1971	N
	C4591001 1204 12041105	Investigations	Blood glucose increased	01JAN2009		Y
			Blood pressure increased	01JAN2019	01FEB2020	N
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
	C4591001 1204 12041107	Surgical and medical procedures	Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1204 12041110	Surgical and medical procedures	Tenotomy	01JAN2015	31DEC2015	N
	C4591001 1204 12041111	Investigations	Blood pressure increased	01JAN2016		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Nervous system disorders	Cluster headache	01JAN2010	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1204 12041112	Psychiatric disorders	Anxiety	01APR2020		Y
	C4591001 1204 12041113	Hepatobiliary disorders	Cholelithiasis	01APR2019	01AUG2019	N
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2019	01JUN2019	N
	C4591001 1204 12041120	Cardiac disorders	Angina pectoris	08SEP2002		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	18SEP1992		Y
		Psychiatric disorders	Depression	18SEP1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	18SEP1981	18SEP2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	18SEP2004		Y
	C4591001 1204 12041121	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
	C4591001 1204 12041122	Surgical and medical procedures	Atrial septal defect repair	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2011	31DEC2011	N
	C4591001 1204 12041125	Gastrointestinal disorders	Gastroesophageal reflux disease	18SEP1990		Y
			Inguinal hernia	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01SEP2020		Y
	C4591001 1204 12041127	Congenital, familial and genetic disorders	Coarctation of the aorta	01JAN1982	31DEC1982	N
	C4591001 1204 12041128	Respiratory, thoracic and mediastinal disorders	Nasal polyps	18SEP2007		Y
		Surgical and medical procedures	Jaw operation	01JAN2008	31DEC2008	N
			Nasal polypectomy	01JAN2018	31DEC2018	N
	C4591001 1204 12041129	Gastrointestinal disorders	Colitis	18SEP2013		Y
		Nervous system disorders	Migraine	18SEP2008		Y
		Surgical and medical procedures	Ligament operation	01JAN2019	31DEC2019	N
	C4591001 1204 12041131	Vascular disorders	Hypertension	08SEP1990		Y
	C4591001 1204 12041132	Infections and infestations	Overgrowth bacterial	01APR2019	01AUG2019	N
	C4591001 1204 12041134	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1204 12041135	Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2000	31DEC2000	N
	C4591001 1204 12041136	Psychiatric disorders	Anxiety	01JAN1988		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
		Social circumstances	Trans-sexualism	01JAN2013		Y
		Surgical and medical procedures	Ankle operation	01JAN2002	31DEC2002	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Mastectomy	01JAN2013	31DEC2013	N
	C4591001 1204 12041137	Endocrine disorders	Hypothyroidism	15JUL2008		Y
	C4591001 1204 12041138	Blood and lymphatic system disorders	Pernicious anaemia	21MAR2019		Y
	C4591001 1204 12041139	Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Haemorrhoid operation	01JAN2013	31DEC2013	N
	C4591001 1204 12041140	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN1996		Y
		Vascular disorders	Deep vein thrombosis	01JAN1996	31DEC1996	N
	C4591001 1204 12041141	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2016	N
		Psychiatric disorders	Anxiety	01OCT2007		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2013	31DEC2013	N
			Eye laser surgery	01JAN2006	31DEC2006	N
			Hysterectomy	02JUN2016	02JUN2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myomectomy	01JAN2009	31DEC2009	N
				01JAN2015	31DEC2015	N
	C4591001 1204 12041143†	Investigations	HIV test positive	15DEC2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
	C4591001 1204 12041145	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Tenoplasty	01JAN2017	31DEC2017	N
	C4591001 1204 12041147	Immune system disorders	Food allergy	01JAN2002		Y
			Seasonal allergy	01JAN2007		Y
	C4591001 1204 12041149†	Investigations	HIV test positive	23SEP1991		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
	C4591001 1204 12041152†	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Investigations	HIV test positive	01OCT1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Social circumstances	Postmenopause	01MAR2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Intra-cerebral aneurysm operation	01JAN2017	31DEC2017	N
	C4591001 1204 12041153	Congenital, familial and genetic disorders	Thalassaemia beta	01JAN1980		Y
	C4591001 1204 12041154†	Investigations	HIV test positive	15MAR1996		Y
		Psychiatric disorders	Depression	01OCT2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041161	Psychiatric disorders	Seasonal affective disorder	15JUL2020		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1204 12041163†	Investigations	HIV test positive	15JUL2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15AUG2020		Y
			Type 2 diabetes mellitus	15JUL2020		Y
			Vitamin D deficiency	15JAN2020		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1204 12041164†	Investigations	HIV test positive	01MAY1994		Y
	C4591001 1204 12041165†	Investigations	HIV test positive	24SEP2017		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	24SEP2017		Y
	C4591001 1204 12041170	Immune system disorders	Seasonal allergy	15JUN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm of appendix	15SEP2018	15SEP2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
	C4591001 1204 12041174	Surgical and medical procedures	Nasal septal operation	01JAN2008	31DEC2008	N
	C4591001 1204 12041176†	Gastrointestinal disorders	Short-bowel syndrome	09MAR2002		Y
		Investigations	HIV test positive	01JAN1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2019		Y
			Type 2 diabetes mellitus	11MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin B12 deficiency	09MAR2020		Y
			Vitamin D deficiency	09MAR2020		Y
		Renal and urinary disorders	Renal disorder	13NOV2018		Y
		Surgical and medical procedures	Cranial operation	09MAR2002	09MAR2002	N
			Gastrointestinal surgery	01JAN2005	31DEC2005	N
			Intestinal operation	09MAR2002	09MAR2002	N
			Limb operation	09MAR2002	09MAR2002	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1204 12041178	Surgical and medical procedures	Knee operation	01JAN2008	31JAN2008	N
	C4591001 1204 12041179	Gastrointestinal disorders	Proctitis ulcerative	01JAN2009	31DEC2010	N
	C4591001 1204 12041182†	Infections and infestations	Hepatitis C	01JAN2012		Y
		Investigations	Blood pressure increased	01OCT2019		Y
			HIV test positive	01JAN2003		Y
	C4591001 1204 12041185	Infections and infestations	Diverticulitis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hernia repair	01JAN2010	31DEC2010	N
	C4591001 1204 12041186	Injury, poisoning and procedural complications	Ligament rupture	01JAN2008	31DEC2008	N
			Meniscus injury	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	11NOV2016	11NOV2016	N
			Ligament operation	01JAN2008	31DEC2008	N
			Mastectomy	30SEP2014	30SEP2014	N
			Meniscus operation	01JAN2008	31DEC2008	N
			Transgender operation	30SEP2014	30SEP2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041188†	Investigations	HIV test positive	05SEP2005		Y
	C4591001 1204 12041189	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Investigations	Blood pressure increased	01JUL2020		Y
		Psychiatric disorders	Anxiety	01AUG2012		Y
			Depression	01AUG2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2020		Y
	C4591001 1204 12041190	Psychiatric disorders	Depression	01JAN1995	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977	31DEC1983	N
		Surgical and medical procedures	Artificial crown procedure	30SEP2020	30SEP2020	N
			Chondroplasty	01JAN2010	31DEC2010	N
			Tooth repair	30SEP2020	30SEP2020	N
	C4591001 1204 12041191	Renal and urinary disorders	Nephritis	01JAN1971	31DEC1971	N
		Social circumstances	Postmenopause	15MAY2016		Y
		Surgical and medical procedures	Caesarean section	05SEP2006	05SEP2006	N
	C4591001 1204 12041192	Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1204 12041193†	Investigations	HIV test positive	01JUN2002		Y
		Psychiatric disorders	Anxiety	07OCT2008		Y
			Schizoaffective disorder	07OCT2008		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041194†	Investigations	HIV test positive	01JUN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
	C4591001 1204 12041195	Surgical and medical procedures	Adenoidectomy	01JAN1983	31DEC1983	N
			Fracture treatment	14JAN2019	14JAN2019	N
			Ligament operation	01MAY2005	31MAY2005	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1204 12041197†	Investigations	HIV test positive	01JAN1989		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1204 12041199	Skin and subcutaneous tissue disorders	Androgenetic alopecia	07MAR2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Keratomileusis	01JAN1999	31DEC1999	N
	C4591001 1204 12041202	Nervous system disorders	Syncope	01JAN1996		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
			Appendicectomy	01JAN2009	31DEC2009	N
	C4591001 1204 12041203	Gastrointestinal disorders	Epigastric discomfort	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2002	31DEC2002	N
	C4591001 1204 12041205	Congenital, familial and genetic disorders	Otospondylomegaepiphyseal dysplasia	(b) (6) 1988	(b) (6) 1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Ear infection	(b) (6) 1988		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01OCT2017	31OCT2017	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Surgical and medical procedures	Cleft palate repair	01JAN1989	31DEC1989	N
			Ear tube insertion	01JAN2015	31DEC2015	N
			Uterine dilation and curettage	01JAN2017	31DEC2017	N
	C4591001 1204 12041206	Surgical and medical procedures	Testicular operation	01JAN2005	31DEC2005	N
	C4591001 1204 12041208	Reproductive system and breast disorders	Testicular torsion	01JAN1993	31DEC1993	N
				01JAN1998	31DEC1998	N
	C4591001 1204 12041209	Surgical and medical procedures	Ankle operation	24JAN2020	24JAN2020	N
	C4591001 1204 12041210†	Investigations	HIV test positive	15JUN2009		Y
	C4591001 1204 12041214	Immune system disorders	Food allergy	01JAN2009		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1204 12041215	Surgical and medical procedures	Fracture treatment	01JAN1986	31DEC1986	N
			Ligament operation	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1204 12041216†	Investigations	HIV test positive	15JUN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	15OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041218	Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	01JAN2005	N
	C4591001 1204 12041220	Blood and lymphatic system disorders	Anaemia	24SEP2020		Y
	C4591001 1204 12041221	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1204 12041222	Surgical and medical procedures	Rotator cuff repair	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1204 12041227	Psychiatric disorders	Depression	01JAN2013		Y
		Vascular disorders	Kawasaki's disease	01MAY1996	01SEP1996	N
	C4591001 1204 12041233†	Investigations	HIV test positive	15JAN2015		Y
		Surgical and medical procedures	Ligament operation	01JAN2018	31DEC2018	N
	C4591001 1204 12041234	Infections and infestations	Pharyngitis streptococcal	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Spondylolysis	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1204 12041235	Infections and infestations	Tonsillitis	01JAN1991	31DEC1992	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1204 12041237	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Fracture treatment	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041238	Immune system disorders	Seasonal allergy	01JAN2013		Y
	C4591001 1204 12041239	Metabolism and nutrition disorders	Obesity	01JAN1978		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Metabolic surgery	18JAN2018	18JAN2018	N
			Renal stone removal	01JAN2017	31DEC2017	N
			Ureteral stent insertion	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1204 12041240	Reproductive system and breast disorders	Ovarian cyst	01JAN2003	31DEC2004	N
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
			Ovarian cystectomy	01JAN2004	31DEC2004	N
	C4591001 1204 12041241	Congenital, familial and genetic disorders	Phimosis	01JAN2019	31DEC2019	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01APR2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01SEP2019		Y
		Surgical and medical procedures	Circumcision	01JUN2019	30JUN2019	N
	C4591001 1204 12041243	Injury, poisoning and procedural complications	Ligament injury	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Ligament operation	01JAN2017	31DEC2017	N
	C4591001 1204 12041246	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2014	31DEC2015	N
		Psychiatric disorders	Depression	01JAN1973		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2015	31DEC2015	N
	C4591001 1204 12041247	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Adenoidectomy	01JAN2010	31DEC2010	N
	C4591001 1204 12041248	Investigations	Biopsy cervix	01JAN2004	31DEC2004	N
		Reproductive system and breast disorders	Smear cervix abnormal Uterine polyp	01JAN2004 01JAN2019	31DEC2004 31DEC2019	N N
		Surgical and medical procedures	Uterine polypectomy	01JAN2019	31DEC2019	N
	C4591001 1204 12041252	Injury, poisoning and procedural complications	Wrist fracture	08AUG2019	11SEP2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	28JUN2020 01JAN2000	17AUG2020 31DEC2006	N N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	08AUG2019	08AUG2019	N
	C4591001 1204 12041253	General disorders and administration site conditions	Injury associated with device	01JAN1991	31DEC1991	N
		Infections and infestations	Ear infection	01JAN1982	31DEC1984	N
		Surgical and medical procedures	Ear tube insertion	01JAN1984	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Removal of foreign body Rotator cuff syndrome	01JAN1991 01JAN2011	31DEC1991 31DEC2011	N N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rotator cuff repair	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	20SEP2020		Y
	C4591001 1204 12041256	Vascular disorders	Hypertension	15FEB2018		Y
	C4591001 1204 12041257	Eye disorders	Myopia	01JAN2011	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Photorefractive keratectomy	01JAN2016	31DEC2016	N
	C4591001 1204 12041258	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1204 12041259	Psychiatric disorders	Anxiety	15MAY2020		Y
	C4591001 1204 12041260	Infections and infestations	Appendicitis	01SEP1994	30SEP1994	N
		Investigations	Smear cervix abnormal	01OCT2011	31OCT2011	N
		Surgical and medical procedures	Appendicectomy	01SEP1994	30SEP1994	N
			Loop electrosurgical excision procedure	01OCT2011	31OCT2011	N
	C4591001 1204 12041262	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1204 12041263	Infections and infestations	Ear infection	01JAN1973	31DEC1973	N
			Pharyngitis streptococcal	01JAN1973	31DEC1973	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Adenoidectomy	01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1204 12041264	Immune system disorders	Orchidectomy	01JAN1993	31DEC1993	N	
			Mite allergy	01JAN1975		Y	
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2006	31DEC2006	N	
		Musculoskeletal and connective tissue disorders	Foot fracture	01JAN2003	31DEC2003	N	
			Chondropathy	01JAN2019	31DEC2019	N	
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN1994	31DEC1994	N	
		Surgical and medical procedures	Caesarean section	01JAN2008	31DEC2008	N	
				01JAN2009	31DEC2009	N	
				Knee operation	01JAN2006	31DEC2006	N
					01JAN2019	31DEC2019	N
				Nasal septal operation	01JAN1986	31DEC1986	N
				Ostectomy	01JAN2003	31DEC2003	N
				Salpingo-oophorectomy	01JAN1994	31DEC1994	N
				Turbinectomy	01JAN1986	31DEC1986	N
	C4591001 1204 12041265	Psychiatric disorders	Anxiety	01JAN2013		Y	
		Vascular disorders	Hypertension	01JAN2017		Y	
	C4591001 1204 12041267	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2009	31DEC2009	N	
				Hip fracture	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01DEC2018		Y	
				Attention deficit hyperactivity disorder	01FEB2020		Y
				Depression	01DEC2018		Y
		Surgical and medical procedures	Hip surgery	01SEP2009	30SEP2009	N	
				Shoulder operation	01SEP2009	30SEP2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041268	Gastrointestinal disorders	Tooth impacted	01JAN2010	31DEC2010	N
		Infections and infestations	Ear infection	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1998	31DEC1998	N
			Wisdom teeth removal	01JAN2010	31DEC2010	N
	C4591001 1204 12041269	Cardiac disorders	Coronary artery occlusion	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1204 12041270	Eye disorders	Strabismus	01JAN1974	31DEC1979	N
		Infections and infestations	Streptococcal infection	01JAN1983	31DEC1984	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1984	31DEC1984	N
			Mammoplasty	01JAN2010	31DEC2010	N
			Meniscus operation	01JAN2004	31DEC2004	N
			Strabismus correction	01JAN1979	31DEC1979	N
	C4591001 1204 12041271	Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Ankle operation	01JAN1995	31DEC1995	N
	C4591001 1204 12041272	Gastrointestinal disorders	Gastroesophageal reflux disease	24SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041273	Immune system disorders	Seasonal allergy	01JAN1996		Y
	C4591001 1204 12041274	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN1992		Y
		Eye disorders	Strabismus	01JAN1974	31DEC1987	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Reproductive system and breast disorders	Prostatitis	01JAN1987		Y
		Surgical and medical procedures	Eye muscle operation	01JAN1974	31DEC1974	N
				01JAN1987	31DEC1987	N
	C4591001 1204 12041276	Gastrointestinal disorders	Barrett's oesophagus	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN2017		Y
			Haemorrhoids	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Haemorrhoid operation	01JAN2015	31DEC2015	N
			Liposuction	01JAN2015	31DEC2015	N
			Rhinoplasty	01JAN2010	31DEC2010	N
	C4591001 1204 12041279	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Chronic sinusitis	01OCT2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Polycystic ovaries	01JAN2007		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN2007	31DEC2007	N
	C4591001 1204 12041280	Injury, poisoning and procedural complications	Stress fracture	01JAN2011	31DEC2020	N
	C4591001 1204 12041281	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Surgical and medical procedures	Myomectomy	01JAN2010	31DEC2010	N
	C4591001 1204 12041283	Congenital, familial and genetic disorders	Non-compaction cardiomyopathy	(b) (6) 1992		Y
	C4591001 1204 12041284	Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2018		Y
			Rosacea	01JAN2004		Y
	C4591001 1204 12041287	Gastrointestinal disorders	Abdominal hernia	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2018	31DEC2018	N
			Tendon sheath incision	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1204 12041288	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Bipolar disorder	01JAN2018		Y
	C4591001 1204 12041290	Congenital, familial and genetic disorders	Thyroglossal cyst	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1204 12041292	Surgical and medical procedures	Thyroglossal cyst excision	01JAN2003	31DEC2003	N	
		Ear and labyrinth disorders	Meniere's disease	01JAN2014		Y	
	C4591001 1204 12041293	Gastrointestinal disorders	Abdominal hernia	01JAN1977	31DEC1977	N	
		Musculoskeletal and connective tissue disorders	Bone disorder	01JAN2013	31DEC2013	N	
			Foot deformity	01JAN1999	31DEC2000	N	
		Surgical and medical procedures	Abdominal hernia repair	01JAN1977	31DEC1977	N	
			Bunion operation	01JAN1999	31DEC1999	N	
				01JAN2000	31DEC2000	N	
			Osteotomy	01JAN2013	31DEC2013	N	
			Vestibular apparatus operation	01DEC2014	31DEC2014	N	
			Infections and infestations	Herpes zoster	01JAN2019	31DEC2019	N
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN2000	31DEC2000	N
	C4591001 1204 12041294	Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N	
			Caesarean section	01JAN2015	31DEC2015	N	
				01JAN2017	31DEC2017	N	
			Infections and infestations	Herpes simplex	01JAN2019		Y
	C4591001 1204 12041294	Psychiatric disorders	Anxiety	01JAN2018		Y	
			Depression	01JAN2018		Y	
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2009		Y	
	C4591001 1205 12051003	Skin and subcutaneous tissue disorders	Acne	23OCT2017		Y	
		Surgical and medical procedures	Ear tube insertion	01JAN1993	01JAN1993	N	
	C4591001 1205 12051004	Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1205 12051012	Surgical and medical procedures	Limb operation	01JAN2016		Y
	C4591001 1205 12051013	Eye disorders	Strabismus	01JAN1978		Y
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N
			Meningitis	01JAN1978	31DEC1978	N
	C4591001 1205 12051014	Surgical and medical procedures	Caesarean section	01JUL2005	01JUL2005	N
				11FEB2011	11FEB2011	N
	C4591001 1205 12051017	Psychiatric disorders	Panic disorder	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1205 12051021	Investigations	Blood zinc decreased	14OCT2020		Y
			Vitamin B12 decreased	14OCT2020		Y
		Metabolism and nutrition disorders	Insulin resistance	14OCT2020		Y
		Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Liposuction	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2000	31DEC2000	N
	C4591001 1205 12051023	Injury, poisoning and procedural complications	Wrist fracture	01APR2019	01MAY2019	N
		Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
	C4591001 1205 12051026	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN2017	01JAN2017	N
			Nasal operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1205 12051027	Surgical and medical procedures	Tetralogy of Fallot repair	01JAN1985	31DEC1985	N
	C4591001 1205 12051032	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Social circumstances	Menopause	01APR2020		Y
	C4591001 1205 12051035	Psychiatric disorders	Anxiety disorder	01JAN2016		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
	C4591001 1205 12051036	Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2000		Y
	C4591001 1205 12051041	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01FEB2000	29FEB2000	N
		Social circumstances	Menopause	01MAR2016	31MAR2016	N
		Surgical and medical procedures	Caesarean section	01JAN2013		Y
				01MAR2004	31MAR2004	N
				01MAR2008	31MAR2008	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Tympanoplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1205 12051043	Congenital, familial and genetic disorders	Thalassaemia minor	(b) (6) 1978		Y
	C4591001 1205 12051044	Endocrine disorders	Autoimmune thyroiditis	01JUN2020		Y
	C4591001 1205 12051047	Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN1996	31DEC1996	N
		Psychiatric disorders	Depression	11OCT2020		Y
		Vascular disorders	Deep vein thrombosis	01JAN2016		Y
			Hypertension	01JAN2016		Y
	C4591001 1205 12051048	Psychiatric disorders	Anxiety disorder	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1205 12051049	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1205 12051050	Psychiatric disorders	Anxiety disorder	01JAN2019		Y
	C4591001 1205 12051054	Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1205 12051065	Nervous system disorders	Migraine	01JAN2018		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1205 12051068	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1205 12051073	Investigations	Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1205 12051077	Musculoskeletal and connective tissue disorders	Neck mass	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1205 12051079	Endocrine disorders	Hypothyroidism	(b) (6) 2000		Y
	C4591001 1205 12051080	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2019		Y
	C4591001 1207 12071002	Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y
		Gastrointestinal disorders	Gastritis	01JAN2015		Y
		Surgical and medical procedures	Coronary artery surgery	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1207 12071006	Vascular disorders	Hypertension	01JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1207 12071007	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1207 12071010	Nervous system disorders	Epilepsy	01JAN2010		Y
	C4591001 1207 12071011	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1207 12071012	Investigations	Hepatitis B antibody positive	01JAN2010		Y
	C4591001 1207 12071013	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1207 12071018	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2015		Y
	C4591001 1207 12071021	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1207 12071023	Psychiatric disorders	Generalised anxiety disorder	01APR2020		Y
	C4591001 1207 12071026	Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2019		Y
	C4591001 1207 12071027	Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1207 12071028	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1207 12071032	Investigations	Blood thyroid stimulating hormone increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1207 12071033	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1207 12071037	Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1207 12071038	Cardiac disorders	Arrhythmia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1207 12071041	Surgical and medical procedures	Thyroid operation	01JAN2008	31DEC2008	N
	C4591001 1207 12071044	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1207 12071047	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1207 12071052	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1207 12071053	Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y
	C4591001 1207 12071064	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1207 12071065	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1208 12081001	Metabolism and nutrition disorders	Insulin resistance	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	24JUL2013	31DEC2013	N
	C4591001 1208 12081003	Surgical and medical procedures	Female sterilisation	01JAN2014		Y
	C4591001 1208 12081004	Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1208 12081005	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1208 12081007	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1208 12081010	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1208 12081011	Psychiatric disorders	Panic attack	01DEC2016		Y
	C4591001 1208 12081013	Nervous system disorders	Cerebral haemorrhage	01JAN2001	31DEC2001	N
	C4591001 1208 12081016	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1208 12081020	Surgical and medical procedures	Female sterilisation	16DEC2008		Y
	C4591001 1208 12081021	Gastrointestinal disorders	Gastritis	01JAN2000		Y
	C4591001 1208 12081022	Immune system disorders	Seasonal allergy	01JAN1999		Y
	C4591001 1208 12081024	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Chronic obstructive pulmonary disease	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1208 12081025	Ear and labyrinth disorders	Auditory disorder	01JAN1980		Y
	C4591001 1208 12081026	Infections and infestations	Hepatitis A	01JAN1979	31DEC1979	N
	C4591001 1208 12081027	Infections and infestations	Hordeolum	26OCT2020	12NOV2020	N
	C4591001 1208 12081028	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1208 12081031	Cardiac disorders	Tachycardia	01SEP2020		Y
	C4591001 1208 12081035	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1208 12081039	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1208 12081040	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1208 12081042	Congenital, familial and genetic disorders	Familial mediterranean fever	01JAN2010		Y
		Social circumstances	Menopause	01MAY2020		Y
	C4591001 1208 12081043	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1208 12081044	Surgical and medical procedures	Intrauterine contraception	01OCT2016		Y
	C4591001 1208 12081047	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Essential thrombocythaemia	01JAN2012		Y
	C4591001 1208 12081048	Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1995		Y
	C4591001 1208 12081049	Surgical and medical procedures	Hysterectomy	01JAN2018		Y
	C4591001 1208 12081050	Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Oophorectomy	01JAN2014	31DEC2014	N
	C4591001 1208 12081052	Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intrauterine contraception	01JUN2020		Y
	C4591001 1208 12081053	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	08AUG2011	31AUG2011	N
	C4591001 1208 12081054	Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01APR2018		Y
	C4591001 1209 12091001	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1209 12091002	Cardiac disorders	Atrial tachycardia	10JUL2020		Y
		Surgical and medical procedures	Bartholin's cyst removal	10JUL2020	10JUL2020	N
			Eye laser surgery	01JAN2012	31DEC2012	N
	C4591001 1209 12091003	Investigations	Cystoscopy normal	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2015	31DEC2015	N
	C4591001 1209 12091004	Immune system disorders	Sarcoidosis	01JAN2009		Y
		Investigations	Bronchoscopy	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Rhinoplasty	01JAN2004	31DEC2004	N
	C4591001 1209 12091006	Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1985	31DEC1985	N
	C4591001 1209 12091007	Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
	C4591001 1209 12091008	Musculoskeletal and connective tissue disorders	Osteolysis	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1209 12091009	Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1209 12091010	Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1990		Y
	C4591001 1209 12091011	Musculoskeletal and connective tissue disorders	Chronic obstructive pulmonary disease Intervertebral disc protrusion	01JAN1998 01JAN2012	31DEC2012	Y N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Menopause	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1209 12091015	Social circumstances	Menopause	01JAN2019		Y
	C4591001 1209 12091016	Ear and labyrinth disorders	Vertigo	01OCT2020		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1209 12091017	Eye disorders	Visual impairment	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Toe amputation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1209 12091018	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
	C4591001 1209 12091019	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
	C4591001 1209 12091020	Investigations	Mediastinoscopy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1209	Surgical and medical procedures	Nasal septal operation	01JAN1998	31DEC1998	N
	12091021	Surgical and medical procedures	Haemorrhoid operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1210	Endocrine disorders	Autoimmune thyroiditis	01JAN2006		Y
	12101002					
	C4591001 1210	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
	12101006					
		Nervous system disorders	Tension headache	01FEB2020		Y
	C4591001 1210	Cardiac disorders	Pericarditis	01MAY2020	31MAY2020	N
	12101009					
	C4591001 1210	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	12101013					
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1210	Vascular disorders	Hypertension	26OCT2019		Y
	12101014					
	C4591001 1210	Cardiac disorders	Pericarditis	01MAY2020	31AUG2020	N
	12101015					
	C4591001 1210	Cardiac disorders	Coronary artery disease	01JAN2000		Y
	12101018					
	C4591001 1210	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAR2020		Y
	12101020					
	C4591001 1210	Congenital, familial and genetic disorders	Familial mediterranean fever	01AUG2020		Y
	12101021					
	C4591001 1210	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	12101024					
	C4591001 1210	Vascular disorders	Hypertension	01JAN2019		Y
	12101027					



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1210 12101030	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2020		Y
	C4591001 1210 12101033	Endocrine disorders	Hypoparathyroidism	01JAN2018		Y
	C4591001 1210 12101039	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1210 12101041	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
	C4591001 1210 12101045	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1210 12101049	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1210 12101053	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer stage III	01JAN2013	31DEC2013	N
	C4591001 1210 12101054	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
	C4591001 1210 12101059	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
	C4591001 1210 12101060	Surgical and medical procedures	Female sterilisation	01JAN2015		Y
	C4591001 1210 12101061	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1212 12121001	Surgical and medical procedures	Gallbladder operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1212 12121002	Metabolism and nutrition disorders	Obesity	22OCT2020		Y
	C4591001 1212 12121004	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1212 12121006	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1212 12121007	Psychiatric disorders	Post-traumatic stress disorder	01JAN2015		Y
			Selective eating disorder	01JAN2019		Y
	C4591001 1212 12121010	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1212 12121011	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1212 12121014	Blood and lymphatic system disorders	Immune thrombocytopenia	08JAN2013	23JUL2013	N
		Surgical and medical procedures	Splenectomy	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1212 12121017	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1212 12121020†	Investigations	HIV test positive	01JAN2018		Y
	C4591001 1212 12121022	Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1212 12121028	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1212 12121029	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2010		Y
	C4591001 1212 12121031	Vascular disorders Metabolism and nutrition disorders	Hypertension Type 2 diabetes mellitus	01JAN2015 01JAN2010		Y Y
	C4591001 1212 12121034	Vascular disorders Vascular disorders	Hypertension Hypertension	01JAN2015 01JAN2012		Y Y
	C4591001 1213 12131005	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1213 12131010	Surgical and medical procedures	Gallbladder operation	01SEP2020	30SEP2020	N
	C4591001 1213 12131019	Surgical and medical procedures	Mitral valve replacement	01JAN2016	31DEC2016	N
	C4591001 1213 12131052	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1213 12131055	Vascular disorders Vascular disorders	Hypertension Hypertension	01JAN2016 01JAN2017		Y Y
	C4591001 1213 12131056	Psychiatric disorders	Insomnia	01DEC2018		Y
	C4591001 1213 12131060	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
	C4591001 1214 12141001	Nervous system disorders	Migraine	01JAN2011		Y
	C4591001 1214 12141004	Surgical and medical procedures Congenital, familial and genetic disorders	Inguinal hernia repair Renal aplasia	01JAN1984 (b) (6) 1968	31DEC1984	N Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
			Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Cholecystectomy	01DEC2011	31DEC2011	N
			Tendon sheath incision	01JAN2018	31DEC2018	N
	C4591001 1214 12141005	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1214 12141007	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2012		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2015	31DEC2015	N
	C4591001 1214 12141013	Nervous system disorders	Migraine	01JAN2007		Y
		Psychiatric disorders	Affective disorder	01APR2019		Y
	C4591001 1214 12141014	Renal and urinary disorders	Neurogenic bladder	01JAN2016		Y
			Urethral stenosis	01JAN2016		Y
	C4591001 1214 12141016	Surgical and medical procedures	Thyroidectomy	01JAN2016		Y
	C4591001 1214 12141018	Surgical and medical procedures	Intervertebral disc operation	01JAN2010	31DEC2010	N
	C4591001 1214 12141020	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1985		Y
	C4591001 1214 12141025	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1214 12141031	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2002		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1214 12141034	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1214 12141036	Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2004		Y
	C4591001 1214 12141038	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Exeresis	01JAN2019	31DEC2019	N
	C4591001 1214 12141041	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
	C4591001 1214 12141044	Ear and labyrinth disorders	Otosclerosis	01JAN2010		Y
		Surgical and medical procedures	Ear operation	01JAN2018	31DEC2018	N
	C4591001 1214 12141045	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1214 12141049	Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1214 12141051	Endocrine disorders	Autoimmune thyroiditis	01JAN2014		Y
	C4591001 1217 12171002	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1991		Y
	C4591001 1217 12171003	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	01JAN2010		Y
	C4591001 1217 12171005†	Investigations	HIV test positive	18JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	31DEC2019		Y
		Surgical and medical procedures	Nephrectomy	31DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1217 12171010	Congenital, familial and genetic disorders	Familial mediterranean fever	01JAN1985		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1217 12171014	Cardiac disorders	Myocardial ischaemia	01JAN2010		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1217 12171015†	Investigations	HIV test positive	14JUN2016		Y
		Psychiatric disorders	Anxiety	01OCT2012		Y
	C4591001 1217 12171017	Gastrointestinal disorders	Gastric ulcer	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
	C4591001 1217 12171018	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1217 12171020	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Social circumstances	Postmenopause	01JUL2019		Y
	C4591001 1217 12171023	Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1217 12171037	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1217 12171039	Investigations	Blood cholesterol increased	01JAN2020		Y
	C4591001 1217 12171040	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1217 12171041	Psychiatric disorders	Bipolar disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1217 12171047	Metabolism and nutrition disorders	Insulin resistance	25JAN2019		Y
	C4591001 1217 12171048	Vascular disorders	Varicose vein	01SEP2020		Y
	C4591001 1217 12171050	Endocrine disorders	Autoimmune thyroiditis	01JAN2008		Y
	C4591001 1217 12171055	Metabolism and nutrition disorders	Hyperglycaemia	01MAR2020		Y
	C4591001 1217 12171059	Vascular disorders	Hyperlipidaemia Hypertension	01JAN2019 01JAN2013		Y Y
	C4591001 1217 12171061	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1217 12171062	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
	C4591001 1218 12181001	Cardiac disorders	Supraventricular tachycardia	24APR2003	24APR2003	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	15AUG2014	30APR2020	N
		Hepatobiliary disorders	Cholelithiasis	09MAR2020	21JAN2021	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	31JUL2019		Y
			Obesity	17DEC2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15AUG2014		Y
		Surgical and medical procedures	Hernia hiatus repair	01SEP2018	30SEP2018	N
	C4591001 1218 12181004	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
	C4591001 121812181005	Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	26AUG2002		Y
	C4591001 121812181006	Surgical and medical procedures	Fracture treatment	11DEC2013	11DEC2013	N
		Immune system disorders	Seasonal allergy	14FEB2020		Y
	C4591001 121812181007	Nervous system disorders	Febrile convulsion	27SEP1994	27SEP1994	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	26FEB2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	16JUN2003		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	21NOV2017		Y
			Hypercholesterolaemia	20OCT2004		Y
		Psychiatric disorders	Anxiety	01MAY1998		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2008	01FEB2008	N
		Vascular disorders	Hypertension	07APR2020		Y
	C4591001 121812181008	Investigations	Blood pressure increased	11JAN2019		Y
		Nervous system disorders	Headache	13OCT2020	13OCT2020	N
	C4591001 121812181009	Immune system disorders	Seasonal allergy	21JAN2020		Y
		Investigations	Blood cholesterol increased	21APR2020		Y
		Metabolism and nutrition disorders	Diabetes mellitus	21SEP2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	24JAN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
	C4591001 121812181011	Renal and urinary disorders	Nephrolithiasis	01JUL2018	31JUL2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 121812181012	Immune system disorders	Drug hypersensitivity	14OCT2020		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
		Surgical and medical procedures	Incisional drainage	15OCT2020	15OCT2020	N
				21OCT2020	21OCT2020	N
			Open reduction of fracture	07OCT2020	07OCT2020	N
	C4591001 121812181013	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Furuncle	29OCT2018		Y
		Metabolism and nutrition disorders	Obesity	26MAY1993		Y
		Nervous system disorders	Headache	31MAR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1993		Y
	C4591001 121812181014	Immune system disorders	Allergic oedema	01JAN2010		Y
			Allergy to arthropod sting	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
	C4591001 121812181016	Nervous system disorders	Migraine	14JAN2015		Y
		Surgical and medical procedures	Caesarean section	26APR2014	26APR2014	N
	C4591001 121812181017	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
	C4591001 121812181018	Immune system disorders	Seasonal allergy	27OCT2016		Y
		Metabolism and nutrition disorders	Diabetes mellitus	12NOV2020		Y
		Nervous system disorders	Migraine	23SEP2014	23SEP2014	N
		Psychiatric disorders	Anxiety	15FEB2019		Y
			Depression	15FEB2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	17AUG2015		Y
		Surgical and medical procedures	Bunion operation	24JAN2017	24JAN2017	N
			Caesarean section	08APR2012	08APR2012	N
	C4591001 121812181019	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	24NOV1997		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	24SEP2012		Y
		Psychiatric disorders	Depression	09DEC2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Knee operation	01JAN2017	31DEC2017	N
	C4591001 121812181022	Injury, poisoning and procedural complications	Ulna fracture	09AUG2020	09SEP2020	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1998		Y
		Surgical and medical procedures	Fracture treatment	14SEP2020	14SEP2020	N
	C4591001 121812181023	Blood and lymphatic system disorders	Iron deficiency anaemia	20JUN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
	C4591001 121812181025	Immune system disorders	Drug hypersensitivity	07SEP2015		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	25AUG2014		Y
			Obesity	01FEB2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal adenoma	01MAR2020		Y
		Nervous system disorders	Migraine	10APR2016		Y
		Psychiatric disorders	Depression	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	06SEP2015	11SEP2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	07SEP2015		Y
		Surgical and medical procedures	Female sterilisation	01MAR2006	01MAR2006	N
			Hernia repair	01FEB2014	28FEB2014	N
	C4591001 1218 12181026	Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Seasonal allergy	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1997		Y
			Urticaria	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1218 12181027	Immune system disorders	Seasonal allergy	30JUL2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Psychiatric disorders	Anxiety	31OCT2019	31MAR2020	N
			Insomnia	01NOV2020		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2020		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	01JAN2009	N
				03APR2005	03APR2005	N
				16JUL2010	16JUL2010	N
				17AUG1996	17AUG1996	N
				26JUN2003	26JUN2003	N
			Endometrial ablation	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2019	31DEC2019	N
	C4591001 1218 12181028	Nervous system disorders	Migraine	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1218 12181030	Surgical and medical procedures	Open reduction of fracture	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	02JAN2008		Y
		Psychiatric disorders	Anxiety	29DEC2016	31DEC2018	N
	C4591001 1218 12181031	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	02FEB2012		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1985		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1996	01JAN1996	N
	C4591001 1218 12181032	Immune system disorders	Seasonal allergy	15FEB2015		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	05NOV2018	31DEC2019	N
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2017		Y
		Surgical and medical procedures	Jaw operation	06AUG2020	06AUG2020	N
	C4591001 1218 12181034	Immune system disorders	Drug hypersensitivity	08MAY2006		Y
				12MAR2001		Y
			Food allergy	06JUN2016		Y
			Seasonal allergy	01JAN2017		Y
		Infections and infestations	Pelvic inflammatory disease	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Nervous system disorders	Dizziness	12MAR2001		Y
		Psychiatric disorders	Depression	06JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Pruritus	08MAY2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urticaria	06JUN2016		Y
		Surgical and medical procedures	Caesarean section	04SEP2009	04SEP2009	N
				15MAY2001	15MAY2001	N
				31JUL2002	31JUL2002	N
			Ligament operation	01AUG2019	31AUG2019	N
				01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	14FEB2019	04NOV2020	N
	C4591001 1218 12181035	Eye disorders	Eye pruritus	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	14NOV2017		Y
		General disorders and administration site conditions	Pain	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Eye injury	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Open reduction of fracture	01JAN1995	31DEC2003	N
	C4591001 1218 12181036	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAY2014	29APR2015	N
	C4591001 1218 12181037	Immune system disorders	Drug hypersensitivity	01MAY1995		Y
				26DEC1996		Y
		Metabolism and nutrition disorders	Obesity	01SEP1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1218 12181039	Gastrointestinal disorders	Gastroesophageal reflux disease	19SEP2016		Y
		Immune system disorders	Allergy to metals	01JAN2005		Y
			Seasonal allergy	03JUN2014		Y
		Nervous system disorders	Migraine	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1218 12181041	Immune system disorders	Milk allergy	01JAN1975		Y
		Investigations	Blood cholesterol increased	12FEB2020		Y
		Metabolism and nutrition disorders	Obesity	05FEB1996		Y
		Surgical and medical procedures	Hernia repair	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1999	31DEC1999	N
	C4591001 1218 12181042	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2008		Y
				01JAN2019		Y
				18JUL2004		Y
			Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	21AUG1999		Y
		Nervous system disorders	Migraine	05SEP2019		Y
		Psychiatric disorders	Depression	10DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	02SEP2006	02SEP2006	N
				18DEC2011	18DEC2011	N
				21JUN2016	21JUN2016	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1218 12181043	Gastrointestinal disorders	Gastrooesophageal reflux disease	28APR2014		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Investigations	Blood cholesterol increased	16SEP2014		Y
			Cardiac murmur	01JAN1981		Y
		Metabolism and nutrition disorders	Diabetes mellitus	08APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	08JUN2016		Y
		Vascular disorders	Hypertension	08APR2019		Y
	C4591001 1218 12181044	Immune system disorders	Seasonal allergy	12JUN2018		Y
		Infections and infestations	Chlamydial infection	01JAN1988	31DEC1988	N
		Investigations	Blood cholesterol increased	18JUN2003		Y
		Metabolism and nutrition disorders	Obesity	14JUN2006		Y
			Type 2 diabetes mellitus	03DEC2003		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN1998	31DEC1998	N
		Psychiatric disorders	Depression	01JAN2015	31DEC2017	N
		Surgical and medical procedures	Abscess drainage	01JAN2016	31DEC2016	N
			Carpal tunnel decompression	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	04SEP2003		Y
	C4591001 1218 12181045	Immune system disorders	Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1992		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1218 12181046	Eye disorders	Glaucoma	24APR2014		Y
			Retinal detachment	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	04FEB2018		Y
		Infections and infestations	Rhinitis	01MAR2016		Y
		Metabolism and nutrition disorders	Diabetes mellitus	08JAN2020		Y
			Obesity	01MAY1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Eye operation	01JAN2012	31DEC2012	N
			Knee operation	01JAN1988	31DEC1988	N
	C4591001 1218 12181047	Immune system disorders	Allergy to animal	01JAN2008		Y
	C4591001 1218 12181048	Cardiac disorders	Aortic valve stenosis	23JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11MAY2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
		Surgical and medical procedures	Aorta coarctation repair	01JAN1986	31DEC1986	N
			Appendicectomy	25JAN2012	25JAN2012	N
			Gallbladder operation	25JAN2012	25JAN2012	N
	C4591001 1218 12181049	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN2010		Y
				01JAN2015		Y
				01JAN2017		Y
			Food allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1218 12181050	Immune system disorders	Seasonal allergy	25JAN2017		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Vascular disorders	Hypertension	09OCT2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1218 12181051	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2018		Y
			Drug hypersensitivity	18APR2002		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
			Cardiac murmur	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2015		Y
			Arthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Wheezing	01JAN2020		Y
		Surgical and medical procedures	Bladder operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2018	31JAN2018	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1218 12181052	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Cerebrovascular accident	04JUL2019	04JUL2019	N
			Seizure	04JUL2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1218 12181053	Immune system disorders	Drug hypersensitivity	16FEB2015		Y
	C4591001 1218 12181054	Musculoskeletal and connective tissue disorders	Back pain	01JUN2015		Y
		Psychiatric disorders	Anxiety	20AUG2019	31DEC2019	N
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
	C4591001 1218 12181055	Gastrointestinal disorders	Gastrooesophageal reflux disease	23JUN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Obesity	23NOV2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
	C4591001 1218 12181057	Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Hepatobiliary disorders	Cirrhosis alcoholic	01JUN2020		Y
			Hepatitis alcoholic	01MAY2020	30JUN2020	N
			Hepatorenal syndrome	16JUN2020	31AUG2020	N
		Metabolism and nutrition disorders	Obesity	07MAR2009		Y
			Type 2 diabetes mellitus	15OCT2020		Y
	C4591001 1218 12181058	Nervous system disorders	Seizure	20NOV2014	17JUN2017	N
		Ear and labyrinth disorders	Deafness unilateral	08JUL2015		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JUL2015	31JUL2015	N
		Metabolism and nutrition disorders	Obesity	13MAR1995		Y
		Psychiatric disorders	Depression	18MAY2019	31MAY2020	N
	C4591001 1218 12181059	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1219 12191001	Nervous system disorders	Migraine	01JAN2005		Y
		Immune system disorders	Hypersensitivity	01JAN2018	31DEC2018	N
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2017		Y
		Nervous system disorders	Headache	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	31JUL2013	31JUL2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ovarian neoplasm surgery	01JAN2010	31DEC2010	N
	C4591001 1219 12191002	Immune system disorders	Seasonal allergy	01JAN1991		Y
		Injury, poisoning and procedural complications	Blindness traumatic	01JAN1991		Y
			Head injury	01JAN1991	31DEC1991	N
			Road traffic accident	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Musculoskeletal pain	01JAN1991		Y
		Nervous system disorders	Post-traumatic headache	01JAN1991		Y
		Psychiatric disorders	Alcohol abuse	01JAN2003	31DEC2011	N
			Drug dependence	01JAN1991	31DEC2011	N
			Post-traumatic stress disorder	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1991		Y
			Sinus disorder	01JAN1991		Y
		Surgical and medical procedures	Detoxification	01JAN2011	31DEC2011	N
			Nasal septal operation	01DEC2018	31DEC2018	N
	C4591001 1219 12191003	Cardiac disorders	Palpitations	01JAN2017		Y
		Gastrointestinal disorders	Diverticulum	01JAN2019		Y
		Infections and infestations	Urinary tract infection	01JAN2013	31DEC2020	N
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Diabetic ketoacidosis	01JAN2017	31DEC2017	N
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Nervous system disorders	Muscle contractions involuntary	01SEP2020		Y
			Paraesthesia	01SEP2020		Y
		Psychiatric disorders	Depression	01JAN2013	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bladder lesion excision	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN1996		Y
	C4591001 1219 12191004	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Oral herpes	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN2016		Y
			Substance use	01JAN2015	31DEC2015	N
			Tobacco user	01JAN2018		Y
	C4591001 1219 12191013	Surgical and medical procedures	Tonsillectomy	01JAN2020	31DEC2020	N
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1219 12191014	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Renal and urinary disorders	Chronic kidney disease	16OCT2019		Y
		Social circumstances	Alcohol use	01JAN1990		Y
			Organ donor	16OCT2019	16OCT2019	N
		Surgical and medical procedures	Vasectomy	01JAN2008		Y
	C4591001 1219 12191016	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
			Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Depression	01AUG2020	30SEP2020	N
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1219 12191017	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Infections and infestations	Chlamydial infection	01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01FEB2020		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Surgical and medical procedures	Female sterilisation	01OCT2015		Y
	C4591001 1219 12191022	Ear and labyrinth disorders	Tinnitus	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Latent tuberculosis	01JAN1990	31DEC1993	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
			Post-traumatic stress disorder	01JAN2006		Y
		Social circumstances	Alcohol use	01JAN1989		Y
			Electronic cigarette user	01JAN2019		Y
			Tobacco user	01JAN2019		Y
		Surgical and medical procedures	Antibiotic prophylaxis	01JAN1992	31DEC1993	N
	C4591001 1219 12191023	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Muscle strain	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010	31DEC2011	N
		Nervous system disorders	Tension headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
			Depression	01JAN2009		Y
		Social circumstances	Substance use	01JAN2000		Y
		Surgical and medical procedures	Ligament operation	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1219 12191024	Skin and subcutaneous tissue disorders	Drug eruption	01JAN1988		Y
		Surgical and medical procedures	Pilonidal sinus repair	01OCT2010	31OCT2010	N
	C4591001 1219 12191026	Hepatobiliary disorders	Gallbladder disorder	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1992	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Fracture treatment	01SEP2008	30SEP2008	N
	C4591001 1219 12191028	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2015		Y
	C4591001 1219 12191029	Infections and infestations	Chlamydial infection	01JAN2020	31JAN2020	N
		Reproductive system and breast disorders	Vaginal haemorrhage	01OCT2020		Y
	C4591001 1219 12191030	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Food allergy	01JAN1976		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Retinopexy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1219 12191033	Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Investigations	Seasonal allergy	01JAN2018		Y
			Cardiac murmur	01JAN2005		Y
			Colonoscopy	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1219 12191034	Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	01JAN1992	31DEC1992	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
		Social circumstances	Tobacco user	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Retinopexy	01JAN2010	31DEC2010	N
	C4591001 1219 12191035	Blood and lymphatic system disorders	Anaemia	01JAN2007	31DEC2008	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2015		Y
		Infections and infestations	Vaginitis chlamydial	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Exposure to communicable disease	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Antibiotic prophylaxis	01JAN1990	31DEC1991	N
			Cholecystectomy	01JAN1997	31DEC1997	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1219 12191039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN1980		Y
	C4591001 1219 12191040	Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1219 12191042	Nervous system disorders	Headache	01JAN2000		Y
		Hepatobiliary disorders	Gallbladder disorder	01NOV2012	30NOV2012	N
		Infections and infestations	Genital herpes	01NOV2018	30NOV2018	N
			Otitis externa	12NOV2020	16NOV2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1219 12191044	Surgical and medical procedures	Cholecystectomy	01NOV2012	30NOV2012	N
		Ear and labyrinth disorders	Hypoacusis	01JAN1981		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Meningitis	01JAN1981	31DEC1981	N
		Respiratory, thoracic and mediastinal disorders	Paranasal cyst	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Intervertebral disc operation	01OCT2011	31OCT2011	N
			Sinus operation	01JAN1995	31DEC1995	N
	C4591001 1219 12191047	Hepatobiliary disorders	Gallbladder disorder	01JAN2008	30JUN2009	N
		Surgical and medical procedures	Cholecystectomy	01JUN2009	30JUN2009	N
	C4591001 1219 12191048	Blood and lymphatic system disorders	Anaemia	01APR2020		Y
		Ear and labyrinth disorders	Vertigo positional	01JAN1995	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN1996		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diverticulum	01AUG2020		Y
			Gastroesophageal reflux disease	01JAN2001	31DEC2005	N
		General disorders and administration site conditions	Oedema peripheral	01AUG2020		Y
		Hepatobiliary disorders	Gallbladder disorder	01MAR2017	31MAR2017	N
			Liver disorder	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Vaginitis chlamydial	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01SEP2019		Y
		Nervous system disorders	Migraine	01JAN1997	31DEC2018	N
		Reproductive system and breast disorders	Amenorrhoea	01JAN1995		Y
			Ovarian cyst	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01MAR2017	31MAR2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1219 12191049	Eye disorders	Vitreous floaters	01JAN2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000	31DEC2015	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cholecystectomy	01MAR2003	31MAY2003	N
	C4591001 1219 12191050	Gastrointestinal disorders	Gastric ulcer	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Gallbladder disorder	01MAR2014	31AUG2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
	C4591001 1219 12191051	Surgical and medical procedures	Cholecystectomy	01AUG2014	31AUG2014	N
		Cardiac disorders	Myocardial infarction	01DEC2018	31DEC2018	N
		Ear and labyrinth disorders	Tinnitus	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1975	31DEC2018	N
		Surgical and medical procedures	Coronary arterial stent insertion	01DEC2018	31DEC2018	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01FEB2006	28FEB2006	N
	C4591001 1219 12191053	Gastrointestinal disorders	Abdominal pain	01JUL2020	31JUL2020	N
			Gastroesophageal reflux disease	01JAN1995		Y
		Hepatobiliary disorders	Hyperbilirubinaemia	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Helicobacter infection	01JUL2020	31JUL2020	N
		Injury, poisoning and procedural complications	Repetitive strain injury	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1995		Y
	C4591001 1219 12191054	Congenital, familial and genetic disorders	Congenital spinal stenosis	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1993		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Back pain	01JAN2007		Y
			Lumbar spinal stenosis	01JAN2007	31DEC2011	N
		Surgical and medical procedures	Contraceptive implant	01JAN2017		Y
			Intervertebral disc operation	01JUN2011	30JUN2011	N
			Tonsillectomy	01JAN2009	31DEC2009	N
	C4591001 1219 12191056	Hepatobiliary disorders	Cholelithiasis	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Oral allergy syndrome	01JAN2017		Y
			Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Sjogren's syndrome	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	18FEB2020	18FEB2020	N
			Female sterilisation	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1219 12191058	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 1219 12191059	Eye disorders	Dry eye	01JAN2018		Y
			Glaucoma	23NOV2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Coeliac disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2011		Y
			Seasonal allergy	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Blood pressure increased	01JAN2018		Y
			Colonoscopy	01JAN2014	31DEC2014	N
			Endoscopy upper gastrointestinal tract	01JAN2016	31DEC2016	N
			HLA-B*27 positive	01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Obesity	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
			Back pain	01JAN2011		Y
			Intervertebral disc protrusion	01JAN2014	31DEC2015	N
			Lumbar spinal stenosis	01JAN2011		Y
			Spinal osteoarthritis	01JAN2017		Y
			Tenosynovitis stenosans	01JAN2012	31DEC2012	N
		Nervous system disorders	Cervical radiculopathy	01JAN2017		Y
			Sinus headache	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2020		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1996		Y
			Limb operation	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN2016	31DEC2016	N
	C4591001 1219 12191062	Congenital, familial and genetic disorders	Phimosis	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Anogenital dysplasia	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JUN2020		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Anorectal human papilloma virus infection	01JAN2015		Y
			Chlamydial infection	01JAN2017	31DEC2017	N
			Clostridium difficile infection	01JAN2016	31DEC2018	N
		Injury, poisoning and procedural complications	Back injury	12NOV2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15JUN2020		Y
		Nervous system disorders	Facial paralysis	01JAN2016	31DEC2016	N
			Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Social circumstances	Tobacco user	01JAN1990		Y
		Surgical and medical procedures	Circumcision	01JAN2017	31DEC2017	N
			Open reduction of fracture	15JUN2020	15JUN2020	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1220 12201003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020	08SEP2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2017		Y
		Infections and infestations	Chlamydial infection	20JUN2016	07JUL2016	N
		Pregnancy, puerperium and perinatal conditions	Delivery	04JAN2017	06JAN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				14SEP2011	16SEP2011	N
		Psychiatric disorders	Suicide attempt	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Acne	29JAN2019	31DEC2019	N
		Surgical and medical procedures	Open reduction of fracture	29NOV2011	29NOV2011	N
	C4591001 1220 12201004	Hepatobiliary disorders	Cholecystitis	14AUG2017	15AUG2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016	31DEC2017	N
	C4591001 1220 12201009	Blood and lymphatic system disorders	Anaemia	01JAN2006	28SEP2020	N
		Infections and infestations	Chlamydial infection	19APR2017	15JUN2017	N
			Herpes virus infection	12AUG2020		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2006		Y
	C4591001 1220 12201012	Immune system disorders	Allergy to animal	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2014	31DEC2017	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2014		Y
		Surgical and medical procedures	Tooth extraction	02JUL2019	02JUL2019	N
	C4591001 1220 12201013	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Chlamydial infection	13OCT2011	13OCT2011	N
		Investigations	Blood cholesterol increased	15FEB2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	18JAN2018		Y
		Surgical and medical procedures	Caesarean section	01APR2012	30APR2012	N
			Knee operation	01JAN2006	31DEC2006	N
			Oral surgery	01JAN1996	31DEC1996	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1220 12201015	Hepatobiliary disorders	Hepatic steatosis	01JUL2018		Y
		Immune system disorders	Food allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2019		Y
			Obesity	01APR2018		Y
		Psychiatric disorders	Anxiety	01JAN2016	31DEC2016	N
			Depression	01JAN2004	31AUG2018	N
			Major depression	01DEC2016	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	14NOV2019	14NOV2019	N
			Caesarean section	15NOV2018	15NOV2018	N
			Medical device removal	02NOV2017	02NOV2017	N
	C4591001 1220 12201017	Immune system disorders	Allergy to animal	01JAN2014		Y
			Seasonal allergy	01JAN2018		Y
	C4591001 1220 12201018	Ear and labyrinth disorders	Deafness neurosensory	01JAN2010		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2014	14DEC2014	N
		Investigations	Blood cholesterol increased	01FEB2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1992	31DEC2020	N
		Nervous system disorders	Migraine with aura	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2009	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	15DEC2014	15DEC2014	N
		Vascular disorders	Hypertension	01JAN2019	31DEC2020	N
	C4591001 1220 12201020	Infections and infestations	Chlamydial infection	13MAR2020	17MAR2020	N
				17JUN2011	17JUN2011	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	13AUG2020		Y
	C4591001 1220 12201021	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	31DEC2019	N
	C4591001 1220 12201022	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC1997	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
		Surgical and medical procedures	Finger amputation	01JAN2007		Y
			Wound closure	01JAN2019	31DEC2019	N
	C4591001 1220 12201024	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985	31DEC1999	N
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
			Female sterilisation	01JAN2009	31DEC2009	N
	C4591001 1220 12201025	Blood and lymphatic system disorders	Anaemia	01MAY2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2016	29FEB2016	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Chlamydial infection	03MAR2017	02MAY2017	N
				13SEP2016	20SEP2016	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAY2017		Y
			Obesity	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2016	29FEB2016	N
			Female sterilisation	01SEP2018	30SEP2018	N
	C4591001 1220 12201026	Immune system disorders	Allergy to plants	01JAN2004		Y
		Infections and infestations	Chlamydial infection	15OCT2018	19OCT2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Nervous system disorders	Neuralgia	01JAN2012	31DEC2018	N
		Psychiatric disorders	Alcoholism	01JAN2017	31DEC2018	N
			Anxiety	01JAN2008	31DEC2012	N
			Depression	01JAN2008	31DEC2012	N
		Social circumstances	Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Fasciotomy	01JAN2012	31DEC2012	N
			Open reduction of fracture	01JAN2012	31DEC2012	N
	C4591001 1220 12201027	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2004	31DEC2010	N
		Infections and infestations	Oral herpes	01JAN2002		Y
		Surgical and medical procedures	Ligament operation	01JAN2006	31DEC2014	N
	C4591001 1220 12201028	Congenital, familial and genetic disorders	Kidney malformation	01JAN1988		Y
		Immune system disorders	Rubber sensitivity	01JAN1994	31DEC2010	N
		Surgical and medical procedures	Nephrectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1220 12201029	Ear and labyrinth disorders	Vestibular disorder	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sinus disorder	01JAN2000	31DEC2018	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
			Turbinectomy	01JAN2018	31DEC2018	N
	C4591001 1220 12201030	Gastrointestinal disorders	Coeliac disease	01FEB2020		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2002		Y
			Rubber sensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2006		Y
		Infections and infestations	Ear infection	01DEC1985	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Spondylitis	01JAN2019		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1220 12201031	Surgical and medical procedures	Open reduction of fracture	01JAN2000	31DEC2000	N
	C4591001 1220 12201032	Endocrine disorders	Hypothyroidism	01JAN2008	31MAY2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1989		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1220 12201033	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Hepatobiliary disorders	Hepatic steatosis	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Chlamydial infection	01AUG2016	31AUG2016	N
			Herpes zoster	01NOV2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01FEB2020	31AUG2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1220 12201035	Blood and lymphatic system disorders	Anaemia	01JAN2013	31DEC2019	N
		Endocrine disorders	Secondary hypogonadism	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2012		Y
		Surgical and medical procedures	Eyelid cyst removal	01JAN1985	31DEC1985	N
	C4591001 1220 12201036	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2012	31JAN2020	N
	C4591001 1220 12201037	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015	31DEC2016	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018	31DEC2020	N
	C4591001 1220 12201039	Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2004		Y
		Nervous system disorders	Migraine with aura	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2011	31DEC2011	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Perinatal depression	12NOV2018	31JAN2020	N
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2016	31DEC2016	N
				04OCT2018	04OCT2018	N
			Female sterilisation	04OCT2020	04OCT2020	N
	C4591001 1220 12201041	Blood and lymphatic system disorders	Anaemia	01JAN2014	31DEC2014	N
		Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Immune system disorders	Rubber sensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2001	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN1992	31DEC2018	N
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN1992	31DEC2018	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2003		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN1996	31DEC1996	N
			Peripheral nerve decompression	01FEB2020	31DEC2020	N
			Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1220 12201042	Hepatobiliary disorders	Gallbladder disorder	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01MAY2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2014		Y
		Reproductive system and breast disorders	Infertility	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1977		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2004	31AUG2004	N
			Knee arthroplasty	01MAY2008	31MAY2008	N
	C4591001 1220 12201043	Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01SEP2017		Y
		Nervous system disorders	Migraine	01JAN1980		Y
			Sciatica	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN1990	31DEC1992	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	10JAN2017	10JAN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	10JAN2017	10JAN2017	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1220 12201044	Cardiac disorders	Tachycardia	01JAN2002	31DEC2005	N
		Surgical and medical procedures	Ankle arthroplasty	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1220 12201045	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Oral herpes	01JAN2007		Y
		Psychiatric disorders	Sleep disorder	01OCT2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1220 12201047	Infections and infestations	Oral herpes	01JAN1984		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1220 12201048	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2006	31DEC2006	N
	C4591001 1220 12201050	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN1999	31DEC2001	N
			Thrombocytopenia	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01DEC2015	31DEC2015	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2013	31DEC2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1999		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pilonidal sinus repair	01JAN1999	31DEC1999	N
			Wrist surgery	01JUL2020	31JUL2020	N
	C4591001 1220 12201051	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2016		Y
	C4591001 1220 12201052	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1999	31DEC2002	N
	C4591001 1220 12201053	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Ear infection	01JAN1976	31DEC1976	N
		Social circumstances	Ex-tobacco user	01JAN1998	31DEC2002	N
		Surgical and medical procedures	Ear tube insertion	01JAN1976	31DEC1976	N
	C4591001 1220 12201056	Eye disorders	Iridocyclitis	01JAN2007		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
			Colonoscopy	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2014	20NOV2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Alcohol rehabilitation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1220 12201057	Surgical and medical procedures	Ligament operation	01OCT2018	31OCT2018	N
	C4591001 1220 12201059	Metabolism and nutrition disorders	Vitamin D deficiency	01FEB2017		Y
		Nervous system disorders	Paraesthesia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1220 12201061	Cardiac disorders	Mitral valve incompetence	23OCT2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1984		Y
		Investigations	Blood cholesterol increased	01DEC2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1997	31DEC2010	N
		Surgical and medical procedures	Renal stone removal	01JAN2010	31DEC2010	N
	C4591001 1220 12201062	Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1220 12201063	Blood and lymphatic system disorders	Anaemia	01NOV2014	30NOV2014	N
		Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01DEC2019	31JAN2020	N
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Viral infection	01NOV2014	30NOV2014	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2014	30JUN2017	N
			Vitamin D deficiency	01DEC2015		Y
		Nervous system disorders	Headache	01JAN2014	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1984	31DEC1998	N
		Surgical and medical procedures	Breast conserving surgery	27SEP2013	27SEP2013	N
			Bunion operation	01FEB2020	29FEB2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratomileusis	02JUL2016	02JUL2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1220 12201065	Gastrointestinal disorders	Umbilical hernia	01AUG2020	31AUG2020	N
		Hepatobiliary disorders	Gallbladder disorder	01AUG2020	31AUG2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2014	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	06OCT2008	06OCT2008	N
				15JAN2020	15JAN2020	N
				29DEC2013	29DEC2013	N
			Cholecystectomy	01AUG2020	31AUG2020	N
			Salpingectomy	15JAN2020	15JAN2020	N
			Skin neoplasm excision	01JAN1991	31DEC1991	N
			Umbilical hernia repair	01AUG2020	31AUG2020	N
	C4591001 1221 12211002	Cardiac disorders	Cardiac failure congestive	01JUL2019		Y
			Coronary artery disease	15JUL2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	15JUL2020		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31OCT2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Circumcision	01OCT2019	31OCT2020	N
			Coronary arterial stent insertion	01JUL2019	31JUL2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	15JUL2020		Y
	C4591001 1221 12211003	Hepatobiliary disorders	Gallbladder disorder	01SEP2016	30SEP2016	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2009		Y
	C4591001 1221 12211005	Hepatobiliary disorders	Gallbladder disorder	01DEC2014	31MAR2015	N
		Infections and infestations	Hepatitis A	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
	C4591001 1221 12211006	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1221 12211007	Eye disorders	Uveitis	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Syphilis	01JAN2013	31DEC2013	N
				01MAR2020	10MAR2020	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2014	30JUN2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JUN2016	31DEC2018	N
		Surgical and medical procedures	Scar excision	01JAN2014	30JUN2014	N
	C4591001 1221 12211010	Hepatobiliary disorders	Cholelithiasis	01JAN2003	31JUL2003	N
		Immune system disorders	Seasonal allergy	01SEP2012		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2003	31JUL2003	N
	C4591001 1221 12211011	Blood and lymphatic system disorders	Anaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01SEP2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017		Y
	C4591001 1221 12211012	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Pneumonia	01JAN2000	31DEC2000	N
		Nervous system disorders	Migraine	01JAN2015	31DEC2018	N
	C4591001 1221 12211013	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01FEB2013		Y
					28FEB2013	N
	C4591001 1221 12211014	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2006		Y
	C4591001 1221 12211020	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN1999		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1986	N
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1221 12211022	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	26AUG2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	26AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Vascular disorders	Hypertension	19MAY2020		Y
	C4591001 1221 12211023	Blood and lymphatic system disorders	Antiphospholipid syndrome	04APR2019		Y
		Endocrine disorders	Hypothyroidism	20MAY2018		Y
		Eye disorders	Astigmatism	04MAY2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Borderline glaucoma	28APR2020		Y
			Myopia	04MAY2018		Y
			Presbyopia	04MAY2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	22MAY2019		Y
		Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	15JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eye naevus	28APR2020		Y
		Nervous system disorders	Intracranial aneurysm	01MAY2018	31JUL2018	N
		Renal and urinary disorders	Lupus nephritis	04APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978	31DEC1995	N
		Surgical and medical procedures	Intra-cerebral aneurysm operation	01JUL2018	31JUL2018	N
		Vascular disorders	Thrombosis	01JUL2010	31JUL2018	N
	C4591001 1221 12211024	Injury, poisoning and procedural complications	Tendon rupture	01MAR1991	31MAR1991	N
		Psychiatric disorders	Depression	01JUL2001		Y
		Surgical and medical procedures	Tenoplasty	01MAR1991	31MAR1991	N
			Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1221 12211026	Investigations	Tuberculin test positive	01JAN1993	31DEC1993	N
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
	C4591001 1221 12211029	Cardiac disorders	Cardiomyopathy	01JAN2018		Y
		Investigations	Cardiac murmur	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rheumatic fever	01JAN1988	31DEC1988	N
		Psychiatric disorders	Alcohol abuse	01JAN2005	31JUL2020	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1221 12211030	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2013		Y
			Obesity	01JAN2005		Y
		Nervous system disorders	Migraine	01FEB2013		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Vascular disorders	Hypertension	01FEB2013		Y
	C4591001 1221 12211031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	30MAR2015		Y
		Metabolism and nutrition disorders	Diabetes mellitus	29SEP2014		Y
		Vascular disorders	Hypertension	05MAY2015		Y
	C4591001 1221 12211032	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Nervous system disorders	Sciatica	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1221 12211033	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1221 12211037	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1221 12211038	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
	C4591001 1221 12211040	Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
			Obesity	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1221 12211041	Metabolism and nutrition disorders	Obesity	20FEB2017		Y
	C4591001 1221 12211042	Metabolism and nutrition disorders	Obesity	24JUL1995		Y
		Surgical and medical procedures	Female sterilisation	28DEC1996	28DEC1996	N
	C4591001 1221 12211043	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Cervical radiculopathy	17JAN2017	20JUL2017	N
			Restless legs syndrome	01JAN1975		Y
		Social circumstances	Menopause	18NOV2016		Y
		Surgical and medical procedures	Ankle operation	08OCT2020	08OCT2020	N
			Fracture treatment	27MAY2020	27MAY2020	N
			Spinal fusion surgery	01JUL2017	31JUL2017	N
		Vascular disorders	Hypertension	18NOV2018		Y
	C4591001 1221 12211044	Cardiac disorders	Myocarditis	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Clostridium difficile colitis	01MAY2018	31DEC2018	N
			Postoperative abscess	01MAY2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01SEP2009	31MAY2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Menorrhagia	17DEC2017	31MAY2018	N
			Ovarian cyst	01SEP2009	30SEP2009	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01MAY2018	31MAY2018	N
			Ovarian cystectomy	01SEP2000	30SEP2009	N
	C4591001 1221 12211045	Immune system disorders	Seasonal allergy	13DEC2013		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	09SEP2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1998		Y
	C4591001 1221 12211046	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
	C4591001 1221 12211047	Blood and lymphatic system disorders	Anaemia of pregnancy	21OCT2020		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01MAY2005	31MAY2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1221 12211053	Investigations	Blood cholesterol increased	01JAN1996		Y
		Nervous system disorders	Extrapyramidal disorder	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN1995	31DEC2015	N
	C4591001 1221 12211054	Surgical and medical procedures	Fracture treatment	28MAY2010	21JUN2010	N
	C4591001 1221 12211055	Injury, poisoning and procedural complications	Ligament rupture	01JAN2012	31DEC2012	N
	C4591001 1221 12211062	Metabolism and nutrition disorders	Overweight	01APR2016		Y
	C4591001 1221 12211064	Cardiac disorders	Long QT syndrome	01FEB2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Irritable bowel syndrome	24FEB2015		Y
		Nervous system disorders	Migraine with aura	01JAN2007		Y
		Reproductive system and breast disorders	Endometriosis	01JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01MAY2017		Y
	C4591001 1221 12211065	Hepatobiliary disorders	Gallbladder disorder	01AUG2014	31AUG2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1221 12211067	Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2016	31DEC2017	N
	C4591001 1221 12211069	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Suicide attempt	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1221 12211070	Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2009	31DEC2011	N
	C4591001 1221 12211071	Ear and labyrinth disorders	Deafness neurosensory	14NOV2017		Y
		Eye disorders	Diabetic retinopathy	07MAY2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1999	25MAY1999	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neuropathic arthropathy	12NOV2019		Y
			Osteoarthritis	01JAN2007		Y
			Spinal stenosis	24SEP2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
C4591001 1221	12211072	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2010		Y
C4591001 1221	12211073	Hepatobiliary disorders	Gallbladder disorder	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2018		Y
C4591001 1221	12211078	Eye disorders	Conjunctivitis allergic	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2017		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Sinus disorder	01JAN1976		Y
		Vascular disorders	Hypertension	01JUN2012		Y
C4591001 1221	12211079	Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N
		Infections and infestations	Helicobacter infection	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
C4591001 1221	12211080	Investigations	Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1221 12211081	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1997		Y
	C4591001 1221 12211082	Endocrine disorders	Hypothyroidism	01JAN1982		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2005	31DEC2005	N
		Infections and infestations	Urinary tract infection	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2010	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Wheezing	01MAR2020	31DEC2020	N
	C4591001 1221 12211083	Cardiac disorders	Supraventricular tachycardia	25OCT2006		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	03AUG2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	03AUG2016		Y
		Immune system disorders	Drug hypersensitivity	15OCT2020		Y
		Injury, poisoning and procedural complications	Traumatic arthritis	07AUG2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	03AUG2016		Y
			Obesity	01AUG2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	05MAY2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	08JUN2018	08JUN2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1221 12211087	Psychiatric disorders	Depression	01SEP2018	31DEC2018	N
	C4591001 1221 12211088	Infections and infestations	Genitourinary chlamydia infection	01JAN2014	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1221 12211089	Hepatobiliary disorders	Gallbladder disorder	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	04AUG2014		Y
			Obesity	01AUG1996		Y
			Type 2 diabetes mellitus	04AUG2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20FEB2018		Y
		Vascular disorders	Hypertension	27AUG2019		Y
	C4591001 1221 12211090	Metabolism and nutrition disorders	Obesity	01NOV1997		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	24OCT2019	31OCT2019	N
		Vascular disorders	Deep vein thrombosis	01JAN2009		Y
	C4591001 1223 12231001	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
	C4591001 1223 12231004	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1223 12231025	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1223 12231026	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231027	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1223 12231030	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1223 12231031	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1223 12231034	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN2006	31DEC2007	N
	C4591001 1223 12231044	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Insomnia	01JAN1985		Y
	C4591001 1223 12231045	Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1223 12231053	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
	C4591001 1223 12231054	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	20FEB2014	20FEB2014	N
	C4591001 1223 12231057	Psychiatric disorders	Insomnia	01AUG2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01AUG2018		Y
	C4591001 1223 12231061	Infections and infestations	Herpes virus infection	01JAN2018		Y
	C4591001 1223 12231062	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1223 12231064	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	03JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2012		Y
	C4591001 1223 12231072	Immune system disorders	Multiple allergies	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Menopause	01DEC2017		Y
	C4591001 1223 12231073	Cardiac disorders	Palpitations	01JAN2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
			Irritable bowel syndrome	01SEP2017		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1223 12231075	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Gastrointestinal disorders	Intestinal perforation	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Ileostomy	01JAN2010	31DEC2010	N
	C4591001 1223 12231079	Psychiatric disorders	Depression	01JAN2008		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2017		Y
	C4591001 1223 12231082	Endocrine disorders	Autoimmune thyroiditis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1223 12231084	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1223 12231087	Endocrine disorders	Hypogonadism	01JAN2015		Y
			Pituitary-dependent Cushing's syndrome	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231090	Skin and subcutaneous tissue disorders	Acne cystic	01JAN2007		Y
	C4591001 1223 12231095	Infections and infestations	Herpes virus infection	01FEB2020	29FEB2020	N
			Lyme disease	01JUL2020	31AUG2020	N
	C4591001 1223 12231101	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1223 12231111	Metabolism and nutrition disorders	Vitamin D deficiency	02SEP2020		Y
	C4591001 1223 12231113	Psychiatric disorders	Bipolar disorder	01JAN2018		Y
	C4591001 1223 12231117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
	C4591001 1223 12231120	Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1223 12231121	Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2016		Y
	C4591001 1223 12231122	Nervous system disorders	Migraine	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1223 12231127	Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1223 12231128	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231133	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2018		Y
		Psychiatric disorders	Depression	01JAN2001		Y
	C4591001 1223 12231135	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1223 12231137	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1223 12231141	Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231147	Surgical and medical procedures	Wisdom teeth removal	02SEP2020	02SEP2020	N
	C4591001 1223 12231148	Psychiatric disorders	Anxiety	01APR2015		Y
			Attention deficit hyperactivity disorder	01SEP2019		Y
	C4591001 1223 12231150	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1223 12231151	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1223 12231153	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1223 12231154	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Multiple allergies	01JAN2010		Y
	C4591001 1223 12231157	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231160	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1223 12231163	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231164	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1223 12231166	Eye disorders	Glaucoma	01JAN2019		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2014		Y
			Gout	01JAN2014		Y
		Nervous system disorders	Cerebellar stroke	01JAN2017	31DEC2017	N
			Cerebrovascular accident	01JAN2019	31JAN2019	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231170	Psychiatric disorders	Anxiety	01JAN2015		Y
			Bipolar disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
	C4591001 1223 12231171	Psychiatric disorders	Schizophrenia	01JAN2018		Y
	C4591001 1223 12231172	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231173	Psychiatric disorders	Schizophrenia	01JAN2012		Y
	C4591001 1223 12231174	Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1223 12231175	Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1223 12231176	Nervous system disorders	Migraine	01JAN2017		Y
			Restless legs syndrome	01OCT2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2019		Y
			Insomnia	01OCT2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1223 12231177	Nervous system disorders	Seizure	01JAN2010		Y
	C4591001 1223 12231179	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1223 12231181	Cardiac disorders	Left ventricular hypertrophy	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2019		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1989		Y
		Nervous system disorders	Migraine	01DEC2011		Y
			Nervous system disorder	01JAN2019		Y
			Neuropathy peripheral	01JAN2011		Y
	C4591001 1223 12231183	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 1 diabetes mellitus	18DEC1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231184	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1223 12231186	Psychiatric disorders	Attention deficit hyperactivity disorder	(b) (6) 1999		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Transgender hormonal therapy	01JAN2019		Y
	C4591001 1223 12231187	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1223 12231188	Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2005		Y
			Insomnia	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1223 12231189	Psychiatric disorders	Drug dependence	01JAN1984	31DEC2003	N
	C4591001 1223 12231190	Psychiatric disorders	Drug dependence	01JAN2005	30JUN2020	N
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1223 12231192	Social circumstances	Postmenopause	01JAN2020		Y
	C4591001 1223 12231195	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231196	Psychiatric disorders	Alcohol abuse	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug abuse	01DEC2000	02JAN2020	N
	C4591001 1223 12231197	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
	C4591001 1223 12231199	Psychiatric disorders	Drug dependence	01JAN2020		Y
			Post-traumatic stress disorder	01MAR2018		Y
	C4591001 1223 12231201	Metabolism and nutrition disorders	Vitamin D deficiency	01DEC2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1223 12231202	Immune system disorders	Seasonal allergy	01JAN2019		Y
	C4591001 1223 12231204	Reproductive system and breast disorders	Menorrhagia	01JAN2019		Y
	C4591001 1223 12231205	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1223 12231210	Psychiatric disorders	Drug dependence	01JAN2017		Y
	C4591001 1223 12231211	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1987		Y
	C4591001 1223 12231212	Nervous system disorders	Neuropathy peripheral	01JAN2011		Y
	C4591001 1223 12231213	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1223 12231214	Psychiatric disorders	Substance abuse	01DEC2016	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003		Y
	C4591001 1223 12231221	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Drug use disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004		Y
	C4591001 1223 12231222	Injury, poisoning and procedural complications	Overdose	28DEC2019	28DEC2019	N
		Psychiatric disorders	Affective disorder	28DEC2019		Y
			Attention deficit hyperactivity disorder	28DEC2019		Y
			Post-traumatic stress disorder	28DEC2019		Y
			Psychotic disorder	28DEC2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2013		Y
		Vascular disorders	Hypertension	28DEC2019		Y
	C4591001 1223 12231223	Skin and subcutaneous tissue disorders	Acne	01JAN1998		Y
	C4591001 1223 12231226	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
	C4591001 1223 12231232	Psychiatric disorders	Schizophrenia	01JAN1974		Y
	C4591001 1223 12231233	Psychiatric disorders	Anxiety	01JUL2020		Y
			Drug dependence	01JAN1995		Y
			Insomnia	12JUL2020		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1223 12231237	Psychiatric disorders	Insomnia	01DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2020		Y
	C4591001 1223 12231238	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1223 12231239	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1223 12231241	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1223 12231242	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Psychiatric disorders	Bipolar disorder	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1223 12231243	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1223 12231245	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1223 12231246	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1223 12231247†	Investigations	HIV test positive	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Aortic dilatation	01JAN2016		Y
	C4591001 1223 12231249	Psychiatric disorders	Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231251	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1223 12231252	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231253	Infections and infestations	Onychomycosis	01JAN2019		Y
	C4591001 1223 12231256	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998	31DEC2008	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1223 12231258	Immune system disorders	Seasonal allergy	01APR2020		Y
	C4591001 1223 12231260	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1223 12231264	Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1223 12231265	Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2016		Y
	C4591001 1224 12241005	Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2018		Y
	C4591001 1224 12241008	Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1224 12241009	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Wisdom teeth removal	01JUN2012	01JUN2012	N
	C4591001 1224 12241010	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1224 12241017	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Humerus fracture	26DEC1993	26DEC1993	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Bone operation	26DEC1993	26DEC1993	N
			Caesarean section	07DEC1993	07DEC1993	N
				13APR2010	13APR2010	N
				18JUN2018	18JUN2018	N
			Knee arthroplasty	01JUN2018	30JUN2018	N
			Therapeutic nerve ablation	01OCT2019	31OCT2019	N
				04AUG2020	04AUG2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241021	Social circumstances	Menopause	01JAN2017		Y
	C4591001 1224 12241024	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241026	Endocrine disorders	Hypothyroidism	01MAY2018		Y
		Immune system disorders	Seasonal allergy	01JUL2017		Y
		Surgical and medical procedures	Hysterectomy	01AUG2018	31AUG2018	N
	C4591001 1224 12241027	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Iodine allergy	01JAN2019		Y
			Seasonal allergy	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Nervous system disorders	Vertebral artery dissection	01JAN2009	31MAY2009	N
		Psychiatric disorders	Anxiety	01JUL2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01SEP2010		Y
	C4591001 1224 12241056	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Surgical and medical procedures	Keratomileusis	01JAN2012	31DEC2012	N
			Varicose vein operation	01JAN2019	31DEC2019	N
	C4591001 1224 12241058	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Chondroplasty	01JAN2008	31DEC2008	N
			Keratomileusis	01JAN2017	31DEC2017	N
			Wisdom teeth removal	01JAN2007	31DEC2007	N
	C4591001 1224 12241060	Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2020		Y
	C4591001 1224 12241065	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1224 12241066	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2020		Y
	C4591001 1224 12241067	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1224 12241068	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
	C4591001 1224 12241069	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2019		Y
			Thrombosis	01JAN2014		Y
	C4591001 1224 12241072	Endocrine disorders	Hypothyroidism	01MAY2016		Y
	C4591001 1224 12241074	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Psychiatric disorders	Depression	21APR2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1991	31DEC1991	N
	C4591001 1224 12241075	Surgical and medical procedures	Appendicectomy	01JUN1976	30JUN1976	N
			Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1224 12241079	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
	C4591001 1224 12241083	Psychiatric disorders	Anxiety	01FEB2000		Y
		Vascular disorders	Hypertension	01FEB2000		Y
	C4591001 1224 12241084	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2002	31DEC2002	N
	C4591001 1224 12241085	Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1224 12241090	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1224 12241091	Reproductive system and breast disorders	Menorrhagia	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010		Y
	C4591001 1224 12241093	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1224 12241096	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01FEB2020	29FEB2020	N
	C4591001 1224 12241098	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	28AUG2020		Y
	C4591001 1224 12241114	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
	C4591001 1224 12241117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1224 12241118	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Breast reconstruction	01AUG2007	31AUG2007	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
			Mastectomy	01AUG2007	31AUG2007	N
			Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1224 12241119	Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2019		Y
	C4591001 1224 12241124	Psychiatric disorders	Depression	01JAN1996		Y
	C4591001 1224 12241134	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1224 12241137	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Infections and infestations	Herpes virus infection	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y
			Neck pain	01JAN2009		Y
			Osteoarthritis	01FEB2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Migraine	01JAN2002		Y
	C4591001 1224 12241141	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1224 12241143	Immune system disorders	Seasonal allergy	01JAN2008		Y
	C4591001 1224 12241144	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1224 12241147	Vascular disorders	Thrombosis	01JAN2013	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241151	Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1224 12241156	Investigations	Blood testosterone decreased	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1224 12241158†	General disorders and administration site conditions	Drug intolerance	01JAN2019		Y
		Investigations	HIV test positive	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	14AUG2020		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241160	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1224 12241161	Psychiatric disorders	Depression	01JAN2008		Y
	C4591001 1224 12241162	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1224 12241165	Gastrointestinal disorders	Abdominal migraine	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2016	31DEC2018	N
					31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Medical device removal	01NOV2000	01NOV2020	N
	C4591001 1224 12241167	Immune system disorders	Seasonal allergy	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2007		Y
	C4591001 1224 12241168	Gastrointestinal disorders	Abdominal pain upper	01JAN2016		Y
	C4591001 1224 12241169	Endocrine disorders	Growth hormone deficiency	01JAN2018		Y
	C4591001 1224 12241170	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1224 12241171	Injury, poisoning and procedural complications	Concussion	01JAN2017		Y
	C4591001 1224 12241173	Immune system disorders	Drug hypersensitivity	01AUG2015		Y
			Food allergy	01JAN2008		Y
	C4591001 1224 12241174	Surgical and medical procedures	Appendicectomy	01AUG2015	31AUG2015	N
		Immune system disorders	Food allergy	01JAN2008		Y
	C4591001 1224 12241175	Blood and lymphatic system disorders	Iron deficiency anaemia	01MAY2019		Y
		Psychiatric disorders	Anxiety	23NOV2020		Y
			Attention deficit hyperactivity disorder	01AUG2018		Y
			Depression	23NOV2020		Y
	C4591001 1224 12241177	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1224 12241180	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241181	Investigations	Vitamin D decreased	01JAN2018		Y
		Psychiatric disorders	Depression	01NOV2018		Y
	C4591001 1224 12241182	Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1224 12241185	Psychiatric disorders	Anxiety	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
		Surgical and medical procedures	Fracture treatment	01JAN2016	31DEC2016	N
	C4591001 1224 12241186	Nervous system disorders	Migraine	01MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Ventricular septal defect repair	02FEB2005	02FEB2005	N
	C4591001 1224 12241187	Reproductive system and breast disorders	Testicular torsion	01JAN2019	31JAN2019	N
	C4591001 1226 12261001	Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1226 12261002	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
	C4591001 1226 12261003	Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1226 12261004	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 1226 12261005	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1226 12261007	Nervous system disorders	Migraine	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261010	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
	C4591001 1226 12261011	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1226 12261016	Social circumstances	Menopause	01JAN2000		Y
	C4591001 1226 12261017	Immune system disorders	Iodine allergy	01JAN2005	31DEC2005	N
		Infections and infestations	Labyrinthitis	27APR2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1226 12261019	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1226 12261021	Gastrointestinal disorders	Intestinal polyp	07OCT2019	07OCT2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	06MAY2020	N
		Surgical and medical procedures	Cholecystectomy	06MAY2020	06MAY2020	N
			Large intestinal polypectomy	07OCT2019	07OCT2019	N
			Vasectomy	20JAN2020	20JAN2020	N
	C4591001 1226 12261024	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Social circumstances	Menopause	01JAN2005	31DEC2005	N
	C4591001 1226 12261025	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1976		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2002		Y
		Vascular disorders	Varicose vein	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261026	Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261027	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
	C4591001 1226 12261029	Eye disorders	Glaucoma	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261030	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12261031	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261032	Gastrointestinal disorders	Hiatus hernia	01JAN2011	31DEC2014	N
			Oesophagitis	01JAN2011	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	12MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2014	31DEC2014	N
	C4591001 1226 12261037	Nervous system disorders	Migraine	01JAN1983		Y
	C4591001 1226 12261041	Metabolism and nutrition disorders	Obesity	01JUN2020		Y
		Vascular disorders	Hypertension	01JUN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261043	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12261045	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2019		Y
	C4591001 1226 12261052	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2005	N
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1226 12261056	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	02JUL2020		Y
	C4591001 1226 12261058	Nervous system disorders	Migraine	01JAN2002		Y
	C4591001 1226 12261060	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261061	Psychiatric disorders	Obsessive-compulsive disorder	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261065	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1226 12261067	Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
	C4591001 1226 12261068	Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1226 12261072	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261075	Hepatobiliary disorders	Cholelithiasis	01JAN2017	28FEB2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2019	28FEB2019	N
	C4591001 1226 12261076	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2003		Y
	C4591001 1226 12261078	Endocrine disorders	Hypothyroidism	02APR2009		Y
	C4591001 1226 12261080	Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1226 12261081	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Obesity	01JAN2004		Y
	C4591001 1226 12261082	Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1226 12261083	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261086	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1226 12261087	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1980		Y
	C4591001 1226 12261088	Congenital, familial and genetic disorders	Pancreas divisum	01JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Pancreatitis acute	01JUN2018	30JUN2018	N
				01JUN2019	30JUN2019	N
		Surgical and medical procedures	Cholecystectomy	01JUN2018	30JUN2018	N
	C4591001 1226 12261091	Vascular disorders	Hypertension	04NOV2013		Y
	C4591001 1226 12261092	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2002	31DEC2005	N
		Surgical and medical procedures	Thyroidectomy	01JAN2005	31DEC2005	N
	C4591001 1226 12261094	Immune system disorders	Drug hypersensitivity	01JUL2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP1995		Y
	C4591001 1226 12261096	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1226 12261097	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261103	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261106	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1226 12261107	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261112	Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
			Hiatus hernia	01JAN2002	31DEC2009	N
		Surgical and medical procedures	Hernia hiatus repair	01JAN2009	31DEC2009	N
	C4591001 1226 12261117	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Rhinitis allergic	01JAN1985		Y
	C4591001 1226 12261119	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1226 12261122	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
	C4591001 1226 12261124	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1226 12261127	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1226 12261132	Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01SEP2018	30SEP2018	N
	C4591001 1226 12261135	Hepatobiliary disorders	Hepatic mass	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN2015		Y
	C4591001 1226 12261136	Gastrointestinal disorders	Haemorrhoids	01FEB2001	26JAN2021	N
	C4591001 1226 12261137	Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261139	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Hyperuricaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1226 12261140	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261144	Infections and infestations	Labyrinthitis	01JAN2014		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2004		Y
	C4591001 1226 12261146	Gastrointestinal disorders	Coeliac disease	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2020		Y
	C4591001 1226 12261147	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1226 12261152	Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Allergic bronchitis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261155	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1226 12261156	Nervous system disorders	Psychomotor hyperactivity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1226 12261157	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261159	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Infections and infestations	Sinusitis	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2001		Y
	C4591001 1226 12261160	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261161	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261164	Gastrointestinal disorders	Oesophagitis	01NOV2019		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
	C4591001 1226 12261176	Surgical and medical procedures	Gastroplasty	01JAN2000	31DEC2000	N
	C4591001 1226 12261177	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261178	Metabolism and nutrition disorders	Hyperuricaemia	01JAN2018		Y
	C4591001 1226 12261179	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012	31DEC2017	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2017	31DEC2017	N
			Vasectomy	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261180	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUN2019		Y
		Reproductive system and breast disorders	Menstruation irregular	01FEB2020		Y
	C4591001 1226 12261182	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12261183	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261184	Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1226 12261191	Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1226 12261193	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
	C4591001 1226 12261194	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1226 12261199	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1226 12261203	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Dental implantation	20JUN2020		Y
	C4591001 1226 12261208	Psychiatric disorders	Stress	01JAN2005		Y
	C4591001 1226 12261210	Blood and lymphatic system disorders	Iron deficiency anaemia	30JUL2020		Y
	C4591001 1226 12261213	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261214	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1226 12261216	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261217	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261228	Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1226 12261229	Social circumstances	Menopause	01FEB2020		Y
	C4591001 1226 12261230	Gastrointestinal disorders	Umbilical hernia	01JAN2018	30JUN2019	N
		Social circumstances	Tobacco user	01JAN2016		Y
		Surgical and medical procedures	Hernia repair	01JUN2019	30JUN2019	N
	C4591001 1226 12261232	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1226 12261233	Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1226 12261234	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	C4591001 1226 12261235	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261237	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1987		Y
	C4591001 1226 12261246	Psychiatric disorders	Panic reaction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261248	Nervous system disorders	Haemorrhagic stroke	01JAN2010	31DEC2010	N
	C4591001 1226 12261250	Gastrointestinal disorders	Gastritis	01JAN2013		Y
	C4591001 1226 12261254	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Cyclothymic disorder	01JAN2012		Y
	C4591001 1226 12261256	Cardiac disorders	Arrhythmia	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1226 12261261	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2017		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1226 12261266	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1226 12261269	Endocrine disorders	Hypothyroidism	01JAN2011		Y
	C4591001 1226 12261270	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1226 12261272	Endocrine disorders	Hypothyroidism	01JAN2004		Y
	C4591001 1226 12261274	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
	C4591001 1226 12261275	Metabolism and nutrition disorders	Obesity	01JAN2005	31DEC2012	N
		Nervous system disorders	Headache	01JAN2008		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2012	31DEC2012	N
	C4591001 1226 12261276	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1978	30JUN2018	N
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
	C4591001 1226 12261278	Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1226 12261280	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2000		Y
	C4591001 1226 12261282	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261285	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261287	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
	C4591001 1226 12261288	Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Thyroidectomy	01JAN2008	31DEC2008	N
	C4591001 1226 12261291	Nervous system disorders	Headache	01JAN1990	31DEC2016	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1226 12261292	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261293	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261295	Gastrointestinal disorders	Dyspepsia	01JUL2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1991		Y
	C4591001 1226 12261298	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261299	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Toe operation	01FEB2019	28FEB2019	N
	C4591001 1226 12261300	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01APR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1226 12261301	Ear and labyrinth disorders	Hypoacusis	01JAN2000		Y
		Immune system disorders	Contrast media allergy	01JAN2012		Y
			Drug hypersensitivity	01JAN1990		Y
	C4591001 1226 12261302	Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261305	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1226 12261306	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1226 12261307	Reproductive system and breast disorders	Endometriosis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261308	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y
	C4591001 1226 12261313	Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261314	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
	C4591001 1226 12261323	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1226 12261324	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261325	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1226 12261328	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1226 12261330	Cardiac disorders	Myocardial infarction	18JAN2017	18JAN2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	20AUG2020		Y
		Surgical and medical procedures	Angioplasty	19JAN2017	19JAN2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261332	Metabolism and nutrition disorders	Obesity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2008		Y
	C4591001 1226 12261336	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261340	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261341	Gastrointestinal disorders	Colitis	01JAN2015		Y
	C4591001 1226 12261343	Gastrointestinal disorders	Gastritis	01JAN2010		Y
	C4591001 1226 12261344	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1226 12261345	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261348	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1226 12261349	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1226 12261351	Gastrointestinal disorders	Oesophagitis	01APR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261352	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1226 12261354	Renal and urinary disorders	Nephrolithiasis	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2015		Y
	C4591001 1226 12261359	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1226 12261360	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261361	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Overweight	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261363	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1226 12261364	Gastrointestinal disorders	Hiatus hernia	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	29JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Adenomyosis	01JAN2019	29JAN2020	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN2020		Y
			Salpingectomy	29JAN2020	29JAN2020	N
	C4591001 1226 12261365	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1226 12261369	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261372	Endocrine disorders	Hypothyroidism	01JAN2009		Y
	C4591001 1226 12261375	Metabolism and nutrition disorders	Obesity	01JAN2006		Y
	C4591001 1226 12261379	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261380	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261382	Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1226 12261383	Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
	C4591001 1226 12261384	Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1226 12261387	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1226 12261390	Endocrine disorders	Hypothyroidism	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261391	Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Hernia hiatus repair	01JAN1999	31DEC1999	N
	C4591001 1226 12261392	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1226 12261395	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003		Y
	C4591001 1226 12261396	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1226 12261397	Surgical and medical procedures	Vasectomy	01JUN2019	30JUN2019	N
	C4591001 1226 12261399	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261400	Gastrointestinal disorders	Gastritis	01JAN2014		Y
	C4591001 1226 12261403	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01NOV2007	31DEC2008	N
		Surgical and medical procedures	Intervertebral disc operation	31OCT2007	31OCT2007	N
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1226 12261407	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
			Rhinitis allergic	01MAR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261410	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261411	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
			Rhinitis allergic	01JAN2001		Y
	C4591001 1226 12261412	Metabolism and nutrition disorders	Obesity	01JUL2018		Y
	C4591001 1226 12261414	Metabolism and nutrition disorders	Obesity	01MAR2016		Y
		Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1226 12261416	Cardiac disorders	Acute myocardial infarction	23NOV2019	23NOV2019	N
			Coronary artery insufficiency	23NOV2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	24NOV2019	24NOV2019	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1226 12261417	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261420	Hepatobiliary disorders	Gallbladder polyp	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Reproductive system and breast disorders	Menstruation irregular	01SEP2019		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261422	Endocrine disorders	Hypothyroidism	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261424	Surgical and medical procedures	Vasectomy	01FEB2020		Y
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1226 12261425	Musculoskeletal and connective tissue disorders	Osteopenia	15JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasm	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1226 12261427	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261428	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261429	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1226 12261430	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Azoospermia	01JAN1984		Y
	C4591001 1226 12261431	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1226 12261432	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1226 12261439	Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261441	Gastrointestinal disorders	Umbilical hernia	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
	C4591001 1226 12261442	Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12261443	Respiratory, thoracic and mediastinal disorders	Asthma	01JUL2019		Y
	C4591001 1226 12261444	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261448	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1226 12261451	Endocrine disorders	Hypothyroidism	01OCT2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01OCT2010		Y
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1226 12261455	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261459	Psychiatric disorders	Insomnia	01JUN2020		Y
	C4591001 1226 12261460	Gastrointestinal disorders	Gastritis	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	09JUN2018	N
		Surgical and medical procedures	Hysterectomy	09JUN2018	09JUN2018	N
	C4591001 1226 12261463	Surgical and medical procedures	Vasectomy	01AUG2016	31AUG2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261465	Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1226 12261466	Psychiatric disorders	Anxiety	01JAN2009		Y
	C4591001 1226 12261469	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1226 12261470	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Menopause	01APR2019		Y
	C4591001 1226 12261476	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01MAR2019	31MAR2019	N
	C4591001 1226 12261478	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12261480	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
	C4591001 1226 12261482	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983		Y
	C4591001 1226 12261486	Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JUL2020	08DEC2020	N
		Surgical and medical procedures	Vasectomy	01OCT2019	31OCT2019	N
	C4591001 1226 12261491	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1226 12261493	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261494	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01OCT2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1226 12261495	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
	C4591001 1226 12261496	Infections and infestations	Oral herpes	01JAN2015		Y
	C4591001 1226 12261498	Infections and infestations	Rhinitis	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1226 12261500	Social circumstances	Menopause	01JAN2010		Y
	C4591001 1226 12261502	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2014		Y
	C4591001 1226 12261503	Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1226 12261504	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1226 12261507	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Obesity	01JAN1990		Y
	C4591001 1226 12261508	Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000		Y
	C4591001 1226 12261509	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261511	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261514	Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2019		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1226 12261516	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31OCT2019	N
			Hepatic steatosis	01JAN2015		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2019	31OCT2019	N
	C4591001 1226 12261517	Social circumstances	Menopause	01SEP2019		Y
	C4591001 1226 12261518	Psychiatric disorders	Anxiety	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1226 12261520	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2019		Y
		Nervous system disorders	Dizziness	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1226 12261522	Endocrine disorders	Hypothyroidism	01AUG2019		Y
		Infections and infestations	Peritonsillar abscess	01JAN2004	31DEC2014	N
		Surgical and medical procedures	Prophylaxis against HIV infection	01JUN2019		Y
			Tonsillectomy	01JAN2014	31DEC2014	N
	C4591001 1226 12261524	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261529	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261530	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Social circumstances	Menopause	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261531	Surgical and medical procedures	Vasectomy	01JAN2008		Y
	C4591001 1226 12261538	Psychiatric disorders	Anxiety disorder	01JAN2019		Y
	C4591001 1226 12261540	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Reproductive system and breast disorders	Metrorrhagia	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1226 12261542	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Epilepsy	01JAN2017		Y
			Headache	01JAN2017		Y
	C4591001 1226 12261543	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261544	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261547	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
	C4591001 1226 12261549	Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Vasectomy	01SEP2019	30SEP2019	N
	C4591001 1226 12261553	Gastrointestinal disorders	Gastritis	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1226 12261555	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
	C4591001 1226 12261557	Renal and urinary disorders	Nephrolithiasis	01JAN2006		Y
		Surgical and medical procedures	Lithotripsy	01JAN2006	31DEC2006	N
	C4591001 1226 12261559	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013	31DEC2015	N
		Psychiatric disorders	Panic disorder	01JAN2017		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1226 12261560	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1226 12261561	Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
	C4591001 1226 12261562	Endocrine disorders	Hypothyroidism	01MAR2020		Y
	C4591001 1226 12261564	Gastrointestinal disorders	Dyspepsia	01APR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Panic disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1226 12261567	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1226 12261568	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261570	Nervous system disorders	Headache	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2007		Y
	C4591001 1226 12261575	Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1226 12261577	Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Social circumstances	Menopause	01JAN2019	31JAN2019	N
	C4591001 1226 12261578	Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2004	N
			Overweight	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2010		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2004	31DEC2004	N
	C4591001 1226 12261579	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261581	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261583	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261585	Nervous system disorders	Migraine	01JAN2020		Y
	C4591001 1226 12261587	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1988		Y
		Surgical and medical procedures	Vasectomy	01JAN2019		Y
	C4591001 1226 12261590	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1226 12261591	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis acute	01JAN2013	31DEC2013	N
		Infections and infestations	Diverticulitis	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Facial paralysis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261592	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1226 12261593	Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1226 12261594	Infections and infestations	Onychomycosis	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JUL2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261595	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2008	N
			Hepatic steatosis	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1226 12261596	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1226 12261597	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261599	Congenital, familial and genetic disorders	Congenital osteodystrophy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1226 12261600	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
	C4591001 1226 12261602	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261603	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01OCT2018		Y
	C4591001 1226 12261606	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1226 12261607	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JUL2020		Y
	C4591001 1226 12261610	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1226 12261611	Nervous system disorders	Headache	01JAN1996		Y
	C4591001 1226 12261614	Reproductive system and breast disorders	Endometriosis	01JAN1992	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1226 12261616	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1226 12261620	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1226 12261621	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1226 12261624	Surgical and medical procedures	Vasectomy	01JAN2010		Y
	C4591001 1226 12261630	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1226 12261631	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261633	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystostomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	02SEP2020		Y
			Varicose vein	01JAN1991		Y
	C4591001 1226 12261637	Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1226 12261641	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Renal and urinary disorders	Hypercalciuria	01JAN2010		Y
		Reproductive system and breast disorders	Menstruation irregular	01SEP2019		Y
			Polycystic ovaries	01JAN2005		Y
	C4591001 1226 12261643	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1226 12261644	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261646	Surgical and medical procedures	Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1226 12261648	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1226 12261649	Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
	C4591001 1226 12261650	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
	C4591001 1226 12261651	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1226 12261654	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2010		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1226 12261655	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12261657	Injury, poisoning and procedural complications	Ligament injury	26JUL2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2019		Y
	C4591001 1226 12261659	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Hyperuricaemia	01JAN2019		Y
	C4591001 1226 12261660	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261661	Immune system disorders	Allergy to chemicals	01JAN1981		Y
			Food allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Aortic dilatation	01JAN2019		Y
	C4591001 1226 12261667	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Glucose tolerance impaired	01JAN2010		Y
	C4591001 1226 12261669	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
	C4591001 1226 12261670	Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261672	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1226 12261674	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
			Intervertebral disc protrusion	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Chloasma	01JAN2007		Y
	C4591001 1226 12261675	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	04SEP2020	04SEP2020	N
	C4591001 1226 12261676	Metabolism and nutrition disorders	Obesity	01JAN1997		Y
	C4591001 1226 12261679	Gastrointestinal disorders	Dyspepsia	01MAY2020		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
	C4591001 1226 12261682	Infections and infestations	Chronic sinusitis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2011		Y
	C4591001 1226 12261683	Social circumstances	Menopause	01JAN2017	31JAN2017	N
	C4591001 1226 12261684	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Thyroidectomy	01JAN2008	31DEC2008	N
	C4591001 1226 12261685	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261686	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261688	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Obesity	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261689	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261691	Social circumstances	Tobacco user	01JAN1996		Y
	C4591001 1226 12261692	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Social circumstances	Menopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261695	Infections and infestations	Oral herpes	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261696	Infections and infestations	Vaginitis gardnerella	28AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
	C4591001 1226 12261697	Social circumstances	Menopause	01JAN2016		Y
	C4591001 1226 12261698	Endocrine disorders	Hypothyroidism	01JAN1990		Y
	C4591001 1226 12261699	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Deep vein thrombosis	01MAY2019	31AUG2019	N
	C4591001 1226 12261703	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261705	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1226 12261706	Blood and lymphatic system disorders	Hypersplenism	01JAN2018		Y
			Thrombocytopenia	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN2008		Y
		Psychiatric disorders	Depression	01MAR2020		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261709	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
	C4591001 1226 12261710	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
	C4591001 1226 12261714	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1226 12261717	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
	C4591001 1226 12261719	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1226 12261720	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261721	Endocrine disorders	Hyperthyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JUL2020		Y
	C4591001 1226 12261722	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261724	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
	C4591001 1226 12261725	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1226 12261726	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Obesity	01JAN2010		Y
	C4591001 1226 12261729	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261730	Surgical and medical procedures	Vasectomy	01JAN2018	31JAN2018	N
	C4591001 1226 12261731	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
	C4591001 1226 12261733	Surgical and medical procedures	Metabolic surgery	01JAN2018	31DEC2018	N
	C4591001 1226 12261734	Infections and infestations	Tinea versicolour	01JAN2018		Y
	C4591001 1226 12261736	Metabolism and nutrition disorders	Obesity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261737	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1226 12261738	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261739	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261740	Injury, poisoning and procedural complications	Abdominal injury	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Splenectomy	01JAN1995	31DEC1995	N
	C4591001 1226 12261741	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2002		Y
	C4591001 1226 12261745	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1226 12261747	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
			Obesity	01MAY2020		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1226 12261750	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1226 12261751	Endocrine disorders	Autoimmune thyroiditis	01JAN2016		Y
			Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261752	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN1985	31DEC1985	N
	C4591001 1226 12261754	Psychiatric disorders	Anxiety disorder	01JAN2016		Y
	C4591001 1226 12261756	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1226 12261757	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261759	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261760	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1226 12261761	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN1998	31DEC2001	N
		Psychiatric disorders	Anxiety	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261762	Gastrointestinal disorders	Gastritis	01JAN2018		Y
	C4591001 1226 12261763	Metabolism and nutrition disorders	Overweight	01JUL2019		Y
	C4591001 1226 12261765	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261766	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1226 12261767	Infections and infestations	Bronchitis	01JAN1985		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2006	31DEC2006	N
	C4591001 1226 12261769	Injury, poisoning and procedural complications	Uterine perforation	01FEB2019	28FEB2019	N
		Metabolism and nutrition disorders	Obesity	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Fibromyalgia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01FEB2019	28FEB2019	N
	C4591001 1226 12261771	Infections and infestations	Bronchitis	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2017	31DEC2017	N
	C4591001 1226 12261773	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1226 12261775	Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261778	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261779	Infections and infestations	Herpes simplex	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1226 12261780	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1226 12261781	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261784	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261790	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2016		Y
	C4591001 1226 12261792	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261796	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12261800	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1226 12261801	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1226 12261802	Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1226 12261803	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1226 12261805	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261806	Gastrointestinal disorders	Gastritis	01JAN2012		Y
		Infections and infestations	Bronchitis	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261807	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1226 12261809	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12261812	Psychiatric disorders	Dissociative disorder	01JAN2019		Y
	C4591001 1226 12261813	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261815	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Gout	01JAN2016		Y
			Overweight	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12261818	Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1226 12261820	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12261821	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1226 12261823	Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1226 12261824	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261826	Infections and infestations	Bronchitis	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
	C4591001 1226 12261828	Infections and infestations	Bronchitis	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12261830	Injury, poisoning and procedural complications	Ligament injury	01JAN2016	14SEP2020	N
			Meniscus injury	01JAN2017	14SEP2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Knee operation	14SEP2020	14SEP2020	N
	C4591001 1226 12261831	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1226 12261832	Immune system disorders	Hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1226 12261834	Nervous system disorders	Migraine	01JAN1975		Y
	C4591001 1226 12261835	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1226 12261839	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261840	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1226 12261841	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01AUG2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1226 12261843	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 1226 12261844	Nervous system disorders	Headache	01JAN2018		Y
	C4591001 1226 12261845	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12261846	Congenital, familial and genetic disorders	Retinitis pigmentosa	01JAN2005		Y
	C4591001 1226 12261848	Reproductive system and breast disorders	Dysmenorrhoea	01DEC2019		Y
	C4591001 1226 12261850	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
	C4591001 1226 12261851	Congenital, familial and genetic disorders	Renal aplasia	01JAN1982		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12261852	Metabolism and nutrition disorders	Obesity	01JAN1996		Y
	C4591001 1226 12261853	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261855	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261856	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261858	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261860	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261864	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2019		Y
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1985	31DEC2001	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Nasal septal operation	01JAN2001	31DEC2001	N
	C4591001 1226 12261865	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
			Lumbar hernia	01JAN2011	31MAR2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01MAR2019	31MAR2019	N
	C4591001 1226 12261867	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1226 12261870	Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1226 12261871	Psychiatric disorders	Anxiety disorder	01JAN2020		Y
		Surgical and medical procedures	Mammoplasty	01MAY2020	31MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261873	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Astrocytoma	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Astrocytoma surgery	01JAN1986	31DEC1986	N
	C4591001 1226 12261876	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1226 12261877	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1226 12261878	Endocrine disorders	Thyroid mass	01JAN2013	31JAN2020	N
		Infections and infestations	Chronic sinusitis	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Lithotripsy	01NOV2019	30NOV2019	N
			Thyroidectomy	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1226 12261880	Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JUL2019	31JUL2019	N
	C4591001 1226 12261884	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2011		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1226 12261887	Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2015		Y
	C4591001 1226 12261890	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
	C4591001 1226 12261893	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1226 12261894	Infections and infestations	Onychomycosis	01JAN2019		Y
	C4591001 1226 12261897	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1226 12261901	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Glucose tolerance impaired	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1226 12261902	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1989		Y
	C4591001 1226 12261904	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
	C4591001 1226 12261907	Infections and infestations	Bronchitis	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261908	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261910	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Obesity	01JAN2010		Y
	C4591001 1226 12261912	Vascular disorders	Hypertension	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1226 12261914	Cardiac disorders	Supraventricular tachycardia	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01AUG2016	31AUG2016	N
	C4591001 1226 12261917	Metabolism and nutrition disorders	Obesity	01JAN1988		Y
	C4591001 1226 12261919	Surgical and medical procedures	Nasal septal operation	01JAN1989	31DEC1989	N
	C4591001 1226 12261920	Infections and infestations	Rhinitis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2009		Y
	C4591001 1226 12261923	Endocrine disorders	Hypothyroidism	01JUL2017		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01OCT2015		Y
	C4591001 1226 12261924	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12261927	Gastrointestinal disorders	Gastritis	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12261928	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261931	Psychiatric disorders	Anxiety	01JAN2013		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2018		Y
	C4591001 1226 12261935	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1226 12261937	Investigations	Weight decreased	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261938	Cardiac disorders	Atrial fibrillation	01AUG2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2011		Y
	C4591001 1226 12261939	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1226 12261942	Reproductive system and breast disorders	Endometriosis	01JAN2015		Y
	C4591001 1226 12261944	Endocrine disorders	Hypothyroidism	01FEB2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01NOV2011	29FEB2012	N
		Surgical and medical procedures	Thyroidectomy	01FEB2012	29FEB2012	N
	C4591001 1226 12261946	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261950	Gastrointestinal disorders	Gastritis	01JUL2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1226 12261952	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Allergic pharyngitis	01JAN1990		Y
			Allergic sinusitis	01JAN1990		Y
	C4591001 1226 12261956	Eye disorders	Glaucoma	01AUG2019		Y
	C4591001 1226 12261959	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1999		Y
	C4591001 1226 12261960	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1226 12261961	Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1226 12261962	Hepatobiliary disorders	Hepatic steatosis	01JUL2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
			Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1226 12261966	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Labyrinthitis	01JAN2000		Y
	C4591001 1226 12261970	Metabolism and nutrition disorders	Obesity	01JUN2020		Y
	C4591001 1226 12261971	Metabolism and nutrition disorders	Overweight	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261973	Reproductive system and breast disorders	Polycystic ovaries	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01AUG2020	31AUG2020	N
			Nasal septal operation	01JAN2001	31DEC2001	N
			Asthma	01JAN2019	31DEC2019	N
	C4591001 1226 12261978	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1226 12261983	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Hyperuricaemia	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
			Hydronephrosis	01JAN2016	31DEC2016	N
	C4591001 1226 12261985	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261988	Gastrointestinal disorders	Inguinal hernia	01DEC2012		Y
			Umbilical hernia	01DEC2019		Y
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
	C4591001 1226 12261989	Endocrine disorders	Thyroid mass	01JAN1994	31DEC1995	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN1995		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1995	31DEC1995	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261992	Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
	C4591001 1226 12261994	Metabolism and nutrition disorders	Obesity	01JAN1994		Y
	C4591001 1226 12261995	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1226 12261997	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2019		Y
			Obesity	01JAN1999		Y
			Type 2 diabetes mellitus	01OCT2019		Y
	C4591001 1226 12261999	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12262000	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2011	31DEC2011	N
	C4591001 1226 12262001	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
	C4591001 1226 12262003	Nervous system disorders	Headache	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998		Y
	C4591001 1226 12262007	Renal and urinary disorders	Nephrolithiasis	01JAN2001		Y
	C4591001 1226 12262008	Metabolism and nutrition disorders	Obesity	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1226 12262012	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	02OCT2019		Y
	C4591001 1226 12262013	Gastrointestinal disorders	Gastritis	01JAN2015		Y
			Haemorrhoids	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1226 12262014	Surgical and medical procedures	Vasectomy	01FEB2020	29FEB2020	N
	C4591001 1226 12262016	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
	C4591001 1226 12262018	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1226 12262019	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12262021	Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1226 12262023	Endocrine disorders	Hypothyroidism	03DEC2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JUN2010	03DEC2010	N
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Thyroidectomy	03DEC2010	03DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12262028	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12262029	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262035	Endocrine disorders	Autoimmune thyroiditis	01JAN2009		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1226 12262042	Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1226 12262046	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Infections and infestations	Herpes zoster	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Social circumstances	Menopause	01JAN2017	31DEC2017	N
	C4591001 1226 12262050	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Obesity	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1226 12262051	Endocrine disorders	Goitre	01JAN2016	31DEC2016	N
			Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Thyroidectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1226 12262052	Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN1999	31DEC1999	N
	C4591001 1226 12262056	Cardiac disorders	Arrhythmia	01OCT2019		Y
		Metabolism and nutrition disorders	Hyperuricaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1226 12262059	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12262063	Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
	C4591001 1226 12262064	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Psychiatric disorders	Anxiety disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1996		Y
	C4591001 1226 12262065	Metabolism and nutrition disorders	Gout	01JAN2015		Y
	C4591001 1226 12262068	Infections and infestations	Chronic sinusitis	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12262072	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1226 12262076	Surgical and medical procedures	Meniscus operation	01FEB2020	29FEB2020	N
	C4591001 1226 12262078	Metabolism and nutrition disorders	Overweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1226 12262079	Skin and subcutaneous tissue disorders	Alopecia	01OCT2019		Y
	C4591001 1226 12262083	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
	C4591001 1226 12262084	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262085	Gastrointestinal disorders	Duodenal ulcer	01FEB2020		Y
		Infections and infestations	Helicobacter gastritis	01FEB2020		Y
	C4591001 1226 12262087	Infections and infestations	Eye infection toxoplasmal	01JAN2001	31DEC2006	N
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1993		Y
	C4591001 1226 12262089	Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1226 12262092	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1226 12262095	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1226 12262097	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2011	31DEC2011	N
	C4591001 1226 12262099	Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1226 12262107	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262112	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2013	31DEC2014	N
		Nervous system disorders	Headache	01JAN1988		Y
		Psychiatric disorders	Depression	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Menorrhagia	12SEP2020		Y
		Surgical and medical procedures	Thyroidectomy	01DEC2014	31DEC2014	N
	C4591001 1226 12262113	Social circumstances	Menopause	04NOV2018		Y
	C4591001 1226 12262114	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980	31DEC1988	N
	C4591001 1226 12262115	Ear and labyrinth disorders	Meniere's disease	01SEP2020		Y
	C4591001 1226 12262121	Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1992		Y
			Rhinitis allergic	01JAN1992		Y
	C4591001 1226 12262122	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1226 12262123	Infections and infestations	Labyrinthitis	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Overweight	01JAN2019		Y
	C4591001 1226 12262124	Endocrine disorders	Hypothyroidism	01JUL2020		Y
	C4591001 1226 12262125	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1226 12262126	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Intervertebral disc protrusion	01JAN2015		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2015	31DEC2015	N
	C4591001 1226 12262127	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2019		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1226 12262128	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1226 12262129	Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
			Metabolic surgery	01JAN2018	31DEC2018	N
	C4591001 1226 12262131	Reproductive system and breast disorders	Endometriosis	01JAN2005		Y
	C4591001 1226 12262132	Metabolism and nutrition disorders	Obesity	01JAN2006		Y
	C4591001 1226 12262133	Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1226 12262134	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262136	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12262137	Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1995		Y
	C4591001 1226 12262138	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
	C4591001 1226 12262143	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis allergic	01JAN2014		Y
	C4591001 1226 12262144	Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2004	31DEC2004	N
	C4591001 1226 12262145	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1226 12262146	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1992		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
		Social circumstances	Menopause	01SEP2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12262152	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1226 12262157	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1226 12262159	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN2014	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12262162	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N
	C4591001 1226 12262163	Infections and infestations	Sinusitis	01JAN1999		Y
	C4591001 1226 12262165	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1226 12262166	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12262167	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262168	Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1226 12262170	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
	C4591001 1226 12262172	Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1226 12262178	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1226 12262179	Endocrine disorders	Hypothyroidism	01DEC2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262182	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12262186	Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1226 12262187	Endocrine disorders	Thyroid mass	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1987		Y
	C4591001 1226 12262188	Endocrine disorders	Hyperthyroidism	01OCT2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1226 12262189	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1226 12262190	Nervous system disorders	Seizure	01JAN1990	31DEC1993	N
	C4591001 1226 12262191	Psychiatric disorders	Depression	01DEC2017		Y
			Insomnia	01DEC2017		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000		Y
	C4591001 1226 12262192	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12262196	Musculoskeletal and connective tissue disorders	Pain in extremity	01MAR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01FEB2020		Y
			Thrombosis	01MAR2020	31JUL2020	N
	C4591001 1226 12262198	Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2002		Y
	C4591001 1226 12262200	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1226 12262201	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2018	31DEC2018	N
			Turbinectomy	01JAN2018	31DEC2018	N
	C4591001 1226 12262204	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1226 12262205	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1226 12262206	Gastrointestinal disorders	Oesophagitis	01FEB2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2018		Y
	C4591001 1226 12262209	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1226 12262211	Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2017		Y
		Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262213	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12262218	Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN2013	31DEC2013	N
	C4591001 1226 12262221	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1226 12262224	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01MAR2013	31MAR2013	N
	C4591001 1226 12262225	Gastrointestinal disorders	Gastritis	01JAN2000		Y
		Nervous system disorders	Dizziness	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1226 12262227	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1226 12262228	Metabolism and nutrition disorders	Obesity	01OCT2013		Y
	C4591001 1226 12262232	Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2010	N
		Infections and infestations	Labyrinthitis	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12262234	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1226 12262236	Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262237	Gastrointestinal disorders	Pancreatitis	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	20AUG2020		Y
			Overweight	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
			Varicose vein	01JAN2005		Y
	C4591001 1226 12262242	Endocrine disorders	Autoimmune thyroiditis	01JAN2012	31DEC2012	N
			Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01OCT2000		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1226 12262245	Psychiatric disorders	Anxiety	01OCT2019		Y
	C4591001 1226 12262249	Gastrointestinal disorders	Gastritis	01JAN2010		Y
	C4591001 1226 12262251	Infections and infestations	Oral herpes	01JAN1982		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1226 12262255†	Investigations	HIV test positive	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
	C4591001 1226 12262256	Nervous system disorders	Headache	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
	C4591001 1226 12262259	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
	C4591001 1226 12262260	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262261	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262262	Psychiatric disorders	Depression	01OCT2019		Y
	C4591001 1226 12262263	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
	C4591001 1226 12262267	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2016	31DEC2016	N
	C4591001 1226 12262273	Infections and infestations	Labyrinthitis	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
	C4591001 1226 12262275	Endocrine disorders	Thyroid cyst	01JAN2016		Y
		Hepatobiliary disorders	Hepatic steatosis	16OCT2020		Y
		Infections and infestations	Rhinitis	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	17OCT2000		Y
	C4591001 1226 12262279	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1226 12262280	Nervous system disorders	Migraine	01JAN2007		Y
	C4591001 1226 12262284	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
	C4591001 1226 12262286	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1226 12262287	Surgical and medical procedures	Vasectomy	01JAN2013		Y
	C4591001 1226 12262289	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1226 12262290	Surgical and medical procedures	Tonsillectomy	01JAN2011	31DEC2011	N
	C4591001 1226 12262291	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1226 12262292	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262293	Infections and infestations	Herpes simplex	01JAN2017		Y
	C4591001 1226 12262294	Psychiatric disorders	Depression	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262299	Endocrine disorders	Hypothyroidism	17OCT2008		Y
	C4591001 1226 12262300	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2010	31JUL2019	N
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Surgical and medical procedures	Metabolic surgery	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12262301	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1226 12262303	Infections and infestations	Meningitis	01JAN1980	31DEC1980	N
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Surgical and medical procedures	Finger amputation	01JAN1980		Y
			Toe amputation	01JAN1980		Y
	C4591001 1226 12262307	Injury, poisoning and procedural complications	Cervical vertebral fracture	01OCT2019		Y
			Thoracic vertebral fracture	01OCT2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Surgical and medical procedures	Spinal operation	01OCT2019	31OCT2019	N
	C4591001 1226 12262311	Musculoskeletal and connective tissue disorders	Ligament disorder	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12262313	Metabolism and nutrition disorders	Obesity	01OCT2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2013		Y
	C4591001 1226 12262314	Congenital, familial and genetic disorders	Factor VII deficiency	01JAN2016		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y
	C4591001 1226 12262315	Gastrointestinal disorders	Hiatus hernia	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Obesity	01JAN2009	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1226 12262320	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1226 12262321	Respiratory, thoracic and mediastinal disorders	Allergic bronchitis	01JAN2014	31DEC2014	N
			Rhinitis allergic	01JAN2005		Y
	C4591001 1226 12262322	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1226 12262329	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1226 12262334	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Breast enlargement	01JAN2015		Y
	C4591001 1226 12262335	Hepatobiliary disorders	Hepatic steatosis	24JUL2000		Y
		Investigations	Blood testosterone decreased	24JUL2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	24JUL2020		Y
			Hypercholesterolaemia	24JUL2020		Y
			Hypertriglyceridaemia	24JUL2020		Y
			Obesity	01JAN2009		Y
	C4591001 1226 12262338	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1226 12262341	Infections and infestations	Vulvovaginal candidiasis	07OCT2020		Y
	C4591001 1226 12262343	Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1226 12262346	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1226 12262350	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1226 12262353	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1226 12262357	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1229 12291001	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1229 12291002	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1229 12291004	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1977		Y
	C4591001 1229 12291006	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1229 12291007	Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2007		Y
	C4591001 1229 12291008	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
			Chronic obstructive pulmonary disease	09JUL2018		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1229 12291009	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1229 12291010	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1229 12291011	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1229 12291012	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291013	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018		Y
	C4591001 1229 12291015	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1229 12291016	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1229 12291019	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1229 12291020	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1229 12291021	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1229 12291022	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Social circumstances	Menopause	01NOV2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
			Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1229 12291024†	Infections and infestations	HIV infection	01AUG2020		Y
		Nervous system disorders	Epilepsy	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01DEC2014		Y
	C4591001 1229 12291025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1229 12291027†	Infections and infestations	HIV infection	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1229 12291029	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
	C4591001 1229 12291030	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
	C4591001 1229 12291031	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1229 12291032	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1229 12291033	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1229 12291035	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1229 12291037	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1229 12291042†	Investigations	HIV test positive	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1229 12291045†	Investigations	HIV test positive	01JAN2012		Y
	C4591001 1229 12291046	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
	C4591001 1229 12291047	Infections and infestations	Tuberculosis	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
			Nasal polyps	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1229 12291048	Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1229 12291049	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Surgical and medical procedures	Sterilisation	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1229 12291051	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1229 12291052†	Infections and infestations	HIV infection	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1229 12291055†	Infections and infestations	HIV infection	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1229 12291057	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004		Y
			Sterilisation	01JAN2004		Y
	C4591001 1229 12291058†	Investigations	HIV test positive	01JAN2008		Y
		Renal and urinary disorders	Renal impairment	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291059	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1229 12291061	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Renal and urinary disorders	Renal impairment	01JAN2018		Y
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1229 12291062	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1229 12291063†	Infections and infestations	HIV infection	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
			Sterilisation	01JAN2012		Y
	C4591001 1229 12291064	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
	C4591001 1229 12291065	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1229 12291066	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Vascular disorders	Hypertension	18JUL2019		Y
	C4591001 1229 12291070†	Infections and infestations	HIV infection	01JAN2004		Y
	C4591001 1229 12291072†	Investigations	HIV test positive	01JAN2014		Y
	C4591001 1229 12291073†	Investigations	HIV test positive	01JAN2006		Y
	C4591001 1229 12291077	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1229 12291078	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1229 12291079	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1229 12291081†	Investigations	HIV test positive	01JAN2014		Y
	C4591001 1229 12291082	Respiratory, thoracic and mediastinal disorders	Asthma	14AUG2014		Y
	C4591001 1229 12291083†	Infections and infestations	HIV infection	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Social circumstances	Menopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1229 12291086†	Infections and infestations	HIV infection	01JAN2019		Y
	C4591001 1229 12291091	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1229 12291092†	Infections and infestations	HIV infection	01JAN2001		Y
	C4591001 1229 12291093	Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Lipoma excision	01JAN1997	31DEC1997	N
	C4591001 1229 12291095	Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1229 12291096†	Infections and infestations	HIV infection	01AUG2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291098	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1229 12291099	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1229 12291100	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
	C4591001 1229 12291101	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2018	31MAR2019	N
		Infections and infestations	Chronic sinusitis	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Menopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1229 12291113†	Infections and infestations	HIV infection	01JAN2011		Y
	C4591001 1229 12291116	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JUN2018	31DEC2018	N
	C4591001 1229 12291117†	Infections and infestations	HIV infection	01JAN2014		Y
	C4591001 1229 12291118	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291119	Infections and infestations	Acarodermatitis	01AUG2020	31AUG2020	N
		Injury, poisoning and procedural complications	Nail injury	03OCT2020		Y
	C4591001 1229 12291122	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1229 12291124	Surgical and medical procedures	Caesarean section	01JAN2017		Y
	C4591001 1229 12291126†	Investigations	HIV test positive	01JAN2015		Y
	C4591001 1229 12291130†	Investigations	HIV test positive	01JAN2013		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1229 12291131†	Investigations	HIV test positive	01JAN2008		Y
	C4591001 1229 12291134†	Investigations	HIV test positive	01JAN2016		Y
	C4591001 1229 12291135†	Investigations	HIV test positive	01JAN2005		Y
	C4591001 1229 12291136	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1229 12291139†	Investigations	HIV test positive	01JAN2007		Y
	C4591001 1229 12291140†	Investigations	HIV test positive	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291141	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
	C4591001 1229 12291142	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
	C4591001 1229 12291143	Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
	C4591001 1229 12291145	Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1229 12291146	Surgical and medical procedures	Female sterilisation	01FEB2018	28FEB2018	N
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1229 12291151	Respiratory, thoracic and mediastinal disorders	Asthma	01APR2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1229 12291152	Injury, poisoning and procedural complications	Stab wound	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Skin graft	01JAN2012	31DEC2012	N
			Wound closure	01JAN2010	31DEC2010	N
	C4591001 1229 12291154	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1229 12291165†	Infections and infestations	HIV infection	01JAN2006		Y
	C4591001 1229 12291166†	Investigations	HIV test positive	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1229 12291167†	Investigations	HIV test positive	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291168	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1229 12291169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1229 12291170†	Investigations	HIV test positive	01JAN2016		Y
	C4591001 1229 12291171†	Investigations	HIV test positive	01JAN2005		Y
	C4591001 1229 12291173	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1229 12291175	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1229 12291176	Surgical and medical procedures	Caesarean section	01JUN2011	30JUN2011	N
			Sterilisation	01JUN2011	30JUN2011	N
	C4591001 1229 12291178†	Infections and infestations	HIV infection	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1229 12291179	Surgical and medical procedures	Haemorrhoid operation	01JAN2010	31DEC2010	N
	C4591001 1229 12291181†	Infections and infestations	HIV infection	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1229 12291186	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1229 12291189	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291194†	Infections and infestations	HIV infection	01JAN2017		Y
	C4591001 1229 12291196	Gastrointestinal disorders	Peptic ulcer	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01AUG2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Caesarean section	01JAN2010	31DEC2010	N
			Sterilisation	01JAN2010		Y
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1229 12291198	Social circumstances	Menopause	01JAN2018		Y
	C4591001 1229 12291200	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1229 12291202	Surgical and medical procedures	Caesarean section	01JAN2015	31DEC2015	N
	C4591001 1229 12291209	Immune system disorders	Drug hypersensitivity	01JUN2020		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Abscess drainage	01JUN2020	30JUN2020	N
	C4591001 1229 12291211†	Infections and infestations	HIV infection	08NOV2016		Y
	C4591001 1229 12291214	Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
				01JAN2017	31DEC2017	N
	C4591001 1229 12291215†	Infections and infestations	HIV infection	01JAN2019		Y
	C4591001 1229 12291216	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301001	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1230 12301002	Eye disorders	Hypermetropia	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1230 12301004	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1230 12301005	Eye disorders	Hypermetropia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2014	31DEC2017	N
	C4591001 1230 12301006	Psychiatric disorders	Depression	01JAN2017	31JAN2018	N
		Surgical and medical procedures	Caesarean section	10OCT1995	10OCT1995	N
				20MAR1993	20MAR1993	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Oophorectomy	01JAN1998	31DEC1998	N
	C4591001 1230 12301008	Psychiatric disorders	Anxiety disorder	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Hernia hiatus repair	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
			Intraocular lens implant	01JAN2007	31JAN2007	N
			Salpingectomy	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1230 12301009	Injury, poisoning and procedural complications	Limb injury	15FEB2019	01MAR2019	N
			Scar	15FEB2019		Y
		Surgical and medical procedures	Tendon graft	15FEB2019	01MAR2019	N
			Tonsillectomy	01JAN1997	31DEC1997	N
	C4591001 1230 12301010	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001	31DEC2011	N
		Surgical and medical procedures	Appendectomy	01NOV2018	30NOV2018	N
			Open reduction of fracture	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1230 12301011	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2014	31AUG2014	N
			Tonsillectomy	01JAN1992	31DEC1992	N
	C4591001 1230 12301015	Surgical and medical procedures	Circumcision	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1230 12301017	Injury, poisoning and procedural complications	Face injury	01JAN1990	31DEC1990	N
			Skin laceration	01JAN1990		Y
	C4591001 1230 12301018	Surgical and medical procedures	Circumcision	01AUG2015	31AUG2015	N
	C4591001 1230 12301020	Nervous system disorders	Epilepsy	01FEB2019		Y
	C4591001 1230 12301021	Injury, poisoning and procedural complications	Clavicle fracture	18DEC2016	18DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Joint injury	01APR2020	30APR2020	N
			Scar	01APR2020		Y
				18DEC2016		Y
	C4591001 1230 12301022	Infections and infestations	Pulmonary tuberculosis	01JAN2008	31DEC2008	N
	C4591001 1230 12301024	Pregnancy, puerperium and perinatal conditions	Delivery	28JUN2018	28JUN2018	N
	C4591001 1230 12301026	Injury, poisoning and procedural complications	Scar	08FEB2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Foetal distress syndrome	08FEB2018	08FEB2018	N
		Surgical and medical procedures	Caesarean section	08FEB2018	08FEB2018	N
	C4591001 1230 12301028	Surgical and medical procedures	Caesarean section	03APR2018	03APR2018	N
				28JUL2014	28JUL2014	N
	C4591001 1230 12301029	Gastrointestinal disorders	Gastritis	01FEB2019	28FEB2019	N
		Infections and infestations	Upper respiratory tract infection	01JUN2019	30JUN2019	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2015		Y
	C4591001 1230 12301031	Pregnancy, puerperium and perinatal conditions	Delivery	09SEP2013	09SEP2013	N
	C4591001 1230 12301032	Gastrointestinal disorders	Haemorrhoids	01JAN2012		Y
	C4591001 1230 12301035	Infections and infestations	Varicella zoster virus infection	01JAN1997	31DEC1997	N
	C4591001 1230 12301037	Surgical and medical procedures	Open reduction of fracture	01JUN2010	30JUN2010	N
				01MAR2015	31MAR2015	N
			Tonsillectomy	01JAN1999	31DEC1999	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301038	Eye disorders	Myopia	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Caesarean section	02MAR1994	02MAR1994	N
				19MAR1996	19MAR1996	N
			Cholecystectomy	01MAR2016	31MAR2016	N
			Hernia hiatus repair	01JAN2016	31DEC2016	N
			Hysterectomy	01JUL1996	31JUL1996	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1230 12301039	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Myopia	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1230 12301040	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Depression	01SEP2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
			Salpingectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1230 12301045†	Investigations	HIV test positive	01SEP2018		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	08OCT2015	08OCT2015	N
		Surgical and medical procedures	Caesarean section	08OCT2015	08OCT2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301047	Surgical and medical procedures	Hand repair operation	01JAN1994	31DEC1994	N
			Rhinoplasty	01JAN1982	31DEC1982	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1230 12301048	Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
			Caesarean section	05JAN2005	05JAN2005	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1230 12301050	Pregnancy, puerperium and perinatal conditions	Delivery	11APR2007	11APR2007	N
				16MAR2011	16MAR2011	N
	C4591001 1230 12301052	Pregnancy, puerperium and perinatal conditions	Delivery	16JAN2018	16JAN2018	N
		Surgical and medical procedures	Antibiotic therapy	01JAN2001	31DEC2001	N
	C4591001 1230 12301055	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	06FEB2018	06FEB2018	N
	C4591001 1230 12301056	Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1230 12301057	Pregnancy, puerperium and perinatal conditions	Delivery	25FEB2018	25FEB2018	N
	C4591001 1230 12301058	Surgical and medical procedures	Caesarean section	25FEB2013	25FEB2013	N
				26MAY2017	26MAY2017	N
	C4591001 1230 12301060	Injury, poisoning and procedural complications	Ankle fracture	01JAN2014	31DEC2014	N
	C4591001 1230 12301068	Pregnancy, puerperium and perinatal conditions	Delivery	09FEB2018	09FEB2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				31DEC2012	31DEC2012	N
	C4591001 1230 12301069	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1230 12301070	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1230 12301071	Social circumstances	Tobacco user	01JAN2009		Y
	C4591001 1230 12301073†	Investigations	HIV test positive	01JAN2014		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	02NOV2008	02NOV2008	N
				21OCT2004	21OCT2004	N
				26MAY2001	26MAY2001	N
				26OCT1993	26OCT1993	N
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1230 12301074	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Social circumstances	Tobacco user	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	03FEB2014	03FEB2014	N
				06AUG2011	06AUG2011	N
	C4591001 1230 12301075	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JUN2018	30SEP2018	N
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
			Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01SEP2018	30SEP2018	N
	C4591001 1230 12301077	Infections and infestations	Sinusitis	29SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	12SEP2003	12SEP2003	N
				24MAR2005	24MAR2005	N
		Respiratory, thoracic and mediastinal disorders	Sinus pain	29SEP2020		Y
		Surgical and medical procedures	Hip arthroplasty	01JUN2017	30JUN2017	N
			Tonsillectomy	01JAN1981	31DEC1981	N
	C4591001 1230 12301078	Surgical and medical procedures	Tonsillectomy	01JUN2019	30JUN2019	N
	C4591001 1230 12301079	Surgical and medical procedures	Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1230 12301083	Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 1230 12301084	Surgical and medical procedures	Caesarean section	14MAY2001	14MAY2001	N
				18MAY2004	18MAY2004	N
			Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Ligament operation	01JAN2017	31DEC2017	N
			Skin graft	01JAN2017	31DEC2017	N
			Tenotomy	01JAN2010	31DEC2010	N
	C4591001 1230 12301085	Surgical and medical procedures	Tonsillectomy	01JAN2006	31DEC2006	N
	C4591001 1230 12301086†	Investigations	HIV test positive	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301087	Surgical and medical procedures	Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1230 12301089	Injury, poisoning and procedural complications	Humerus fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2000	N
	C4591001 1230 12301091	Social circumstances	Tobacco user	01JAN2016		Y
	C4591001 1230 12301092	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2019	29FEB2020	N
	C4591001 1230 12301094	Surgical and medical procedures	Open reduction of fracture	01NOV2017	31DEC2017	N
	C4591001 1230 12301095	Gastrointestinal disorders	Large intestine perforation	27AUG2019	27AUG2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Surgical and medical procedures	Enterostomy	27AUG2019	27AUG2019	N
			Sinus operation	01JAN2000	31DEC2000	N
	C4591001 1230 12301097	Social circumstances	Tobacco user	01JAN2015		Y
	C4591001 1230 12301099	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y
		Psychiatric disorders	Depression	01AUG2019		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1230 12301100	Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1230 12301101	Pregnancy, puerperium and perinatal conditions	Delivery	02JUN2011	02JUN2011	N
				14FEB2006	14FEB2006	N
	C4591001 1230 12301105	Vascular disorders	Hypertension	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301110	Pregnancy, puerperium and perinatal conditions	Delivery	28OCT2001	28OCT2001	N
	C4591001 1230 12301112	Surgical and medical procedures	Caesarean section	02FEB2001	02FEB2001	N
	C4591001 1230 12301113	Eye disorders	Blindness unilateral	01JAN1984		Y
	C4591001 1230 12301114	Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1230 12301115	Gastrointestinal disorders	Chronic gastritis	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1230 12301116	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1230 12301117	Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Nervous system disorders	Epilepsy	01OCT2018		Y
			Migraine	01OCT2018		Y
			Restless legs syndrome	01OCT2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2008		Y
			Bipolar disorder	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
			Ear tube insertion	01JAN1993	31DEC1993	N
	C4591001 1230 12301118	Injury, poisoning and procedural complications	Limb injury	01AUG2017	31AUG2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				20MAY1987	20MAY1987	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1230 12301122	Injury, poisoning and procedural complications	Hand fracture	01JAN2005	31DEC2005	N
	C4591001 1230 12301123	Pregnancy, puerperium and perinatal conditions	Delivery	01JUL1990	01JUL1990	N
				(b) (6) 1973	(b) (6) 1973	N
		Social circumstances	Tobacco user	01JAN1992		Y
		Surgical and medical procedures	Caesarean section	22MAR1986	22MAR1986	N
			Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1230 12301124	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Breast tumour excision	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN2017	31DEC2017	N
			Salpingectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1230 12301125	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1230 12301129	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	13AUG2011	13AUG2011	N
				25DEC1996	25DEC1996	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				29NOV2000	29NOV2000	N
				29OCT2014	29OCT2014	N
	C4591001 1230 12301130	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Pregnancy, puerperium and perinatal conditions	Complication of pregnancy	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N
			Caesarean section	13JAN2003	13JAN2003	N
				18APR2005	18APR2005	N
			Hysterectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1230 12301132	Surgical and medical procedures	Circumcision	01JAN2018	31DEC2018	N
	C4591001 1230 12301136	Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Toe operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1230 12301137	Congenital, familial and genetic disorders	Hydrocele	01JAN2018	31DEC2018	N
		Social circumstances	Tobacco user	01JAN1998		Y
		Surgical and medical procedures	Hydrocele operation	01JAN2018	31DEC2018	N
			Papilloma excision	01JAN1996	31DEC1996	N
			Spinal fusion surgery	25MAR2020	28MAR2020	N
			Tonsillectomy	01JAN1982	31DEC1982	N
	C4591001 1230 12301138	Vascular disorders	Hypertension	01APR2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301139†	Infections and infestations	HIV infection	01JAN2014		Y
		Social circumstances	Tobacco user	01JAN1993		Y
	C4591001 1230 12301140†	Infections and infestations	HIV infection	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1230 12301142	Pregnancy, puerperium and perinatal conditions	Delivery	03MAR2018	03MAR2018	N
				19JUL2007	19JUL2007	N
				30DEC2010	30DEC2010	N
	C4591001 1230 12301144	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JUL1996	01JUL1996	N
				08MAY1992	08MAY1992	N
				09AUG1999	09AUG1999	N
				25OCT2006	25OCT2006	N
	C4591001 1230 12301146	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1230 12301147	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Major depression	01JAN2000		Y
	C4591001 1230 12301150	Gastrointestinal disorders	Umbilical hernia	(b) (6) 1987	31DEC2002	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301151	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 1230 12301152	Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1230 12301153	Surgical and medical procedures	Open reduction of fracture	01JAN2016	31DEC2016	N
	C4591001 1230 12301154	Social circumstances	Tobacco user	01JAN1989		Y
	C4591001 1230 12301157	Social circumstances	Tobacco user	01JAN2015		Y
	C4591001 1230 12301158	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1230 12301159	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Pregnancy, puerperium and perinatal conditions	Delivery	24AUG1984	24AUG1984	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1230 12301161	Psychiatric disorders	Anxiety disorder	01JAN2016		Y
			Insomnia	01JAN2009		Y
		Social circumstances	Tobacco user	01JAN1986		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1230 12301162	Social circumstances	Tobacco user	01JAN2000		Y
	C4591001 1230 12301163	Cardiac disorders	Cardiac failure	01JAN2011		Y
		Social circumstances	Tobacco user	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Open reduction of fracture	01MAY2000	31MAY2000	N
			Suture insertion	01JAN2000	31DEC2000	N
	C4591001 1230 12301164	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1230 12301165	Surgical and medical procedures	Tonsillectomy	01JAN1979	31DEC1979	N
	C4591001 1230 12301166	Surgical and medical procedures	Tonsillectomy	01JAN2007	31DEC2007	N
	C4591001 1230 12301171	Injury, poisoning and procedural complications	Back injury	09SEP2017	09SEP2017	N
			Road traffic accident	09SEP2017	09SEP2017	N
	C4591001 1230 12301172	Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1230 12301174†	Investigations	HIV test positive	01JAN2006		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	08JUN2015	08JUN2015	N
				16JUL1997	16JUL1997	N
				16SEP2006	16SEP2006	N
				21DEC2008	21DEC2008	N
				21JAN1990	21JAN1990	N
	C4591001 1230 12301176†	Investigations	HIV test positive	01NOV2019		Y
	C4591001 1230 12301177	Pregnancy, puerperium and perinatal conditions	Delivery	12JUL2000	12JUL2000	N
				13MAR1984	13MAR1984	N
				15SEP1990	15SEP1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				20SEP2004	20SEP2004	N
		Surgical and medical procedures	Caesarean section	07JUL1994	07JUL1994	N
	C4591001 1230 12301181	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	22DEC2015	22DEC2015	N
			Female sterilisation	22DEC2015	22DEC2015	N
			Salpingectomy	22DEC2015	22DEC2015	N
	C4591001 1230 12301182	Injury, poisoning and procedural complications	Femur fracture	01JAN1994	31DEC1994	N
	C4591001 1230 12301183	Social circumstances	Tobacco user	01JAN2007		Y
	C4591001 1230 12301184†	Investigations	HIV test positive	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN2015		Y
	C4591001 1230 12301186	Surgical and medical procedures	Caesarean section	27MAY2016	27MAY2016	N
	C4591001 1230 12301187	Injury, poisoning and procedural complications	Face injury	01FEB2019	28FEB2019	N
	C4591001 1230 12301188	Gastrointestinal disorders	Gastric ulcer perforation	01MAR2018	31MAR2018	N
		Social circumstances	Tobacco user	01JAN1999		Y
		Surgical and medical procedures	Laparotomy	01MAR2018	31DEC2018	N
	C4591001 1230 12301192	Social circumstances	Tobacco user	01JAN2011		Y
	C4591001 1230 12301193	Psychiatric disorders	Persistent depressive disorder	01APR2020		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301196	Metabolism and nutrition disorders	Obesity	01JAN1997		Y
	C4591001 1230 12301197	Gastrointestinal disorders	Chronic gastritis	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN2007		Y
	C4591001 1230 12301198	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1230 12301199	Surgical and medical procedures	Caesarean section	10FEB2010	10FEB2010	N
				18NOV2011	18NOV2011	N
				24JUN2014	24JUN2014	N
			Female sterilisation	24JUN2014	24JUN2014	N
			Ligament operation	01JAN1996	31DEC1996	N
			Salpingectomy	24JUN2014	24JUN2014	N
	C4591001 1230 12301201	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Pregnancy, puerperium and perinatal conditions	Delivery	15MAY2002	15MAY2002	N
		Surgical and medical procedures	Caesarean section	02MAY2006	02MAY2006	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1230 12301204	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2017		Y
	C4591001 1230 12301205	Social circumstances	Tobacco user	01MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1230 12301206	Social circumstances	Tobacco user	01JAN2013		Y
	C4591001 1230 12301207	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1230 12301208	Social circumstances	Tobacco user	01JAN2014		Y
	C4591001 1230 12301211	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Cephalo-pelvic disproportion	17JUN2019	17JUN2019	N
		Surgical and medical procedures	Caesarean section	12JUN2019	17JUN2019	N
	C4591001 1230 12301213	Social circumstances	Tobacco user	01JAN2017		Y
	C4591001 1230 12301214	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2015		Y
	C4591001 1230 12301216	Surgical and medical procedures	Circumcision	01JAN2015	31DEC2015	N
	C4591001 1230 12301222	Injury, poisoning and procedural complications	Hand fracture	01JAN2017	31DEC2017	N
	C4591001 1230 12301224	Eye disorders	Hypermetropia	01JAN2012		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Open reduction of fracture	01JAN2008	31DEC2008	N
	C4591001 1231 12311001	Nervous system disorders	Syncope	06AUG2020	06AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311002	Endocrine disorders	Hypothyroidism	01SEP2018		Y
	C4591001 1231 12311004	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
		Injury, poisoning and procedural complications	Dislocation of vertebra	01MAY2018		Y
	C4591001 1231 12311010	Psychiatric disorders	Anxiety disorder	15DEC2019		Y
	C4591001 1231 12311012	Psychiatric disorders	Anxiety disorder	01JAN2014		Y
	C4591001 1231 12311013	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
	C4591001 1231 12311019	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
	C4591001 1231 12311023	Endocrine disorders	Hypothyroidism	01JAN2009		Y
	C4591001 1231 12311025	Congenital, familial and genetic disorders	Thalassaemia beta	01JAN1990		Y
	C4591001 1231 12311027	Metabolism and nutrition disorders	Obesity	10OCT2015		Y
		Musculoskeletal and connective tissue disorders	Osteitis	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12311030	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1231 12311034	Cardiac disorders	Atrial fibrillation	01JUL2007	10DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311040	Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1977	31DEC1978	N
	C4591001 1231 12311043	Nervous system disorders	Migraine	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JUN2019	01JUN2019	N
	C4591001 1231 12311045	Nervous system disorders	Migraine	01JAN2009		Y
	C4591001 1231 12311047	Surgical and medical procedures	Tonsillectomy	01JUL2007	02JUL2007	N
	C4591001 1231 12311049	Psychiatric disorders	Persistent depressive disorder	01JAN1978		Y
	C4591001 1231 12311051	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1231 12311052	Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2002		Y
	C4591001 1231 12311053	Surgical and medical procedures	Coronary arterial stent insertion	01FEB2014		Y
	C4591001 1231 12311058	Infections and infestations	American trypanosomiasis	02NOV1999		Y
	C4591001 1231 12311065	Endocrine disorders	Hypothyroidism	12APR2019		Y
		Injury, poisoning and procedural complications	Hip fracture	01JUL2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01SEP2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JUL2005		Y
		Vascular disorders	Hypertension	01JUL2008		Y
	C4591001 1231 12311068	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01MAR1996		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311070	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1231 12311072	General disorders and administration site conditions	Lithiasis	01JAN2000	01MAY2020	N
		Renal and urinary disorders	Calculus urinary	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1974	31DEC1974	N
			Caesarean section	01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
	C4591001 1231 12311073	Metabolism and nutrition disorders	Hypercholesterolaemia	12JAN2019		Y
	C4591001 1231 12311074	Ear and labyrinth disorders	Tinnitus	15OCT2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01AUG2000		Y
	C4591001 1231 12311077	Cardiac disorders	Pericarditis	01AUG1995	07AUG1995	N
		Nervous system disorders	Facial paralysis	08JUN2019	30JUN2019	N
	C4591001 1231 12311078	Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1231 12311080	Infections and infestations	Pneumonia	07JUL1991	30JUL1991	N
	C4591001 1231 12311081	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01AUG2020		Y
	C4591001 1231 12311082	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02AUG2019		Y
	C4591001 1231 12311087	Eye disorders	Glaucoma	01AUG1995		Y
	C4591001 1231 12311088	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JUN2015		Y
		Vascular disorders	Raynaud's phenomenon	01JUN2015		Y
	C4591001 1231 12311092	Immune system disorders	Drug hypersensitivity	01AUG1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311093	Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1231 12311096	Infections and infestations	Cytomegalovirus hepatitis	01MAY2008	20MAY2008	N
	C4591001 1231 12311097	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1973		Y
	C4591001 1231 12311099	Endocrine disorders	Hypothyroidism	15SEP2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	15SEP2005		Y
		Vascular disorders	Hypertension	15SEP2005		Y
	C4591001 1231 12311100	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
	C4591001 1231 12311103	Congenital, familial and genetic disorders	Congenital cystic lung	15AUG1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY1974		Y
		Surgical and medical procedures	Lung lobectomy	15AUG1986		Y
	C4591001 1231 12311105	Renal and urinary disorders	Nephrolithiasis	01JAN2001	04JAN2001	N
	C4591001 1231 12311110	Endocrine disorders	Autoimmune thyroiditis	01JUN2017		Y
	C4591001 1231 12311116	Gastrointestinal disorders	Irritable bowel syndrome	01MAY2015		Y
	C4591001 1231 12311118	Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
			Renal colic	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
	C4591001 1231 12311119	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	10JUL2017	N
		Surgical and medical procedures	Hysterectomy	10JUL2017	10JUL2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311140	Cardiac disorders	Myocardial infarction	10AUG2010	24AUG2010	N
	C4591001 1231 12311141	Infections and infestations	Genital herpes	03APR2020		Y
	C4591001 1231 12311147	Metabolism and nutrition disorders	Obesity	01JUN2000		Y
	C4591001 1231 12311152	Endocrine disorders	Hypothyroidism	01MAR2014		Y
	C4591001 1231 12311159	Surgical and medical procedures	Knee operation	13MAR2019	13MAR2019	N
		Gastrointestinal disorders	Abdominal hernia	11APR1998	30OCT2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	12SEP2000		Y
	C4591001 1231 12311167		Rhinitis allergic	12SEP2000		Y
		Endocrine disorders	Autoimmune thyroiditis	01NOV2007		Y
		Nervous system disorders	Posterior reversible encephalopathy syndrome	01MAY2012	20MAY2012	N
		Vascular disorders	Hypertension	01MAY2012	20MAY2012	N
	C4591001 1231 12311172	Infections and infestations	Cat scratch disease	02MAY2003	02JUN2003	N
	C4591001 1231 12311177	Endocrine disorders	Hypothyroidism	15AUG2018		Y
	C4591001 1231 12311179	Infections and infestations	Dengue fever	19NOV2019	27NOV2019	N
		Endocrine disorders	Hypothyroidism	24DEC1999		Y
	C4591001 1231 12311180	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN1992	01JUN2015	N
	C4591001 1231 12311185	Vascular disorders	Hypertension	11JUN2008		Y
	C4591001 1231 12311186	Vascular disorders	Hypertension	01MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311187	Immune system disorders	Seasonal allergy	10OCT2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	04APR2019		Y
		Vascular disorders	Hypertension	04APR2019		Y
	C4591001 1231 12311189	Injury, poisoning and procedural complications	Lower limb fracture	04JAN1992	05FEB1992	N
	C4591001 1231 12311190	Infections and infestations	Dengue fever	21MAR2015	05APR2015	N
	C4591001 1231 12311200	Ear and labyrinth disorders	Vestibular disorder	01AUG2012		Y
		Endocrine disorders	Hypothyroidism	01JUN2014		Y
		Immune system disorders	Seasonal allergy	01FEB1974		Y
	C4591001 1231 12311202	Vascular disorders	Hypertension	01MAR2005		Y
	C4591001 1231 12311204	Gastrointestinal disorders	Oesophageal achalasia	06JAN2018	10FEB2018	N
		Surgical and medical procedures	Vasectomy	03MAY2019	03MAY2019	N
	C4591001 1231 12311207	Metabolism and nutrition disorders	Dyslipidaemia	01MAY2019		Y
			Obesity	01JAN2019		Y
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1231 12311208	Gastrointestinal disorders	Gastrooesophageal reflux disease	19JUN2019		Y
	C4591001 1231 12311210	Endocrine disorders	Hypothyroidism	19MAR2011		Y
		Nervous system disorders	Essential tremor	01MAR1980		Y
		Surgical and medical procedures	Caesarean section	19SEP2011	19SEP2011	N
			Rhinoplasty	01SEP1996	01SEP1996	N
	C4591001 1231 12311211	Gastrointestinal disorders	Barrett's oesophagus	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311214	Renal and urinary disorders	Nephrolithiasis	26JUL2020	01AUG2020	N
	C4591001 1231 12311217	Infections and infestations	Peritonitis	12APR2016	03MAY2016	N
		Injury, poisoning and procedural complications	Femur fracture	12AUG1991	31AUG1991	N
			Fibula fracture	12AUG1991	31AUG1991	N
			Tibia fracture	12AUG1991	31AUG1991	N
		Social circumstances	Tobacco user	30MAR2008		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	10JAN1990	N
	C4591001 1231 12311221	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2017		Y
	C4591001 1231 12311222	Vascular disorders	Raynaud's phenomenon	01MAY2012		Y
	C4591001 1231 12311224	Gastrointestinal disorders	Abdominal distension	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1231 12311232	Vascular disorders	Subclavian vein thrombosis	01JAN2004	01JAN2005	N
	C4591001 1231 12311233	Surgical and medical procedures	Endodontic procedure	01DEC2018	01DEC2018	N
			Gastric bypass	01MAR2016	12DEC2016	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1231 12311237	Surgical and medical procedures	Skin graft	01APR2006	02APR2006	N
			Tympanoplasty	14AUG1996	15AUG1996	N
	C4591001 1231 12311239	Hepatobiliary disorders	Cholelithiasis	01JAN2009	01OCT2012	N
			Hepatic steatosis	01JUN2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	06JAN2008	01FEB2019	N
	C4591001 1231 12311241	Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	10SEP2019	10SEP2020	N
		Social circumstances	Tobacco user	03AUG1988	01AUG2020	N
	C4591001 1231 12311245	Congenital, familial and genetic disorders	Heart disease congenital	(b) (6) 1987		Y
		Psychiatric disorders	Anxiety	01APR2019		Y
			Depression	01APR2019		Y
		Surgical and medical procedures	Plastic surgery	03FEB1990	03FEB1990	N
				18AUG1992	18AUG1992	N
	C4591001 1231 12311246	Gastrointestinal disorders	Large intestine polyp	01MAR2019		Y
		Vascular disorders	Hypertension	07JUL2010		Y
	C4591001 1231 12311248	Congenital, familial and genetic disorders	Limb reduction defect	(b) (6) 1988		Y
			Syndactyly	(b) (6) 1988		Y
	C4591001 1231 12311252	Eye disorders	Glaucoma	01AUG2020		Y
		Psychiatric disorders	Panic attack	01AUG2007	01AUG2008	N
	C4591001 1231 12311263	Gastrointestinal disorders	Inflammatory bowel disease	13JUL2001	01DEC2014	N
	C4591001 1231 12311264	Surgical and medical procedures	Gastric bypass	01JAN2011		Y
	C4591001 1231 12311268	Infections and infestations	Cellulitis	24APR2019	06MAY2020	N
	C4591001 1231 12311270	Ear and labyrinth disorders	Hypoacusis	20APR1970		Y
	C4591001 1231 12311272	Reproductive system and breast disorders	Ovarian cyst	01JAN2019	28JUN2019	N
		Surgical and medical procedures	Oophorectomy bilateral	28JUN2019	28JUN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311273	Endocrine disorders	Hypothyroidism	14JUN2009		Y
		Gastrointestinal disorders	Abdominal distension	12JAN2019		Y
			Dyspepsia	18JUL2018		Y
		Psychiatric disorders	Anxiety disorder	01FEB2020		Y
		Reproductive system and breast disorders	Amenorrhoea	15AUG2018		Y
	C4591001 1231 12311274	Endocrine disorders	Hypothyroidism	14JAN2005		Y
	C4591001 1231 12311277	Psychiatric disorders	Anxiety	20NOV1997	20DEC1998	N
		Surgical and medical procedures	Elbow operation	01MAR1991	01MAR1991	N
			Knee operation	01JUN1991	01JUN1991	N
	C4591001 1231 12311281	Gastrointestinal disorders	Abdominal pain upper	01APR2020		Y
			Gastritis	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	04APR2019		Y
	C4591001 1231 12311282	Psychiatric disorders	Insomnia	01AUG2020	28SEP2020	N
	C4591001 1231 12311283	Nervous system disorders	Migraine	01JUN2019		Y
	C4591001 1231 12311285	Nervous system disorders	Narcolepsy	11JAN2020		Y
	C4591001 1231 12311288	Surgical and medical procedures	Caesarean section	26FEB2018	26FEB2018	N
	C4591001 1231 12311294	Hepatobiliary disorders	Cholelithiasis	29MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01APR2013	15APR2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1231 12311295	Nervous system disorders	Migraine	01JAN2001		Y
	C4591001 1231 12311296	Vascular disorders	Hypertension	10JUN2020		Y
	C4591001 1231 12311297	Cardiac disorders	Wolff-Parkinson-White syndrome	01MAY2008	01MAY2008	N
		Infections and infestations	Appendicitis	01JAN2014	01JAN2014	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	01JAN2014	N
			Exeresis	01MAY2008	01MAY2008	N
	C4591001 1231 12311301	Respiratory, thoracic and mediastinal disorders	Asthma	02JAN1996	02MAY2000	N
	C4591001 1231 12311306	Nervous system disorders	Migraine	02AUG2018	01FEB2020	N
	C4591001 1231 12311307	Gastrointestinal disorders	Gastric ulcer	20OCT1999	11AUG2005	N
			Hiatus hernia	04AUG2005		Y
		Infections and infestations	Tooth abscess	01JUL2003	01AUG2003	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JUL1983	01JUL1983	N
		Metabolism and nutrition disorders	Overweight	01AUG2018		Y
		Social circumstances	Tobacco user	01JUN1990	01MAY2020	N
		Surgical and medical procedures	Inguinal hernia repair	02APR1982	02APR1982	N
	C4591001 1231 12311327	Respiratory, thoracic and mediastinal disorders	Asthma	10JUN2015		Y
	C4591001 1231 12311328	Endocrine disorders	Hyperthyroidism	01OCT2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311330	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUL1979		Y
	C4591001 1231 12311333	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
	C4591001 1231 12311334	Endocrine disorders	Hypothyroidism	01OCT2018		Y
	C4591001 1231 12311336	Cardiac disorders	Sinus bradycardia	27AUG1986		Y
		Eye disorders	Uveitis	13SEP1994	18OCT2003	N
		Surgical and medical procedures	Fracture treatment	09DEC2008	15FEB2009	N
	C4591001 1231 12311337	Infections and infestations	Infectious mononucleosis	01APR2000	14APR2000	N
			Parotitis	01MAR2000	11MAR2000	N
			Rubella	01MAY2000	08MAY2000	N
			Varicella	01MAR1993	12MAR1993	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
	C4591001 1231 12311338	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN2007		Y
	C4591001 1231 12311340	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y
		Vascular disorders	Hypertension	08AUG2009		Y
	C4591001 1231 12311341	Metabolism and nutrition disorders	Dyslipidaemia	01FEB2020		Y
	C4591001 1231 12311342	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN1979	01JUN2001	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JUN2014		Y
		Surgical and medical procedures	Cholecystectomy	11DEC2011	26DEC2011	N
	C4591001 1231 12311343	Vascular disorders	Hypertension	10AUG1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311347	Eye disorders	Ocular hypertension	07JUL2010		Y
	C4591001 1231 12311348	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992	01JAN2008	N
	C4591001 1231 12311352	Gastrointestinal disorders	Chronic gastritis	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 1231 12311354	Respiratory, thoracic and mediastinal disorders	Asthma	01NOV1986		Y
	C4591001 1231 12311355	Endocrine disorders	Thyroid mass	21FEB2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12311356	Gastrointestinal disorders	Coeliac disease	09JUN2017		Y
	C4591001 1231 12311358	Surgical and medical procedures	Hysterectomy	06DEC2015	06DEC2015	N
	C4591001 1231 12311360	Reproductive system and breast disorders	Ovarian cyst	01DEC2015	01DEC2015	N
		Surgical and medical procedures	Ovarian cystectomy	01DEC2015	01DEC2015	N
	C4591001 1231 12311361	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN2018	31DEC2018	N
	C4591001 1231 12311362	Psychiatric disorders	Anxiety disorder	01AUG2019		Y
	C4591001 1231 12311364	Vascular disorders	Hypertension	15JUL2019		Y
	C4591001 1231 12311365	Metabolism and nutrition disorders	Obesity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311366	Endocrine disorders	Hyperprolactinaemia	14SEP2017		Y
			Hypothyroidism	10APR2019		Y
	C4591001 1231 12311367	Nervous system disorders	Optic neuritis	01SEP2016	01JUL2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Surgical and medical procedures	Spinal operation	04APR2018	01MAY2018	N
	C4591001 1231 12311371	Vascular disorders	Hypertension	05APR2012		Y
	C4591001 1231 12311373	Ear and labyrinth disorders	Tinnitus	21SEP2017		Y
		Metabolism and nutrition disorders	Overweight	05JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN1991	31JUL1991	N
		Skin and subcutaneous tissue disorders	Acne	01AUG1985	01OCT1991	N
			Keloid scar	01AUG1988	01JAN1991	N
	C4591001 1231 12311374	Endocrine disorders	Hyperthyroidism	01JUL1994	01MAY1996	N
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JUN2019		Y
	C4591001 1231 12311375	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	30AUG1990		Y
	C4591001 1231 12311377	Gastrointestinal disorders	Diverticulum	29AUG2006	14AUG2018	N
	C4591001 1231 12311381	Surgical and medical procedures	Meniscus operation	01JAN2009	20JAN2009	N
	C4591001 1231 12311385	Hepatobiliary disorders	Cholelithiasis	15JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311387	Psychiatric disorders	Bulimia nervosa	01APR2015	10DEC2015	N
	C4591001 1231 12311388	Gastrointestinal disorders	Pancreatitis	01AUG2014	09AUG2014	N
		Surgical and medical procedures	Gastric bypass	07JAN2019		Y
	C4591001 1231 12311389	Infections and infestations	Onychomycosis	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1231 12311391	Immune system disorders	Drug hypersensitivity	12JUN1993		Y
		Pregnancy, puerperium and perinatal conditions	Gestational hypertension	04APR2016	20JUL2018	N
			Premature baby	04APR2016	20JUL2018	N
	C4591001 1231 12311392	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2004		Y
	C4591001 1231 12311393	Surgical and medical procedures	Spinal operation	01SEP2013	01AUG2019	N
	C4591001 1231 12311395	Vascular disorders	Hypertension	10JAN2010		Y
	C4591001 1231 12311396	Congenital, familial and genetic disorders	Thalassaemia	04AUG2015		Y
	C4591001 1231 12311397	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2017		Y
	C4591001 1231 12311401	Metabolism and nutrition disorders	Type 1 diabetes mellitus	16AUG2008		Y
	C4591001 1231 12311402	Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1231 12311403	Congenital, familial and genetic disorders	Thalassaemia	(b) (6) 1992		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
	C4591001 1231 12311405	Eye disorders	Glaucoma	01FEB2016	01FEB2020	N
	C4591001 1231 12311410	Nervous system disorders	Migraine	08SEP1990		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	10SEP2012	05OCT2012	N
		Psychiatric disorders	Post-traumatic stress disorder	05JUN2013		Y
	C4591001 1231 12311414	Renal and urinary disorders	Nephrolithiasis	01OCT2018		Y
	C4591001 1231 12311417	Nervous system disorders	Migraine	01JUN2018		Y
	C4591001 1231 12311418	Hepatobiliary disorders	Hepatic steatosis	01AUG2017		Y
		Infections and infestations	Genital herpes	13JUL2020	20JUL2020	N
	C4591001 1231 12311422	Endocrine disorders	Hypothyroidism	01JUN2016		Y
	C4591001 1231 12311425	Renal and urinary disorders	Nephrolithiasis	01APR2019	01APR2019	N
	C4591001 1231 12311427	Metabolism and nutrition disorders	Dyslipidaemia	09JAN2020		Y
	C4591001 1231 12311428	Vascular disorders	Hypertension	01AUG2012		Y
	C4591001 1231 12311436	Psychiatric disorders	Anxiety disorder	21MAY2019	01JAN2020	N
	C4591001 1231 12311439	Injury, poisoning and procedural complications	Femur fracture	01FEB2000	01APR2001	N
	C4591001 1231 12311443	Respiratory, thoracic and mediastinal disorders	Asthma	06AUG2015		Y
	C4591001 1231 12311444	Respiratory, thoracic and mediastinal disorders	Emphysema	01JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Tobacco user	01JUN1991	01MAY2019	N
	C4591001 1231 12311447	Surgical and medical procedures	Varicocele repair	05AUG2013	01MAR2014	N
	C4591001 1231 12311448	Psychiatric disorders	Adjustment disorder with depressed mood	06JUN2008	01JUN2010	N
		Social circumstances	Tobacco user	01MAY2014		Y
	C4591001 1231 12311452	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1231 12311457	Psychiatric disorders	Anxiety disorder	25MAR2020		Y
	C4591001 1231 12311459	Psychiatric disorders	Anxiety disorder	01SEP2018		Y
	C4591001 1231 12311465	Immune system disorders	Drug hypersensitivity	01MAR2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
	C4591001 1231 12311468	Surgical and medical procedures	Ovarian operation	01JUN2014	01JUN2014	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1231 12311474	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2015		Y
	C4591001 1231 12311475	Surgical and medical procedures	Mammoplasty	20JUN2012	20JUN2012	N
	C4591001 1231 12311476	Psychiatric disorders	Adjustment disorder with depressed mood	01OCT2011		Y
	C4591001 1231 12311479	Vascular disorders	Hypertension	06JUN2006		Y
	C4591001 1231 12311480	Metabolism and nutrition disorders	Hypercholesterolaemia	10JUN1998		Y
		Psychiatric disorders	Insomnia	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311481	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1231 12311485	Skin and subcutaneous tissue disorders	Miliaria	15JUL2020		Y
	C4591001 1231 12311492	Endocrine disorders	Hypothyroidism	03APR2015		Y
	C4591001 1231 12311494	Infections and infestations	Dengue fever	01JAN2016	01FEB2016	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
	C4591001 1231 12311496	Blood and lymphatic system disorders	Iron deficiency anaemia	01AUG2020		Y
	C4591001 1231 12311503	Respiratory, thoracic and mediastinal disorders	Asthma	07NOV2019		Y
	C4591001 1231 12311505	Musculoskeletal and connective tissue disorders	Seronegative arthritis	01MAR2017	01AUG2019	N
	C4591001 1231 12311506	Infections and infestations	Pneumonia	01AUG2019	15AUG2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteosarcoma	01AUG2015	01DEC2015	N
	C4591001 1231 12311507	Psychiatric disorders	Generalised anxiety disorder	01FEB2020		Y
	C4591001 1231 12311508	Metabolism and nutrition disorders	Hypertriglyceridaemia	19AUG2015		Y
	C4591001 1231 12311509	Metabolism and nutrition disorders	Overweight	01AUG2001		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	02JAN1998		Y
		Social circumstances	Tobacco user	05MAR1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311516	Psychiatric disorders	Depression	02MAY2006		Y
	C4591001 1231 12311520	Endocrine disorders	Hypothyroidism	14AUG2002		Y
	C4591001 1231 12311526	Congenital, familial and genetic disorders	Thalassaemia minor	02JUL2011		Y
		Endocrine disorders	Hypothyroidism	01JUL2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2000		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01NOV2017		Y
		Social circumstances	Tobacco user	01JUL1990		Y
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1231 12311529	Endocrine disorders	Hypothyroidism	06JUN2010		Y
		Vascular disorders	Hypertension	03JUN2019		Y
	C4591001 1231 12311538	Eye disorders	Diabetic retinopathy	01JAN2017		Y
		Injury, poisoning and procedural complications	Multiple injuries	01MAY2003	30JUN2003	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	29JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01MAR2008	30APR2008	N
		Skin and subcutaneous tissue disorders	Skin ulcer	15JUN2019		Y
		Social circumstances	Tobacco user	01MAR1990	31MAR2012	N
		Surgical and medical procedures	Cataract operation	01MAR2017	31MAR2017	N
				01MAY2017	31MAY2017	N
			Skin neoplasm excision	01APR2008	30APR2008	N
			Toe amputation	19APR2018	19APR2018	N
		Vascular disorders	Extremity necrosis	19APR2018	19APR2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311543	Metabolism and nutrition disorders	Type 2 diabetes mellitus	03JUN2019		Y
	C4591001 1231 12311544	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUN2006		Y
	C4591001 1231 12311548	Immune system disorders	Atopy	01JAN1994		Y
	C4591001 1231 12311559	Respiratory, thoracic and mediastinal disorders	Bronchospasm	06DEC2015		Y
	C4591001 1231 12311560	Vascular disorders	Hypertension	01MAR2015		Y
	C4591001 1231 12311565	Gastrointestinal disorders	Coeliac disease	10JUN2019		Y
		Hepatobiliary disorders	Hepatic steatosis	04MAR2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	11AUG2020		Y
			Type 2 diabetes mellitus	01JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	16MAR2016		Y
	C4591001 1231 12311567	Congenital, familial and genetic disorders	Congenital hearing disorder	(b) (6) 1995		Y
	C4591001 1231 12311568	Vascular disorders	Peripheral venous disease	01JAN1998		Y
	C4591001 1231 12311570	Nervous system disorders	Epilepsy	20JAN2020		Y
	C4591001 1231 12311571	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
	C4591001 1231 12311582	Endocrine disorders	Hypothyroidism	16AUG2009		Y
	C4591001 1231 12311584	Surgical and medical procedures	Appendicectomy	06MAY2009	06MAY2009	N
	C4591001 1231 12311585	Metabolism and nutrition disorders	Obesity	20MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311587	Metabolism and nutrition disorders	Hyperglycaemia	01NOV2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
	C4591001 1231 12311591	Surgical and medical procedures	Bone operation	08FEB2014	08FEB2014	N
	C4591001 1231 12311592	Gastrointestinal disorders	Chronic gastritis	07JUL2020		Y
		Pregnancy, puerperium and perinatal conditions	Placenta accreta	22DEC2014	22DEC2014	N
		Surgical and medical procedures	Hysterectomy	22DEC2014	22DEC2014	N
	C4591001 1231 12311594	Endocrine disorders	Hypothyroidism	01FEB2017		Y
	C4591001 1231 12311602	Vascular disorders	Aortic aneurysm	01OCT2008		Y
	C4591001 1231 12311605	Nervous system disorders	Migraine with aura	13SEP2019		Y
	C4591001 1231 12311607	Congenital, familial and genetic disorders	Thalassaemia	(b) (6) 1983		Y
	C4591001 1231 12311611	Metabolism and nutrition disorders	Obesity	10AUG2010		Y
		Nervous system disorders	Migraine	11OCT1998		Y
	C4591001 1231 12311616	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01NOV2014		Y
	C4591001 1231 12311618	Musculoskeletal and connective tissue disorders	Osteoarthritis	11AUG2014		Y
	C4591001 1231 12311621	Endocrine disorders	Hypothyroidism	16JUN2010		Y
	C4591001 1231 12311623	Psychiatric disorders	Generalised anxiety disorder	01MAR2020		Y
		Surgical and medical procedures	Renal stone removal	17JAN2019	18JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311626	Endocrine disorders	Hypothyroidism	01JUN2015		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1231 12311627	Surgical and medical procedures	Appendicectomy	05AUG2012	05AUG2012	N
	C4591001 1231 12311633	Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2010		Y
	C4591001 1231 12311634	Reproductive system and breast disorders	Ovarian cyst	20JAN2014	01MAR2014	N
	C4591001 1231 12311637	Psychiatric disorders	Obsessive-compulsive disorder	18SEP2012		Y
	C4591001 1231 12311642	Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12311647	Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12311648	Endocrine disorders	Hypothyroidism	01SEP2006		Y
	C4591001 1231 12311650	Metabolism and nutrition disorders	Dyslipidaemia	14JUN2019		Y
			Vitamin D deficiency	14JUN2019		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	15JAN2014		Y
	C4591001 1231 12311651	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2017	01SEP2017	N
		Surgical and medical procedures	Hysterectomy	20DEC2016	20DEC2016	N
			Mammoplasty	07JUL2018	07JUL2018	N
			Mastectomy	01SEP2017	01SEP2017	N
	C4591001 1231 12311652	Surgical and medical procedures	Tonsillectomy	21FEB2012	21FEB2012	N
	C4591001 1231 12311653	Cardiac disorders	Palpitations	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1231 12311660	Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Ovarian lesion excision	03AUG1998	03AUG1998	N
	C4591001 1231 12311661	Nervous system disorders	Psychomotor hyperactivity	(b) (6) 1996		Y
	C4591001 1231 12311665	Surgical and medical procedures	Female sterilisation	01JAN2018	01JAN2018	N
	C4591001 1231 12311673	Respiratory, thoracic and mediastinal disorders	Asthma	01MAR1998		Y
	C4591001 1231 12311679	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2012		Y
	C4591001 1231 12311681	Psychiatric disorders	Bipolar disorder	01JAN1995		Y
	C4591001 1231 12311683	Infections and infestations	Parasite allergy	03SEP2019		Y
		Nervous system disorders	Migraine	07JUN2019		Y
	C4591001 1231 12311685	Ear and labyrinth disorders	Otosclerosis	01JUL2018	01JUL2018	N
		Surgical and medical procedures	Cholecystectomy	23JUL2015	23JUL2015	N
			Middle ear prosthesis insertion	01JUL2018	01JUL2018	N
	C4591001 1231 12311689	Surgical and medical procedures	Fracture treatment	01OCT2009	31OCT2009	N
			Internal fixation of fracture	01JAN2006	31DEC2006	N
	C4591001 1231 12311690	Nervous system disorders	Epilepsy	01JUL1991		Y
	C4591001 1231 12311691	Psychiatric disorders	Generalised anxiety disorder	08MAY2019		Y
	C4591001 1231 12311702	Injury, poisoning and procedural complications	Meniscus injury	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2010		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01AUG2006		Y
		Social circumstances	Ex-tobacco user	06AUG1979	01SEP2007	N
		Surgical and medical procedures	Lung lobectomy	03SEP2007	04SEP2007	N
			Metabolic surgery	08SEP2019	10SEP2019	N
		Vascular disorders	Hypertension	07AUG2012	01OCT2019	N
		Eye disorders	Glaucoma	01JAN2010		Y
	C4591001 1231 12311705					
	C4591001 1231 12311724	Immune system disorders	Seasonal allergy	01MAR2007		Y
	C4591001 1231 12311730	Surgical and medical procedures	Gastric bypass	22JAN2015	22JAN2015	N
	C4591001 1231 12311734	Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Tobacco user	02JAN1996	03OCT2020	N
	C4591001 1231 12311740	Congenital, familial and genetic disorders	Ventricular septal defect	(b) (6) 1988		Y
	C4591001 1231 12311747	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	05MAY2015	05MAY2015	N
		Surgical and medical procedures	Hysterectomy	05MAY2015	05MAY2015	N
	C4591001 1231 12311754	Injury, poisoning and procedural complications	Ligament sprain	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	07SEP2005	12AUG2008	N
		Musculoskeletal and connective tissue disorders	Osteochondritis	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311755	Immune system disorders	Seasonal allergy	01JAN1993		Y
	C4591001 1231 12311760	Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1231 12311765	Gastrointestinal disorders	Chronic gastritis	15JAN2020		Y
	C4591001 1231 12311766	Surgical and medical procedures	Cholecystectomy	01APR2011	30APR2011	N
	C4591001 1231 12311769	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2013		Y
		Nervous system disorders	Paraesthesia	01JAN2020	14JAN2021	N
		Psychiatric disorders	Anxiety disorder	01JUN2008		Y
			Bulimia nervosa	01NOV2007	01NOV2010	N
		Social circumstances	Alcohol use	01FEB2008		Y
	C4591001 1231 12311770	Metabolism and nutrition disorders	Type 2 diabetes mellitus	19MAY2019		Y
	C4591001 1231 12311782	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2016		Y
		Vascular disorders	Hypertension	03APR2016		Y
	C4591001 1231 12311786	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1231 12311789	Metabolism and nutrition disorders	Hypercholesterolaemia	03MAR2015	06JUN2020	N
	C4591001 1231 12311794	Metabolism and nutrition disorders	Insulin resistance	01JUL2019		Y
		Vascular disorders	Hypertension	01JUL2005		Y
	C4591001 1231 12311797	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01DEC2015		Y
	C4591001 1231 12311799	Surgical and medical procedures	Metabolic surgery	05JAN2017	05JAN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311801	Vascular disorders	Hypertension	10AUG2017		Y
	C4591001 1231 12311816	Gastrointestinal disorders	Gastritis	15JUN2007	30JUN2007	N
	C4591001 1231 12311819	Vascular disorders	Hypertension	01MAR2013		Y
	C4591001 1231 12311821	Endocrine disorders	Secondary hypogonadism	01MAR2018		Y
		Psychiatric disorders	Anxiety disorder	05SEP1999		Y
	C4591001 1231 12311824	Respiratory, thoracic and mediastinal disorders	Asthma	01OCT1980		Y
	C4591001 1231 12311825	Nervous system disorders	Migraine	12MAR1986		Y
	C4591001 1231 12311833	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Reproductive system and breast disorders	Varicocele	01JUL2000	02JUL2000	N
	C4591001 1231 12311834	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	03APR2017	17NOV2017	N
	C4591001 1231 12311837	Psychiatric disorders	Anxiety disorder	01JUN2010		Y
	C4591001 1231 12311839	Psychiatric disorders	Insomnia	15JUN2020		Y
	C4591001 1231 12311841	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999	01JAN2012	N
	C4591001 1231 12311844	Endocrine disorders	Hypothyroidism	01JUL2000		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUL2011		Y
	C4591001 1231 12311850	Cardiac disorders	Arrhythmia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1990		Y
	C4591001 1231 12311854	Gastrointestinal disorders	Dysphagia	13MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01AUG1992	01AUG1995	N
	C4591001 1231 12311857	Metabolism and nutrition disorders	Insulin resistance	03MAR2020		Y
			Obesity	06JUN2016		Y
	C4591001 1231 12311858	Nervous system disorders	Migraine	08OCT1998		Y
	C4591001 1231 12311860	Surgical and medical procedures	Limb operation	16DEC2019	16DEC2019	N
	C4591001 1231 12311861	Metabolism and nutrition disorders	Dyslipidaemia	03MAR2020		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12311862	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JUN2004	02MAR2021	N
	C4591001 1231 12311863	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1993		Y
	C4591001 1231 12311865	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
	C4591001 1231 12311866	Gastrointestinal disorders	Irritable bowel syndrome	01MAR2020		Y
	C4591001 1231 12311869	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2017		Y
		Vascular disorders	Hypertension	01AUG1997		Y
	C4591001 1231 12311870	Metabolism and nutrition disorders	Dyslipidaemia	17AUG2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311871	Gastrointestinal disorders	Lumbar hernia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1997		Y
		Psychiatric disorders	Anxiety disorder	01JUL2017		Y
	C4591001 1231 12311874	Psychiatric disorders	Depression	01JUL2018		Y
	C4591001 1231 12311876	Psychiatric disorders	Anxiety disorder	01DEC2018		Y
	C4591001 1231 12311882	Infections and infestations	Peritonitis	17AUG2014	31AUG2014	N
		Respiratory, thoracic and mediastinal disorders	Pleural effusion	03SEP2014	18SEP2014	N
	C4591001 1231 12311884	Infections and infestations	Rhinitis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01AUG2020		Y
		Social circumstances	Tobacco user	01JAN1990		Y
	C4591001 1231 12311885	Metabolism and nutrition disorders	Type 2 diabetes mellitus	06NOV2019		Y
		Vascular disorders	Hypertension	06NOV2019		Y
	C4591001 1231 12311888	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1231 12311898	Nervous system disorders	Migraine	01AUG2010		Y
	C4591001 1231 12311899	Respiratory, thoracic and mediastinal disorders	Asthma	19AUG1985		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12311901	Psychiatric disorders	Insomnia	15JUN2019		Y
			Post-traumatic stress disorder	01OCT2016	01OCT2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311907	Endocrine disorders	Hypothyroidism	01AUG2000		Y
	C4591001 1231 12311908	Surgical and medical procedures	Appendicectomy	01JAN1986	01JAN1986	N
	C4591001 1231 12311911	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Surgical and medical procedures	Salpingectomy	31MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	20JAN2017		Y
	C4591001 1231 12311917	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12311920	Eye disorders	Amaurosis	01DEC1991		Y
	C4591001 1231 12311922	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014	01APR2019	N
		Surgical and medical procedures	Metabolic surgery	09JAN2019	09JAN2019	N
	C4591001 1231 12311923	Renal and urinary disorders	Acute kidney injury	01SEP2013	08SEP2013	N
	C4591001 1231 12311924	Gastrointestinal disorders	Chronic gastritis	15JUN2012		Y
	C4591001 1231 12311928	Gastrointestinal disorders	Dental caries	20JAN2016	23FEB2016	N
		Surgical and medical procedures	Artificial crown procedure	23FEB2016	23FEB2016	N
	C4591001 1231 12311929	Hepatobiliary disorders	Hepatic steatosis	11AUG2015		Y
		Vascular disorders	Hypertension	15DEC2017		Y
	C4591001 1231 12311934	Nervous system disorders	Psychomotor hyperactivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1231 12311938	Cardiac disorders	Mitral valve incompetence	18AUG2002		Y
	C4591001 1231 12311941	Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2011		Y
		Social circumstances	Andropause	01JAN2017		Y
		Vascular disorders	Varicose vein	01JAN2001		Y
	C4591001 1231 12311942	Endocrine disorders	Autoimmune thyroiditis	06JUN2010		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	06JUN2005		Y
	C4591001 1231 12311945	Immune system disorders	Drug hypersensitivity	09JUL2012		Y
			Seasonal allergy	01SEP2015		Y
	C4591001 1231 12311947	Immune system disorders	Seasonal allergy	11AUG2010		Y
	C4591001 1231 12311949	Blood and lymphatic system disorders	Hypercoagulation	01SEP2017		Y
		Surgical and medical procedures	Appendectomy	01JUN2001	05JUN2001	N
			Haemorrhoid operation	01JUN2008	01JUN2008	N
	C4591001 1231 12311950	Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	01JAN2014	N
			Rhinitis allergic	01JAN2000		Y
	C4591001 1231 12311951	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12311952	Psychiatric disorders	Anxiety disorder	01JUL2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311957	Metabolism and nutrition disorders	Obesity	01AUG2000		Y
		Social circumstances	Tobacco user	15DEC2019		Y
	C4591001 1231 12311958	Vascular disorders	Hypertension	09JUN2009		Y
	C4591001 1231 12311961	Metabolism and nutrition disorders	Obesity	01JUN1990		Y
	C4591001 1231 12311962	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
	C4591001 1231 12311964	General disorders and administration site conditions	Cyst	01DEC2018		Y
		Psychiatric disorders	Insomnia	31AUG2017		Y
	C4591001 1231 12311967	Respiratory, thoracic and mediastinal disorders	Asthma	01JUL1997		Y
	C4591001 1231 12311968	Metabolism and nutrition disorders	Hypercholesterolaemia	10MAY2020		Y
	C4591001 1231 12311969	Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1231 12311972	Vascular disorders	Hypertension	01APR2016		Y
	C4591001 1231 12311973	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2019		Y
	C4591001 1231 12311974	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2018	06JUN2018	N
	C4591001 1231 12311982	Metabolism and nutrition disorders	Hypercholesterolaemia	10OCT1995		Y
	C4591001 1231 12311984	Skin and subcutaneous tissue disorders	Psoriasis	08MAY2000		Y
	C4591001 1231 12311985	Vascular disorders	Hypertension	01JUN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311986	Endocrine disorders	Hypothyroidism	01FEB2000		Y
	C4591001 1231 12311989	Gastrointestinal disorders	Large intestine polyp	02DEC2011	03DEC2011	N
	C4591001 1231 12311997	Metabolism and nutrition disorders	Obesity	01OCT2010		Y
	C4591001 1231 12311998	Endocrine disorders	Hypothyroidism	23JUN2020		Y
	C4591001 1231 12312001	Vascular disorders	Hypertension	01JUL2018		Y
	C4591001 1231 12312004	Endocrine disorders	Hypothyroidism	18AUG1983		Y
		Gastrointestinal disorders	Gastritis	10AUG2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN1982		Y
		Psychiatric disorders	Anxiety	10MAR2007		Y
	C4591001 1231 12312007	Psychiatric disorders	Depression	01AUG2008		Y
	C4591001 1231 12312015	Vascular disorders	Hypertension	02FEB2007		Y
	C4591001 1231 12312020	Surgical and medical procedures	Valvuloplasty cardiac	04DEC2017		Y
		Vascular disorders	Hypertension	02NOV2010		Y
	C4591001 1231 12312027	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y
	C4591001 1231 12312028	Psychiatric disorders	Depression	01APR2004		Y
	C4591001 1231 12312029	Psychiatric disorders	Anxiety	15AUG2018		Y
	C4591001 1231 12312030	Congenital, familial and genetic disorders	Phimosi	01DEC2019	02OCT2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312038	Metabolism and nutrition disorders	Dyslipidaemia	10FEB2010		Y
			Overweight	01AUG2010		Y
	C4591001 1231 12312044	Gastrointestinal disorders	Gastritis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2011		Y
	C4591001 1231 12312048	Gastrointestinal disorders	Toothache	01AUG2020		Y
	C4591001 1231 12312052	Endocrine disorders	Hypothyroidism	01JAN1995		Y
	C4591001 1231 12312061	Endocrine disorders	Hypothyroidism	01AUG2010		Y
	C4591001 1231 12312065	Psychiatric disorders	Depression	07MAR2014		Y
	C4591001 1231 12312069	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2010		Y
	C4591001 1231 12312077	Immune system disorders	Seasonal allergy	01JUN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2017		Y
			Type 2 diabetes mellitus	01AUG2014		Y
	C4591001 1231 12312078	Endocrine disorders	Hypothyroidism	01NOV2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	01JAN2018	N
	C4591001 1231 12312080	Immune system disorders	Seasonal allergy	01APR2010		Y
		Social circumstances	Tobacco user	01MAY2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312088	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	10JAN2019		Y
	C4591001 1231 12312105	Endocrine disorders	Hypothyroidism	01AUG2018		Y
	C4591001 1231 12312107	Psychiatric disorders	Anxiety disorder	11AUG2005		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2012	01JUL2012	N
	C4591001 1231 12312111	Skin and subcutaneous tissue disorders	Androgenetic alopecia	01APR2020		Y
	C4591001 1231 12312118	Reproductive system and breast disorders	Polymenorrhoea	01SEP2019		Y
	C4591001 1231 12312121	Vascular disorders	Hypertension	10JUL2019		Y
	C4591001 1231 12312128	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02AUG2018		Y
	C4591001 1231 12312129	Cardiac disorders	Acute myocardial infarction	22FEB2018	28FEB2018	N
		Hepatobiliary disorders	Hepatic steatosis	01MAR2004		Y
		Surgical and medical procedures	Stent placement	22FEB2018	28FEB2018	N
	C4591001 1231 12312135	Vascular disorders	Hypertension	01FEB2014		Y
	C4591001 1231 12312136	Surgical and medical procedures	Meniscus removal	10JAN2007	18JAN2007	N
	C4591001 1231 12312138	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
	C4591001 1231 12312141	Vascular disorders	Hypertension	05FEB2014		Y
	C4591001 1231 12312142	Surgical and medical procedures	Ovarian cystectomy	10JAN2018	17JAN2018	N
	C4591001 1231 12312150	Gastrointestinal disorders	Irritable bowel syndrome	07AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312153	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG1999		Y
	C4591001 1231 12312154	Vascular disorders	Varicose vein	01JAN2011	18DEC2020	N
	C4591001 1231 12312155	Skin and subcutaneous tissue disorders	Acne	01MAR2020		Y
	C4591001 1231 12312169	Gastrointestinal disorders	Gastroesophageal reflux disease	12DEC2019		Y
	C4591001 1231 12312173	Endocrine disorders	Hypothyroidism	01MAY2012		Y
	C4591001 1231 12312174	Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2000		Y
		Surgical and medical procedures	Metabolic surgery	11NOV2011	12NOV2011	N
	C4591001 1231 12312175	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Eye disorders	Keratoconus	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01APR1985		Y
	C4591001 1231 12312176	General disorders and administration site conditions	Pyrexia	16AUG2020		Y
	C4591001 1231 12312185	Metabolism and nutrition disorders	Obesity	01MAY2017		Y
	C4591001 1231 12312186	Surgical and medical procedures	Cholecystectomy	01SEP2005	03SEP2005	N
		Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 1231 12312188	Immune system disorders	Seasonal allergy	01MAR2018		Y
	C4591001 1231 12312191	Immune system disorders	Seasonal allergy	01SEP2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	04MAR2005		Y
	C4591001 1231 12312192	Infections and infestations	Atypical pneumonia	15NOV2005	10JAN2006	N
			Hepatitis A	10FEB1998	28FEB1998	N
			Varicella	10AUG1998	20AUG1998	N
	C4591001 1231 12312195	Cardiac disorders	Acute myocardial infarction	27JUN2019	02DEC2019	N
	C4591001 1231 12312198	Vascular disorders	Hypertension	01MAR2010		Y
	C4591001 1231 12312200	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2002		Y
	C4591001 1231 12312202	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12312211	Metabolism and nutrition disorders	Type 2 diabetes mellitus	03JUL2017		Y
		Vascular disorders	Hypertension	03JUL2017		Y
	C4591001 1231 12312212	Endocrine disorders	Hypothyroidism	01JUN2002		Y
		Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1231 12312219	Nervous system disorders	Cervical radiculopathy	08SEP2019		Y
	C4591001 1231 12312227	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1231 12312236	Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1231 12312242	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Surgical and medical procedures	Ankle operation	01SEP2016	01SEP2016	N
			Cholecystectomy	01SEP1996	04SEP1996	N
			Umbilical hernia repair	09AUG1999	09AUG1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312243	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal papilloma	01JUN2010		Y
	C4591001 1231 12312244	Metabolism and nutrition disorders	Hypercholesterolaemia	10MAY2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2016		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	10JUN2012		Y
	C4591001 1231 12312247	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
	C4591001 1231 12312255	Vascular disorders	Hypertension	19AUG2000		Y
	C4591001 1231 12312257	Congenital, familial and genetic disorders	Renal aplasia	(b) (6) 1986		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	17AUG2010	14AUG2012	N
	C4591001 1231 12312260	Psychiatric disorders	Depression	01MAR2018		Y
	C4591001 1231 12312263	Social circumstances	Tobacco user	14AUG2008		Y
	C4591001 1231 12312268	Psychiatric disorders	Insomnia	02MAR2020		Y
	C4591001 1231 12312270	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1231 12312271	Nervous system disorders	Sciatica	01JUL2011	31DEC2014	N
		Surgical and medical procedures	Nerve block	01JAN2015	31DEC2019	N
			Spinal nerve stimulator implantation	11DEC2019	11DEC2019	N
	C4591001 1231 12312274	Surgical and medical procedures	Ligament operation	22JUN2006	20OCT2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312276	Surgical and medical procedures	Intervertebral disc operation	15APR2019	25APR2019	N
			Knee operation	26DEC2010	29DEC2010	N
	C4591001 1231 12312283	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1231 12312284	Nervous system disorders	Epilepsy	23JUN2015		Y
	C4591001 1231 12312286	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1231 12312287	Hepatobiliary disorders	Cholelithiasis	20APR2020		Y
	C4591001 1231 12312288	Infections and infestations	Chronic sinusitis	01JAN1992		Y
		Injury, poisoning and procedural complications	Nasal injury	01JAN1992	31DEC1992	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1992		Y
	C4591001 1231 12312289	Reproductive system and breast disorders	Infertility female	01JAN1990		Y
			Ovarian failure	01JAN1990		Y
	C4591001 1231 12312291	Endocrine disorders	Hypothyroidism	02JUN2009		Y
	C4591001 1231 12312297	Endocrine disorders	Hypothyroidism	01JAN2020		Y
	C4591001 1231 12312300	Psychiatric disorders	Persistent depressive disorder	01JUN2017		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12312304	Eye disorders	Uveitis	03SEP1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312305	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2010		Y
	C4591001 1231 12312306	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
	C4591001 1231 12312309	Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
	C4591001 1231 12312313	Vascular disorders	Hypertension	01JUL2017	01MAR2017 01APR2017	Y
	C4591001 1231 12312319	Metabolism and nutrition disorders	Type 2 diabetes mellitus	12DEC2019		Y
	C4591001 1231 12312324	Vascular disorders Psychiatric disorders	Hypertension Anxiety	01JAN2005 26AUG2014		Y Y
	C4591001 1231 12312327	Vascular disorders	Hypertension	10JUN2012		Y
	C4591001 1231 12312329	Infections and infestations	Pneumonia streptococcal	01FEB2019	11FEB2019	N
	C4591001 1231 12312331	Respiratory, thoracic and mediastinal disorders Endocrine disorders	Pleural effusion Hypothyroidism	01FEB2019	11FEB2019	N Y
	C4591001 1231 12312333	Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	01JAN2000		Y
	C4591001 1231 12312335	Cardiac disorders	Myocardial infarction	26AUG2017	26DEC2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	19AUG2017		Y
			Type 1 diabetes mellitus	19AUG1976		Y
		Surgical and medical procedures	Leg amputation	20DEC2017	20DEC2017	N
		Vascular disorders	Hypertension	19AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312336	Endocrine disorders	Hypothyroidism	10AUG2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16SEP1998		Y
	C4591001 1231 12312339	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23JUL2013		Y
	C4591001 1231 12312340	Endocrine disorders	Hypothyroidism	10JAN2010		Y
		Vascular disorders	Hypertension	10JAN2020		Y
	C4591001 1231 12312342	Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1231 12312344	Surgical and medical procedures	Tonsillectomy	01JUN2005	01AUG2005	N
	C4591001 1231 12312346	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25SEP2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	25SEP2013		Y
			Dermatitis atopic	25SEP2013		Y
	C4591001 1231 12312355	Surgical and medical procedures	Female sterilisation	11JUN2015	11JUN2015	N
	C4591001 1231 12312356	Endocrine disorders	Hypothyroidism	13AUG1991		Y
	C4591001 1231 12312358	Injury, poisoning and procedural complications	Meniscus injury	11NOV2016	11NOV2016	N
	C4591001 1231 12312359	Respiratory, thoracic and mediastinal disorders	Asthma	15FEB2020		Y
	C4591001 1231 12312360	Endocrine disorders	Hypothyroidism	13MAY2015		Y
		Surgical and medical procedures	Caesarean section	31JUL2018	31JUL2018	N
			Lipectomy	01DEC2018	01DEC2018	N
	C4591001 1231 12312361	Surgical and medical procedures	Thyroidectomy	01APR2017	01APR2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312363	Cardiac disorders	Acute myocardial infarction	27JUN2018	18JUL2018	N
			Cardiac failure	27JUN2018	28DEC2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Coronary artery bypass	11JUL2018	18JUL2018	N
	C4591001 1231 12312371	Cardiac disorders	Acute myocardial infarction	02MAY2019	09MAY2019	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUL2009		Y
		Vascular disorders	Hypertension	03MAR2009		Y
	C4591001 1231 12312372	Ear and labyrinth disorders	Meniere's disease	01JAN2020		Y
		Infections and infestations	Chronic sinusitis	26FEB2020		Y
		Psychiatric disorders	Anxiety	01JUL2012		Y
			Depression	01JUL2012		Y
	C4591001 1231 12312373	Metabolism and nutrition disorders	Type 2 diabetes mellitus	05NOV2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2020		Y
			Hypertrophic scar	01SEP2017		Y
		Surgical and medical procedures	Lipectomy	01SEP2017	30SEP2017	N
			Metabolic surgery	15MAY2015	15MAY2015	N
	C4591001 1231 12312375	Endocrine disorders	Hypothyroidism	01FEB2012		Y
	C4591001 1231 12312376	Endocrine disorders	Hypothyroidism	26AUG2010		Y
	C4591001 1231 12312382	Reproductive system and breast disorders	Polycystic ovaries	01AUG2014		Y
	C4591001 1231 12312384	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2019		Y
	C4591001 1231 12312396	Skin and subcutaneous tissue disorders	Alopecia	08AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312397	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Elastofibroma	02MAR2019		Y
	C4591001 1231 12312407	Respiratory, thoracic and mediastinal disorders	Asthma	19AUG1993		Y
	C4591001 1231 12312414	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Surgical and medical procedures	Transgender hormonal therapy	01JAN2016		Y
	C4591001 1231 12312417	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1980		Y
	C4591001 1231 12312418	Psychiatric disorders	Bipolar disorder	01JAN2015		Y
	C4591001 1231 12312420	Vascular disorders	Hypertension	13SEP2019		Y
	C4591001 1231 12312427	Gastrointestinal disorders	Irritable bowel syndrome	14MAR2018		Y
	C4591001 1231 12312434	Psychiatric disorders	Anxiety	05MAY2019		Y
	C4591001 1231 12312439	Vascular disorders	Hypertension	08AUG2017		Y
	C4591001 1231 12312441	Gastrointestinal disorders	Irritable bowel syndrome	19MAY2020		Y
	C4591001 1231 12312442	Immune system disorders	Drug hypersensitivity	02AUG2001		Y
	C4591001 1231 12312444	Surgical and medical procedures	Hysterectomy	19JUL2010	19JUL2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12312461	Endocrine disorders	Hypothyroidism	01OCT2016		Y
	C4591001 1231 12312462	Nervous system disorders	Trigeminal neuralgia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312464	Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1995	01DEC2008	N
	C4591001 1231 12312472	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2016		Y
		Surgical and medical procedures	Metabolic surgery	02MAY2014	02MAY2014	N
	C4591001 1231 12312476	Hepatobiliary disorders	Cholelithiasis	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01FEB2015		Y
	C4591001 1231 12312477	Endocrine disorders	Autoimmune thyroiditis	01JUN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2011		Y
	C4591001 1231 12312479	Endocrine disorders	Hypothyroidism	12APR2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
	C4591001 1231 12312481	Surgical and medical procedures	Female sterilisation	02NOV2013		Y
	C4591001 1231 12312487	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2002		Y
	C4591001 1231 12312488	Psychiatric disorders	Anorexia nervosa	01JAN2009	01JAN2016	N
	C4591001 1231 12312491	Endocrine disorders	Hypothyroidism	02FEB2010		Y
		Gastrointestinal disorders	Coeliac disease	02FEB2010		Y
	C4591001 1231 12312493	Vascular disorders	Hypertension	26AUG2008		Y
	C4591001 1231 12312501	Vascular disorders	Hypertension	15JAN2017		Y
	C4591001 1231 12312503	Nervous system disorders	Restless legs syndrome	01DEC2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1231 12312519	Metabolism and nutrition disorders	Type 2 diabetes mellitus	09MAY2014		Y
	C4591001 1231 12312525	Endocrine disorders	Hypothyroidism	01JUN2013		Y
	C4591001 1231 12312529	Psychiatric disorders	Bipolar disorder	01FEB2010	01MAR2011	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2011	31DEC2011	N
	C4591001 1231 12312532	Injury, poisoning and procedural complications	Tooth fracture	01NOV2014	01NOV2014	N
		Metabolism and nutrition disorders	Obesity	16JUL2017		Y
		Nervous system disorders	Migraine with aura	01JAN2000		Y
	C4591001 1231 12312533	Musculoskeletal and connective tissue disorders	Tendonitis	01JAN1988		Y
	C4591001 1231 12312538	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1231 12312542	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1231 12312543	Metabolism and nutrition disorders	Dyslipidaemia	01AUG1999		Y
	C4591001 1231 12312545	Surgical and medical procedures	Cholecystectomy	01FEB2020		Y
	C4591001 1231 12312553	Infections and infestations	Candida infection	01JAN2018	01JAN2018	N
	C4591001 1231 12312570	Psychiatric disorders	Sleep disorder	03MAR2020		Y
	C4591001 1231 12312575	Endocrine disorders	Hypothyroidism	04MAY2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JUL2012		Y
				12DEC2013		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	15AUG2010		Y
		Reproductive system and breast disorders	Uterine polyp	01JUL2020		Y
	C4591001 1231 12312577	Endocrine disorders	Hypothyroidism	13DEC2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung adenocarcinoma	01JUL2019	07JAN2020	N
		Psychiatric disorders	Depression	01OCT2019		Y
		Surgical and medical procedures	Exeresis	07JAN2020	07JAN2020	N
			Thyroidectomy	13DEC2019	13DEC2019	N
	C4591001 1231 12312578	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2017	01DEC2017	N
		Psychiatric disorders	Insomnia	01JUL2019		Y
	C4591001 1231 12312580	Psychiatric disorders	Depression	01MAR2013		Y
	C4591001 1231 12312592	Investigations	Electrocardiogram QT prolonged	01JAN2007	02JAN2007	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
	C4591001 1231 12312593	Metabolism and nutrition disorders	Obesity	09APR2002		Y
	C4591001 1231 12312596	Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	22SEP2020	N
		Metabolism and nutrition disorders	Gout	10JUN2013		Y
			Hypertriglyceridaemia	10APR2018		Y
	C4591001 1231 12312597	Psychiatric disorders	Anxiety	01AUG2018		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12312608	Reproductive system and breast disorders	Amenorrhoea	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312611	Surgical and medical procedures	Coronary arterial stent insertion	13JAN2009		Y
	C4591001 1231 12312612	Endocrine disorders	Hypothyroidism	06JUN1990		Y
	C4591001 1231 12312623	Congenital, familial and genetic disorders	Thalassaemia	01JUN2002		Y
	C4591001 1231 12312630	Respiratory, thoracic and mediastinal disorders	Asthma	06AUG1983		Y
	C4591001 1231 12312632	Psychiatric disorders	Depression	08NOV2019		Y
		Reproductive system and breast disorders	Gynaecomastia	01JUN2005	17DEC2020	N
	C4591001 1231 12312640	Endocrine disorders	Hypothyroidism	20AUG2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	20AUG2018		Y
	C4591001 1231 12312641	Psychiatric disorders	Depression	08AUG2019		Y
	C4591001 1231 12312645	Renal and urinary disorders	Nephrolithiasis	01NOV2019		Y
	C4591001 1231 12312651	Gastrointestinal disorders	Coeliac disease	01MAY2010		Y
			Umbilical hernia	01MAR2020		Y
		Surgical and medical procedures	Abdominal hernia repair	06SEP2017	06SEP2017	N
			Hysterectomy	01AUG2010	01AUG2010	N
	C4591001 1231 12312653	Metabolism and nutrition disorders	Type 1 diabetes mellitus	17AUG2017		Y
	C4591001 1231 12312658	Vascular disorders	Hypertension	01AUG2006		Y
	C4591001 1231 12312659	Reproductive system and breast disorders	Polycystic ovaries	16AUG2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12312663	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN2016		Y
			Polycystic liver disease	01JAN2016		Y
	C4591001 1231 12312665	Psychiatric disorders	Anxiety disorder	01JAN2019		Y
			Depression	01JAN2019		Y
			Persistent depressive disorder	01JUN2020		Y
	C4591001 1231 12312674	Endocrine disorders	Hypothyroidism	01DEC2019		Y
	C4591001 1231 12312675	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2000		Y
		Musculoskeletal and connective tissue disorders	Epiphysiolysis	01JAN2012	01FEB2012	N
	C4591001 1231 12312678	Congenital, familial and genetic disorders	Heart disease congenital	09JUN2006	09AUG2006	N
	C4591001 1231 12312679	Skin and subcutaneous tissue disorders	Psoriasis	02MAR2002		Y
	C4591001 1231 12312681	Metabolism and nutrition disorders	Hypercholesterolaemia	14AUG2018		Y
		Vascular disorders	Hypertension	14AUG2018		Y
	C4591001 1231 12312683	Metabolism and nutrition disorders	Type 2 diabetes mellitus	20AUG2016		Y
	C4591001 1231 12312697	Endocrine disorders	Hyperprolactinaemia	01AUG2019		Y
	C4591001 1231 12312702	Endocrine disorders	Hypothyroidism	01FEB2018		Y
	C4591001 1231 12312705	Cardiac disorders	Atrial fibrillation	01JAN2020	01FEB2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	08AUG2012		Y
			Hyperuricaemia	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312708	Endocrine disorders	Hypothyroidism	01MAR2016		Y
	C4591001 1231 12312714	Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1231 12312716	Blood and lymphatic system disorders	Hypochromic anaemia	12FEB2020		Y
	C4591001 1231 12312718	Endocrine disorders	Hypothyroidism	04AUG2019		Y
	C4591001 1231 12312725	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2010		Y
	C4591001 1231 12312727	Eye disorders	Glaucoma	04MAR2005		Y
	C4591001 1231 12312728	Surgical and medical procedures	Cholecystectomy	01DEC2017	02DEC2017	N
	C4591001 1231 12312734	Metabolism and nutrition disorders	Obesity	10OCT2010		Y
	C4591001 1231 12312735	Cardiac disorders	Aortic valve incompetence	01JAN2017		Y
	C4591001 1231 12312737	Congenital, familial and genetic disorders	Thalassaemia minor	(b) (6) 1965		Y
	C4591001 1231 12312738	Cardiac disorders	Wolff-Parkinson-White syndrome	03APR2015		Y
	C4591001 1231 12312741	Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JUN2006	01JUN2018	N
	C4591001 1231 12312744	Respiratory, thoracic and mediastinal disorders	Nasal polyps	15MAY2016		Y
			Nasal septum deviation	15MAY2016	01OCT2020	N
			Respiratory failure	15MAY2016	01OCT2020	N
			Rhinitis allergic	15MAY2016		Y
	C4591001 1231 12312747	Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312752	Congenital, familial and genetic disorders	Gilbert's syndrome	12FEB2012		Y
	C4591001 1231 12312753	Skin and subcutaneous tissue disorders	Psoriasis	07AUG1980		Y
	C4591001 1231 12312759	Skin and subcutaneous tissue disorders	Urticaria	01JUN2013	01MAR2014	N
	C4591001 1231 12312761	Eye disorders	Glaucoma	08AUG1994		Y
	C4591001 1231 12312762	Hepatobiliary disorders	Hepatic steatosis	01AUG2018		Y
	C4591001 1231 12312763	Infections and infestations	Meningitis herpes	13AUG2018	18AUG2018	N
	C4591001 1231 12312773	Endocrine disorders	Hypothyroidism	11AUG2010		Y
	C4591001 1231 12312775	Metabolism and nutrition disorders	Type 1 diabetes mellitus	05MAY2003		Y
	C4591001 1231 12312796	Immune system disorders	Drug hypersensitivity	18FEB2014		Y
		Respiratory, thoracic and mediastinal disorders	Dysphonia	01JAN2014		Y
			Nasal turbinate hypertrophy	01JAN2005		Y
	C4591001 1231 12312797	Metabolism and nutrition disorders	Obesity	01JUN2011		Y
	C4591001 1231 12312798	Vascular disorders	Hypertension	10AUG2019		Y
	C4591001 1231 12312807	Endocrine disorders	Hypothyroidism	06JUN2000		Y
		Vascular disorders	Hypertension	15JUL2014		Y
	C4591001 1231 12312810	Metabolism and nutrition disorders	Obesity	01OCT2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312811	Psychiatric disorders	Anxiety disorder	01JUN2009		Y
		Social circumstances	Tobacco user	01AUG1990		Y
	C4591001 1231 12312813	Surgical and medical procedures	Hysterectomy	01SEP2017	01SEP2017	N
	C4591001 1231 12312814	Congenital, familial and genetic disorders	Thalassaemia	04SEP1996		Y
		Metabolism and nutrition disorders	Dyslipidaemia	15JAN2020		Y
	C4591001 1231 12312823	Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 1231 12312824	Nervous system disorders	Migraine	01JAN2014	01DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	02JAN2015	N
	C4591001 1231 12312825	Nervous system disorders	Headache	09AUG2019		Y
	C4591001 1231 12312826	Psychiatric disorders	Anxiety	12JAN2020		Y
	C4591001 1231 12312827	Vascular disorders	Hypertension	12JUN1996		Y
	C4591001 1231 12312829	Metabolism and nutrition disorders	Obesity	10OCT2016		Y
			Type 2 diabetes mellitus	10OCT2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUN2009		Y
	C4591001 1231 12312840	Gastrointestinal disorders	Lumbar hernia	01SEP2019		Y
	C4591001 1231 12312842	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312847	Gastrointestinal disorders	Hiatus hernia	01JAN2018		Y
		Renal and urinary disorders	Renal cyst	01JAN2019		Y
	C4591001 1231 12312853	Renal and urinary disorders	Hypertonic bladder	01JUL2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2019	13JAN2020	N
	C4591001 1231 12312854	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1231 12312857	Infections and infestations	Sinusitis	01JAN2005		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN2005	31DEC2005	N
	C4591001 1231 12312860	Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2019		Y
	C4591001 1231 12312861	Gastrointestinal disorders	Chronic gastritis	04MAY2017		Y
	C4591001 1231 12312868	Psychiatric disorders	Depression	15MAR2020		Y
	C4591001 1231 12312874	Psychiatric disorders	Anxiety disorder	01MAR2016		Y
	C4591001 1231 12312877	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	02APR2009	02JUN2009	N
		Surgical and medical procedures	Hysterectomy	02APR2009	02JUN2009	N
	C4591001 1231 12312890	Gastrointestinal disorders	Diarrhoea	01JUL2007		Y
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1231 12312895	Endocrine disorders	Hypothyroidism	01AUG2018		Y
	C4591001 1231 12312899	Psychiatric disorders	Generalised anxiety disorder	12MAY2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312900	Surgical and medical procedures	Eye laser surgery	01JAN2020	01JAN2020	N
	C4591001 1231 12312903	Vascular disorders	Hypertension	17AUG2017		Y
	C4591001 1231 12312906	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2017		Y
	C4591001 1231 12312917	Psychiatric disorders	Alcoholism	16JUL2011		Y
	C4591001 1231 12312923	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG2001		Y
	C4591001 1231 12312925	Respiratory, thoracic and mediastinal disorders	Asthma	15JUN1994		Y
	C4591001 1231 12312926	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN1981		Y
	C4591001 1231 12312948	Endocrine disorders	Hypothyroidism	02JUL2018		Y
	C4591001 1231 12312955	Musculoskeletal and connective tissue disorders	Fibromyalgia	12MAR2012		Y
		Psychiatric disorders	Anxiety	12APR2012		Y
		Social circumstances	Tobacco user	01JAN2005		Y
	C4591001 1231 12312958	Infections and infestations	Chronic sinusitis	10DEC2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1231 12312959	Congenital, familial and genetic disorders	Congenital cystic kidney disease	(b) (6) 1988		Y
	C4591001 1231 12312965	Psychiatric disorders	Insomnia	01OCT2019		Y
			Panic attack	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312968	Gastrointestinal disorders	Dental caries	01JAN2017		Y
		Surgical and medical procedures	Metabolic surgery	01FEB2018	21FEB2018	N
	C4591001 1231 12312972	Skin and subcutaneous tissue disorders	Dermatitis atopic	15OCT2018		Y
	C4591001 1231 12312975	Psychiatric disorders	Anxiety disorder	20AUG2019		Y
	C4591001 1231 12312979	Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1231 12312985	Endocrine disorders	Hypothyroidism	01NOV2007		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	03DEC2012		Y
			Spondylolisthesis	03DEC2012		Y
	C4591001 1231 12312986	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1231 12312988	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
	C4591001 1231 12312989	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01OCT2015	01MAR2016	N
		Surgical and medical procedures	Hysterectomy	01MAR2016	01MAR2016	N
	C4591001 1231 12312990	Infections and infestations	Chronic tonsillitis	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	20NOV2017		Y
	C4591001 1231 12312991	Skin and subcutaneous tissue disorders	Acne	01JAN2004		Y
	C4591001 1231 12312996	Respiratory, thoracic and mediastinal disorders	Asthma	23AUG2004		Y
	C4591001 1231 12313002	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313006	Skin and subcutaneous tissue disorders	Psoriasis	01MAR1984		Y
	C4591001 1231 12313012	Musculoskeletal and connective tissue disorders	Back pain	10DEC2017		Y
			Intervertebral disc protrusion	16DEC2017	19JUN2019	N
		Surgical and medical procedures	Arthrodesis	19JUN2019	19JUN2019	N
			Facet joint block	06JUN2018	06JUN2018	N
	C4591001 1231 12313013	Endocrine disorders	Hypothyroidism	17MAY2007		Y
	C4591001 1231 12313014	Respiratory, thoracic and mediastinal disorders	Asthma	09SEP2012		Y
	C4591001 1231 12313019	Immune system disorders	Drug hypersensitivity	01AUG1988		Y
	C4591001 1231 12313020	Reproductive system and breast disorders	Polycystic ovaries	12JUN2011		Y
	C4591001 1231 12313026	Psychiatric disorders	Anxiety	21AUG2011		Y
	C4591001 1231 12313028	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	04JUL2015		Y
		Endocrine disorders	Hypothyroidism	04JUL2015		Y
		Nervous system disorders	Migraine	01JAN2003		Y
	C4591001 1231 12313033	Vascular disorders	Hypertension	02AUG2010		Y
	C4591001 1231 12313034	Gastrointestinal disorders	Gastroesophageal reflux disease	02APR2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	03SEP2014		Y
	C4591001 1231 12313040	Vascular disorders	Hypertension	05JUN2012		Y
	C4591001 1231 12313041	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	08NOV2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1231 12313043	Vascular disorders	Thrombosis	06DEC2018	02FEB2019	N
	C4591001 1231 12313048	Congenital, familial and genetic disorders	Congenital cerebrovascular anomaly	28OCT2000	01MAR2005	N
			Thalassaemia beta	15JUL1993		Y
	C4591001 1231 12313049	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12313069	Surgical and medical procedures	Bilateral orchidectomy	30AUG1997	30AUG1997	N
	C4591001 1231 12313070	Gastrointestinal disorders	Haemorrhoids	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN2015		Y
					01MAY2015	N
		Psychiatric disorders	Bruxism	01JUN2015		Y
		Surgical and medical procedures	Myomectomy	01MAY2015	01MAY2015	N
	C4591001 1231 12313074	Skin and subcutaneous tissue disorders	Vitiligo	01JAN2020		Y
	C4591001 1231 12313076	Metabolism and nutrition disorders	Obesity	01SEP2004	16MAY2019	N
	C4591001 1231 12313082	Surgical and medical procedures	Coronary revascularisation	02JAN2015	02JAN2015	N
		Vascular disorders	Hypertension	02JAN2015		Y
	C4591001 1231 12313086	Skin and subcutaneous tissue disorders	Rosacea	15FEB2020		Y
	C4591001 1231 12313087	Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313091	Endocrine disorders	Hypothyroidism	13AUG2014		Y
	C4591001 1231 12313093	Vascular disorders	Peripheral venous disease	01MAY2019		Y
	C4591001 1231 12313096	Immune system disorders	Mite allergy	01JAN1994		Y
			Mycotic allergy	01JAN1994		Y
			Seasonal allergy	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
	C4591001 1231 12313111	Endocrine disorders	Hypothyroidism	01FEB2005		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2010		Y
		Nervous system disorders	Cerebrovascular accident	29MAR2020	01MAY2020	N
	C4591001 1231 12313113	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1231 12313117	Eye disorders	Myopia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09OCT2005		Y
	C4591001 1231 12313123	Vascular disorders	Hypertension	20AUG2019		Y
	C4591001 1231 12313124	Endocrine disorders	Hypothyroidism	15MAR2015		Y
	C4591001 1231 12313125	Psychiatric disorders	Insomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313132	Nervous system disorders	Trigeminal neuralgia	01APR2020		Y
		Surgical and medical procedures	Female sterilisation	01JUN2015	01JUN2015	N
	C4591001 1231 12313136	Infections and infestations	Appendicitis	01AUG2006	03AUG2006	N
	C4591001 1231 12313138	Nervous system disorders	Restless legs syndrome	02FEB2020		Y
	C4591001 1231 12313139	Vascular disorders	Hypertension	09FEB2019		Y
	C4591001 1231 12313153	Respiratory, thoracic and mediastinal disorders	Asthma	10APR2003		Y
	C4591001 1231 12313155	Gastrointestinal disorders	Gastritis	04OCT2017		Y
			Malabsorption	04OCT2017		Y
	C4591001 1231 12313156	Surgical and medical procedures	Gastric bypass	04OCT2017	04OCT2017	N
		Immune system disorders	Drug hypersensitivity	04AUG2010		Y
				27AUG1998		Y
		Skin and subcutaneous tissue disorders	Urticaria	13MAY2020		Y
	C4591001 1231 12313162	Infections and infestations	Chronic sinusitis	01FEB1970		Y
	C4591001 1231 12313164	Endocrine disorders	Hypothyroidism	14AUG2018		Y
	C4591001 1231 12313165	Endocrine disorders	Hypothyroidism	12MAY2018		Y
	C4591001 1231 12313174	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01FEB2009	01FEB2009	N
	C4591001 1231 12313177	Respiratory, thoracic and mediastinal disorders	Obliterative bronchiolitis	01JAN1996		Y
	C4591001 1231 12313179	Blood and lymphatic system disorders	Iron deficiency anaemia	01DEC2018	20MAY2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01AUG2006		Y
		Reproductive system and breast disorders	Breast pain	01AUG2020		Y
	C4591001 1231 12313184	Surgical and medical procedures	Cholecystectomy	01JAN2016	01JAN2016	N
	C4591001 1231 12313192	Endocrine disorders	Hypothyroidism	01MAR2010		Y
	C4591001 1231 12313193	Renal and urinary disorders	Haematuria	14JAN2020		Y
	C4591001 1231 12313198	Nervous system disorders	Migraine	01JAN1992		Y
	C4591001 1231 12313199	Skin and subcutaneous tissue disorders	Acne	19AUG2020		Y
	C4591001 1231 12313204	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2008	05JAN2009	N
		Psychiatric disorders	Affect lability	03AUG2010		Y
		Surgical and medical procedures	Chemotherapy	01MAR2009	01SEP2009	N
			Mastectomy	05JAN2009	22AUG2010	N
	C4591001 1231 12313205	Endocrine disorders	Hypothyroidism	06JUN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2017		Y
		Nervous system disorders	Sciatica	20FEB2019		Y
	C4591001 1231 12313209	Blood and lymphatic system disorders	Anaemia	13JUL2011		Y
		Surgical and medical procedures	Gastric bypass	16APR2010	21APR2010	N
	C4591001 1231 12313211	Gastrointestinal disorders	Haemorrhoids	01DEC2019		Y
		Psychiatric disorders	Anxiety disorder	01JUN2016		Y
	C4591001 1231 12313218	Endocrine disorders	Hypothyroidism	23AUG2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313223	Infections and infestations	Onychomycosis	20OCT2019		Y
	C4591001 1231 12313225	Endocrine disorders	Hypothyroidism	05AUG2010		Y
	C4591001 1231 12313229	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2015		Y
	C4591001 1231 12313231	Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2018		Y
	C4591001 1231 12313235	Hepatobiliary disorders	Cholelithiasis	01FEB2019	01OCT2019	N
		Injury, poisoning and procedural complications	Pneumothorax traumatic	23APR2007	23APR2007	N
		Surgical and medical procedures	Cholecystectomy	01OCT2019	01OCT2019	N
			Female sterilisation	13MAY2016	13MAY2016	N
	C4591001 1231 12313249	Infections and infestations	Herpes zoster	18AUG2020	22AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2003		Y
	C4591001 1231 12313253	Endocrine disorders	Hypothyroidism	01JUN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2011		Y
		Psychiatric disorders	Anxiety disorder	01JUN2013		Y
	C4591001 1231 12313255	Endocrine disorders	Hypothyroidism	04APR2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	04APR2006	04APR2007	N
	C4591001 1231 12313257	Reproductive system and breast disorders	Ovarian cyst	12SEP2014		Y
	C4591001 1231 12313266	Endocrine disorders	Hypothyroidism	22AUG2008		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	22AUG2010		Y
		Vascular disorders	Hypertension	22AUG2012		Y
	C4591001 1231 12313269	Gastrointestinal disorders	Gastritis	01JAN2019		Y
	C4591001 1231 12313270	Surgical and medical procedures	Female sterilisation	07MAR2008	07MAR2008	N
	C4591001 1231 12313271	Endocrine disorders	Hypothyroidism	02AUG1993		Y
	C4591001 1231 12313272	Endocrine disorders	Hypothyroidism	10MAY2014		Y
	C4591001 1231 12313276	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12313277	Metabolism and nutrition disorders	Dyslipidaemia	20APR2017		Y
	C4591001 1231 12313281	Immune system disorders	Seasonal allergy	01SEP1983		Y
	C4591001 1231 12313283	Endocrine disorders	Hypothyroidism	01JUN2002		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JUL2017		Y
		Psychiatric disorders	Depression	01MAR2015		Y
		Reproductive system and breast disorders	Endometriosis	15DEC2013	27FEB2014	N
		Surgical and medical procedures	Radical hysterectomy	27FEB2014	27FEB2014	N
	C4591001 1231 12313284	Infections and infestations	Cervicitis human papilloma virus	22AUG2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2007	31DEC2008	N
		Reproductive system and breast disorders	Cervical dysplasia	22AUG2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313288	Psychiatric disorders	Anxiety	06JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
	C4591001 1231 12313289	Infections and infestations	Appendicitis	01JUL2005	01JUL2005	N
	C4591001 1231 12313293	Congenital, familial and genetic disorders	Hypochondroplasia	(b) (6) 1988		Y
	C4591001 1231 12313296	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10AUG2015		Y
		Vascular disorders	Hypertension	10AUG2015		Y
	C4591001 1231 12313300	Endocrine disorders	Hypothyroidism	16OCT2001		Y
	C4591001 1231 12313301	Gastrointestinal disorders	Coeliac disease	25AUG2004		Y
	C4591001 1231 12313306	Respiratory, thoracic and mediastinal disorders	Asthma	20APR2017		Y
	C4591001 1231 12313307	Surgical and medical procedures	Caesarean section	19SEP2009	19SEP2009	N
			Tonsillectomy	08AUG1977	08AUG1977	N
	C4591001 1231 12313308	Psychiatric disorders	Panic disorder	07JUL2017		Y
	C4591001 1231 12313314	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	10MAY2019		Y
	C4591001 1231 12313316	Eye disorders	Cataract	01AUG2018	01SEP2018	N
					25OCT2020	N
					25SEP2020	N
		Infections and infestations	Cervicitis human papilloma virus	06FEB2020		Y
		Reproductive system and breast disorders	Cervical dysplasia	06FEB2020		Y
		Surgical and medical procedures	Cataract operation	01SEP2018	01SEP2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313319	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2013		Y
		Vascular disorders	Hypertension	16AUG2016		Y
	C4591001 1231 12313321	Endocrine disorders	Hypothyroidism	01JUN2005		Y
	C4591001 1231 12313327	Psychiatric disorders	Anxiety	01JUN2018		Y
			Depression	01JUN1990		Y
		Surgical and medical procedures	Gastric bypass	01JUN2008	02JUN2008	N
	C4591001 1231 12313330	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1985		Y
	C4591001 1231 12313332	Gastrointestinal disorders	Crohn's disease	01JAN2010		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12313337	Blood and lymphatic system disorders	Anaemia	06FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01FEB2020	18JAN2021	N
		Reproductive system and breast disorders	Menorrhagia	06FEB2020		Y
	C4591001 1231 12313345	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
	C4591001 1231 12313351	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1231 12313356	Psychiatric disorders	Depression	01JAN2019		Y
	C4591001 1231 12313357	Nervous system disorders	Epilepsy	23AUG2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313360	Cardiac disorders	Acute myocardial infarction	15FEB2016	29FEB2016	N
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Vascular disorders	Hypertension	15FEB2016		Y
	C4591001 1231 12313361	Surgical and medical procedures	Hysterectomy	20JAN2013	25JAN2013	N
			Thyroidectomy	20AUG2013	25AUG2013	N
		Vascular disorders	Hypertension	12SEP1997		Y
	C4591001 1231 12313363	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	20JAN2014	24JAN2014	N
		Surgical and medical procedures	Hysterectomy	20JAN2014	24JAN2014	N
	C4591001 1231 12313365	Endocrine disorders	Hypothyroidism	01JUN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2000		Y
		Surgical and medical procedures	Hysterectomy	01JUL2011	03JUL2011	N
	C4591001 1231 12313368	Endocrine disorders	Hypothyroidism	04MAY1993		Y
	C4591001 1231 12313381	Congenital, familial and genetic disorders	Dysmorphism	(b) (6) 1999	30OCT2020	N
	C4591001 1231 12313383	Endocrine disorders	Hypothyroidism	29MAY2011	07JAN2020	N
	C4591001 1231 12313388	Cardiac disorders	Acute myocardial infarction	01AUG2014	02AUG2014	N
	C4591001 1231 12313389	Endocrine disorders	Hypothyroidism	01JAN2002		Y
	C4591001 1231 12313390	Endocrine disorders	Hypothyroidism	15AUG2013		Y
		Surgical and medical procedures	Female sterilisation	15JUN2017	17JUN2017	N
	C4591001 1231 12313400	Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12313409	Metabolism and nutrition disorders	Hyperuricaemia	02MAY2015		Y
	C4591001 1231 12313414	Vascular disorders	Hypertension	01FEB2018		Y
	C4591001 1231 12313415	Metabolism and nutrition disorders	Dyslipidaemia	02AUG2018		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1231 12313416	Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12313417	Endocrine disorders	Hypothyroidism	21NOV2014		Y
	C4591001 1231 12313430	Surgical and medical procedures	Vesicoureteral reflux surgery	01DEC2009	04DEC2009	N
	C4591001 1231 12313431	Vascular disorders	Hypertension	10AUG2019		Y
	C4591001 1231 12313432	Congenital, familial and genetic disorders	Renal aplasia	(b) (6) 1996		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1231 12313434	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17AUG2010		Y
	C4591001 1231 12313439	Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1231 12313440	Gastrointestinal disorders	Barrett's oesophagus	01JAN2019		Y
			Hiatus hernia	01JAN2015		Y
	C4591001 1231 12313445	Hepatobiliary disorders	Cholelithiasis	09JUL2018	15JUL2018	N
	C4591001 1231 12313452	Vascular disorders	Hypertension	01AUG2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313454	Hepatobiliary disorders	Cholelithiasis	01JUL2017		Y
		Metabolism and nutrition disorders	Overweight	01AUG1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1980		Y
	C4591001 1231 12313466	Gastrointestinal disorders	Hiatus hernia	03JUN2010		Y
	C4591001 1231 12313467	Reproductive system and breast disorders	Varicocele	06FEB2019		Y
	C4591001 1231 12313469	Nervous system disorders	Neuralgia	01OCT2016		Y
		Vascular disorders	Varicose vein	01SEP2016	01OCT2016	N
	C4591001 1231 12313470	Endocrine disorders	Hypothyroidism	28AUG2014		Y
	C4591001 1231 12313471	Nervous system disorders	Migraine without aura	01JUN2007		Y
	C4591001 1231 12313488	Hepatobiliary disorders	Cholelithiasis	01JUN2019		Y
	C4591001 1231 12313489	Gastrointestinal disorders	Coeliac disease	01DEC2007		Y
	C4591001 1231 12313490	Musculoskeletal and connective tissue disorders	CREST syndrome	01JAN2013		Y
	C4591001 1231 12313491	Respiratory, thoracic and mediastinal disorders	Asthma	10FEB1983		Y
	C4591001 1231 12313493	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Surgical and medical procedures	Stent placement	01MAY2019		Y
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1231 12313494	Endocrine disorders	Hypothyroidism	01AUG1990		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313499	Congenital, familial and genetic disorders	Cerebrovascular arteriovenous malformation	(b) (6) 1974	04NOV2009	N
		Reproductive system and breast disorders	Ovarian cyst	01MAR2020		Y
	C4591001 1231 12313500	Metabolism and nutrition disorders	Hypercholesterolaemia	09AUG2017		Y
	C4591001 1231 12313506	Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1231 12313508	Endocrine disorders	Hypothyroidism	01MAR2015		Y
	C4591001 1231 12313512	Ear and labyrinth disorders	Vertigo	02FEB2020		Y
		Endocrine disorders	Hypothyroidism	01JUN2010		Y
		Gastrointestinal disorders	Gastritis	10MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05MAY2018		Y
		Psychiatric disorders	Sleep disorder	01JUN2010		Y
	C4591001 1231 12313516	Metabolism and nutrition disorders	Hypertriglyceridaemia	01AUG2017		Y
		Obesity		01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tongue neoplasm	29MAY2018	29NOV2018	N
	C4591001 1231 12313517	Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JUN2012		Y
	C4591001 1231 12313525	Endocrine disorders	Hypothyroidism	10OCT2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1231 12313526	Endocrine disorders	Hypothyroidism	01JAN2017		Y
	C4591001 1231 12313528	Infections and infestations	Chronic sinusitis	01SEP2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	06AUG2006		Y
	C4591001 1231 12313548	Vascular disorders	Hypertension	01FEB2011		Y
	C4591001 1231 12313560	Endocrine disorders	Hypothyroidism	10AUG2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	20JUL1991		Y
		Vascular disorders	Hypertension	16AUG2000		Y
	C4591001 1231 12313563	Respiratory, thoracic and mediastinal disorders	Asthma	10MAR2004		Y
	C4591001 1231 12313567	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1231 12313569	Vascular disorders	Hypertension	01AUG2008		Y
	C4591001 1231 12313571	Surgical and medical procedures	Vasectomy	01DEC2019	25AUG2020	N
	C4591001 1231 12313576	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
	C4591001 1231 12313583	Endocrine disorders	Hypothyroidism	30MAY2020		Y
		Metabolism and nutrition disorders	Insulin resistance	15JUL2013		Y
			Obesity	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1231 12313587	Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	11OCT2010	13APR2011	N
		Surgical and medical procedures	Laryngeal operation	13APR2011	13APR2011	N
	C4591001 1231 12313598	Endocrine disorders	Hypothyroidism	12AUG1998		Y
	C4591001 1231 12313616	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2019	03NOV2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01MAY2008	03NOV2020	N
			Micromastia	01DEC2002		Y
			Varicose veins pelvic	01DEC2019	03NOV2020	N
	C4591001 1231 12313624	Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12313630	Eye disorders	Keratoconus	04OCT2010	06OCT2010	N
		Surgical and medical procedures	Corneal transplant	04OCT2010	06OCT2010	N
	C4591001 1231 12313635	Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
	C4591001 1231 12313636	Endocrine disorders	Hypothyroidism	23JUN2002		Y
	C4591001 1231 12313638	Cardiac disorders	Atrial fibrillation	01APR2017		Y
		Psychiatric disorders	Insomnia	01APR2017		Y
	C4591001 1231 12313643	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2015		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01DEC2019		Y
	C4591001 1231 12313646	Infections and infestations	Meningitis viral	13SEP2005	28SEP2005	N
			Urinary tract infection	01JAN1990		Y
		Injury, poisoning and procedural complications	Lower limb fracture	07SEP2017	01AUG2018	N
	C4591001 1231 12313653	Endocrine disorders	Hypothyroidism	01JUN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
			Pleural effusion	15APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313656	Psychiatric disorders	Anxiety disorder	01FEB2020		Y
	C4591001 1231 12313661	Skin and subcutaneous tissue disorders	Alopecia	20DEC2009		Y
		Vascular disorders	Hypertension	01JUN2003		Y
	C4591001 1231 12313670	Vascular disorders	Hypertension	01JUN2011		Y
	C4591001 1231 12313672	Endocrine disorders	Hypothyroidism	25AUG2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	04AUG2020		Y
	C4591001 1231 12313675	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1231 12313677	Respiratory, thoracic and mediastinal disorders	Asthma	02JUN1995		Y
	C4591001 1231 12313693	Endocrine disorders	Hypothyroidism	12JUN2005		Y
			Thyroid mass	14MAR2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2005		Y
	C4591001 1231 12313696	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2015		Y
	C4591001 1231 12313698	Metabolism and nutrition disorders	Decreased appetite	22AUG2018		Y
		Psychiatric disorders	Bulimia nervosa	22AUG2018		Y
	C4591001 1231 12313699	Metabolism and nutrition disorders	Hypertriglyceridaemia	01MAR2010		Y
	C4591001 1231 12313701	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Pneumothorax spontaneous	01OCT2003	01NOV2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313706	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
	C4591001 1231 12313709	Respiratory, thoracic and mediastinal disorders	Bronchospasm	01AUG1990		Y
			Sleep apnoea syndrome	01AUG2019		Y
	C4591001 1231 12313713	Psychiatric disorders	Bipolar disorder	17JAN2020		Y
	C4591001 1231 12313717	Respiratory, thoracic and mediastinal disorders	Asthma	12MAR1991		Y
	C4591001 1231 12313718	Nervous system disorders	Migraine	01JAN2014		Y
	C4591001 1231 12313722	Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2008		Y
	C4591001 1231 12313724	Respiratory, thoracic and mediastinal disorders	Asthma	04AUG2017		Y
	C4591001 1231 12313729	Respiratory, thoracic and mediastinal disorders	Asthma	24AUG2000		Y
	C4591001 1231 12313732	Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1231 12313734	Metabolism and nutrition disorders	Obesity	02MAR2010		Y
		Surgical and medical procedures	Gastric bypass	02MAR2013	04MAR2013	N
	C4591001 1231 12313738	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute lymphocytic leukaemia	01JAN1977	01JAN1981	N
		Surgical and medical procedures	Appendicectomy	15JAN2007	15JAN2007	N
			Female sterilisation	22DEC2012	22DEC2012	N
			Mammoplasty	01AUG2008	01AUG2008	N
	C4591001 1231 12313749	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12313752	Surgical and medical procedures	Benign breast lump removal	10MAY2013	10MAY2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313756	Psychiatric disorders	Anxiety disorder	01FEB2013		Y
		Surgical and medical procedures	Hysterectomy	04OCT2007	04OCT2007	N
		Vascular disorders	Hypertension	01APR2016		Y
	C4591001 1231 12313764	Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
	C4591001 1231 12313772	Respiratory, thoracic and mediastinal disorders	Asthma	08JUN2016		Y
	C4591001 1231 12313773	Nervous system disorders	Migraine without aura	01JUN1990		Y
	C4591001 1231 12313777	Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y
	C4591001 1231 12313778	Psychiatric disorders	Depression	20AUG2013		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01MAR2007		Y
	C4591001 1231 12313780	Vascular disorders	Hypertension	01JUL2015		Y
	C4591001 1231 12313785	Eye disorders	Diplopia	15DEC1999		Y
		Nervous system disorders	Headache	01MAR2000		Y
			Hemiparesis	15DEC1999		Y
		Renal and urinary disorders	Calculus bladder	01JAN2016	05APR2016	N
		Surgical and medical procedures	Cancer surgery	15DEC1999	15DEC1999	N
			Cholecystectomy	05APR2016	05APR2016	N
	C4591001 1231 12313804	Infections and infestations	Salpingitis	26APR2019	26APR2019	N
		Surgical and medical procedures	Salpingectomy	26APR2019	26APR2019	N
	C4591001 1231 12313806	Endocrine disorders	Hypothyroidism	01JUN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313809	Immune system disorders	Drug hypersensitivity	03MAY2004		Y
	C4591001 1231 12313810	Respiratory, thoracic and mediastinal disorders	Asthma	17AUG2016		Y
	C4591001 1231 12313815	Vascular disorders	Hypertension	15JUN2008		Y
	C4591001 1231 12313818	Cardiac disorders	Acute myocardial infarction	26JUN2016	30JUN2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUL2016		Y
	C4591001 1231 12313819	Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2017		Y
	C4591001 1231 12313823	Respiratory, thoracic and mediastinal disorders	Asthma	25AUG2000		Y
	C4591001 1231 12313824	Metabolism and nutrition disorders	Obesity	01MAY2017		Y
	C4591001 1231 12313831	Vascular disorders	Varicose vein	01JAN2010		Y
	C4591001 1231 12313843	Vascular disorders	Hypertension	12APR2018		Y
	C4591001 1231 12313847	Metabolism and nutrition disorders	Obesity	01JUL2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15AUG1990		Y
	C4591001 1231 12313853	Eye disorders	Retinal artery thrombosis	03OCT2010	03NOV2010	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	17AUG1976		Y
	C4591001 1231 12313854	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1231 12313862	Endocrine disorders	Hypothyroidism	08SEP2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313870	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1980		Y
	C4591001 1231 12313871	Cardiac disorders	Arrhythmia	07FEB2000		Y
	C4591001 1231 12313877	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2017		Y
		Vascular disorders	Hypertension	02MAY2014		Y
	C4591001 1231 12313886	Reproductive system and breast disorders	Oligomenorrhoea	01OCT2018		Y
	C4591001 1231 12313889	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	C4591001 1231 12313892	Cardiac disorders	Arrhythmia	03OCT2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	23OCT2018		Y
	C4591001 1231 12313895	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	09OCT1990		Y
	C4591001 1231 12313900	Psychiatric disorders	Panic attack	01JUN2010	01JUN2012	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1231 12313904	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	03JUN1997	20JUL2018	N
		Surgical and medical procedures	Metabolic surgery	19JUN2017	19JUN2017	N
	C4591001 1231 12313905	Endocrine disorders	Hypothyroidism	02FEB1995		Y
	C4591001 1231 12313910	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1980		Y
	C4591001 1231 12313915	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01FEB2020		Y
		Vascular disorders	Peripheral venous disease	01DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313916	Metabolism and nutrition disorders	Overweight	01NOV2016		Y
	C4591001 1231 12313919	Congenital, familial and genetic disorders	Klinefelter's syndrome	10OCT2017		Y
	C4591001 1231 12313925	Eye disorders	Diabetic retinopathy	08MAY2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2016		Y
		Nervous system disorders	Carpal tunnel syndrome	15MAR2020	30JAN2021	N
		Psychiatric disorders	Drug dependence	01JAN1996	31JUL2018	N
	C4591001 1231 12313937	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Nervous system disorders	Carotid arterial embolus	01AUG2018	31AUG2018	N
			Intracranial aneurysm	01AUG2018		Y
	C4591001 1231 12313941	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2009		Y
	C4591001 1231 12313945	Psychiatric disorders	Generalised anxiety disorder	03AUG2017		Y
	C4591001 1231 12313946	Immune system disorders	Seasonal allergy	01SEP2010		Y
	C4591001 1231 12313949	Endocrine disorders	Hypothyroidism	01DEC2019		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JUN2012		Y
			Type 2 diabetes mellitus	01JUN2009		Y
	C4591001 1231 12313953	Gastrointestinal disorders	Gastritis	10JUN2008		Y
	C4591001 1231 12313964	Infections and infestations	Onychomycosis	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	02AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313968	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2013		Y
		Renal and urinary disorders	Renal disorder	01SEP2013		Y
		Vascular disorders	Hypertension	01SEP2013		Y
	C4591001 1231 12313970	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1231 12313973	Surgical and medical procedures	Eye operation	01JUL2010	01JUL2010	N
	C4591001 1231 12313989	Immune system disorders	Seasonal allergy	01SEP2018		Y
	C4591001 1231 12313993	Hepatobiliary disorders	Cholelithiasis	01MAY2010	01MAY2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1231 12313994	Psychiatric disorders	Generalised anxiety disorder	01MAR2020		Y
	C4591001 1231 12313996	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2013	04AUG2013	N
		Surgical and medical procedures	Hysterectomy	01AUG2013	04AUG2013	N
	C4591001 1231 12313998	Blood and lymphatic system disorders	Anaemia	15AUG2015		Y
	C4591001 1231 12314002	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1231 12314005	Respiratory, thoracic and mediastinal disorders	Emphysema	01SEP2017		Y
	C4591001 1231 12314011	Endocrine disorders	Hypothyroidism	01AUG2000		Y
	C4591001 1231 12314020	Infections and infestations	Gonorrhoea	01MAY2010	01MAY2010	N
			Papilloma viral infection	01MAY2010	01MAY2010	N
			Syphilis	01MAY2010	01MAY2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314047	Gastrointestinal disorders	Gastritis	01AUG1994		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01FEB2018		Y
		Psychiatric disorders	Anxiety disorder	01AUG2018		Y
	C4591001 1231 12314050	Gastrointestinal disorders	Hiatus hernia	01SEP2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2019		Y
		Psychiatric disorders	Sleep disorder	01MAR2000		Y
		Surgical and medical procedures	Metabolic surgery	01SEP2010	01SEP2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12314058	Skin and subcutaneous tissue disorders	Dermal cyst	01JUN2009	01JUN2009	N
		Surgical and medical procedures	Skin cyst excision	01JUN2009	01JUN2009	N
	C4591001 1231 12314059	Infections and infestations	Hepatitis A	01JUL1987	01AUG1987	N
	C4591001 1231 12314061	Metabolism and nutrition disorders	Hypercholesterolaemia	08AUG2018		Y
		Vascular disorders	Hypertension	08AUG2016		Y
	C4591001 1231 12314068	Cardiac disorders	Prinzmetal angina	01OCT2019		Y
		Congenital, familial and genetic disorders	Thalassaemia	(b) (6) 1973		Y
	C4591001 1231 12314070	Gastrointestinal disorders	Gastritis	01FEB2004		Y
			Irritable bowel syndrome	01JUN2006	01JUN2010	N
	C4591001 1231 12314071	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prolactin-producing pituitary tumour	18JUN2015		Y
	C4591001 1231 12314073	Gastrointestinal disorders	Coeliac disease	02JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Seronegative arthritis	01JUN2017		Y
	C4591001 1231 12314074	Immune system disorders	Drug hypersensitivity	02MAY2000		Y
	C4591001 1231 12314075	Musculoskeletal and connective tissue disorders	Back pain	01JUN2019		Y
			Intervertebral disc protrusion	01JUN2019		Y
	C4591001 1231 12314078	Psychiatric disorders	Anxiety disorder	01JAN2017		Y
	C4591001 1231 12314080	Psychiatric disorders	Anxiety disorder	01JAN2019		Y
	C4591001 1231 12314084	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
	C4591001 1231 12314086	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Surgical and medical procedures	Metabolic surgery	13NOV2018	14NOV2018	N
	C4591001 1231 12314098	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
	C4591001 1231 12314100	Gastrointestinal disorders	Gastritis	05JAN2020		Y
			Irritable bowel syndrome	08MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal adenoma	03MAR2020		Y
	C4591001 1231 12314107	Surgical and medical procedures	Tympanoplasty	02MAY1995	03MAY1995	N
	C4591001 1231 12314111	Ear and labyrinth disorders	Deafness unilateral	01OCT2002		Y
			Tinnitus	01OCT2002		Y
	C4591001 1231 12314115	Endocrine disorders	Hyperthyroidism	01FEB2020		Y
		Infections and infestations	Rhinitis	01SEP2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Haemorrhagic stroke	05NOV2017	15NOV2017	N
	C4591001 1231 12314116	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
	C4591001 1231 12314117	Endocrine disorders	Hypothyroidism	01AUG2010		Y
	C4591001 1231 12314119	Psychiatric disorders	Anxiety disorder	01JAN2005		Y
	C4591001 1231 12314123	Gastrointestinal disorders	Sleep disorder Gastritis	01JAN2005 01JAN2018		Y Y
	C4591001 1231 12314129	Metabolism and nutrition disorders	Dyslipidaemia	31AUG2009		Y
	C4591001 1231 12314130	Vascular disorders Endocrine disorders	Hypertension Hypothyroidism	26AUG2009 01AUG2017		Y Y
	C4591001 1231 12314133	Vascular disorders Metabolism and nutrition disorders	Hypertension Type 2 diabetes mellitus	01MAR2020 26MAY2000		Y Y
	C4591001 1231 12314135	Injury, poisoning and procedural complications	Road traffic accident	01JAN2011	31DEC2011	N
	C4591001 1231 12314137	Surgical and medical procedures Endocrine disorders	Spinal operation Hypothyroidism	01JAN2011 01OCT2017		Y Y
	C4591001 1231 12314140	Endocrine disorders	Hypothyroidism	02JAN2010		Y
	C4591001 1231 12314141	Endocrine disorders	Hypothyroidism	02MAR1988		Y
	C4591001 1231 12314142	Endocrine disorders	Thyroid mass Hypothyroidism	02JAN2012 09JUL2015		Y Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314143	Gastrointestinal disorders	Tooth loss	10JAN2002	30NOV2012	N
	C4591001 1231 12314145	Gastrointestinal disorders	Gastritis	31AUG2017		Y
		Vascular disorders	Hypertension	08AUG2017		Y
	C4591001 1231 12314152	Gastrointestinal disorders	Chronic gastritis	02MAR2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	23JUL2000		Y
	C4591001 1231 12314161	Metabolism and nutrition disorders	Type 2 diabetes mellitus	11FEB2020		Y
	C4591001 1231 12314167	Musculoskeletal and connective tissue disorders	Osteochondritis	01JAN2017		Y
	C4591001 1231 12314175	Nervous system disorders	Epilepsy	16DEC1992	20NOV2019	N
	C4591001 1231 12314178	Infections and infestations	Dengue fever	09JUN2015	22JUN2020	N
	C4591001 1231 12314181	Nervous system disorders	Migraine	01JAN2003		Y
	C4591001 1231 12314186	Skin and subcutaneous tissue disorders	Psoriasis	01FEB1997		Y
	C4591001 1231 12314188	Psychiatric disorders	Depression	12JUN2016		Y
		Renal and urinary disorders	Bladder dysfunction	12JUN2012		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2020		Y
	C4591001 1231 12314191	Psychiatric disorders	Depression	01JUN2017		Y
		Social circumstances	Tobacco user	01JAN2005	31DEC2020	N
	C4591001 1231 12314193	Immune system disorders	Seasonal allergy	01MAR1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314212	Eye disorders	Open angle glaucoma	02MAY2000		Y
	C4591001 1231 12314215	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2020		Y
			Osteoarthritis	01MAY2020		Y
		Nervous system disorders	Parkinson's disease	01JAN2014		Y
	C4591001 1231 12314223	Endocrine disorders	Hypothyroidism	31AUG2000		Y
	C4591001 1231 12314224	Endocrine disorders	Hypothyroidism	10JUN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2015		Y
			Osteopenia	01JUN2010		Y
		Nervous system disorders	Sciatica	20AUG2020		Y
	C4591001 1231 12314229	Gastrointestinal disorders	Irritable bowel syndrome	01APR2020		Y
	C4591001 1231 12314236	Vascular disorders	Hypertension	03JUL2019		Y
	C4591001 1231 12314243	Congenital, familial and genetic disorders	Klippel-Feil syndrome	(b) (6) 1997		Y
		Renal and urinary disorders	Single functional kidney	(b) (6) 1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2013		Y
		Surgical and medical procedures	Spinal fusion surgery	10OCT2012		Y
	C4591001 1231 12314246	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	04AUG2013		Y
		Social circumstances	Tobacco user	01JUN1969		Y
	C4591001 1231 12314252	Psychiatric disorders	Depression	10DEC2019		Y
	C4591001 1231 12314256	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Atrial septal defect repair	(b) (6) 1982	24AUG1984	N
				27AUG1984	30AUG1984	N
	C4591001 1231 12314259	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1231 12314260	Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1231 12314264	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1231 12314265	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1231 12314266	Respiratory, thoracic and mediastinal disorders	Emphysema	24JUL2020		Y
	C4591001 1231 12314268	Vascular disorders	Hypertension	02FEB2014		Y
	C4591001 1231 12314270	Immune system disorders	Drug hypersensitivity	06JUN1983		Y
	C4591001 1231 12314271	Endocrine disorders	Autoimmune thyroiditis	01AUG2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2019	01AUG2019	N
		Surgical and medical procedures	Hysterectomy	01AUG2019	01AUG2019	N
	C4591001 1231 12314272	Endocrine disorders	Hypothyroidism	18APR2004		Y
	C4591001 1231 12314276	Psychiatric disorders	Depression	01AUG2012		Y
	C4591001 1231 12314277	Eye disorders	Keratitis	14AUG2020		Y
		Infections and infestations	Conjunctivitis viral	01APR2020	30APR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314278	Congenital, familial and genetic disorders	Arteriovenous malformation	01MAY2019	01JUN2019	N
	C4591001 1231 12314290	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	06NOV2019		Y
	C4591001 1231 12314297	Metabolism and nutrition disorders	Type 2 diabetes mellitus	08AUG2019		Y
		Vascular disorders	Hypertension	04JUL2015		Y
	C4591001 1231 12314298	Gastrointestinal disorders	Gastritis	05MAY2008		Y
		Immune system disorders	Atopy	10OCT2008		Y
			Drug hypersensitivity	02AUG2008	02AUG2008	N
	C4591001 1231 12314308	Vascular disorders	Peripheral venous disease	01MAR2020		Y
	C4591001 1231 12314322	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Pancreatitis	19MAY2017	25MAY2017	N
	C4591001 1231 12314324	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1231 12314325	Gastrointestinal disorders	Colitis ulcerative	01MAR2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1231 12314327	Musculoskeletal and connective tissue disorders	Back pain	25AUG2020		Y
	C4591001 1231 12314329	Metabolism and nutrition disorders	Dyslipidaemia	04APR2013		Y
	C4591001 1231 12314330	Metabolism and nutrition disorders	Obesity	14FEB2015		Y
			Type 2 diabetes mellitus	14FEB2015		Y
	C4591001 1231 12314333	Metabolism and nutrition disorders	Obesity	11AUG2010		Y
		Vascular disorders	Hypertension	15AUG2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314339	Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
	C4591001 1231 12314340	Injury, poisoning and procedural complications	Joint dislocation	01APR2013	01APR2013	N
		Surgical and medical procedures	Varicocele repair	01JAN1991	01JAN1991	N
	C4591001 1231 12314346	Metabolism and nutrition disorders	Dyslipidaemia	10OCT2017		Y
		Vascular disorders	Hypertension	01JUL2005		Y
	C4591001 1231 12314358	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	06AUG2015		Y
			Syncope	21SEP2019		Y
	C4591001 1231 12314373	Endocrine disorders	Hypothyroidism	17SEP1991		Y
		Eye disorders	Cataract	19MAR2020		Y
	C4591001 1231 12314380	Investigations	Prostatic specific antigen increased	12AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05DEC2010		Y
	C4591001 1231 12314381	Metabolism and nutrition disorders	Type 1 diabetes mellitus	03MAR2010		Y
	C4591001 1231 12314385	Metabolism and nutrition disorders	Obesity	01MAR2003		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
	C4591001 1231 12314396	Gastrointestinal disorders	Coeliac disease	28AUG2002		Y
	C4591001 1231 12314397	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01MAY2016	01JUN2016	N
		Surgical and medical procedures	Thyroidectomy	01JUN2016	02JUN2016	N
	C4591001 1231 12314400	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	02FEB1989		Y
	C4591001 1231 12314405	Surgical and medical procedures	Spinal operation	01JAN2017		Y
	C4591001 1231 12314406	Congenital, familial and genetic disorders	Thalassaemia beta	02AUG2010		Y
	C4591001 1231 12314407	Infections and infestations	Dengue fever	15APR2020	01MAY2020	N
	C4591001 1231 12314416	Infections and infestations	American trypanosomiasis	10JUN2012	10JUN2012	N
	C4591001 1231 12314419	Gastrointestinal disorders	Haemorrhoids	01JUN1986		Y
		Psychiatric disorders	Bruxism	01JAN1975		Y
	C4591001 1231 12314424	Blood and lymphatic system disorders	Iron deficiency anaemia	03JUL2004		Y
		Cardiac disorders	Acute coronary syndrome	18JUL2017	25JUL2017	N
			Coronary artery occlusion	22JUL2004	22JUL2004	N
		General disorders and administration site conditions	Vascular stent occlusion	03JUL2019	03JUL2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Surgical and medical procedures	Coronary arterial stent insertion	22JUL2004	22JUL2004	N
			Gastric bypass	18JUL2017	25JUL2017	N
	C4591001 1231 12314435	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	02MAR2011		Y
	C4591001 1231 12314442	Endocrine disorders	Hypothyroidism	01JUN2015		Y
	C4591001 1231 12314450	Gastrointestinal disorders	Anal fistula	03APR2003		Y
	C4591001 1231 12314452	Endocrine disorders	Autoimmune thyroiditis	06JUN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314454	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1231 12314457	Psychiatric disorders	Anxiety disorder	01JUL2019		Y
	C4591001 1231 12314461	Infections and infestations	Tinea versicolour	01MAR2020		Y
	C4591001 1231 12314466	Psychiatric disorders	Generalised anxiety disorder	01AUG2013		Y
	C4591001 1231 12314474	Psychiatric disorders	Drug dependence	01JAN2000	01JAN2000	N
	C4591001 1231 12314475	Renal and urinary disorders	Nephrolithiasis	15FEB2014		Y
	C4591001 1231 12314479	Psychiatric disorders	Renal colic Sleep disorder	15FEB2014	20FEB2014	N Y
	C4591001 1231 12314480	Surgical and medical procedures	Haemangioma removal	17FEB2016	17FEB2016	N
	C4591001 1231 12314482	Infections and infestations	Syphilis	11JUL2019	25JUL2019	N
	C4591001 1231 12314486	Immune system disorders	Seasonal allergy	01JUL2000		Y
	C4591001 1231 12314489	Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2015		Y
	C4591001 1231 12314490	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	07MAY2018		Y
		Psychiatric disorders	Insomnia	19APR2018		Y
		Vascular disorders	Hypertension	30JUL2020		Y
	C4591001 1231 12314491	Respiratory, thoracic and mediastinal disorders	Glottal incompetence	01AUG2011		Y
	C4591001 1231 12314496	Vascular disorders	Hypertension	08AUG2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314499	Immune system disorders	Seasonal allergy	20SEP1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26AUG1986		Y
		Vascular disorders	Hypertension	22JUN2018		Y
	C4591001 1231 12314500	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	04JAN2018	04JAN2018	N
		Vascular disorders	Hot flush	03APR2017		Y
	C4591001 1231 12314502	Gastrointestinal disorders	Gastrointestinal necrosis	20APR2009	20APR2009	N
		Surgical and medical procedures	Gastrectomy	20APR2009	20APR2009	N
	C4591001 1231 12314506	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	29MAY2017	29MAY2017	N
		Surgical and medical procedures	Radical hysterectomy	29MAY2017	29MAY2017	N
	C4591001 1231 12314508	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1231 12314512	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1231 12314515	Gastrointestinal disorders	Gastritis	01MAR2020		Y
	C4591001 1231 12314520	Psychiatric disorders	Insomnia	01APR2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01MAR2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12314521	Endocrine disorders	Autoimmune thyroiditis	10FEB2013		Y
	C4591001 1231 12314522	Psychiatric disorders	Mental disorder	01JUN2012		Y
	C4591001 1231 12314523	Endocrine disorders	Hypothyroidism	01JUN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1231 12314525	Psychiatric disorders	Anxiety	02MAR2013		Y
	C4591001 1231 12314526	Psychiatric disorders	Anxiety disorder	01JUN2015		Y
			Depression	01JUN2018		Y
	C4591001 1231 12314528	Metabolism and nutrition disorders	Dyslipidaemia	03MAY2015		Y
	C4591001 1231 12314529	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	03OCT2011	03OCT2011	N
		Surgical and medical procedures	Hysterectomy	03OCT2011	03OCT2011	N
	C4591001 1231 12314530	Blood and lymphatic system disorders	Hypercoagulation	01AUG2005		Y
		Nervous system disorders	Sciatica	01JUN2020		Y
	C4591001 1231 12314537	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	02JUL2013	02JUN2014	N
	C4591001 1231 12314542	Vascular disorders	Hypertension	27AUG2012		Y
	C4591001 1231 12314547	Endocrine disorders	Hypothyroidism	02AUG2010		Y
	C4591001 1231 12314550	Endocrine disorders	Hypothyroidism	01FEB2015		Y
		Metabolism and nutrition disorders	Insulin resistance	01JUN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2019		Y
		Psychiatric disorders	Depression	01AUG2015	01DEC2017	N
	C4591001 1231 12314552	Gastrointestinal disorders	Diverticulum	01AUG2015		Y
	C4591001 1231 12314555	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314557	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 1231 12314562	Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 1231 12314564	Vascular disorders	Hypertension	08AUG2014		Y
	C4591001 1231 12314565	Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Psychiatric disorders	Anxiety	01AUG2019		Y
	C4591001 1231 12314571	Gastrointestinal disorders	Gastritis	29AUG2017		Y
			Haemorrhoids	01AUG2018		Y
	C4591001 1231 12314574	Psychiatric disorders	Autism spectrum disorder	01AUG2018		Y
			Sleep disorder	01AUG2018		Y
	C4591001 1231 12314575	Gastrointestinal disorders	Irritable bowel syndrome	08AUG2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2005		Y
	C4591001 1231 12314580	Nervous system disorders	Epilepsy	09APR1990		Y
	C4591001 1231 12314582	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
	C4591001 1231 12314585	Immune system disorders	Drug hypersensitivity	01JUN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01NOV2000	02NOV2000	N
	C4591001 1231 12314586	Endocrine disorders	Hypothyroidism	15MAR2006		Y
	C4591001 1231 12314590	Cardiac disorders	Ventricular extrasystoles	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314599	Reproductive system and breast disorders	Cervical dysplasia	01JAN2002	01JAN2008	N
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2008	01JAN2008	N
	C4591001 1231 12314602	Endocrine disorders	Hypothyroidism	05AUG2000		Y
		Psychiatric disorders	Bipolar disorder	05AUG2017		Y
	C4591001 1231 12314603	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	27AUG2015	27DEC2015	N
		Psychiatric disorders	Depression	27AUG2015		Y
		Surgical and medical procedures	Radical hysterectomy	27AUG2015	27AUG2015	N
	C4591001 1231 12314604	Reproductive system and breast disorders	Infertility female	01AUG2017		Y
	C4591001 1231 12314607	Congenital, familial and genetic disorders	Pulmonary hypoplasia	(b) (6) 1972		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01OCT2017		Y
		Nervous system disorders	Fine motor skill dysfunction	01OCT2017		Y
	C4591001 1231 12314610	Gastrointestinal disorders	Large intestine polyp	03JAN2015		Y
	C4591001 1231 12314615	Endocrine disorders	Autoimmune hypothyroidism	01SEP2010		Y
	C4591001 1231 12314616	Respiratory, thoracic and mediastinal disorders	Asthma	08AUG1977		Y
	C4591001 1231 12314620	Endocrine disorders	Hypothyroidism	01APR2014		Y
	C4591001 1231 12314630	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Chronic gastritis	01JAN2001		Y
	C4591001 1231 12314639	Endocrine disorders	Autoimmune thyroiditis	01JUL2000		Y
		Gastrointestinal disorders	Hiatus hernia	01MAR2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	26FEB2014	26FEB2014	N
		Surgical and medical procedures	Radical hysterectomy	26FEB2014	26FEB2014	N
	C4591001 1231 12314643	Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1231 12314644	Metabolism and nutrition disorders	Type 1 diabetes mellitus	18JAN2008		Y
	C4591001 1231 12314646	Respiratory, thoracic and mediastinal disorders	Asthma	15JAN2013	15JAN2019	N
	C4591001 1231 12314655	Endocrine disorders	Hypothyroidism	01MAY2012		Y
		Infections and infestations	Sinusitis	01SEP2014		Y
	C4591001 1231 12314665	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2015		Y
		Surgical and medical procedures	Gastric bypass	19OCT2016		Y
	C4591001 1231 12314666	Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1231 12314670	Endocrine disorders	Hypothyroidism	01JAN1990		Y
	C4591001 1231 12314671	Endocrine disorders	Hypothyroidism	05MAY2015		Y
	C4591001 1231 12314678	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2016		Y
	C4591001 1231 12314679	Metabolism and nutrition disorders	Obesity	02FEB2010		Y
	C4591001 1231 12314680	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
	C4591001 1231 12314685	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314688	Nervous system disorders	Transient ischaemic attack	27AUG2018	27OCT2018	N
	C4591001 1231 12314691	Surgical and medical procedures	Hysterectomy	01JAN2018		Y
			Oophorectomy	01JAN2018		Y
	C4591001 1231 12314693	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Vascular disorders	Hypertension	31JAN2018		Y
	C4591001 1231 12314700	Vascular disorders	Hypertension	20MAR2019		Y
	C4591001 1231 12314701	Metabolism and nutrition disorders	Dyslipidaemia	19AUG2015		Y
	C4591001 1231 12314714	Psychiatric disorders	Trichotillomania	01JAN2014		Y
	C4591001 1231 12314727	Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12314730	Vascular disorders	Peripheral venous disease	29JUL2020		Y
	C4591001 1231 12314731	Musculoskeletal and connective tissue disorders	Arthralgia	17AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	16JUL2019	20JUL2020	N
		Surgical and medical procedures	Thyroidectomy	16JUL2019	20JUL2020	N
	C4591001 1231 12314734	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12314740	Metabolism and nutrition disorders	Obesity	01MAR2014		Y
	C4591001 1231 12314742	Congenital, familial and genetic disorders	Thalassaemia minor	29AUG2006		Y
	C4591001 1231 12314743	Gastrointestinal disorders	Dental caries	01MAR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314744	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Reproductive system and breast disorders	Polycystic ovaries	01MAY1990		Y
	C4591001 1231 12314745	Respiratory, thoracic and mediastinal disorders	Asthma	28APR1980		Y
	C4591001 1231 12314746	Psychiatric disorders	Anxiety	01DEC2018		Y
	C4591001 1231 12314750	Endocrine disorders	Hypothyroidism	06MAY2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
			Vitamin D deficiency	18MAR2017		Y
	C4591001 1231 12314751	Reproductive system and breast disorders	Polycystic ovaries	06JAN2014	09JAN2014	N
				26DEC2016	29DEC2016	N
		Surgical and medical procedures	Ovarian operation	06JAN2014	09JAN2014	N
				26DEC2016	29DEC2016	N
	C4591001 1231 12314754	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10JUN2010		Y
	C4591001 1231 12314756	Injury, poisoning and procedural complications	Meniscus injury	01JUN2020		Y
	C4591001 1231 12314782	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02NOV2018		Y
	C4591001 1231 12314789	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1231 12314790	Psychiatric disorders	Anxiety disorder	01JUN2010		Y
	C4591001 1231 12314792	Skin and subcutaneous tissue disorders	Androgenetic alopecia	30AUG2005		Y
	C4591001 1231 12314797	Metabolism and nutrition disorders	Hypercholesterolaemia	15MAY2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12314800	Reproductive system and breast disorders	Menstrual disorder	01JAN2015		Y
	C4591001 1231 12314801	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2017		Y
	C4591001 1231 12314809	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12314813	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01OCT2000		Y
	C4591001 1231 12314816	Metabolism and nutrition disorders	Hypercholesterolaemia	03MAR2013		Y
		Vascular disorders	Hypertension	09SEP2018		Y
	C4591001 1231 12314818	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2012		Y
	C4591001 1231 12314824	Congenital, familial and genetic disorders	Tuberous sclerosis complex	02MAY2015		Y
	C4591001 1231 12314836	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1231 12314842	Psychiatric disorders	Anxiety	01JUN2020		Y
	C4591001 1231 12314844	Reproductive system and breast disorders	Endometriosis	08AUG2014	16JUL2019	N
	C4591001 1231 12314845	Nervous system disorders	Headache	01JUN2010		Y
	C4591001 1231 12314846	Gastrointestinal disorders	Hiatus hernia	01JAN2010		Y
			Oesophagitis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1231 12314853	Metabolism and nutrition disorders	Type 2 diabetes mellitus	17AUG2016		Y
		Vascular disorders	Hypertension	17AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314855	Psychiatric disorders	Panic attack	19DEC2019		Y
	C4591001 1231 12314857	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	01MAY2015		Y
			Insomnia	01FEB2008		Y
	C4591001 1231 12314862	Metabolism and nutrition disorders	Obesity	10FEB2020		Y
	C4591001 1231 12314869	Cardiac disorders	Sinus node dysfunction	05MAR2005		Y
		Skin and subcutaneous tissue disorders	Alopecia areata	18JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	08AUG2018		Y
	C4591001 1231 12314870	Metabolism and nutrition disorders	Obesity	18JAN2018		Y
			Type 2 diabetes mellitus	02AUG2017		Y
		Psychiatric disorders	Anxiety	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2018		Y
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 1231 12314872	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2015		Y
			Hypertriglyceridaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1231 12314873	Infections and infestations	Oral herpes	01JUN2010		Y
		Nervous system disorders	Migraine	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2001		Y
	C4591001 1231 12314877	Gastrointestinal disorders	Dental caries	01MAR2001	01SEP2019 09OCT2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	08JUN2009	08JUN2009	N
	C4591001 1231 12314880	Metabolism and nutrition disorders	Hypertriglyceridaemia	11AUG2010		Y
		Vascular disorders	Hypertension	12AUG2010		Y
	C4591001 1231 12314884	Gastrointestinal disorders	Gastritis	04APR2000		Y
	C4591001 1231 12314885	Gastrointestinal disorders	Abdominal distension	01JAN2017		Y
			Abdominal pain	01JAN2017		Y
			Diarrhoea	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN1990		Y
			Lumbar hernia	01JAN2013		Y
			Rectal haemorrhage	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1982		Y
	C4591001 1231 12314890	Vascular disorders	Hypertension	10SEP2014		Y
	C4591001 1231 12314892	Nervous system disorders	Seizure	01JAN1992	01AUG2014	N
	C4591001 1231 12314894	Infections and infestations	Pneumonia	01JUN2005	15JUN2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2005	01JUN2006	N
	C4591001 1231 12314900	Endocrine disorders	Endocrine disorder	04MAY1985	04MAY1992	N
			Hypothyroidism	04MAY1985		Y
	C4591001 1231 12314901	Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1231 12314903	Skin and subcutaneous tissue disorders	Alopecia	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314914	Blood and lymphatic system disorders	Iron deficiency anaemia	15MAR2020		Y
		Investigations	Coagulation factor VIII level decreased	15MAR2020		Y
	C4591001 1231 12314925	Skin and subcutaneous tissue disorders	Pityriasis rosea	12MAR2017		Y
	C4591001 1231 12314929	Metabolism and nutrition disorders	Hypertriglyceridaemia	01AUG2011		Y
	C4591001 1231 12314934	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1231 12314935	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2018		Y
			Hypertriglyceridaemia	01AUG2018		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1231 12314940	Nervous system disorders	Epilepsy	01JUN1978		Y
	C4591001 1231 12314945	Blood and lymphatic system disorders	Anaemia	15JUN2005		Y
		Vascular disorders	Subclavian vein thrombosis	01JUL2015	01JUL2016	N
	C4591001 1231 12314954	Musculoskeletal and connective tissue disorders	Bone cyst	01JAN2015		Y
	C4591001 1231 12314955	Respiratory, thoracic and mediastinal disorders	Asthma	16AUG2000		Y
	C4591001 1231 12314959	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Psychiatric disorders	Insomnia	02FEB2020		Y
	C4591001 1231 12314967	Metabolism and nutrition disorders	Type 1 diabetes mellitus	19SEP1977		Y
		Skin and subcutaneous tissue disorders	Psoriasis	23MAR2020		Y
		Vascular disorders	Hypertension	18AUG2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12314968	Gastrointestinal disorders	Chronic gastritis	28AUG2012		Y
	C4591001 1231 12314970	Vascular disorders	Hypertension	03MAR2020		Y
	C4591001 1231 12314977	Gastrointestinal disorders	Gastritis	10MAY2009		Y
	C4591001 1231 12314987	Metabolism and nutrition disorders	Type 1 diabetes mellitus	26NOV2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Social circumstances	Tobacco user	01JAN1993		Y
	C4591001 1231 12314992	Vascular disorders	Hypertension	14MAR2018		Y
		Vascular disorders	Hypertension	08NOV2019		Y
	C4591001 1231 12314995	Endocrine disorders	Hypothyroidism	01DEC2019		Y
	C4591001 1231 12314998	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign muscle neoplasm	01FEB2011	25OCT2017	N
		Surgical and medical procedures	Hysterectomy	25OCT2017	25OCT2017	N
	C4591001 1231 12314999	Infections and infestations	Tinea versicolour	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	10APR2008		Y
	C4591001 1231 12315000	Eye disorders	Chorioretinopathy	01MAR2020		Y
	C4591001 1231 12315001	Endocrine disorders	Hypothyroidism	01AUG2008		Y
	C4591001 1231 12315013	Respiratory, thoracic and mediastinal disorders	Bronchospasm	14JUN2006		Y
	C4591001 1231 12315015	Endocrine disorders	Hypothyroidism	01SEP2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315036	Endocrine disorders	Hypothyroidism	06NOV2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1231 12315039	Psychiatric disorders	Anxiety disorder	28AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01SEP2019		Y
	C4591001 1231 12315047	Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1231 12315048	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	21SEP2016		Y
	C4591001 1231 12315053	Nervous system disorders	Transient ischaemic attack	03MAR2011	03MAR2011	N
	C4591001 1231 12315054	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1231 12315057	Blood and lymphatic system disorders	Anaemia	13MAR2010	12APR2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	13MAR2010		Y
	C4591001 1231 12315060	Endocrine disorders	Hypothyroidism	08OCT2014		Y
	C4591001 1231 12315061	Gastrointestinal disorders	Gastritis	01JAN2019		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	15AUG2020		Y
	C4591001 1231 12315064	Nervous system disorders	Migraine	01JAN1997		Y
	C4591001 1231 12315066	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2000		Y
	C4591001 1231 12315068	Skin and subcutaneous tissue disorders	Psoriasis	01JUN2012		Y
	C4591001 1231 12315070	Nervous system disorders	Essential tremor	01JAN2015		Y
	C4591001 1231 12315071	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	08FEB2021	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2018	08FEB2021	N
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1231 12315073	Surgical and medical procedures	Female sterilisation	01JAN2017	01JAN2017	N
	C4591001 1231 12315080	Endocrine disorders	Thyroid mass	06JUN2016		Y
	C4591001 1231 12315082	Vascular disorders	Hypertension	03AUG2011		Y
	C4591001 1231 12315083	Respiratory, thoracic and mediastinal disorders	Asthma	03MAY1989		Y
	C4591001 1231 12315094	Nervous system disorders	Restless legs syndrome	01MAY2019		Y
	C4591001 1231 12315095	Musculoskeletal and connective tissue disorders	Muscle contracture	14AUG2019		Y
		Vascular disorders	Peripheral venous disease	28DEC2018		Y
	C4591001 1231 12315098	Endocrine disorders	Hypothyroidism	29AUG2006		Y
		Psychiatric disorders	Generalised anxiety disorder	29FEB2020		Y
	C4591001 1231 12315101	Psychiatric disorders	Anxiety disorder	01JAN2018		Y
	C4591001 1231 12315136	Respiratory, thoracic and mediastinal disorders	Asthma	10MAR2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315140	Endocrine disorders	Hypothyroidism	12MAY1998		Y
	C4591001 1231 12315154	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Extragenital primary seminoma (pure)	10DEC2008	15DEC2009	N
	C4591001 1231 12315169	Congenital, familial and genetic disorders	Thalassaemia	01JAN2006		Y
	C4591001 1231 12315182	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1231 12315183	Respiratory, thoracic and mediastinal disorders	Emphysema	28MAY2020		Y
	C4591001 1231 12315186	Gastrointestinal disorders	Gastritis erosive	01SEP2016		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JUL2019		Y
	C4591001 1231 12315187	Vascular disorders	Hypertension	18OCT2018		Y
	C4591001 1231 12315189	Infections and infestations	Conjunctivitis	01JUL2005		Y
	C4591001 1231 12315190	Metabolism and nutrition disorders	Obesity	01NOV2019		Y
	C4591001 1231 12315191	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1231 12315198	Psychiatric disorders	Anxiety	01FEB2010		Y
	C4591001 1231 12315202	General disorders and administration site conditions	Perforated ulcer	07JUL1995	07JUL1995	N
		Renal and urinary disorders	Nephrolithiasis	11NOV2018	11NOV2018	N
		Surgical and medical procedures	Inguinal hernia repair	06JUN1992	06JUN1992	N
	C4591001 1231 12315204	Cardiac disorders	Ventricular extrasystoles	01JUN2015		Y
	C4591001 1231 12315206	Gastrointestinal disorders	Tooth loss	01NOV2019	04MAR2021	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315208	Renal and urinary disorders	Calculus bladder	01NOV2011		Y
	C4591001 1231 12315209	Metabolism and nutrition disorders	Dyslipidaemia	27AUG2014		Y
			Type 2 diabetes mellitus	12AUG2014		Y
	C4591001 1231 12315214	Social circumstances	Menopause	01DEC2019		Y
	C4591001 1231 12315224	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
	C4591001 1231 12315225	Endocrine disorders	Hypothyroidism	01FEB1993		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1231 12315238	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12315239	Endocrine disorders	Hypothyroidism	28MAR1992		Y
	C4591001 1231 12315241	Renal and urinary disorders	Nephrolithiasis	01FEB2017		Y
	C4591001 1231 12315247	Renal and urinary disorders	Ureteric stenosis	01AUG2015	10MAR2016	N
		Surgical and medical procedures	Ureteric operation	10AUG2015	10AUG2015	N
				10MAR2016	10MAR2016	N
	C4591001 1231 12315249	Gastrointestinal disorders	Gastritis	01JAN2010		Y
	C4591001 1231 12315263	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1995		Y
	C4591001 1231 12315264	Congenital, familial and genetic disorders	Thalassaemia minor	07JUL1984		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	06JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	03MAR2000		Y
		Vascular disorders	Varicose vein	06JUN2010		Y
	C4591001 1231 12315271	Nervous system disorders	Essential tremor	04AUG2005		Y
	C4591001 1231 12315279	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2019		Y
	C4591001 1231 12315282	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1231 12315291	Eye disorders	Amblyopia	(b) (6) 1968		Y
			Myopia	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	26AUG1977		Y
		Infections and infestations	Herpes zoster	28DEC2016		Y
		Nervous system disorders	Migraine	01JUN1977		Y
		Psychiatric disorders	Depression	01JUN2005	01OCT2010	N
	C4591001 1231 12315292	Surgical and medical procedures	Hysterectomy	04APR2015	04APR2015	N
	C4591001 1231 12315296	Metabolism and nutrition disorders	Hypercholesterolaemia	10AUG2017		Y
		Vascular disorders	Hypertension	10AUG2017		Y
	C4591001 1231 12315297	Vascular disorders	Deep vein thrombosis	03APR2012	03OCT2012	N
	C4591001 1231 12315299	Skin and subcutaneous tissue disorders	Angioedema	11AUG2005	12AUG2015	N
	C4591001 1231 12315300	Psychiatric disorders	Post-traumatic stress disorder	01JUN2020		Y
	C4591001 1231 12315302	Metabolism and nutrition disorders	Dyslipidaemia	16AUG2016		Y
		Vascular disorders	Hypertension	15JUN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315304	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
	C4591001 1231 12315306	Endocrine disorders	Hyperthyroidism	01AUG2017		Y
		Metabolism and nutrition disorders	Insulin resistance	01JUN2020		Y
	C4591001 1231 12315307	Immune system disorders	Drug hypersensitivity	12AUG2015		Y
		Psychiatric disorders	Depression	09AUG2010		Y
	C4591001 1231 12315311	Nervous system disorders	Carpal tunnel syndrome	01JAN2016		Y
	C4591001 1231 12315316	Musculoskeletal and connective tissue disorders	Osteoporosis	18APR2019		Y
	C4591001 1231 12315322	Nervous system disorders	Sciatica	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06AUG1977		Y
		Vascular disorders	Hypertension	02AUG2017		Y
	C4591001 1231 12315325	Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	07NOV2017	07NOV2017	N
		Surgical and medical procedures	Salpingectomy	07NOV2017	07NOV2017	N
	C4591001 1231 12315330	Respiratory, thoracic and mediastinal disorders	Asthma	17AUG2000		Y
		Vascular disorders	Hypertension	01DEC2018		Y
	C4591001 1231 12315334	Respiratory, thoracic and mediastinal disorders	Asthma	04APR1981		Y
	C4591001 1231 12315342	Endocrine disorders	Hypothyroidism	31AUG2005		Y
	C4591001 1231 12315343	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2005		Y
	C4591001 1231 12315348	Psychiatric disorders	Insomnia	10JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315349	Endocrine disorders	Hypothyroidism	07AUG2010		Y
	C4591001 1231 12315351	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2013		Y
	C4591001 1231 12315353	Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2000		Y
	C4591001 1231 12315355	Endocrine disorders	Hypothyroidism	04MAY2001		Y
		Vascular disorders	Hypertension	03APR2017		Y
	C4591001 1231 12315357	Nervous system disorders	Migraine	01JUN2018		Y
	C4591001 1231 12315363	Endocrine disorders	Hypothyroidism	10AUG2016		Y
		Nervous system disorders	Hyposmia	30AUG1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1231 12315368	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1231 12315369	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	14APR1974	14APR1974	N
		Nervous system disorders	Transient ischaemic attack	30NOV2014	30NOV2014	N
		Surgical and medical procedures	Brain lobectomy	14APR1974	14APR1974	N
	C4591001 1231 12315370	Congenital, familial and genetic disorders	Neurofibromatosis	(b) (6) 1991		Y
	C4591001 1231 12315371	Blood and lymphatic system disorders	Neutropenia	13SEP2019		Y
		Endocrine disorders	Hypothyroidism	01MAR2007		Y
	C4591001 1231 12315372	Endocrine disorders	Hypothyroidism	24AUG2000		Y
	C4591001 1231 12315373	Metabolism and nutrition disorders	Overweight	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	06AUG1986		Y
	C4591001 1231 12315377	Respiratory, thoracic and mediastinal disorders	Allergic bronchitis	01JAN2005		Y
	C4591001 1231 12315380	Endocrine disorders	Hypothyroidism	05AUG2004		Y
		Surgical and medical procedures	Gastric bypass	11AUG2016		Y
	C4591001 1231 12315391	Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 1231 12315393	Respiratory, thoracic and mediastinal disorders	Asthma	12MAR2010		Y
	C4591001 1231 12315402	Endocrine disorders	Hypothyroidism	01MAY2011		Y
	C4591001 1231 12315406	Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
	C4591001 1231 12315407	Injury, poisoning and procedural complications	Meniscus injury	10JUL2020		Y
	C4591001 1231 12315408	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2015	01AUG2015	N
		Surgical and medical procedures	Radical hysterectomy	01AUG2015	01AUG2015	N
	C4591001 1231 12315409	Metabolism and nutrition disorders	Hypercholesterolaemia	14AUG2019		Y
		Psychiatric disorders	Depression	15AUG2018		Y
		Vascular disorders	Hypertension	20AUG2019		Y
	C4591001 1231 12315412	Metabolism and nutrition disorders	Dyslipidaemia	02AUG2016		Y
	C4591001 1231 12315415	Reproductive system and breast disorders	Mastoptosis	01JAN2015		Y
	C4591001 1231 12315419	Psychiatric disorders	Anxiety disorder	13MAR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315420	Vascular disorders	Hypertension	01AUG2012		Y
	C4591001 1231 12315435	Gastrointestinal disorders	Chronic gastritis	15JAN2020		Y
		Surgical and medical procedures	Radical hysterectomy	12MAR2013	12MAR2013	N
	C4591001 1231 12315436	Immune system disorders	Seasonal allergy	01SEP2004		Y
	C4591001 1231 12315441	Metabolism and nutrition disorders	Type 2 diabetes mellitus	30AUG2000		Y
	C4591001 1231 12315446	Surgical and medical procedures	Thyroidectomy	28JUL2011	28JUL2011	N
	C4591001 1231 12315448	Metabolism and nutrition disorders	Hypercholesterolaemia	04AUG2015		Y
	C4591001 1231 12315450	Metabolism and nutrition disorders	Hyperglycaemia	01FEB2012	01JAN2015	N
	C4591001 1231 12315451	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2019		Y
		Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12315460	Metabolism and nutrition disorders	Obesity	01AUG1985		Y
		Nervous system disorders	Tension headache	01MAR2020		Y
	C4591001 1231 12315462	Skin and subcutaneous tissue disorders	Acne	10JAN2019		Y
	C4591001 1231 12315463	Endocrine disorders	Hypothyroidism	01JAN2001		Y
	C4591001 1231 12315465	Skin and subcutaneous tissue disorders	Alopecia	01JAN2020		Y
	C4591001 1231 12315467	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
	C4591001 1231 12315471	Skin and subcutaneous tissue disorders	Vitiligo	26MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315472	Reproductive system and breast disorders	Endometriosis	01AUG2000		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2002	01JUL2002	N
			Salpingectomy	01JAN2020	01JAN2020	N
	C4591001 1231 12315473	Cardiac disorders	Myocardial infarction	18JAN2015	19JAN2015	N
		Congenital, familial and genetic disorders	Congenital toxoplasmosis	(b) (6) 1970	18AUG1986	N
		Metabolism and nutrition disorders	Dyslipidaemia	20AUG2015		Y
			Obesity	01JAN1992		Y
		Social circumstances	Tobacco user	03MAR1986	18JAN2015	N
		Surgical and medical procedures	Angioplasty	01JAN2015	31JAN2015	N
			Stent placement	01JAN2015	31JAN2015	N
		Vascular disorders	Hypertension	19AUG2015		Y
	C4591001 1231 12315475	Endocrine disorders	Hypothyroidism	03JUN2014		Y
	C4591001 1231 12315477	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01DEC2008	01AUG2009	N
	C4591001 1231 12315487	Vascular disorders	Hypertension	08AUG2018		Y
	C4591001 1231 12315492	Endocrine disorders	Hypothyroidism	01JUN2011		Y
	C4591001 1231 12315497	Gastrointestinal disorders	Dental caries	15JAN2020	25JAN2020	N
		Nervous system disorders	Cervicogenic headache	11JUL2020	14JUL2020	N
		Surgical and medical procedures	Tooth extraction	15JUL2020	15JUL2020	N
	C4591001 1231 12315499	Endocrine disorders	Hypothyroidism	15AUG2001		Y
	C4591001 1231 12315502	Vascular disorders	Hypertension	07AUG2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315504	Congenital, familial and genetic disorders	Gilbert's syndrome	01AUG2000		Y
	C4591001 1231 12315514	Metabolism and nutrition disorders	Obesity	07FEB2011		Y
		Pregnancy, puerperium and perinatal conditions	Gestational hypertension	07FEB2011	01JAN2015	N
	C4591001 1231 12315516	Nervous system disorders	Migraine	01APR2015		Y
	C4591001 1231 12315518	Metabolism and nutrition disorders	Overweight	01MAR2017		Y
	C4591001 1231 12315519	Endocrine disorders	Autoimmune thyroiditis	04NOV2000		Y
		Investigations	Hysteroscopy	29DEC2019	29DEC2019	N
		Nervous system disorders	Migraine	01NOV1987		Y
		Psychiatric disorders	Depression	20APR2017	29DEC2018	N
		Social circumstances	Tobacco user	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	10NOV2004	10NOV2004	N
				27FEB2000	27FEB2000	N
			Exeresis	01MAY1999	01MAY1999	N
			Eye laser surgery	15AUG2000	15AUG2000	N
			Wrist surgery	23APR2016	23APR2016	N
	C4591001 1231 12315521	Metabolism and nutrition disorders	Type 2 diabetes mellitus	13JUL2017		Y
	C4591001 1231 12315527	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1231 12315528	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2008		Y
	C4591001 1231 12315529	Nervous system disorders	Epilepsy	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315533	Metabolism and nutrition disorders	Obesity	10MAY2020		Y
	C4591001 1231 12315538	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	30AUG2000	30AUG2010	N
		Surgical and medical procedures	Thyroidectomy	30AUG2000	30AUG2000	N
	C4591001 1231 12315544	Blood and lymphatic system disorders	Immune thrombocytopenia	01JUN2000	01OCT2000	N
		Immune system disorders	Drug hypersensitivity	01JUN1980		Y
		Psychiatric disorders	Anxiety disorder	01JUL2020		Y
	C4591001 1231 12315546	Endocrine disorders	Hypothyroidism	02AUG2005		Y
	C4591001 1231 12315547	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1231 12315550	Nervous system disorders	Neuralgia	01AUG2019		Y
		Renal and urinary disorders	Trigonitis	05AUG2019		Y
	C4591001 1231 12315552	Vascular disorders	Hypertension	01JUN2005		Y
	C4591001 1231 12315554	Cardiac disorders	Cardiac failure	02JAN1999		Y
		Congenital, familial and genetic disorders	Congenital heart valve disorder	02JAN1999		Y
	C4591001 1231 12315559	Respiratory, thoracic and mediastinal disorders	Asthma	01JUL1987		Y
	C4591001 1231 12315563	Metabolism and nutrition disorders	Type 1 diabetes mellitus	15JUN2015		Y
	C4591001 1231 12315566	Vascular disorders	Raynaud's phenomenon	12AUG2015		Y
	C4591001 1231 12315580	Endocrine disorders	Hyperthyroidism	01JUN1999	01FEB2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315581	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2011		Y
	C4591001 1231 12315603	Metabolism and nutrition disorders	Obesity	01JUL2000		Y
		Vascular disorders	Hypertension	01FEB2017		Y
	C4591001 1231 12315605	Psychiatric disorders	Depression	01JUN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07JUL1982		Y
	C4591001 1231 12315626	Respiratory, thoracic and mediastinal disorders	Asthma	12SEP1980		Y
	C4591001 1231 12315635	Endocrine disorders	Hypothyroidism	07JUL2014		Y
		Surgical and medical procedures	Female sterilisation	06AUG2013	06AUG2013	N
	C4591001 1231 12315642	Vascular disorders	Hypertension	01FEB2018		Y
	C4591001 1231 12315643	Metabolism and nutrition disorders	Dyslipidaemia	06AUG2020		Y
		Psychiatric disorders	Depression	17MAY2018		Y
	C4591001 1231 12315645	Metabolism and nutrition disorders	Obesity	01MAR1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Psychiatric disorders	Anxiety disorder	01MAR1995		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01MAR1995		Y
	C4591001 1231 12315648	Surgical and medical procedures	Cholecystectomy	06JUN2016	06JUN2016	N
			Tonsillectomy	08AUG2014	08AUG2014	N
	C4591001 1231 12315651	Hepatobiliary disorders	Cholelithiasis	01DEC2019	17MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Helicobacter gastritis	01MAY2020		Y
		Surgical and medical procedures	Cholecystectomy	17MAR2020	17MAR2020	N
	C4591001 1231 12315659	Endocrine disorders	Hypothyroidism	01JUN2015		Y
	C4591001 1231 12315676	Metabolism and nutrition disorders	Type 2 diabetes mellitus	08JAN2020		Y
		Vascular disorders	Hypertension	08JAN2020		Y
	C4591001 1231 12315678	Nervous system disorders	Encephalopathy	18AUG1998		Y
	C4591001 1231 12315682	Psychiatric disorders	Insomnia	02FEB2018		Y
		Vascular disorders	Capillary fragility	03MAR2020		Y
	C4591001 1231 12315684	Endocrine disorders	Hypothyroidism	05NOV2015		Y
		Metabolism and nutrition disorders	Metabolic syndrome	05NOV2015		Y
	C4591001 1232 12321002	Surgical and medical procedures	Hysterectomy	07JUN2019	07JUN2019	N
	C4591001 1232 12321006	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer metastatic	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Oophorectomy bilateral	01JAN2017	31DEC2017	N
	C4591001 1232 12321007	Immune system disorders	Seasonal allergy	01JUL2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
	C4591001 1232 12321012	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1232 12321014	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01FEB2003		Y
	C4591001 1232 12321019	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Insomnia	01JUN2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1232 12321025	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1232 12321027	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01APR2014	01APR2014	N
		Vascular disorders	Deep vein thrombosis	01JAN2013		Y
	C4591001 1232 12321028	Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1232 12321030	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1232 12321036	Endocrine disorders	Hypothyroidism	01JAN2019		Y
	C4591001 1232 12321040	Congenital, familial and genetic disorders	Sickle cell trait	01JAN1981		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
		Nervous system disorders	Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Bipolar disorder	01JAN2007		Y
			Depression	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1232 12321042	Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1232 12321043	Psychiatric disorders	Anxiety	01JAN2016		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1232 12321046	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1232 12321049	Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1232 12321053	Cardiac disorders	Arrhythmia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321056	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2020		Y
			Psoriasis	01JAN2020		Y
	C4591001 1232 12321057	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1232 12321061	Gastrointestinal disorders	Abdominal pain upper	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1232 12321071	Surgical and medical procedures	Hysterectomy	01JAN2014		Y
	C4591001 1232 12321072	Psychiatric disorders	Depression	01JAN2002		Y
	C4591001 1232 12321080	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1232 12321084	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1232 12321086	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Sleep apnoea syndrome	01JAN2006		Y
	C4591001 1232 12321090	Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321091	Infections and infestations	Hepatitis C	01JAN2001	30APR2020	N
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2013		Y
	C4591001 1232 12321094	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
	C4591001 1232 12321099	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1232 12321101	Surgical and medical procedures	Caesarean section	30JUN2020	30JUN2020	N
	C4591001 1232 12321108	Investigations	Blood cholesterol increased	01JAN2016		Y
		Surgical and medical procedures	Hip arthroplasty	01JUN2019	30JUN2019	N
	C4591001 1232 12321111	Nervous system disorders	Migraine	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013		Y
	C4591001 1232 12321112	Surgical and medical procedures	Hysterectomy	01JAN2013		Y
	C4591001 1232 12321114	Musculoskeletal and connective tissue disorders	Sjogren's syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1232 12321116	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Allergy to animal	(b) (6) 1985		Y
	C4591001 1232 12321119	Nervous system disorders	Migraine	01JAN1992		Y
	C4591001 1232 12321120	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01SEP2001		Y
		Psychiatric disorders	Depression	01JUN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321121	Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1232 12321122	Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2000	31DEC2017	N
	C4591001 1232 12321123	Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1232 12321124	Psychiatric disorders	Bipolar disorder	01JAN1991		Y
		Surgical and medical procedures	Female sterilisation	01JUL2000	31JUL2000	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1232 12321132	Nervous system disorders	Cerebrovascular accident	01NOV2018	30NOV2018	N
			Migraine	01JAN2011		Y
	C4591001 1232 12321140	Surgical and medical procedures	Female sterilisation	01JAN2016		Y
	C4591001 1232 12321141	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1232 12321146	Psychiatric disorders	Schizophrenia	01JAN2017		Y
	C4591001 1232 12321147	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1232 12321151	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1232 12321155	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1232 12321158	Surgical and medical procedures	Hysterectomy	01JUL2015	31JUL2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321159	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
	C4591001 1232 12321168	Skin and subcutaneous tissue disorders	Eczema	01JAN1999		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1232 12321169	Immune system disorders	Allergy to arthropod sting	01JAN1991		Y
			Allergy to chemicals	01JAN1988		Y
			Drug hypersensitivity	01JAN1988		Y
	C4591001 1232 12321173	Blood and lymphatic system disorders	Anaemia	01JAN1988		Y
		Congenital, familial and genetic disorders	Sickle cell trait	01JAN1988		Y
		Psychiatric disorders	Anxiety	01NOV2014		Y
			Bipolar disorder	01NOV2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB1993		Y
	C4591001 1232 12321177	Surgical and medical procedures	Hysterectomy	01SEP2019	30SEP2019	N
	C4591001 1232 12321179	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2008		Y
	C4591001 1232 12321181	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2018		Y
			Depression	01JAN2008		Y
	C4591001 1232 12321185	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2013		Y
	C4591001 1232 12321186	Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321190	Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2013		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JUN2020		Y
	C4591001 1232 12321198	Metabolism and nutrition disorders	Hypercholesterolaemia	15AUG2020		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1232 12321202	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1232 12321204	General disorders and administration site conditions	Pain	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
	C4591001 1232 12321206	Immune system disorders	Food allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1232 12321207	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1232 12321216	Psychiatric disorders	Bipolar disorder	01JAN2018		Y
			Post-traumatic stress disorder	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Schizoaffective disorder	01JAN2018		Y
	C4591001 1232 12321221	Congenital, familial and genetic disorders	Leptin receptor deficiency	01NOV2018		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Polycystic ovaries	01NOV2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
			Hysterectomy	01APR2019	30APR2019	N
	C4591001 1232 12321231	Skin and subcutaneous tissue disorders	Skin disorder	01JUN2020		Y
	C4591001 1232 12321236	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
			Hypertension	01JAN2010		Y
	C4591001 1232 12321249	Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1232 12321253	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321260	Psychiatric disorders	Anxiety	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1232 12321280	Psychiatric disorders	Depression	01APR2010		Y
		Social circumstances	Menopause	01DEC2017		Y
	C4591001 1232 12321285	Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1232 12321287	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Multiple allergies	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1232 12321289	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321292	Psychiatric disorders	Substance abuse	01JAN2013	31DEC2017	N
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1232 12321296	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Social circumstances	Menopause	01AUG2018		Y
	C4591001 1232 12321305	Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
	C4591001 1232 12321310	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
	C4591001 1232 12321316	Immune system disorders	Seasonal allergy	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321319	Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
			Post-traumatic stress disorder	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1232 12321320	Blood and lymphatic system disorders	Anaemia	01JAN2007		Y
		Immune system disorders	Cockroach allergy	01JAN2015		Y
			Dust allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1232 12321321	Psychiatric disorders	Bipolar disorder	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1232 12321324	Psychiatric disorders	Bipolar disorder	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
	C4591001 1232 12321327	Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1232 12321328	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1232 12321329	Vascular disorders	Hypertension	01JAN1998		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1232 12321330	Congenital, familial and genetic disorders	Tourette's disorder	01JAN1984		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
	C4591001 1232 12321333	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2011		Y
	C4591001 1232 12321335	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2000		Y
			Hyperlipidaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Menopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1232 12321337	General disorders and administration site conditions	Hernia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2015		Y
	C4591001 1232 12321347	Gastrointestinal disorders	Barrett's oesophagus	01JAN2005		Y
			Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN1994		Y
			Mite allergy	01JAN1994		Y
			Mycotic allergy	01JAN1994		Y
			Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
		Surgical and medical procedures	Fracture treatment	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal operation	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1232 12321350	Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1232 12321351	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
	C4591001 1232 12321353	Blood and lymphatic system disorders	Anaemia	01JAN1998		Y
		Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety disorder	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN1986		Y
			Depression	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1992		Y
		Surgical and medical procedures	Ankle operation	01JAN2016	31DEC2016	N
			Bone operation	01JAN1997	31DEC1997	N
	C4591001 1232 12321356	Blood and lymphatic system disorders	Anaemia	01JAN2007		Y
		Immune system disorders	Multiple allergies	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Gastric bypass	01JAN2005	31DEC2007	N
	C4591001 1232 12321359	Psychiatric disorders	Anxiety	01JAN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar disorder	01JAN2018		Y
			Depression	01JAN2015		Y
	C4591001 1232 12321361	Psychiatric disorders	Post-traumatic stress disorder	01JAN2007		Y
	C4591001 1232 12321364	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2003		Y
	C4591001 1232 12321366	General disorders and administration site conditions	Hernia	01JAN2015	31DEC2015	N
		Infections and infestations	Sepsis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Eye operation	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2014	31DEC2014	N
			Renal stone removal	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
				01JAN2020	31DEC2020	N
	C4591001 1232 12321370	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
			Osteoarthritis	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321374	Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1232 12321376	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321377	Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321382	Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1232 12321385	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1232 12321391	Blood and lymphatic system disorders	Anaemia	01JAN1982		Y
		Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2012		Y
	C4591001 1232 12321393	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2020		Y
	C4591001 1232 12321394	Surgical and medical procedures	Hysterectomy	01JUL2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321395	Social circumstances	Menopause	01JAN2015		Y
	C4591001 1232 12321402	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1232 12321404	Psychiatric disorders	Depression	01JAN2012		Y
			Post-traumatic stress disorder	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321406	Nervous system disorders	Epilepsy	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321408	Investigations	Heart rate irregular	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Reynold's syndrome	01JAN2017		Y
		Vascular disorders	Erythromelalgia	01JAN2019		Y
	C4591001 1232 12321416	Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1986		Y
	C4591001 1232 12321417	Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1232 12321419	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1998		Y
		Surgical and medical procedures	Spinal operation	01JAN1998	31DEC1998	N
	C4591001 1232 12321425	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
	C4591001 1232 12321429	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1232 12321431	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2005		Y
			Hyperlipidaemia	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	17MAR2016	17MAR2016	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1232 12321434	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351003	Psychiatric disorders	Depression	01MAR2020		Y
			Insomnia	01NOV2019		Y
	C4591001 1235 12351004	Renal and urinary disorders	Bladder spasm	01JAN2015		Y
		Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1235 12351006	Infections and infestations	Oral herpes	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
	C4591001 1235 12351008	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1235 12351009	Nervous system disorders	Migraine	01JAN2006		Y
	C4591001 1235 12351011	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1235 12351013	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2003		Y
	C4591001 1235 12351014	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1235 12351015	Psychiatric disorders	Chronic tic disorder	01JAN2003		Y
	C4591001 1235 12351016	Reproductive system and breast disorders	Polycystic ovaries	01FEB2016		Y
	C4591001 1235 12351017	Infections and infestations	Urinary tract infection	01JAN2019		Y
	C4591001 1235 12351019	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1235 12351020	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1235 12351023	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1235 12351025	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1235 12351026	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351027	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351029	Skin and subcutaneous tissue disorders	Alopecia	01MAR2020		Y
	C4591001 1235 12351030	Musculoskeletal and connective tissue disorders	Back pain	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351033	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Carcinoid tumour	01JAN2018		Y
	C4591001 1235 12351034	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351035	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1235 12351036	Nervous system disorders	Chronic inflammatory demyelinating polyradiculoneuropathy	01JAN2014		Y
	C4591001 1235 12351038	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
	C4591001 1235 12351040	Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1235 12351041	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
		Surgical and medical procedures	Prophylaxis against HIV infection	01JAN2019		Y
	C4591001 1235 12351044	Cardiac disorders	Arrhythmia	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013		Y
			Mitral valve replacement	01JAN2012		Y
	C4591001 1235 12351045	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1235 12351048	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1235 12351050	Psychiatric disorders	Anxiety	01JAN1999		Y
	C4591001 1235 12351052	Cardiac disorders	Supraventricular tachycardia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1235 12351055	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351057	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Rhabdomyolysis	01NOV2019		Y
		Psychiatric disorders	Panic disorder	01JAN2020		Y
	C4591001 1235 12351058	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
			Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351059	Nervous system disorders	Seizure	01JAN2003		Y
	C4591001 1235 12351061	Investigations	Lipids increased	01JUL2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
		Social circumstances	Postmenopause	01AUG2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996		Y
	C4591001 1235 12351064	Psychiatric disorders	Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Contraception	01JAN2014		Y
	C4591001 1235 12351065	Endocrine disorders	Autoimmune thyroiditis	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1235 12351067	Psychiatric disorders	Depression	01JAN2009		Y
	C4591001 1235 12351068	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1235 12351070	Psychiatric disorders	Anxiety	01JUN2020		Y
	C4591001 1235 12351071	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis allergic	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1235 12351072	Infections and infestations	Hepatitis B	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Cancer surgery	01MAR2020	30APR2020	N
	C4591001 1235 12351073	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1235 12351079	Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
	C4591001 1235 12351084	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1235 12351088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN2019	31DEC2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351089	Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01APR2020		Y
		Surgical and medical procedures	Salpingectomy	01DEC2019	31DEC2019	N
	C4591001 1235 12351090	Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Surgical and medical procedures	Contraception	01JUL2020		Y
	C4591001 1235 12351092	Surgical and medical procedures	Contraception	01JAN2018		Y
	C4591001 1235 12351093	Surgical and medical procedures	Contraception	01FEB2019		Y
	C4591001 1235 12351100	Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JUL2020		Y
	C4591001 1235 12351101	General disorders and administration site conditions	Pain	01MAR2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1235 12351103	Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1235 12351105	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1235 12351106	Gastrointestinal disorders	Colitis microscopic	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351108	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
	C4591001 1235 12351110	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1235 12351112	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1235 12351116	Blood and lymphatic system disorders	Anaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JUL2020		Y
			Depression	01JUL2020		Y
			Insomnia	01JAN2011		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2014		Y
			Female sterilisation	01JAN2011		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1235 12351121	Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009		Y
	C4591001 1235 12351124	Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1235 12351126	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1235 12351127	Surgical and medical procedures	Intrauterine contraception	01JAN2019		Y
	C4591001 1235 12351128	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351130	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Contraception	01JAN2017		Y
	C4591001 1235 12351131	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01JAN1996		Y
	C4591001 1235 12351134	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1985		Y
	C4591001 1235 12351137	Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1992		Y
	C4591001 1235 12351142	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01APR2020	30APR2020	N
	C4591001 1235 12351143	Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1235 12351144	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Major depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2019		Y
	C4591001 1235 12351145	Eye disorders	Dry eye	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Perinatal depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Contraception	01JAN1999		Y
	C4591001 1235 12351146	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
	C4591001 1235 12351149	Cardiac disorders	Atrial tachycardia	01JAN2018		Y
	C4591001 1235 12351152	Skin and subcutaneous tissue disorders	Vitiligo	01JAN2000		Y
	C4591001 1235 12351153	Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Intrauterine contraception	01JUL2020		Y
	C4591001 1235 12351155	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351156	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2014		Y
	C4591001 1235 12351157	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2013		Y
			Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Contraception	01DEC2016		Y
	C4591001 1235 12351161	Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
	C4591001 1235 12351162	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1235 12351165	Infections and infestations	Furuncle	29SEP2020		Y
	C4591001 1235 12351166	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Rhinitis allergic	01JAN2004		Y
	C4591001 1235 12351167	Endocrine disorders	Thyroid mass	01JAN2010		Y
		Investigations	SARS-CoV-2 antibody test positive	01JAN2020		Y
	C4591001 1235 12351169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Affective disorder	01JAN2017		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018		Y
	C4591001 1235 12351170	Gastrointestinal disorders	Erosive oesophagitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1235 12351171	Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Contraception	01JAN2015		Y
	C4591001 1235 12351172	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2008		Y
	C4591001 1235 12351174	Surgical and medical procedures	Hysterectomy	01JAN2016		Y
	C4591001 1235 12351175	Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Insomnia	01OCT2020		Y
		Surgical and medical procedures	Contraception	01APR2020		Y
	C4591001 1235 12351186	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1235 12351188	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 1235 12351191	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1235 12351192	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1235 12351193	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01APR2012		Y
	C4591001 1235 12351196	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010		Y
	C4591001 1235 12351197	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
	C4591001 1235 12351207	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
	C4591001 1235 12351208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1235 12351209	Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1235 12351212	Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Investigations	Vitamin D decreased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1235 12351215	Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351218	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Perinatal depression	01MAY2020		Y
	C4591001 1235 12351222	Injury, poisoning and procedural complications	Ankle fracture	01JUL2020	31JUL2020	N
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1235 12351223	Gastrointestinal disorders	Irritable bowel syndrome	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01MAY2020		Y
		Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1235 12351224	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1235 12351226	Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1235 12351228	Reproductive system and breast disorders	Polycystic ovaries	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
	C4591001 1235 12351237	Cardiac disorders	Sinus tachycardia	01JAN2014		Y
		Congenital, familial and genetic disorders	Muscular dystrophy	01JAN2003		Y
		Gastrointestinal disorders	Diaphragmatic hernia	01JAN2003		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Thoracic insufficiency syndrome	01JAN2003		Y
	C4591001 1235 12351240	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1235 12351241	Psychiatric disorders	Depression	01SEP2020		Y
	C4591001 1241 12411001	Surgical and medical procedures	Wisdom teeth removal	04DEC2020		Y
		Immune system disorders	Food allergy	01JAN1997		Y
		Infections and infestations	Sinusitis	01JUN2019	30JUN2019	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
	C4591001 1241 12411002	Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	30JAN2008	10FEB2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010	31JUL2020	N
	C4591001 1241 12411004	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Nervous system disorders	Migraine	01MAY2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31JAN2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019	31JAN2019	N
	C4591001 1241 12411005	Nervous system disorders	Migraine	01JAN2010	05JUL2020	N
	C4591001 1241 12411006	Endocrine disorders	Secondary hypothyroidism	01JAN2013		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1241 12411009	Infections and infestations	Tinea pedis	01JUL2020	14AUG2020	N
		Nervous system disorders	Headache	01AUG2020	01AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411010	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUL2020		Y
	C4591001 1241 12411011	Nervous system disorders	Migraine	01JAN2017	30JUN2018	N
		Reproductive system and breast disorders	Polycystic ovaries	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Benign breast lump removal	01NOV2016	30NOV2016	N
	C4591001 1241 12411012	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1996		Y
	C4591001 1241 12411013	Musculoskeletal and connective tissue disorders	Myofascial pain syndrome	01JUL2012		Y
	C4591001 1241 12411016	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN1980	31DEC1990	N
	C4591001 1241 12411017	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2015		Y
	C4591001 1241 12411018	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1985	31JUL2020	N
	C4591001 1241 12411019	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1241 12411020	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1990		Y
	C4591001 1241 12411022	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2009	30JUN2009	N
		Vascular disorders	Hypertension	01FEB2018		Y
	C4591001 1241 12411023	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1995	31MAY2020	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411024	Congenital, familial and genetic disorders	Sickle cell trait	(b) (6) 1991		Y
	C4591001 1241 12411025	Ear and labyrinth disorders	Deafness bilateral	01NOV1995		Y
	C4591001 1241 12411026	Immune system disorders	Food allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1241 12411027	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2010	27JUL2020	N
	C4591001 1241 12411028	Immune system disorders	Dust allergy	01JAN2017		Y
		Nervous system disorders	Tension headache	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
	C4591001 1241 12411029	Nervous system disorders	Post herpetic neuralgia	05AUG2020		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2015	30JUN2015	N
	C4591001 1241 12411030	Musculoskeletal and connective tissue disorders	Back pain	07AUG2020	07AUG2020	N
	C4591001 1241 12411031	Immune system disorders	Drug hypersensitivity	01APR1986		Y
			Food allergy	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1996		Y
		Vascular disorders	Hypertension	01APR2016		Y
	C4591001 1241 12411032	Endocrine disorders	Hypothyroidism	05JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010		Y
	C4591001 1241 12411034	Surgical and medical procedures	Vasectomy	02MAR2015		Y
	C4591001 1241 12411034	Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1241 12411036	Reproductive system and breast disorders	Endometriosis	08FEB2020		Y
	C4591001 1241 12411038	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411039	Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1241 12411041	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411041	Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
	C4591001 1241 12411042	Cardiac disorders	Arrhythmia	01JAN2015		Y
	C4591001 1241 12411044	Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
	C4591001 1241 12411044	Surgical and medical procedures	Cholecystectomy	01MAR2020	31MAR2020	N
	C4591001 1241 12411045	Nervous system disorders	Headache	01JUL2020	31JUL2020	N
	C4591001 1241 12411046	Surgical and medical procedures	Hysterosalpingectomy	06DEC2018	06DEC2018	N
	C4591001 1241 12411047	Gastrointestinal disorders	Toothache	07AUG2020	07AUG2020	N
		Infections and infestations	Chikungunya virus infection	01MAY2020	31MAY2020	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
		Surgical and medical procedures	Salpingectomy	01JAN2017	19NOV2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411048	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1241 12411049	Injury, poisoning and procedural complications	Femur fracture	01JAN2011	31DEC2011	N
	C4591001 1241 12411050	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12411051	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2005		Y
	C4591001 1241 12411053	Nervous system disorders	Headache	11AUG2020	11AUG2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411055	Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411056	Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411057	Musculoskeletal and connective tissue disorders	Bursitis	01JUN2020		Y
	C4591001 1241 12411060	Infections and infestations	Chikungunya virus infection	01FEB2020	31MAR2020	N
	C4591001 1241 12411062	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411063	Psychiatric disorders	Anxiety disorder	01JAN2000		Y
	C4591001 1241 12411065	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411066	Infections and infestations	Nasopharyngitis	01JAN2019	31JAN2019	N
		Reproductive system and breast disorders	Dysmenorrhoea	12JUL2020	17JUL2020	N
	C4591001 1241 12411070	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1241 12411073	Infections and infestations	Sinusitis	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008		Y
	C4591001 1241 12411077	Surgical and medical procedures	Tooth extraction	24JUL2020	24JUL2020	N
	C4591001 1241 12411081	Infections and infestations	Sinusitis	01JAN2018		Y
	C4591001 1241 12411082	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Overweight	03AUG2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
	C4591001 1241 12411083	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2000	31OCT2007	N
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1241 12411085	Infections and infestations	Chikungunya virus infection	01MAY2020		Y
		Surgical and medical procedures	Salpingectomy	20MAR2015	20MAR2015	N
	C4591001 1241 12411087	Endocrine disorders	Hypothyroidism	07JUL2012		Y
	C4591001 1241 12411089	Musculoskeletal and connective tissue disorders	Back pain	10AUG2020	11AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411091	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	06FEB2021	N
	C4591001 1241 12411097	Immune system disorders	Food allergy	01DEC2019		Y
	C4591001 1241 12411098	Nervous system disorders	Headache	19JUL2020	19JUL2020	N
	C4591001 1241 12411101	Immune system disorders	Dust allergy	01JAN2017		Y
	C4591001 1241 12411103	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12411106	Cardiac disorders	Extrasystoles	01DEC2018	25NOV2019	N
		Infections and infestations	Ear infection	11AUG2020	12AUG2020	N
	C4591001 1241 12411108	Hepatobiliary disorders	Biliary cyst	01AUG2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017	31DEC2018	N
		Nervous system disorders	Tension headache	01JAN2010		Y
		Renal and urinary disorders	Renal cyst	01AUG2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1241 12411111	Surgical and medical procedures	Female sterilisation	07DEC2019	07DEC2019	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1241 12411112	Surgical and medical procedures	Appendicectomy	01MAR2012	31MAR2012	N
	C4591001 1241 12411113	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1241 12411114	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1986	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411118	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12411120	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1241 12411122	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411125	Nervous system disorders	Headache	09AUG2020	09AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12411127	Gastrointestinal disorders	Flatulence	12AUG2020	12AUG2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1241 12411129	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2016	31DEC2016	N
	C4591001 1241 12411131	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411133	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1992		Y
	C4591001 1241 12411134	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411135	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 1241 12411137	Eye disorders	Glaucoma	01OCT2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2017		Y
	C4591001 1241 12411138	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Psychiatric disorders	Anxiety disorder	25MAR2020		Y
	C4591001 1241 12411141	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017		Y
	C4591001 1241 12411144	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2018	31JAN2020	N
	C4591001 1241 12411145	Reproductive system and breast disorders	Premenstrual syndrome	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993	31DEC1999	N
	C4591001 1241 12411146	Infections and infestations	Sinusitis	01JUN2018		Y
	C4591001 1241 12411148	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12411149	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2017		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 1241 12411152	Nervous system disorders	Headache	02AUG2020	02AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411154	Surgical and medical procedures	Metabolic surgery	10MAR2020	10MAR2020	N
	C4591001 1241 12411155	Infections and infestations	Sinusitis	01JUL2020		Y
		Reproductive system and breast disorders	Breast mass	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Salpingectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01OCT2011		Y
	C4591001 1241 12411156	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411157	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1241 12411161	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996	31DEC2018	N
			Rhinitis allergic	01JAN1986		Y
		Surgical and medical procedures	Hysterectomy	01AUG2018	31AUG2018	N
	C4591001 1241 12411163	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2010	30JUN2020	N
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
	C4591001 1241 12411164	Gastrointestinal disorders	Gastritis	01JAN2002	31DEC2004	N
	C4591001 1241 12411165	Metabolism and nutrition disorders	Lactose intolerance	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411166	Gastrointestinal disorders	Toothache	20JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	16DEC2018	N
		Surgical and medical procedures	Hysterectomy	16DEC2018	16DEC2018	N
	C4591001 1241 12411167	Reproductive system and breast disorders	Polycystic ovaries	01JAN1995		Y
		Surgical and medical procedures	Female sterilisation	06APR2008	06APR2008	N
	C4591001 1241 12411168	Reproductive system and breast disorders	Polycystic ovaries	01JAN2008		Y
	C4591001 1241 12411170	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1997	31DEC2019	N
	C4591001 1241 12411175	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
	C4591001 1241 12411177	Infections and infestations	Pulmonary tuberculosis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000	31JAN2020	N
			Asthma	01JAN2000		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1241 12411178	Gastrointestinal disorders	Toothache	01AUG2020	01AUG2020	N
	C4591001 1241 12411179	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
	C4591001 1241 12411181	Immune system disorders	Drug hypersensitivity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411183	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Headache	10AUG2020	10AUG2020	N
	C4591001 1241 12411184	Immune system disorders	Iodine allergy	28OCT2000		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2016		Y
			Tendon disorder	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411185	Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411186	Infections and infestations	Hepatitis A	01JAN1997	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1990	30JUN2020	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2009		Y
	C4591001 1241 12411203	Surgical and medical procedures	Benign breast lump removal	08NOV2019	08NOV2019	N
			Hysterectomy	01JAN2020	01JAN2020	N
	C4591001 1241 12411204	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Myomectomy	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411206	Reproductive system and breast disorders	Breast mass	01JAN2018		Y
	C4591001 1241 12411207	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1241 12411208	Nervous system disorders	Headache	01JUL2020	31JUL2020	N
	C4591001 1241 12411212	Immune system disorders	Seasonal allergy	01JAN2005	31DEC2019	N
		Infections and infestations	Chikungunya virus infection	01JUN2020	31JUL2020	N
	C4591001 1241 12411213	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1993	30JUN2020	N
	C4591001 1241 12411215	Injury, poisoning and procedural complications	Rib fracture	01OCT2018	31DEC2018	N
	C4591001 1241 12411216	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2019		Y
	C4591001 1241 12411219	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020	01AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Oophorectomy	01APR2019	30APR2019	N
	C4591001 1241 12411220	Infections and infestations	Pulmonary tuberculosis	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411221	Musculoskeletal and connective tissue disorders	Back pain	03AUG2020	03AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	11MAY2019	11MAY2019	N
	C4591001 1241 12411223	Injury, poisoning and procedural complications	Road traffic accident	30DEC2019	30DEC2019	N
			Skin injury	30DEC2019		Y
		Nervous system disorders	Extrapyramidal disorder	30DEC2019	30DEC2019	N
			Migraine	01JAN2018	15AUG2020	N
	C4591001 1241 12411224	Immune system disorders	Food allergy	01JAN2010		Y
			Iodine allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1999	10AUG2020	N
	C4591001 1241 12411225	Infections and infestations	Chikungunya virus infection	01APR2020	30APR2020	N
		Surgical and medical procedures	Salpingectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12411226	Reproductive system and breast disorders	Dysmenorrhoea	01JAN1999		Y
	C4591001 1241 12411227	Surgical and medical procedures	Salpingectomy	01JAN1995	31DEC1995	N
	C4591001 1241 12411230	Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Salpingectomy	12DEC2016	12DEC2016	N
	C4591001 1241 12411231	Endocrine disorders	Goitre	01FEB2020	29FEB2020	N
			Hypothyroidism	01FEB2020		Y
		Nervous system disorders	Headache	01MAR2020		Y
		Surgical and medical procedures	Thyroidectomy	01FEB2020	29FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411233	Surgical and medical procedures	Metabolic surgery	23MAR2017	23MAR2017	N
	C4591001 1241 12411234	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411237	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411243	Reproductive system and breast disorders	Dysmenorrhoea	01DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1992		Y
	C4591001 1241 12411245	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01JUN2009	30JUN2009	N
	C4591001 1241 12411248	Social circumstances	Menopause	01AUG2018		Y
	C4591001 1241 12411250	Surgical and medical procedures	Hysterectomy	06DEC2018	06DEC2018	N
	C4591001 1241 12411253	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2017		Y
	C4591001 1241 12411256	Psychiatric disorders	Anxiety	01JAN2014		Y
		Surgical and medical procedures	Metabolic surgery	28AUG2018	28AUG2018	N
	C4591001 1241 12411258	Nervous system disorders	Tension headache	06AUG2020	06AUG2020	N
	C4591001 1241 12411261	Endocrine disorders	Thyroid mass	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2009	31DEC2019	N
	C4591001 1241 12411262	Gastrointestinal disorders	Lumbar hernia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1995		Y
			Synovial cyst	03JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1241 12411263	Surgical and medical procedures	Metabolic surgery	09JAN2003	09JAN2003	N
	C4591001 1241 12411264	Musculoskeletal and connective tissue disorders	Back pain	01JUL2020		Y
	C4591001 1241 12411265	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000	31JAN2020	N
	C4591001 1241 12411266	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1988	30APR2020	N
	C4591001 1241 12411267	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411268	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Rubber sensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
		Nervous system disorders	Epilepsy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411269	Surgical and medical procedures	Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1241 12411270	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411277	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1987	22JUL2020	N
		Surgical and medical procedures	Dental care	30MAR2020		Y
			Endodontic procedure	01MAR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411279	Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Surgical and medical procedures	Metabolic surgery	05JAN2013	05JAN2013	N
	C4591001 1241 12411280	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1241 12411281	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1241 12411282	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411283	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411284	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1241 12411286	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2020		Y
		Psychiatric disorders	Borderline personality disorder	01JUL2014		Y
			Depression	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1992		Y
			Asthma	01JAN1990	31DEC2016	N
	C4591001 1241 12411288	Surgical and medical procedures	Hysterectomy	06MAY2015	06MAY2015	N
	C4591001 1241 12411289	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12411290	Psychiatric disorders	Anxiety disorder	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2018	10AUG2020	N
		Surgical and medical procedures	Salpingectomy	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411291	Nervous system disorders	Headache	18AUG2020	18AUG2020	N
	C4591001 1241 12411292	Nervous system disorders	Migraine	01JAN1993	31DEC2019	N
	C4591001 1241 12411293	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
	C4591001 1241 12411295	Gastrointestinal disorders	Gastritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1241 12411296	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Psychiatric disorders	Premature ejaculation	01FEB2020		Y
	C4591001 1241 12411297	Endocrine disorders	Hypothyroidism	01JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1241 12411299	Cardiac disorders	Sinus tachycardia	01JAN1999		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1996		Y
			Polycystic ovaries	01JAN1998		Y
	C4591001 1241 12411300	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	18AUG2020	18AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1241 12411303	Nervous system disorders	Tension headache	17AUG2020		Y
	C4591001 1241 12411307	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12411308	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1995		Y
	C4591001 1241 12411310	Infections and infestations	Sinusitis	01JAN1995		Y
	C4591001 1241 12411311	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411312	Infections and infestations	Rhinitis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1241 12411314	Renal and urinary disorders	Urinary incontinence	01JAN2019		Y
	C4591001 1241 12411316	Infections and infestations	Rhinitis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1241 12411318	Infections and infestations	Hordeolum	01AUG2020	12AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12411319	Surgical and medical procedures	Salpingectomy	06APR2004	06APR2004	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411323	Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1241 12411324	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Salpingectomy	07DEC1997	07DEC1997	N
	C4591001 1241 12411327	Gastrointestinal disorders	Nausea	15AUG2020	15AUG2020	N
	C4591001 1241 12411329	Immune system disorders	Food allergy	01JAN2000		Y
		Infections and infestations	Rhinitis	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1241 12411330	Psychiatric disorders	Anxiety	10AUG2020		Y
	C4591001 1241 12411331	Nervous system disorders	Tension headache	10AUG2020		Y
		Surgical and medical procedures	Salpingectomy	13SEP2015	13SEP2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411333	Infections and infestations	Rhinitis	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411334	Reproductive system and breast disorders	Adenomyosis	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12411335	Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1241 12411336	Infections and infestations	Tuberculous pleurisy	01JUL2014	31AUG2015	N
	C4591001 1241 12411337	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2017	31JAN2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411339	Musculoskeletal and connective tissue disorders	Bursitis	01DEC2019		Y
		Social circumstances	Menopause	01OCT2018		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2016	31OCT2016	N
	C4591001 1241 12411343	Gastrointestinal disorders	Abdominal pain	30JUL2020	30JUL2020	N
	C4591001 1241 12411344	Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
			Female sterilisation	06NOV2011	06NOV2011	N
			Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1241 12411345	Infections and infestations	Rhinitis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1241 12411346	Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01NOV2018	30NOV2018	N
	C4591001 1241 12411347	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2010		Y
	C4591001 1241 12411349	Infections and infestations	Sinusitis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411350	Reproductive system and breast disorders	Testicular cyst	01JAN2018		Y
	C4591001 1241 12411353	Surgical and medical procedures	Vasectomy	01JAN2017	31JAN2017	N
	C4591001 1241 12411354	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411358	Musculoskeletal and connective tissue disorders	Back pain	05AUG2020	05AUG2020	N
		Surgical and medical procedures	Hysterectomy	01AUG2018	31AUG2018	N
	C4591001 1241 12411362	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006	28FEB2019	N
	C4591001 1241 12411363	Nervous system disorders	Migraine	01JAN2011		Y
	C4591001 1241 12411366	Surgical and medical procedures	Eye operation	01AUG2016	31AUG2016	N
	C4591001 1241 12411367	Musculoskeletal and connective tissue disorders	Myalgia	30JUL2020	30JUL2020	N
		Surgical and medical procedures	Metabolic surgery	01DEC2010	31DEC2010	N
	C4591001 1241 12411369	Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2020		Y
		Reproductive system and breast disorders	Premenstrual headache	01JAN1985		Y
	C4591001 1241 12411370	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Salpingectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411372	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
	C4591001 1241 12411373	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003	31AUG2020	N
	C4591001 1241 12411376	Congenital, familial and genetic disorders	Sickle cell trait	01JAN1995		Y
	C4591001 1241 12411380	Injury, poisoning and procedural complications	Tendon rupture	25JUL2020		Y
		Surgical and medical procedures	Varicocele repair	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411381	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993	31DEC2019	N
	C4591001 1241 12411382	Nervous system disorders	Tension headache	16AUG2020	16AUG2020	N
		Surgical and medical procedures	Salpingectomy	01OCT2015	31OCT2015	N
	C4591001 1241 12411383	Surgical and medical procedures	Inguinal hernia repair	01APR2017	30APR2017	N
			Umbilical hernia repair	01APR2017	30APR2017	N
	C4591001 1241 12411385	Nervous system disorders	Headache	11AUG2020	11AUG2020	N
	C4591001 1241 12411387	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1241 12411388	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1241 12411390	Nervous system disorders	Migraine	01JAN2013		Y
			Tension headache	01AUG2019		Y
	C4591001 1241 12411393	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2018	30JUN2020	N
	C4591001 1241 12411395	Nervous system disorders	Migraine	01JAN1984	31DEC2013	N
	C4591001 1241 12411396	Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1241 12411400	Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411402	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Infections and infestations	Papilloma viral infection	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997	10AUG2020	N
	C4591001 1241 12411403	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1985	25JUL2020	N
	C4591001 1241 12411407	Vascular disorders	Hypertension	17AUG2020		Y
	C4591001 1241 12411408	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1241 12411409	Surgical and medical procedures	Fracture treatment	01AUG2009	31AUG2009	N
			Myopia correction	14NOV2018	14NOV2018	N
	C4591001 1241 12411410	Immune system disorders	Food allergy	01JAN2013		Y
	C4591001 1241 12411412	Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1241 12411413	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411416	Nervous system disorders	Migraine	01JAN2005	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000	31DEC2019	N
		Surgical and medical procedures	Nasal septal operation	01JAN2019	31JAN2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411417	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
	C4591001 1241 12411418	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2009		Y
				01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1241 12411419	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000		Y
	C4591001 1241 12411420	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2012		Y
	C4591001 1241 12411421	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12411423	Gastrointestinal disorders	Umbilical hernia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411426	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000	31DEC2018	N
	C4591001 1241 12411427	Infections and infestations	Subcutaneous abscess	01JUN2017	30JUN2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411431	Immune system disorders	Drug hypersensitivity	01FEB2008		Y
		Musculoskeletal and connective tissue disorders	Lordosis	01JAN2000		Y
			Scoliosis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	08AUG2018	08AUG2018	N
	C4591001 1241 12411432	Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Surgical and medical procedures	Plastic surgery to the face	01JAN2008	31DEC2008	N
	C4591001 1241 12411433	Nervous system disorders	Seizure	19JUN2020	19JUN2020	N
	C4591001 1241 12411435	Endocrine disorders	Hypothyroidism	01SEP2017		Y
		Infections and infestations	Labyrinthitis	01JAN2007	31DEC2014	N
		Metabolism and nutrition disorders	Insulin resistance	01JAN2019		Y
		Surgical and medical procedures	Limb operation	01JAN1988	31DEC1988	N
			Thyroidectomy	01JUL2007	31JUL2007	N
	C4591001 1241 12411437	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1995	31DEC2019	N
	C4591001 1241 12411438	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Psychiatric disorders	Panic reaction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1241 12411439	Surgical and medical procedures	Mammoplasty	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411440	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994	30APR2019	N
	C4591001 1241 12411441	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1241 12411442	Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
	C4591001 1241 12411443	Surgical and medical procedures	Hysterectomy	01AUG2016	31AUG2016	N
	C4591001 1241 12411444	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983	10JAN2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1241 12411447	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001	30JUN2020	N
	C4591001 1241 12411450	Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2020		Y
	C4591001 1241 12411452	Immune system disorders	Drug hypersensitivity	01AUG2018		Y
	C4591001 1241 12411453	Gastrointestinal disorders	Haemorrhoids	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	01SEP2010	30SEP2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1241 12411454	Nervous system disorders	Migraine	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01SEP2019		Y
	C4591001 1241 12411455	Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	30APR2020	N
	C4591001 1241 12411456	Gastrointestinal disorders	Gastritis	04AUG2020		Y
	C4591001 1241 12411458	Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1241 12411460	Surgical and medical procedures	Umbilical hernia repair	01DEC2019	31DEC2019	N
	C4591001 1241 12411461	Reproductive system and breast disorders	Breast mass	01FEB2020		Y
	C4591001 1241 12411463	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005	31DEC2018	N
	C4591001 1241 12411464	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017		Y
		Nervous system disorders	Headache	24AUG2000	24AUG2020	N
			Morton's neuralgia	01JAN2017		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
	C4591001 1241 12411465	Congenital, familial and genetic disorders	Talipes	01JAN1991		Y
	C4591001 1241 12411466	Injury, poisoning and procedural complications	Spinal fracture	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411467	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1997	29FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411468	Surgical and medical procedures	Cholecystectomy	01MAY2019	31MAY2019	N
	C4591001 1241 12411469	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1241 12411470	Nervous system disorders	Migraine	01JAN1985		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1241 12411471	Nervous system disorders	Headache	20AUG2020	20AUG2020	N
	C4591001 1241 12411472	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002	03AUG2020	N
		Surgical and medical procedures	Umbilical hernia repair	01JAN2000	31DEC2000	N
	C4591001 1241 12411473	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	31DEC2019	N
	C4591001 1241 12411475	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
	C4591001 1241 12411476	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008	10AUG2020	N
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2008		Y
	C4591001 1241 12411477	Gastrointestinal disorders	Irritable bowel syndrome	01NOV2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
	C4591001 1241 12411478	Nervous system disorders	Migraine	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411480	Surgical and medical procedures	Breast conserving surgery	01SEP2018	30SEP2018	N
			Finger amputation	01JAN2001	31DEC2001	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1241 12411481	Reproductive system and breast disorders	Dysmenorrhoea	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000		Y
	C4591001 1241 12411482	Psychiatric disorders	Anxiety disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01OCT2015	31OCT2015	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1241 12411484	Surgical and medical procedures	Appendectomy	01MAR2014	31MAR2014	N
	C4591001 1241 12411486	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12411488	Cardiac disorders	Tachycardia	01MAY2020		Y
		Congenital, familial and genetic disorders	Antithrombin III deficiency	01JAN2004		Y
	C4591001 1241 12411489	Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1241 12411490	Nervous system disorders	Migraine	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
	C4591001 1241 12411492	Surgical and medical procedures	Mammoplasty	03JUL2020	03JUL2020	N
	C4591001 1241 12411494	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411497	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	15JUL2020	15JUL2020	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411499	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1241 12411500	Surgical and medical procedures	Oophorectomy	01DEC2010	01DEC2010	N
	C4591001 1241 12411502	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abdominal neoplasm	01JAN2012	31OCT2012	N
		Surgical and medical procedures	Splenectomy	01OCT2012	31OCT2012	N
	C4591001 1241 12411506	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12411508	Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1241 12411509	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411510	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Social circumstances	Menopause	01APR2016		Y
	C4591001 1241 12411511	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1241 12411514	Nervous system disorders	Migraine	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411517	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1241 12411518	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411520	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12411526	Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1241 12411528	Skin and subcutaneous tissue disorders	Alopecia	01JUN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411530	Immune system disorders	Rubber sensitivity	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31OCT2019	N
		Surgical and medical procedures	Hysterectomy	01OCT2019	31OCT2019	N
	C4591001 1241 12411531	Gastrointestinal disorders	Gastritis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411535	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Food allergy	01JAN1981		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411537	Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	29AUG2020	N
	C4591001 1241 12411538	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1241 12411539	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411540	Gastrointestinal disorders	Gastritis	01JUN2006		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411541	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2014		Y
	C4591001 1241 12411544	Injury, poisoning and procedural complications	Ligament injury	01MAR2020	31MAR2020	N
	C4591001 1241 12411547	Gastrointestinal disorders	Gastritis	01JAN2019		Y
	C4591001 1241 12411549	Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
	C4591001 1241 12411556	Nervous system disorders	Tension headache	01JAN2014	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2019	31AUG2020	N
	C4591001 1241 12411557	Surgical and medical procedures	Salpingectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411558	Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411561	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1995	31DEC1995	N
		Vascular disorders	Varicose vein	01MAY2020		Y
	C4591001 1241 12411562	Gastrointestinal disorders	Haemorrhoids	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411564	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2005		Y
	C4591001 1241 12411565	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1241 12411567	Surgical and medical procedures	Haemorrhoid operation	01JUN2019	30JUN2019	N
	C4591001 1241 12411568	Reproductive system and breast disorders	Endometriosis	01JAN2007		Y
	C4591001 1241 12411570	Nervous system disorders	Headache	01JUN2020	29AUG2020	N
		Reproductive system and breast disorders	Breast mass	01JAN2010		Y
	C4591001 1241 12411573	Surgical and medical procedures	Abdominoplasty	16AUG2019	16AUG2019	N
			Liposuction	16AUG2019	16AUG2019	N
			Mammoplasty	01MAR2012	31MAR2012	N
	C4591001 1241 12411574	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1241 12411575	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1994	31JUL2020	N
	C4591001 1241 12411576	Surgical and medical procedures	Cholecystectomy	01MAR2013	31MAR2013	N
			Metabolic surgery	11DEC2012	11DEC2012	N
	C4591001 1241 12411577	Psychiatric disorders	Personality disorder	01JAN2015		Y
	C4591001 1241 12411578	Infections and infestations	Genital herpes	01JAN2015	30AUG2020	N
			Oral herpes	01JAN2015	30AUG2020	N
		Psychiatric disorders	Depression	01SEP2017	31JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411580	Surgical and medical procedures	Vasectomy	01AUG2003	31AUG2003	N
	C4591001 1241 12411581	Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411583	Nervous system disorders	Headache	27AUG2020	27AUG2020	N
	C4591001 1241 12411584	Psychiatric disorders	Anxiety disorder	01JAN2018		Y
	C4591001 1241 12411586	General disorders and administration site conditions	Adverse drug reaction	01DEC2017		Y
				01MAR2002		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01NOV2016		Y
	C4591001 1241 12411588	Infections and infestations	Pulmonary tuberculosis	01APR2016	30APR2016	N
	C4591001 1241 12411590	Infections and infestations	Vulvovaginal candidiasis	01SEP2020	01SEP2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004	15AUG2020	N
	C4591001 1241 12411592	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12411595	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1241 12411596	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
		Psychiatric disorders	Anxiety	01NOV2018		Y
	C4591001 1241 12411598	Nervous system disorders	Tension headache	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411600	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2020		Y
	C4591001 1241 12411604	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1241 12411605	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
	C4591001 1241 12411606	Nervous system disorders	Migraine	01JAN2000	30JUN2020	N
	C4591001 1241 12411608	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Psychiatric disorders	Anxiety disorder	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987	31JUL2020	N
	C4591001 1241 12411609	Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1241 12411616	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1992	31DEC1992	N
	C4591001 1241 12411617	Infections and infestations	Actinomycosis	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Obesity	01JAN2000		Y
	C4591001 1241 12411619	Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411624	Immune system disorders	Food allergy	01JAN2009		Y
	C4591001 1241 12411625	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411626	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1241 12411629	Psychiatric disorders	Insomnia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1241 12411630	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1241 12411631	Musculoskeletal and connective tissue disorders	Back pain	01SEP2020	01SEP2020	N
			Intervertebral disc protrusion	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411632	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1241 12411635	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1998	31DEC1998	N
	C4591001 1241 12411636	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Rhinitis allergic	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12411637	Immune system disorders	Food allergy	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	27AUG2020		Y
	C4591001 1241 12411638	Eye disorders	Amaurosis	01JAN2012		Y
	C4591001 1241 12411640	Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
	C4591001 1241 12411646	Endocrine disorders	Hypothyroidism	01JUL2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN2013		Y
			Thyroidectomy	01JUL2009	31JUL2009	N
	C4591001 1241 12411647	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
	C4591001 1241 12411651	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12411653	Nervous system disorders	Migraine	01MAY2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1241 12411658	Surgical and medical procedures	Pulmonary bullectomy	01APR2018	30APR2018	N
	C4591001 1241 12411659	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01AUG2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411660	Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1241 12411661	Surgical and medical procedures	Amputation	(b) (6) 1986	(b) (6) 1986	N
	C4591001 1241 12411663	Nervous system disorders	Sciatica	01JAN2003		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2015		Y
	C4591001 1241 12411672	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Surgical and medical procedures	Physiotherapy	24AUG2020	31AUG2020	N
	C4591001 1241 12411674	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006	31AUG2020	N
	C4591001 1241 12411677	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12411678	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2012		Y
				01JAN2017		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2004		Y
	C4591001 1241 12411679	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1241 12411680	Infections and infestations	Genital herpes	01JAN2016	31JAN2016	N
				25AUG2020	30AUG2020	N
			Varicella	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon rupture	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1241 12411681	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2019		Y
		Social circumstances	Menopause	01AUG2020		Y
	C4591001 1241 12411683	Surgical and medical procedures	Inguinal hernia repair	01MAY2000	31MAY2000	N
	C4591001 1241 12411684	Psychiatric disorders	Anxiety disorder	01NOV2018		Y
	C4591001 1241 12411685	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1241 12411687	Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Salpingectomy	01JAN1993	31DEC1993	N
	C4591001 1241 12411688	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2005		Y
	C4591001 1241 12411689	Surgical and medical procedures	Abdominoplasty	01JUL2018	31JUL2018	N
			Salpingectomy	10DEC2012	10DEC2012	N
	C4591001 1241 12411693	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411694	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
		Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411698	Surgical and medical procedures	Sympathectomy	01JAN2014	31DEC2014	N
	C4591001 1241 12411699	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2020		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1241 12411700	Psychiatric disorders	Anxiety	01MAR2019		Y
			Depression	01MAR2019		Y
			Insomnia	01MAR2019		Y
	C4591001 1241 12411701	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
	C4591001 1241 12411702	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Superior mesenteric artery syndrome	10JUL2020	10JUL2020	N
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1241 12411703	Infections and infestations	Upper respiratory tract infection	20AUG2020	25AUG2020	N
	C4591001 1241 12411706	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1241 12411707	Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1241 12411708	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
	C4591001 1241 12411709	Infections and infestations	Tinea versicolour	15MAR2020		Y
		Nervous system disorders	Extrapyramidal disorder	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999	30JUN2020	N
	C4591001 1241 12411712	Surgical and medical procedures	Orthopaedic procedure	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411713	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411714	Infections and infestations	Oral herpes	01JAN1988		Y
	C4591001 1241 12411715	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12411716	Infections and infestations	Urinary tract infection	09SEP2020	13SEP2020	N
			Vulvovaginal candidiasis	01SEP2020	09SEP2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2020	30APR2020	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1241 12411718	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	31AUG2020	N
		Surgical and medical procedures	Vaginal operation	01JAN2017	31DEC2017	N
	C4591001 1241 12411719	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411720	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2017	31AUG2020	N
	C4591001 1241 12411723	Surgical and medical procedures	Hysterectomy	01APR2015	30APR2015	N
	C4591001 1241 12411724	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1984		Y
	C4591001 1241 12411726	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Glucose tolerance impaired	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411727	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1973	31AUG2020	N
			Asthma	01JAN1973	31DEC2018	N
		Surgical and medical procedures	Female sterilisation	08FEB2008	08FEB2008	N
	C4591001 1241 12411729	Nervous system disorders	Epilepsy	01JAN2002		Y
	C4591001 1241 12411730	Nervous system disorders	Migraine	01JAN2019	31AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003	29FEB2020	N
	C4591001 1241 12411731	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1241 12411734	Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2020	31JAN2020	N
			Gastrointestinal surgery	01JAN2002		Y
	C4591001 1241 12411736	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1241 12411741	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1241 12411742	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993	31DEC2018	N
	C4591001 1241 12411744	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411747	Infections and infestations	Furuncle	20AUG2000	09SEP2020	N
		Surgical and medical procedures	Varicocele repair	01JAN2001	31DEC2001	N
	C4591001 1241 12411749	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411758	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
	C4591001 1241 12411762	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1241 12411763	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1996		Y
	C4591001 1241 12411765	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411766	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411767	Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2017		Y
		Surgical and medical procedures	Oophorectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411769	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1241 12411771	Cardiac disorders	Mitral valve incompetence	01JAN1988		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12411774	Cardiac disorders	Tachycardia	01JAN2013		Y
		Psychiatric disorders	Depression	01JUL2019	31MAY2020	N
	C4591001 1241 12411775	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1241 12411777	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1241 12411778	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
	C4591001 1241 12411780	Endocrine disorders	Hypothyroidism	01OCT2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2008		Y
	C4591001 1241 12411781	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Ovarian neoplasm surgery	01JAN2009	31DEC2009	N
	C4591001 1241 12411782	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1241 12411784	Gastrointestinal disorders	Constipation	01JUN2020		Y
	C4591001 1241 12411785	Eye disorders	Glaucoma	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1983		Y
	C4591001 1241 12411787	Immune system disorders	Drug hypersensitivity	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
	C4591001 1241 12411790	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01APR2020		Y
	C4591001 1241 12411791	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1241 12411792	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2020		Y
		Surgical and medical procedures	Appendicectomy	01MAY2005	31MAY2005	N
	C4591001 1241 12411793	Psychiatric disorders	Anxiety disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	31DEC2019	N
	C4591001 1241 12411797	Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004	31DEC2019	N
	C4591001 1241 12411798	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1241 12411799	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
	C4591001 1241 12411801	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411802	Endocrine disorders	Hypothyroidism	01DEC1998		Y
	C4591001 1241 12411803	Reproductive system and breast disorders	Varicocele	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411804	Psychiatric disorders	Depression	01JAN1993		Y
		Surgical and medical procedures	Salpingectomy	01JAN2006	31DEC2006	N
	C4591001 1241 12411807	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411809	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Nervous system disorders	Essential tremor	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01DEC2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12411810	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12411812	Reproductive system and breast disorders	Amenorrhoea	01DEC2018		Y
	C4591001 1241 12411813	Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
	C4591001 1241 12411814	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1241 12411815	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411816	Infections and infestations	Urinary tract infection	04SEP2020	11SEP2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01SEP2018	30SEP2018	N
		Surgical and medical procedures	Thyroidectomy	01SEP2018	30SEP2018	N
	C4591001 1241 12411817	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Psychiatric disorders	Anxiety disorder	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988	31JUL2020	N
	C4591001 1241 12411818	Infections and infestations	Chikungunya virus infection	01FEB2020	30JUN2020	N
	C4591001 1241 12411820	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411823	Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Varicose vein operation	01JAN2015	31DEC2015	N
	C4591001 1241 12411824	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2018	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2018		Y
	C4591001 1241 12411826	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
	C4591001 1241 12411827	Reproductive system and breast disorders	Polycystic ovaries	01JAN2019		Y
	C4591001 1241 12411830	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
	C4591001 1241 12411833	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Nervous system disorders	Myasthenia gravis	01JAN2007		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Thymectomy	01JAN2007	31JAN2007	N
	C4591001 1241 12411834	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1241 12411835	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2017		Y
	C4591001 1241 12411836	Cardiac disorders	Fibroadenoma of breast Mitral valve prolapse	01JAN2009 01JAN2016		Y Y
	C4591001 1241 12411837	Immune system disorders Nervous system disorders Congenital, familial and genetic disorders	Drug hypersensitivity Migraine Hydrocele	01JAN2013 01JAN2009 01JAN2000	31DEC2000	Y Y N
	C4591001 1241 12411839	Vascular disorders Metabolism and nutrition disorders	Hypertension Lactose intolerance	01JAN2012 01MAR2020		Y Y
	C4591001 1241 12411840	Infections and infestations	Vaginal infection	04SEP2020		Y
	C4591001 1241 12411841	Nervous system disorders Surgical and medical procedures	Tension headache Urinary bladder suspension	01JAN2003 01JAN2018	07SEP2020 31DEC2018	N N
	C4591001 1241 12411845	Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1241 12411846	Infections and infestations	Herpes zoster	01SEP2020	16SEP2020	N
	C4591001 1241 12411847	Infections and infestations	Helicobacter gastritis	01AUG2020		Y
	C4591001 1241 12411848	Surgical and medical procedures Surgical and medical procedures	Female sterilisation Bone cyst excision	01FEB2016 01JAN2006	29FEB2016 31DEC2006	N N
	C4591001 1241 12411849	Endocrine disorders	Hypoparathyroidism	01DEC2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypothyroidism	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2012	31DEC2012	N
	C4591001 1241 12411850	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012	31JUL2020	N
	C4591001 1241 12411851	Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411856	Nervous system disorders	Tension headache	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018	01SEP2020	N
	C4591001 1241 12411858	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
	C4591001 1241 12411860	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2016		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2018	31DEC2018	N
	C4591001 1241 12411861	Immune system disorders	Food allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Nervous system disorders	Tension headache	01JAN2008		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2015	31DEC2015	N
	C4591001 1241 12411862	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981	31DEC1990	N
			Rhinitis allergic	01MAR2020	31MAR2020	N
	C4591001 1241 12411863	Musculoskeletal and connective tissue disorders	Chondromalacia	01JAN2010		Y
	C4591001 1241 12411865	Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005	05SEP2020	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JUN2020		Y
	C4591001 1241 12411866	Reproductive system and breast disorders	Polycystic ovaries	01JAN2009		Y
	C4591001 1241 12411867	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
	C4591001 1241 12411868	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN1995		Y
		Infections and infestations	Mastitis	01JUN2020	30JUN2020	N
		Reproductive system and breast disorders	Breast mass	01JAN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2005		Y
	C4591001 1241 12411869	Metabolism and nutrition disorders	Obesity	01JAN2014	31MAR2019	N
		Surgical and medical procedures	Metabolic surgery	01JAN2018	31DEC2018	N
	C4591001 1241 12411870	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1241 12411871	Surgical and medical procedures	Bone operation	01JAN2017	31DEC2017	N
	C4591001 1241 12411872	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12411873	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411874	Surgical and medical procedures	Salivary gland operation	01JAN2010	31DEC2010	N
	C4591001 1241 12411875	Cardiac disorders	Mitral valve incompetence	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thymoma	01JAN1988	31DEC1989	N
		Nervous system disorders	Arachnoid cyst	01JAN1998	31DEC2000	N
	C4591001 1241 12411877	Psychiatric disorders	Anxiety	01MAY2020		Y
			Depression	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1241 12411879	Surgical and medical procedures	Benign breast lump removal	01JAN2014	31DEC2014	N
	C4591001 1241 12411880	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01MAR2019	31MAR2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411881	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
	C4591001 1241 12411882	Metabolism and nutrition disorders	Lactose intolerance	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12411884	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1241 12411885	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411886	Nervous system disorders	Tension headache	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411888	Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1241 12411889	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005	31DEC2018	N
	C4591001 1241 12411892	Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
	C4591001 1241 12411893	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1241 12411895	Gastrointestinal disorders	Gastritis	01JAN2015		Y
		Infections and infestations	Tuberculous pleurisy	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
	C4591001 1241 12411897	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
	C4591001 1241 12411898	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Pneumothorax spontaneous	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411899	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014		Y
	C4591001 1241 12411900	Nervous system disorders	Migraine	01JAN2005		Y
	C4591001 1241 12411901	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018	31DEC2019	N
	C4591001 1241 12411903	Gastrointestinal disorders	Inguinal hernia	01JAN2019	25AUG2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411904	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1241 12411906	Reproductive system and breast disorders	Polycystic ovaries	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12411908	Infections and infestations	Sinusitis	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2005		Y
	C4591001 1241 12411914	Cardiac disorders	Mitral valve prolapse	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411917	Psychiatric disorders	Depression	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1241 12411919	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1241 12411920	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2008		Y
			Lactose intolerance	01JAN2008		Y
	C4591001 1241 12411921	Psychiatric disorders	Depression	01JUL2019		Y
	C4591001 1241 12411924	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Metabolic surgery	01SEP2015	30SEP2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12411926	Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
			Sleep apnoea syndrome	01OCT2019		Y
	C4591001 1241 12411927	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2000		Y
				01JAN2001		Y
	C4591001 1241 12411929	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Sinusitis	01JAN1989		Y
	C4591001 1241 12411930	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411931	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411932	Surgical and medical procedures	Varicocele repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1241 12411935	Metabolism and nutrition disorders	Obesity	01NOV2019		Y
	C4591001 1241 12411936	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
	C4591001 1241 12411937	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
	C4591001 1241 12411940	Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1241 12411942	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
	C4591001 1241 12411943	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411944	Surgical and medical procedures	Umbilical hernia repair	01JAN2005		Y
			Vasectomy	01DEC2019		Y
	C4591001 1241 12411945	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1241 12411947	Infections and infestations	Sinusitis	01JAN1998		Y
	C4591001 1241 12411948	Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
	C4591001 1241 12411949	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411951	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1241 12411952	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1991	31DEC1991	N
	C4591001 1241 12411955	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12411956	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Chikungunya virus infection	01MAR2020	31MAR2020	N
			Dengue fever	01MAR2020	31MAR2020	N
	C4591001 1241 12411960	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2012	31DEC2012	N
	C4591001 1241 12411962	Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411963	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12411965	Metabolism and nutrition disorders	Lactose intolerance	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN2010		Y
			Scoliosis	01JAN2010		Y
	C4591001 1241 12411967	Eye disorders	Pterygium	01JAN2000		Y
		Surgical and medical procedures	Anorectal operation	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411968	Endocrine disorders	Hypothyroidism	01MAY2020		Y
		Immune system disorders	Food allergy	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Metabolic surgery	01JAN2006	31DEC2006	N
	C4591001 1241 12411970	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989	31AUG2020	N
		Surgical and medical procedures	Corneal transplant	07FEB2020	07FEB2020	N
	C4591001 1241 12411971	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2013		Y
		Surgical and medical procedures	Hysterectomy	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1241 12411972	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411973	Musculoskeletal and connective tissue disorders	Muscle disorder	18AUG2020	18AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995	10SEP2020	N
	C4591001 1241 12411974	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12411975	Nervous system disorders	Tension headache	01JAN2011		Y
	C4591001 1241 12411977	Ear and labyrinth disorders	Meniere's disease	01JAN2012		Y
	C4591001 1241 12411978	General disorders and administration site conditions	Adverse drug reaction	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1977	31DEC2019	N
	C4591001 1241 12411980	Infections and infestations	Viral myocarditis	01JAN2016	31AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014		Y
	C4591001 1241 12411981	Social circumstances	Menopause	01JAN2014		Y
		Eye disorders	Glaucoma	01JAN2010		Y
			Optic nerve cupping	01JAN1996		Y
		Injury, poisoning and procedural complications	Muscle injury	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
	C4591001 1241 12411982	Surgical and medical procedures	Varicocele repair	01JAN1998	31DEC1998	N
		Social circumstances	Menopause	01NOV2019		Y
	C4591001 1241 12411983	Gastrointestinal disorders	Gastritis	01APR2020		Y
			Umbilical hernia	01APR2020		Y
		Psychiatric disorders	Anxiety disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1241 12411984	Surgical and medical procedures	Orthopaedic procedure	01JAN2005	31DEC2005	N
	C4591001 1241 12411985	Infections and infestations	Chronic sinusitis	01JAN2008	31DEC2008	N
	C4591001 1241 12411986	Surgical and medical procedures	Umbilical hernia repair	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Lactose intolerance	01MAR2020		Y
	C4591001 1241 12411987	Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Surgical and medical procedures	Varicocele repair	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411988	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
	C4591001 1241 12411990	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997	31DEC1999	N
			Rhinitis allergic	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1994		Y
	C4591001 1241 12411991	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1241 12411992	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411993	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1997	06MAR2019	N
		Surgical and medical procedures	Knee operation	01JAN2017	31DEC2017	N
			Orthognathic surgery	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
	C4591001 1241 12411994	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411995	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1241 12411996	Infections and infestations	Chronic sinusitis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1241 12411997	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12411998	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1241 12411999	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Tension headache	01JAN2007		Y
		Surgical and medical procedures	Mammoplasty	01NOV2017		Y
	C4591001 1241 12412001	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412002	Gastrointestinal disorders	Coeliac disease	01JAN1998		Y
		Psychiatric disorders	Anxiety disorder	01DEC2019		Y
		Surgical and medical procedures	Tympanoplasty	01JUN2019	30JUN2019	N
	C4591001 1241 12412003	Immune system disorders	Food allergy	01JAN1988		Y
	C4591001 1241 12412004	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1994		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12412006	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
	C4591001 1241 12412007	Renal and urinary disorders	Nephrolithiasis	01MAR2020	31MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2019		Y
			Rhinitis allergic	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ureteral stent insertion	01MAR2020	31MAR2020	N
	C4591001 1241 12412008	Infections and infestations	Helicobacter gastritis	01JAN2006	31DEC2006	N
			Oesophagitis bacterial	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
	C4591001 1241 12412009	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1241 12412010	Eye disorders	Glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Gastritis	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
	C4591001 1241 12412012	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
	C4591001 1241 12412013	Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1241 12412014	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
	C4591001 1241 12412015	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
		Surgical and medical procedures	Metabolic surgery	20AUG2012	20AUG2012	N
	C4591001 1241 12412016	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
			Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Splenectomy	01JAN2009	31DEC2009	N
	C4591001 1241 12412018	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Orthopaedic procedure	01JAN2011	31DEC2011	N
	C4591001 1241 12412020	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
	C4591001 1241 12412022	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
	C4591001 1241 12412023	Hepatobiliary disorders	Cholelithiasis	01JAN2017		Y
		Infections and infestations	Genital herpes	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1241 12412024	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1241 12412025	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412026	Immune system disorders	Food allergy	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
			Urinary tract infection	02SEP2020	09SEP2020	N
	C4591001 1241 12412027	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2009		Y
	C4591001 1241 12412028	Blood and lymphatic system disorders	Leukopenia	01JAN2000		Y
	C4591001 1241 12412029	Immune system disorders	Seasonal allergy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412034	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412035	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Surgical and medical procedures	Salpingectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12412036	Nervous system disorders	Seizure	01NOV2018		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Haemangioma removal	01NOV2018	30NOV2018	N
	C4591001 1241 12412037	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
			Rhinitis allergic	01JAN1996		Y
	C4591001 1241 12412038	Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1241 12412039	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
	C4591001 1241 12412043	Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2015	31DEC2015	N
			Nephrectomy	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412044	Injury, poisoning and procedural complications	Meniscus injury	01JAN2010		Y
	C4591001 1241 12412045	Endocrine disorders	Hypothyroidism	01JUL2019		Y
	C4591001 1241 12412046	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Gastrointestinal surgery	01JAN2005	31DEC2005	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1241 12412051	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
	C4591001 1241 12412053	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412057	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1241 12412060	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Polyp	01JAN2014		Y
	C4591001 1241 12412062	Endocrine disorders	Autoimmune thyroiditis	01JAN2002		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2000		Y
	C4591001 1241 12412063	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
	C4591001 1241 12412064	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412065	Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1241 12412071	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412072	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12412073	Skin and subcutaneous tissue disorders	Acanthosis nigricans	30SEP2020		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2017		Y
	C4591001 1241 12412074	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Surgical and medical procedures	Umbilical hernia repair	01OCT2015	31OCT2015	N
	C4591001 1241 12412080	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2000		Y
		Psychiatric disorders	Anxiety	18AUG2020		Y
	C4591001 1241 12412081	Psychiatric disorders	Depression	19SEP2019		Y
	C4591001 1241 12412082†	Infections and infestations	HIV infection	01JAN2003		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUL2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Inguinal hernia repair	01JAN2012	31DEC2012	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1241 12412083	Nervous system disorders	Tension headache	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412088	Surgical and medical procedures	Knee operation	01DEC2008	31DEC2008	N
	C4591001 1241 12412089	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12412092	Nervous system disorders	Epilepsy	01JAN1996		Y
	C4591001 1241 12412093	Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1241 12412096	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
				01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	(b) (6) 1986		Y
	C4591001 1241 12412098	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989	31DEC1997	N
	C4591001 1241 12412099	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
	C4591001 1241 12412100	Metabolism and nutrition disorders	Obesity	01JUL2020		Y
		Surgical and medical procedures	Metabolic surgery	01DEC2006	31DEC2006	N
	C4591001 1241 12412101	Endocrine disorders	Autoimmune thyroiditis	01JAN1998		Y
		Infections and infestations	Sinusitis	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JUL2020		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1241 12412102	Congenital, familial and genetic disorders	Haemangioma congenital	(b) (6) 1977		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
	C4591001 1241 12412104	Immune system disorders	Food allergy	01JAN1972		Y
		Psychiatric disorders	Anxiety disorder	01JAN2013		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
	C4591001 1241 12412105	Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412106	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01DEC2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
	C4591001 1241 12412107	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
	C4591001 1241 12412108	Endocrine disorders	Thyroid mass	01JAN2004		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990	31DEC2008	N
			Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412109	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
	C4591001 1241 12412110	Immune system disorders	Drug hypersensitivity	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412111	Endocrine disorders	Hypothyroidism	15FEB2020		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2007	31DEC2007	N
			Thyroidectomy	15FEB2020	15FEB2020	N
	C4591001 1241 12412113	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Nervous system disorders	Tension headache	01JAN2017		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1241 12412114	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2013		Y
				01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1241 12412118	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412119	Immune system disorders	Food allergy	01JUN2020		Y
	C4591001 1241 12412120	Cardiac disorders	Mitral valve prolapse	01JAN1991		Y
		Vascular disorders	Peripheral venous disease	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412121	Surgical and medical procedures	Thyroidectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12412122	Surgical and medical procedures	Spinal operation	10JUN2019	10JUN2019	N
		Vascular disorders	Hypertension	01SEP2018		Y
	C4591001 1241 12412126	Hepatobiliary disorders	Hepatic steatosis	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12412127	Reproductive system and breast disorders	Premature menopause	01JAN2009		Y
	C4591001 1241 12412130	Surgical and medical procedures	Benign breast lump removal	01JAN2016	31DEC2016	N
	C4591001 1241 12412131	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12412132	Eye disorders	Glaucoma	01JAN2017		Y
		Infections and infestations	Sinusitis	01JAN2010		Y
	C4591001 1241 12412133	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
	C4591001 1241 12412134	Infections and infestations	Sinusitis	01JAN2010		Y
	C4591001 1241 12412135	Psychiatric disorders	Depression	01SEP2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412136	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JUN2019		Y
	C4591001 1241 12412138	Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
	C4591001 1241 12412139	Gastrointestinal disorders	Chronic gastritis	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	01JAN2004		Y
		Psychiatric disorders	Anxiety disorder	01JAN2019		Y
	C4591001 1241 12412141	Surgical and medical procedures	Bone lesion excision	01AUG2020	31AUG2020	N
	C4591001 1241 12412143	Metabolism and nutrition disorders	Hyperuricaemia	01JAN2010		Y
	C4591001 1241 12412148	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Parotidectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12412149	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000		Y
	C4591001 1241 12412150	Eye disorders	Glaucoma	01JAN2019		Y
	C4591001 1241 12412151	Endocrine disorders	Thyroid cyst	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412152	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12412154	Endocrine disorders	Hypothyroidism	01JAN2013		Y
			Thyroid mass	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1241 12412155	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412156	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412157	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
	C4591001 1241 12412158	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2006		Y
	C4591001 1241 12412159	Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1241 12412160	Cardiac disorders	Pericardial effusion	01JAN2000	31DEC2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412161	Gastrointestinal disorders	Gastritis	01APR2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
	C4591001 1241 12412162	Metabolism and nutrition disorders	Hypertriglyceridaemia	01AUG2010		Y
	C4591001 1241 12412163	Infections and infestations	Hepatitis B	01JAN2016		Y
	C4591001 1241 12412165	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
	C4591001 1241 12412166	Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Panic reaction	01JAN2015		Y
	C4591001 1241 12412168	Nervous system disorders	Tension headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412169	Injury, poisoning and procedural complications	Foot fracture	01SEP2020		Y
	C4591001 1241 12412170	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412171	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996	31DEC2012	N
			Rhinitis allergic	01JAN1998		Y
	C4591001 1241 12412172	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412173	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12412174	Neoplasms benign, malignant and unspecified (incl cysts and polyps) Surgical and medical procedures	Uterine leiomyoma Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12412176	Nervous system disorders Psychiatric disorders	Tension headache Insomnia	01JAN2010		Y
	C4591001 1241 12412177	Surgical and medical procedures Immune system disorders	Metabolic surgery Drug hypersensitivity	01AUG2009	01AUG2009	N
		Nervous system disorders Psychiatric disorders	Migraine Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2020		Y
	C4591001 1241 12412179	Infections and infestations Skin and subcutaneous tissue disorders	Chronic sinusitis Androgenetic alopecia	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1999	31DEC1999	N
	C4591001 1241 12412180	Infections and infestations	Sinusitis	01JAN1990		Y
	C4591001 1241 12412182	Cardiac disorders	Coronary artery aneurysm	01JAN2018		Y
		Metabolism and nutrition disorders Vascular disorders	Dyslipidaemia Hypertension	01JAN2010		Y
	C4591001 1241 12412183	Immune system disorders	Allergy to arthropod sting	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1241 12412186	Psychiatric disorders	Depression	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Metabolic surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1241 12412190	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01OCT2019	31OCT2019	N
			Prosthesis implantation	01JAN2016	31DEC2016	N
	C4591001 1241 12412193	Surgical and medical procedures	Umbilical hernia repair	01JAN2008	31DEC2008	N
	C4591001 1241 12412197	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2011		Y
		Surgical and medical procedures	Metabolic surgery	27SEP2011	27SEP2011	N
	C4591001 1241 12412199	Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1241 12412201	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Psychiatric disorders	Anxiety disorder	01JAN2008		Y
	C4591001 1241 12412206	Cardiac disorders	Sinus arrhythmia	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Autoimmune thyroiditis	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2020		Y
		Psychiatric disorders	Depression	01OCT2019		Y
	C4591001 1241 12412207	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1241 12412208	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412209	Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1241 12412210	Gastrointestinal disorders	Gastritis	01JUL2015		Y
	C4591001 1241 12412212	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
	C4591001 1241 12412215	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412218	Nervous system disorders	Migraine	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412221	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412222	Surgical and medical procedures	Renal stone removal	17JUN2017	17JUN2017	N
	C4591001 1241 12412223	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01DEC2016	31DEC2016	N
	C4591001 1241 12412225	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412226	Surgical and medical procedures	Metabolic surgery	01OCT2016	31OCT2016	N
	C4591001 1241 12412227	Gastrointestinal disorders	Gastritis	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1241 12412228	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Rhinitis allergic	01JAN1980		Y
	C4591001 1241 12412232	Infections and infestations	Sinusitis	01JAN2013		Y
	C4591001 1241 12412233	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1241 12412236	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Intervertebral disc degeneration	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1996		Y
	C4591001 1241 12412237	Injury, poisoning and procedural complications	Joint injury	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412240	Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y
			Insomnia	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1241 12412243	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Metabolic surgery	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412244	Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1241 12412245	Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
			Lithotripsy	01JAN2008	31DEC2008	N
	C4591001 1241 12412246	Cardiac disorders	Sinus arrhythmia	01JAN1985	31DEC2011	N
		Eye disorders	Glaucoma	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012	31DEC2015	N
	C4591001 1241 12412247	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Glucose tolerance impaired	01JAN2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUL2007	31JUL2007	N
		Nervous system disorders	Tension headache	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Carotid endarterectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JUL2007	31JUL2007	N
	C4591001 1241 12412248	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Thyroidectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12412249	Immune system disorders	Food allergy	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1241 12412252	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1241 12412253	Immune system disorders	Mite allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1241 12412254	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01MAY2019		Y
	C4591001 1241 12412255	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2012	31DEC2013	N
		Renal and urinary disorders	Post streptococcal glomerulonephritis	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1241 12412257	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1241 12412258	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412259	Nervous system disorders	Tension headache	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
			Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412260	Infections and infestations	Sinusitis	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1241 12412261	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN1992		Y
		Infections and infestations	Sinusitis	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1241 12412262	Congenital, familial and genetic disorders	Sickle cell trait	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
	C4591001 1241 12412264	Gastrointestinal disorders	Gastritis	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412267	Infections and infestations	Sinusitis	01JAN2000		Y
	C4591001 1241 12412268	Gastrointestinal disorders	Gastritis	01JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
	C4591001 1241 12412269	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Renal and urinary disorders	Cystitis glandularis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1241 12412270	Nervous system disorders	Migraine	01JAN2002		Y
	C4591001 1241 12412271	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1241 12412275	Reproductive system and breast disorders	Polycystic ovaries	01JAN2014		Y
	C4591001 1241 12412277	Nervous system disorders	Tension headache	01MAR2020		Y
	C4591001 1241 12412278	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1241 12412281	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412282	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Type 1 diabetes mellitus	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412284	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1241 12412285	Infections and infestations	Rhinitis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1241 12412288	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
	C4591001 1241 12412289	Gastrointestinal disorders	Gastritis	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
	C4591001 1241 12412290	Endocrine disorders	Thyroiditis	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12412291	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
				01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Thyroidectomy	01JAN2009	31DEC2009	N
	C4591001 1241 12412295	Infections and infestations	Sinusitis	01JAN2000		Y
	C4591001 1241 12412296	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
	C4591001 1241 12412299	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412303	Musculoskeletal and connective tissue disorders	Neck pain	01AUG2020		Y
		Nervous system disorders	Headache	01AUG2020		Y
		Surgical and medical procedures	Varicose vein operation	01JAN2011	31DEC2011	N
	C4591001 1241 12412304	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
			Rhinitis allergic	01JAN1985		Y
	C4591001 1241 12412306	Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1241 12412307	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2019		Y
		Surgical and medical procedures	Gastric operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412308	Metabolism and nutrition disorders	Lactose intolerance	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12412312	Congenital, familial and genetic disorders	Spine malformation	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1241 12412313	Psychiatric disorders	Anxiety	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
			Haemorrhoid operation	01JAN2005	31DEC2005	N
	C4591001 1241 12412315	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	19OCT2017	19OCT2017	N
		Surgical and medical procedures	Thyroidectomy	19OCT2017	19OCT2017	N
	C4591001 1241 12412317	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
	C4591001 1241 12412320	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12412321	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12412322	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Surgical and medical procedures	Phlebectomy	01JAN2005	31DEC2005	N
	C4591001 1241 12412323	Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Endometriosis	01JAN2018		Y
			Polycystic ovaries	01JAN2018		Y
	C4591001 1241 12412324	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412327	Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Bone lesion excision	01JAN2015	31DEC2015	N
	C4591001 1241 12412329	Endocrine disorders	Hypothyroidism	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1241 12412330	Surgical and medical procedures	Tonsillectomy	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
	C4591001 1241 12412331	Metabolism and nutrition disorders	Umbilical hernia repair Dyslipidaemia	01JAN1980 01JAN2014	31DEC1980	N Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
	C4591001 1241 12412333	Vascular disorders	Hypertension	01JAN2014		Y
		Infections and infestations	Sinusitis	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017		Y
			Plantar fasciitis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
	C4591001 1241 12412334	Metabolism and nutrition disorders	Obesity	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Metabolic surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12412335	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2020		Y
	C4591001 1241 12412337	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Lactose intolerance	01AUG2017		Y
	C4591001 1241 12412338	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
			Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412339	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
	C4591001 1241 12412342	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412345	Infections and infestations	Sinusitis	01MAR2020		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2012	31DEC2012	N
	C4591001 1241 12412346	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2008		Y
	C4591001 1241 12412347	Immune system disorders	Iodine allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Lactose intolerance	01SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01OCT2017	31OCT2017	N
	C4591001 1241 12412350	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412351	Congenital, familial and genetic disorders	Thalassaemia	01JAN1997		Y
	C4591001 1241 12412352	Immune system disorders	Food allergy	01JAN2002		Y
			Iodine allergy	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2002		Y
	C4591001 1241 12412355	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Abdominal wall neoplasm	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Abdominal wall operation	01JAN2018	31DEC2018	N
	C4591001 1241 12412357	Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Metabolic surgery	02JAN2007	02JAN2007	N
	C4591001 1241 12412360	Congenital, familial and genetic disorders	Congenital jaw malformation	01JAN2019		Y
		Gastrointestinal disorders	Lumbar hernia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1241 12412362	Endocrine disorders	Hypothyroidism	01JAN2019		Y
	C4591001 1241 12412363	Endocrine disorders	Goitre	01JAN2009	31DEC2009	N
			Hypothyroidism	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP2018	30SEP2018	N
		Surgical and medical procedures	Hysterectomy	01SEP2018	30SEP2018	N
			Thyroidectomy	01JAN2009	31DEC2009	N
	C4591001 1241 12412364	Immune system disorders	Food allergy	01JAN1999		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
	C4591001 1241 12412365	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412366	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
	C4591001 1241 12412367	Endocrine disorders	Thyroid cyst	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412369	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412370	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412371	Nervous system disorders	Migraine	01JAN1987		Y
	C4591001 1241 12412373	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1241 12412377	Metabolism and nutrition disorders	Lactose intolerance	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
	C4591001 1241 12412380	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
	C4591001 1241 12412381	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412383	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012	31DEC2014	N
	C4591001 1241 12412385	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412386	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12412387	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1241 12412389	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1241 12412390	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
	C4591001 1241 12412391	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
			Rhinitis allergic	01JAN1998		Y
	C4591001 1241 12412392	Gastrointestinal disorders	Gastritis	01JAN2019		Y
		Injury, poisoning and procedural complications	Nasal injury	16OCT2020		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1241 12412394	Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1241 12412395	Infections and infestations	Labyrinthitis	01JAN2019		Y
	C4591001 1241 12412396	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412397	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
	C4591001 1241 12412398	Psychiatric disorders	Anxiety	01APR2019		Y
			Depression	01APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412399	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412404	Hepatobiliary disorders	Cholelithiasis	27AUG2020	27AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	27AUG2020	27AUG2020	N
	C4591001 1241 12412407	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
	C4591001 1241 12412410	Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2019	31DEC2019	N
	C4591001 1241 12412411	Metabolism and nutrition disorders	Lactose intolerance	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
	C4591001 1241 12412412	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412414	Infections and infestations	Ear infection	10OCT2020	17OCT2020	N
			Oral herpes	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic adenoma	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412416	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
	C4591001 1241 12412417	Nervous system disorders	Cerebral venous thrombosis	01NOV2018	30JUN2019	N
	C4591001 1241 12412418	Nervous system disorders	Tension headache	01JAN2009		Y
	C4591001 1241 12412420	Vascular disorders	Varicose vein	01JAN2010		Y
	C4591001 1241 12412421	Infections and infestations	Sinusitis	01JAN2008		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
	C4591001 1241 12412424	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Glucose tolerance impaired	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
			Venous thrombosis	01JAN2019	31DEC2019	N
	C4591001 1241 12412425	Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis reactive	01JAN2011		Y
			Fibromyalgia	01JAN2019		Y
	C4591001 1241 12412426	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
			Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412430	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018		Y
	C4591001 1241 12412431	Endocrine disorders	Hypothyroidism	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1241 12412432	Hepatobiliary disorders	Cholelithiasis	01JAN2020	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2020	31JAN2020	N
	C4591001 1241 12412433	Psychiatric disorders	Anxiety disorder	01JAN2018	31MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2000	31DEC2000	N
	C4591001 1241 12412434	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
	C4591001 1241 12412435	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412437	Reproductive system and breast disorders	Endometriosis	01JAN2018		Y
		Surgical and medical procedures	Endometriosis ablation	01JUN2018	30JUN2018	N
	C4591001 1241 12412438	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12412439	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1968		Y
	C4591001 1241 12412441	Respiratory, thoracic and mediastinal disorders	Cough	01JAN2013		Y
			Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12412442	Eye disorders	Optic neuropathy	01JUL2020		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412443	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
			Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412444	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412445	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Varicose vein operation	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412447	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412448	Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1241 12412449	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	22JAN2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	22JAN2019	22JAN2019	N
	C4591001 1241 12412450	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412451	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
		Surgical and medical procedures	Hysterectomy	01FEB2019	28FEB2019	N
	C4591001 1241 12412452	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412453	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412456	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412457	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1241 12412458	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412461	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Metabolic surgery	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412462	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12412463	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412464	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412465	Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12412467	Reproductive system and breast disorders	Ovarian failure	01JAN2010		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1241 12412468	Endocrine disorders	Hypothyroidism	01SEP2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JUL2006	30SEP2006	N
		Surgical and medical procedures	Thyroidectomy	01SEP2006	30SEP2006	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12412471	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2020		Y
	C4591001 1241 12412472	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1989		Y
	C4591001 1241 12412476	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412477	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Surgical and medical procedures	Metabolic surgery	09JAN2008	09JAN2008	N
	C4591001 1241 12412478	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1241 12412479	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412482	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2017		Y
	C4591001 1241 12412485	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
	C4591001 1241 12412486	Nervous system disorders	Migraine	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
			Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1241 12412493	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1241 12412494	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1994		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
	C4591001 1241 12412498	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412500	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1241 12412501	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2016		Y
	C4591001 1241 12412504	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412505	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412506	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12412507	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
	C4591001 1241 12412509	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31JAN2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31JAN2018	N
	C4591001 1241 12412510	Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412512	Gastrointestinal disorders	Oesophagitis	01AUG2020		Y
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1241 12412513	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Psychiatric disorders	Anxiety disorder	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412515	Hepatobiliary disorders	Cholelithiasis	01SEP2012	30SEP2012	N
		Surgical and medical procedures	Cholecystectomy	01SEP2012	30SEP2012	N
			Metabolic surgery	01JUL2011	31JUL2011	N
	C4591001 1241 12412517	Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
	C4591001 1241 12412518	Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2002	31DEC2007	N
			Panic reaction	01JAN2010	31DEC2011	N
	C4591001 1241 12412519	Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Fracture treatment	01JAN2001	31DEC2001	N
	C4591001 1241 12412525	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412527	Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Dyslexia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1241 12412528	Gastrointestinal disorders	Dyspepsia	08OCT2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUL2012	31JUL2012	N
		Social circumstances	Menopause	01JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JUL2012	31JUL2012	N
	C4591001 1241 12412529	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
		Surgical and medical procedures	Metabolic surgery	01MAR2018	31MAR2018	N
	C4591001 1241 12412532	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412534	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2003		Y
	C4591001 1241 12412537	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1241 12412539	Nervous system disorders	Migraine	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412540	Gastrointestinal disorders	Gastritis	01JAN2016	31DEC2018	N
		Infections and infestations	Labyrinthitis	01JAN2016	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412543	Nervous system disorders	Tension headache	01JUN2020		Y
	C4591001 1241 12412544	Metabolism and nutrition disorders	Hypertriglyceridaemia	10SEP2020		Y
			Hyperuricaemia	10SEP2020		Y
	C4591001 1241 12412549	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12412551	Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
	C4591001 1241 12412554	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
	C4591001 1241 12412556	Infections and infestations	Sinusitis	01JAN2000		Y
	C4591001 1241 12412557	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2015	31DEC2015	N
		Vascular disorders	Venous thrombosis limb	01JAN2018	31DEC2018	N
	C4591001 1241 12412559	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412560	Surgical and medical procedures	Hysterectomy	01MAR2017	31MAR2017	N
	C4591001 1241 12412561	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12412564	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1241 12412565	Gastrointestinal disorders	Gastritis	01SEP2020		Y
	C4591001 1241 12412566†	Infections and infestations	HIV infection	01FEB2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1246 12461002	Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	07JAN2016	07JAN2016	N
	C4591001 1246 12461004	Psychiatric disorders	Bipolar disorder	01AUG2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1246 12461006	General disorders and administration site conditions	Pain	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	21DEC2010	21DEC2010	N
			Female sterilisation	21DEC2010	21DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1246 12461007	Surgical and medical procedures	Caesarean section	01JAN2019	31DEC2019	N
	C4591001 1246 12461008	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1246 12461009	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Social circumstances	Postmenopause	01APR2019		Y
	C4591001 1246 12461010	Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1992		Y
	C4591001 1246 12461012	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
		Infections and infestations	Sinusitis	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1999		Y
	C4591001 1246 12461014	Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2013		Y
	C4591001 1246 12461015	Vascular disorders	Hypertension	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1246 12461018	Infections and infestations	Chronic sinusitis	01JAN2018		Y
	C4591001 1246 12461020	Ear and labyrinth disorders	Hypoacusis	01JAN2010		Y
	C4591001 1246 12461021	Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	30AUG2001	30AUG2001	N
			Female sterilisation	30AUG2001	30AUG2001	N
	C4591001 1246 12461022	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
	C4591001 1246 12461025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1246 12461026	Cardiac disorders	Palpitations	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1246 12461028	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1246 12461030	Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1246 12461031	Cardiac disorders	Myocardial infarction	01JAN2012	31DEC2012	N
		Immune system disorders	Iodine allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2017	31DEC2017	N
			Percutaneous coronary intervention	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
	C4591001 1246 12461032	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1246 12461034	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
	C4591001 1246 12461036	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1246 12461037	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1246 12461038	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01AUG2020		Y
	C4591001 1246 12461043	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1246 12461046	Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JUN2020	31DEC2020	N
				01MAR2019	31MAR2019	N
	C4591001 1246 12461047	Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1246 12461049†	Investigations	HIV test positive	01JAN2014		Y
	C4591001 1246 12461050	Metabolism and nutrition disorders	Overweight	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Social circumstances	Postmenopause	01MAR2019		Y
		Surgical and medical procedures	Female sterilisation	11AUG2011	11AUG2011	N
	C4591001 1246 12461052	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1246 12461053	Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1246 12461055†	Investigations	HIV test positive	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
				01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1246 12461057	Nervous system disorders	Headache	01JAN2000		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1246 12461058	Surgical and medical procedures	Contraceptive implant	01JAN2019	31JAN2019	N
	C4591001 1246 12461068	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1983		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1983		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1246 12461070	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1246 12461071	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1246 12461072	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Hip arthroplasty	01FEB2019	28FEB2019	N
				01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1246 12461073†	Investigations	HIV test positive	01JUL2019		Y
	C4591001 1246 12461074	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	24MAY2001	24MAY2001	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1246 12461075	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1246 12461076	General disorders and administration site conditions	Pain	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1246 12461078	Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2014		Y
	C4591001 1246 12461080	Psychiatric disorders	Bipolar II disorder	01JUN2020		Y
	C4591001 1246 12461084	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1246 12461085	Gastrointestinal disorders	Diarrhoea	01JAN2005		Y
			Irritable bowel syndrome	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1246 12461086	Infections and infestations	Chronic sinusitis	01JAN1996		Y
		Surgical and medical procedures	Caesarean section	01JAN2003	31DEC2003	N
				01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
	C4591001 1246 12461087	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1246 12461088	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1246 12461089	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1246 12461093	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
			Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1246 12461098	Surgical and medical procedures	Caesarean section	31JAN2019	31JAN2019	N
	C4591001 1246 12461100	Infections and infestations	Chronic sinusitis	01JAN2012		Y
	C4591001 1246 12461103	Endocrine disorders	Hypothyroidism	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2012	31DEC2012	N
	C4591001 1246 12461104	Nervous system disorders	Headache	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1246 12461106	Surgical and medical procedures	Caesarean section	01JAN2016	31DEC2016	N
	C4591001 1246 12461108	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1246 12461109	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1246 12461112	Infections and infestations	Chronic sinusitis	01JAN2018		Y
	C4591001 1246 12461114	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
	C4591001 1246 12461115	Gastrointestinal disorders	Peptic ulcer	01JAN2019		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2019	31JAN2019	N
	C4591001 1246 12461120	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1246 12461122	Infections and infestations	Chronic sinusitis	01JAN2016		Y
	C4591001 1246 12461126	Gastrointestinal disorders	Peptic ulcer	01JAN2015		Y
	C4591001 1246 12461131	Reproductive system and breast disorders	Endometriosis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1246 12461135	Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
	C4591001 1246 12461136	Surgical and medical procedures	Caesarean section	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1247 12471004	Respiratory, thoracic and mediastinal disorders	Cough	01JAN2000		Y
	C4591001 1247 12471009	Cardiac disorders	Mitral valve stenosis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1247 12471010	Eye disorders	Refraction disorder	01OCT2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1247 12471012	Endocrine disorders	Anovulatory cycle	01NOV2019		Y
	C4591001 1247 12471018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
	C4591001 1247 12471023	Vascular disorders	Hypertension	24SEP2018		Y
	C4591001 1247 12471025	Surgical and medical procedures	Hysterectomy	01JAN2020	31JAN2020	N
	C4591001 1247 12471028	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis allergic	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1247 12471031	Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1247 12471040	Eye disorders	Conjunctivitis allergic	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Psychiatric disorders	Depression	01DEC2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1247 12471044	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
	C4591001 1247 12471045	Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				01JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1247 12471046	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2003		Y
		Metabolism and nutrition disorders	Central obesity	01JAN2008		Y
			Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01MAR1996	31MAR1996	N
	C4591001 1247 12471048	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1247 12471054	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1247 12471058	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic Asthma	01JAN1990 01JAN2011		Y Y
	C4591001 1247 12471059	Vascular disorders Social circumstances	Hypertension Postmenopause	01JAN2014 01JAN2016		Y Y
	C4591001 1247 12471061	Vascular disorders Metabolism and nutrition disorders	Hypertension Hypercholesterolaemia	01JAN2014 01JAN2019		Y Y
	C4591001 1247 12471062	Metabolism and nutrition disorders	Vitamin D deficiency Hypercholesterolaemia	01JAN2019 01JAN2008		Y Y
	C4591001 1247 12471064	Investigations	Type 2 diabetes mellitus	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypotension	01JAN2008		Y
	C4591001 1247 12471064	Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Social circumstances	Postmenopause	01MAY2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1247 12471069	Surgical and medical procedures	Female sterilisation	17NOV2010	17NOV2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471071	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1247 12471073	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1247 12471077	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1247 12471078	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1247 12471079	Infections and infestations	Sinusitis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1247 12471082	Nervous system disorders	Cerebrovascular accident	01JAN1998	31DEC1998	N
			Epilepsy	01JAN1998		Y
	C4591001 1247 12471084	Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2013	30JUN2013	N
			Depression	01MAR2013	31MAR2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1247 12471085	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1247 12471086	Infections and infestations	Encephalitis	01JAN1989	31DEC1989	N
		Nervous system disorders	Petit mal epilepsy	01JAN1989	31DEC2000	N
	C4591001 1247 12471087	Immune system disorders	Seasonal allergy	01JAN2004		Y
	C4591001 1247 12471088	Infections and infestations	Sinusitis	01JAN2003		Y
	C4591001 1247 12471089	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1247 12471090	Immune system disorders	Seasonal allergy	01JAN2020		Y
	C4591001 1247 12471099	Social circumstances	Postmenopause	01MAR2018		Y
	C4591001 1247 12471101	Surgical and medical procedures	Intrauterine contraception	01JAN2018		Y
	C4591001 1247 12471106	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1247 12471108	Cardiac disorders	Myocardial infarction	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	29SEP2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1247 12471113	Cardiac disorders	Atrial fibrillation	21MAY2018		Y
	C4591001 1247 12471114	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Social circumstances	Postmenopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471118	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1247 12471123	Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1247 12471126†	Investigations	HIV test positive	01JAN2018		Y
	C4591001 1247 12471130	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1247 12471133	Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1247 12471137	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc protrusion	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1247 12471147	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1247 12471148	Eye disorders	Glaucoma	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1981		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1247 12471152	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1247 12471153	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471154	Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1247 12471155	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1247 12471162	Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2013		Y
	C4591001 1247 12471165	Surgical and medical procedures	Salpingectomy	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
	C4591001 1247 12471167†	Investigations	HIV test positive	26SEP2017		Y
	C4591001 1247 12471168	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
	C4591001 1247 12471172	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1247 12471173	Surgical and medical procedures	Salpingectomy	01JAN2012	31DEC2012	N
	C4591001 1247 12471174	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
	C4591001 1247 12471178	Surgical and medical procedures	Salpingectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1247 12471181	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1993		Y
	C4591001 1247 12471185	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1247 12471193	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1247 12471196	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y
	C4591001 1247 12471197	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
	C4591001 1247 12471200	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1247 12471204†	Investigations	HIV test positive	01JAN2010		Y
	C4591001 1247 12471212	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1247 12471213	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1247 12471214	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1247 12471215	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1247 12471217	Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1247 12471220	Nervous system disorders	Temporal lobe epilepsy	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN2018	31DEC2018	N
	C4591001 1247 12471221	Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471222	Psychiatric disorders	Anxiety	01JAN1974		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2012		Y
	C4591001 1247 12471223	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2019		Y
		Psychiatric disorders	Depression	01MAR2019		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1247 12471226	Gastrointestinal disorders	Oesophageal achalasia	01JAN2005		Y
		Psychiatric disorders	Major depression	01APR2020		Y
	C4591001 1247 12471232	Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1247 12471239	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01FEB1999	28FEB1999	N
	C4591001 1247 12471242	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Insulin resistance	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1247 12471244	Nervous system disorders	Facial paralysis	01FEB2018	30APR2018	N
				01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
	C4591001 1247 12471245	Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1247 12471251	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1247 12471255	Cardiac disorders	Cardiovascular disorder	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1247 12471256	Surgical and medical procedures	Female sterilisation	01JAN2013	31DEC2013	N
	C4591001 1247 12471260	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1248 12481005	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992	31DEC2018	N
	C4591001 1248 12481011	Surgical and medical procedures	Female sterilisation	09SEP1997	09SEP1997	N
	C4591001 1248 12481012	Metabolism and nutrition disorders	Diabetes mellitus	04MAR2009		Y
	C4591001 1248 12481013	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1248 12481025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1248 12481032	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1248 12481035	Cardiac disorders	Mitral valve prolapse	01JAN1990		Y
	C4591001 1248 12481036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1992		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1969		Y
			Depression	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1248 12481038	Psychiatric disorders	Bipolar disorder	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481055	Immune system disorders	Mite allergy	01JAN2018		Y
	C4591001 1248 12481061	Gastrointestinal disorders	Dyspepsia	01JUN2020		Y
	C4591001 1248 12481062	Infections and infestations	Herpes virus infection	01JAN2013		Y
	C4591001 1248 12481063	Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1248 12481068	Nervous system disorders	Depression Migraine	01JAN2005 01JAN1982		Y Y
	C4591001 1248 12481069	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014	31DEC2016	N
	C4591001 1248 12481077	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1248 12481081	Surgical and medical procedures	Abdominal hernia repair	01JAN2014	31DEC2014	N
	C4591001 1248 12481085	Psychiatric disorders	Pulmonary resection Bipolar disorder	01JAN2014 01JAN1995		Y Y
	C4591001 1248 12481086	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1248 12481086	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1248 12481086	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1248 12481086	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998		Y
	C4591001 1248 12481086	Reproductive system and breast disorders	Ovarian cyst	01JAN2019		Y
	C4591001 1248 12481094	Surgical and medical procedures	Uterine dilation and curettage	31JAN2020	31JAN2020	N
	C4591001 1248 12481094	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481097	Gastrointestinal disorders	Vomiting	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2010		Y
				01JAN2015		Y
	C4591001 1248 12481098	Psychiatric disorders	Depression	01JAN1995	31DEC2018	N
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2006		Y
	C4591001 1248 12481099	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006	31DEC2012	N
	C4591001 1248 12481104	Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
	C4591001 1248 12481118	Eye disorders	Hypermetropia	30AUG2020		Y
		Nervous system disorders	Migraine	30AUG2020		Y
		Renal and urinary disorders	Incontinence	01JAN2018		Y
	C4591001 1248 12481121	Injury, poisoning and procedural complications	Femur fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Orthopaedic procedure	01JAN2017	31DEC2017	N
	C4591001 1248 12481123	Psychiatric disorders	Bipolar disorder	01FEB2016		Y
	C4591001 1248 12481130	Social circumstances	Postmenopause	01MAR2018		Y
		Surgical and medical procedures	Limb operation	19OCT2019	19OCT2019	N
			Tenoplasty	10AUG2019	10AUG2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481131	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31JAN2018	N
		Nervous system disorders	Headache	01JAN1994		Y
	C4591001 1248 12481145	Social circumstances	Familial risk factor	01JAN2013		Y
		Surgical and medical procedures	Appendectomy	01JUN2019	30JUN2019	N
	Caesarean section		12APR2016	12APR2016	N	
	Contraception		01JAN2013		Y	
	C4591001 1248 12481146	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1248 12481150	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1248 12481151	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Cardiac murmur	(b) (6) 1974		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1248 12481154	Reproductive system and breast disorders	Endometriosis	01NOV2017		Y
		Surgical and medical procedures	Endometriosis ablation	01JAN2018	31JAN2018	N
			Fracture treatment	01JAN2018	31DEC2018	N
	C4591001 1248 12481156	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1248 12481159	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1248 12481162	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1248 12481165	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	06AUG2016	06AUG2016	N
	C4591001 1248 12481169	Cardiac disorders	Cardiac failure congestive	01JUL2017		Y
		Investigations	Blood cholesterol increased	01JUL2017		Y
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1248 12481172	Injury, poisoning and procedural complications	Ankle fracture	01JAN2020	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1248 12481175	Immune system disorders	Food allergy	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
	C4591001 1248 12481176	Psychiatric disorders	Depression	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2020		Y
			Drug eruption	01JAN1993		Y
	C4591001 1248 12481178	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
	C4591001 1248 12481185	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Immune system disorders	Allergic oedema	01JAN1999	31DEC1999	N
			Drug hypersensitivity	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1248 12481186	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1248 12481187	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1248 12481189	Immune system disorders	Multiple allergies	01JAN2003		Y
	C4591001 1248 12481190	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1248 12481191	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1248 12481192	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011		Y
			Depression	01JAN2011		Y
	C4591001 1248 12481193	Immune system disorders	Allergy to animal	01JAN2006		Y
			Seasonal allergy	01JAN2006		Y
		Surgical and medical procedures	Foot operation	01JAN2017	31DEC2017	N
	C4591001 1248 12481194	Immune system disorders	Seasonal allergy	01JAN2012		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1248 12481195	Reproductive system and breast disorders	Ovarian cyst	01JUL2019	31JUL2019	N
	C4591001 1248 12481200	Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1248 12481201	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1248 12481204	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000		Y
	C4591001 1248 12481205	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Psychiatric disorders	Bipolar disorder	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
	C4591001 1248 12481208	Eye disorders	Blindness unilateral	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1996		Y
	C4591001 1248 12481210	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2020		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2008		Y
		Surgical and medical procedures	Joint stabilisation	01JAN2019	31DEC2019	N
	C4591001 1248 12481211	Psychiatric disorders	Anxiety	01APR2020		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Skin disorder	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Osteotomy	01JUL2019	31JUL2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin operation	01MAR2020	31MAR2020	N
	C4591001 1248 12481212	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01MAY2019	31MAY2019	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01MAY2019	31MAY2019	N
	C4591001 1248 12481215	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2008	31DEC2010	N
			Attention deficit hyperactivity disorder	01JAN1993	31DEC2010	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
	C4591001 1248 12481216	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Food allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2015		Y
			Urticaria	01JAN1993		Y
	C4591001 1248 12481217	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Anaphylactic reaction	01JAN2007		Y
			Food allergy	01JAN2007		Y
			Reaction to food additive	01JAN1992		Y
	C4591001 1248 12481219	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
			Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1248 12481220	Nervous system disorders	Headache	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2019	31DEC2019	N
	C4591001 1248 12481221	Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
	C4591001 1248 12481224	Immune system disorders	Iodine allergy	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1248 12481227	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1248 12481228	Immune system disorders	Seasonal allergy	01JAN1982		Y
	C4591001 1248 12481230	Psychiatric disorders	Depression	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1248 12481232	Immune system disorders	Food allergy	01JAN1988		Y
			Seasonal allergy	01JAN1988		Y
	C4591001 1248 12481235	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
	C4591001 1248 12481240	Psychiatric disorders	Bipolar disorder	15OCT2019		Y
			Depression	15OCT2019		Y
	C4591001 1248 12481243	Metabolism and nutrition disorders	Iron deficiency	22JUL2020		Y
	C4591001 1248 12481244	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1993		Y
	C4591001 1248 12481246	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Attention deficit hyperactivity disorder	01JAN2020		Y
			Gender dysphoria	01JAN2017		Y
	C4591001 1248 12481252	Social circumstances	Substance use	01JAN2000	30APR2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1248 12481253	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01APR2020		Y
	C4591001 1251 12511003	Gastrointestinal disorders	Anal prolapse	01DEC2019	31DEC2019	N
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN1997		Y
		Surgical and medical procedures	Anorectal operation	01DEC2019	31DEC2019	N
	C4591001 1251 12511005	Reproductive system and breast disorders	Endometriosis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Endometrial ablation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511007	Social circumstances	Tobacco user	01JAN2018		Y
	C4591001 1251 12511013	Immune system disorders	Drug hypersensitivity	(b) (6) 1971		Y
			Rubber sensitivity	(b) (6) 1971		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1251 12511016	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Sleep terror	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1251 12511021	Gastrointestinal disorders	Dyspepsia	05MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	07NOV2018		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Depression	04JUN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	14SEP2016		Y
	C4591001 1251 12511022	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN1999		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004		Y
				01JAN2008		Y
				01JAN2012		Y
				01JAN2016		Y
		Psychiatric disorders	Anxiety	01DEC2019		Y
			Depression	01AUG2019		Y
	C4591001 1251 12511025	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01DEC2019		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Reproductive system and breast disorders	Adenomyosis	01SEP2019	28SEP2020	N
	C4591001 1251 12511027	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Alopecia	01FEB2019		Y
	C4591001 1251 12511030	Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1251 12511031	Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1251 12511032	Nervous system disorders	Migraine	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	02APR2019	02APR2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				25JUN2016	25JUN2016	N
	C4591001 1251 12511033	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1251 12511037	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 1 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Mite allergy	(b) (6) 1967		Y
		Infections and infestations	Oral herpes	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Osteoarthritis	01JAN2001		Y
		Nervous system disorders	Migraine	01JAN2002		Y
	C4591001 1251 12511041	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Hiatus hernia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	27AUG2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
				01JAN2016		Y
			Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	27AUG2016		Y
			Psychotic disorder	01JAN2019		Y
			Schizophrenia	27AUG2012		Y
		Renal and urinary disorders	Hypertonic bladder	20AUG2013		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2014		Y
	C4591001 1251 12511044	Immune system disorders	Seasonal allergy	01JAN1984		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1993		Y
			Insomnia	01JAN1988		Y
			Nicotine dependence	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1251 12511045	Immune system disorders	Allergy to animal	01JAN1984		Y
			Drug hypersensitivity	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511046	Blood and lymphatic system disorders	Anaemia	01MAR2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Nervous system disorders	Headache	01JAN2018		Y
			Trigeminal neuralgia	01JAN2008		Y
		Psychiatric disorders	Alcohol abuse	01JAN1990	31DEC2012	N
			Depression	01JAN1997		Y
			Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Nerve block	01JAN2010	31DEC2010	N
	C4591001 1251 12511049	Social circumstances	Tobacco user	01JAN2004		Y
	C4591001 1251 12511059	Blood and lymphatic system disorders	Anaemia	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Food allergy	01JAN1996		Y
			Rubber sensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2020		Y
	C4591001 1251 12511060	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Haemorrhoids	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sinus headache	01JAN2000		Y
	C4591001 1251 12511061	Hepatobiliary disorders	Cholecystitis	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1251 12511065	Surgical and medical procedures	Cholecystectomy	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
				01JAN2008		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
			Fibromyalgia	01JAN2011		Y
			Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1251 12511066	Immune system disorders	Seasonal allergy	01JAN1997		Y
	C4591001 1251 12511068	Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1251 12511070	Immune system disorders	Drug hypersensitivity	(b) (6) 1994		Y
		Surgical and medical procedures	Strabismus correction	03JUL2020	03JUL2020	N
	C4591001 1251 12511074	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511075	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Psychiatric disorders	Anxiety disorder	01FEB2020		Y
			Depression	01JAN2010		Y
	C4591001 1251 12511077	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1251 12511079	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2001		Y
	C4591001 1251 12511081	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009		Y
			Osteoarthritis	01JAN2019		Y
		Social circumstances	Tobacco user	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1251 12511083	Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511089	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Rubber sensitivity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
	C4591001 1251 12511091	Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1251 12511093	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
	C4591001 1251 12511094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
			Depression	01JAN1994		Y
			Insomnia	01JAN2018		Y
	C4591001 1251 12511095	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
				01JAN1999		Y
				01JAN2002		Y
			Rubber sensitivity	01JAN2006		Y
		Infections and infestations	Sinusitis	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN1996		Y
		Social circumstances	Tobacco user	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01DEC2011	31DEC2011	N
			Female sterilisation	01SEP2017		Y
			Foot operation	01JAN2005	31DEC2005	N
	C4591001 1251 12511096	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1251 12511097	Cardiac disorders	Myocardial infarction	02FEB2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
			Sleep apnoea syndrome	01JAN2003		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2003		Y
			Gastrectomy	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1251 12511098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1251 12511099	Immune system disorders	Drug hypersensitivity	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
	C4591001 1251 12511101	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
	C4591001 1251 12511103	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
	C4591001 1251 12511104	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAR2003	31MAR2004	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1251 12511108	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1251 12511109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511112	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1251 12511113	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	01JAN1997	N
	C4591001 1251 12511114	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1251 12511115	Surgical and medical procedures	Female sterilisation	01JAN2018	01JAN2018	N
	C4591001 1251 12511121	Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1251 12511122	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1974		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511124	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
				01JAN2006		Y
		Psychiatric disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1251 12511127	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1251 12511128	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
	C4591001 1251 12511129	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
	C4591001 1251 12511130	Surgical and medical procedures	Cyst removal	16SEP2019	16SEP2019	N
			Hysterectomy	16SEP2019	16SEP2019	N
			Limb operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1251 12511131	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1251 12511135	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
	C4591001 1251 12511137	Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511138	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
			Depression	01JAN1995		Y
	C4591001 1251 12511139	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1251 12511141	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Genital herpes	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1251 12511143	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1251 12511146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
	C4591001 1251 12511147	Congenital, familial and genetic disorders	VACTERL syndrome	(b) (6) 1989		Y
	C4591001 1251 12511148	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	30NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1251 12511149	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
	C4591001 1251 12511153	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Essential tremor	01JAN1994		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2013		Y
	C4591001 1251 12511154	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2003		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2017	30JUN2020	N
		Surgical and medical procedures	Gastric bypass	01JAN2005		Y
			Hysterectomy	01JUN2020	30JUN2020	N
	C4591001 1251 12511155	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
	C4591001 1251 12511156	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1251 12511157	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511159	Social circumstances	Tobacco user	01JAN1999		Y
		Surgical and medical procedures	Female sterilisation	03JAN2018	03JAN2018	N
	C4591001 1251 12511161	Investigations	Human papilloma virus test positive	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1251 12511162	Gastrointestinal disorders	Constipation	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Fibromyalgia	01JAN2017		Y
			Osteoporosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1251 12511163	Gastrointestinal disorders	Dyspepsia	01MAY2020		Y
		Nervous system disorders	Migraine	01MAY2020		Y
		Surgical and medical procedures	Sinus operation	01MAY2005	01MAY2005	N
	C4591001 1251 12511165	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JAN2018	31JUL2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Chemotherapy	01JAN2018	31JUL2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511166	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
			Generalised anxiety disorder	01JAN2013		Y
	C4591001 1251 12511171	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Intervertebral disc protrusion	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
		Surgical and medical procedures	Nerve block	02JUN2020	02JUN2020	N
	C4591001 1251 12511173	Cardiac disorders	Supraventricular tachycardia	01JAN2016	31DEC2016	N
		Investigations	Aspiration breast	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2016	31DEC2016	N
			Endometrial ablation	01JAN2006	31DEC2006	N
			Urinary bladder suspension	01JAN2015	31DEC2015	N
	C4591001 1251 12511179	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1251 12511180	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1251 12511183	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1251 12511185	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1251 12511187	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
			Spinal stenosis	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1251 12511188	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Headache	01JAN1980		Y
			Migraine	01NOV2011		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01OCT2016	01OCT2016	N
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1251 12511194	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
	C4591001 1251 12511196	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1251 12511197	Immune system disorders	Seasonal allergy	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN2017		Y
			Tonsillectomy	01JAN1998	31DEC1998	N
	C4591001 1251 12511201	Metabolism and nutrition disorders	Lactose intolerance	08JUN2015		Y
	C4591001 1251 12511204	Gastrointestinal disorders	Colitis ulcerative	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01APR2016	30APR2016	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Mastectomy	01APR2016	31DEC2016	N
	C4591001 1251 12511205	Infections and infestations	Diverticulitis	01JUN2017		Y
		Surgical and medical procedures	Caesarean section	01MAR2020		Y
	C4591001 1251 12511207	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1251 12511208	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN1993		Y
		Surgical and medical procedures	Female sterilisation	01JAN2017	31DEC2017	N
	C4591001 1251 12511212	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1251 12511214	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2017		Y
			Seasonal allergy	02FEB2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1251 12511215	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
			Mammoplasty	01JAN1995	31DEC1995	N
	C4591001 1251 12511216	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Surgical and medical procedures	Nasal operation	01JAN2002	01JAN2002	N
			Vasectomy	08JUL2016	08JUL2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511217	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1996		Y
	C4591001 1251 12511218	Psychiatric disorders	Insomnia	01JAN2020		Y
	C4591001 1251 12511220	Gastrointestinal disorders	Substance abuse Toothache	01JAN2012	31OCT2018	N
	C4591001 1251 12511223	Metabolism and nutrition disorders	Iron deficiency	25SEP2020	25SEP2020	N
	C4591001 1251 12511226	Surgical and medical procedures	Caesarean section	01JAN2009	01JAN2012	Y
	C4591001 1251 12511226	Social circumstances	Tobacco user	01JAN2012	01JAN2012	N
	C4591001 1251 12511226	Surgical and medical procedures	Female sterilisation	01JAN2000		Y
	C4591001 1251 12511228	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
	C4591001 1251 12511228	Musculoskeletal and connective tissue disorders	Seasonal allergy Spinal osteoarthritis	01JAN1976		Y
	C4591001 1251 12511228	Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
	C4591001 1251 12511228	Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1251 12511228	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
	C4591001 1251 12511228	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1251 12511232	Social circumstances	Postmenopause	01JAN1992		Y
	C4591001 1251 12511232	Psychiatric disorders	Attention deficit hyperactivity disorder	01JUN2019		Y
	C4591001 1251 12511233	Surgical and medical procedures	Female sterilisation	01JAN2012		Y
	C4591001 1251 12511233	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1251 12511234	Reproductive system and breast disorders	Ovarian cyst	01JAN2010		Y
	C4591001 1251 12511234	Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1251 12511234	Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511239	Cardiac disorders	Cardiac failure congestive	01JAN2018		Y
		General disorders and administration site conditions	Chest pain	01AUG2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2018		Y
			Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	21NOV2014		Y
		Psychiatric disorders	Depression	01JAN2006		Y
			Schizophrenia	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511240	Psychiatric disorders	Schizophrenia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Surgical and medical procedures	Caesarean section	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511241	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1251 12511242	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
		General disorders and administration site conditions	Oedema	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2014	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01JAN2017		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01APR2016	01APR2016	N
			Gastric operation	01JAN2017	31DEC2017	N
			Ligament operation	01JAN1999	31DEC1999	N
				01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Metabolic surgery	01FEB2017	01FEB2017	N
	C4591001 1251 12511245	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2019		Y
	C4591001 1251 12511247	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
	C4591001 1251 12511256	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2016		Y
		Psychiatric disorders	Insomnia	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Surgical and medical procedures	Shoulder operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1251 12511259	Immune system disorders	Drug hypersensitivity	01JAN2001		Y
				01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Pregnancy, puerperium and perinatal conditions	Postpartum haemorrhage	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511262	Vascular disorders	Hypertension	01JAN2009		Y
		Cardiac disorders	Atrial fibrillation	01JAN2018		Y
	C4591001 1252 12521001	Infections and infestations	Hepatitis C	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01AUG2020		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Epilepsy	01APR2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Substance abuse	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Pregnancy, puerperium and perinatal conditions	Postpartum haemorrhage	01JAN2006	31DEC2006	N
	C4591001 1252 12521002	Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	04MAR2006	04MAR2006	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Hysterotomy	01JAN2006	31DEC2006	N
		Gastrointestinal disorders	Abdominal pain	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1252 12521004	Endocrine disorders	Hypothyroidism	11DEC2018		Y
		Infections and infestations	Perirectal abscess	12AUG2019	30SEP2019	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2019	31DEC2019	N
			Osteoarthritis	06SEP2019		Y
		Nervous system disorders	Migraine	11DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1252 12521016	Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1252 12521019	Gastrointestinal disorders	Colitis	11JUN2018	11JUN2018	N
		Infections and infestations	Ear infection	01JAN2013	31DEC2013	N
		Nervous system disorders	Headache	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Appendicectomy	29MAY2018	29MAY2018	N
			Colectomy	11JUN2018	11JUN2018	N
			Sinus operation	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1252 12521020	Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1252 12521021	Surgical and medical procedures	Caesarean section	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1252 12521023	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1252 12521024	Renal and urinary disorders	Nephrolithiasis	01JUN2020	30JUN2020	N
	C4591001 1252 12521029	Injury, poisoning and procedural complications	Femur fracture	01FEB1992	29FEB1992	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1252 12521034	Psychiatric disorders	Anxiety	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy bilateral	01JAN2019	31DEC2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1252 12521035	Psychiatric disorders	Anxiety	01JAN2006		Y
	C4591001 1252 12521036	Surgical and medical procedures	Wisdom teeth removal	01JAN2015	31DEC2015	N
	C4591001 1252 12521039	Gastrointestinal disorders	Colitis ulcerative	01JAN2009	31DEC2009	N
		Nervous system disorders	Facial nerve disorder	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	01JAN2012		Y
		Surgical and medical procedures	Colectomy total	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Sinus operation	01JAN2012	31DEC2012	N
	C4591001 1252 12521041	Gastrointestinal disorders	Gastroesophageal reflux disease	04MAY2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	15MAY2020	15MAY2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1254 12541005	Eye disorders	Astigmatism	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2017	31DEC2017	N
	C4591001 1254 12541007	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1254 12541008	Psychiatric disorders	Alcohol abuse	01JAN2001	01AUG2019	N
			Drug abuse	01JAN2001	01AUG2019	N
			Insomnia	01AUG2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Knee operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1254 12541020	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1254 12541023	Ear and labyrinth disorders	Deafness	01JAN1997		Y
			Tympanic membrane perforation	01JAN1997		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2014		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2011	31DEC2011	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	05AUG2020	15AUG2020	N
				15AUG2020	30NOV2020	N
			Morning sickness	01JUL2020	31DEC2020	N
		Psychiatric disorders	Bipolar disorder	01JAN1997		Y
			Schizophrenia	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Fracture treatment	01JAN2011	31DEC2011	N
			Uterine dilation and curettage	15AUG2020	15AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541027	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN2000	31DEC2005	N
		Surgical and medical procedures	Lymphadenectomy	01FEB2000	29FEB2000	N
	C4591001 1254 12541029	Eye disorders	Myopia	01JAN1978		Y
				01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Psychiatric disorders	Bipolar disorder	01JAN1994		Y
	C4591001 1254 12541030	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Meningitis viral	01JUN2016	31JUL2016	N
		Injury, poisoning and procedural complications	Clavicle fracture	01NOV2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011	31DEC2016	N
		Surgical and medical procedures	Bone operation	01DEC2011	31DEC2011	N
	C4591001 1254 12541031	Eye disorders	Myopia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2019		Y
	C4591001 1254 12541032	Eye disorders	Myopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1254 12541033	Ear and labyrinth disorders	Deafness	01JAN2002	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	07DEC2006	07DEC2006	N
				22JUL2005	22JUL2005	N
			Stapedectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01FEB2019	30JUN2020	N
	C4591001 1254 12541034	Eye disorders	Myopia	01JAN2018		Y
		Injury, poisoning and procedural complications	Foot fracture	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541035	Immune system disorders	Seasonal allergy	01JAN2005		Y
	C4591001 1254 12541036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1987		Y
				01JAN2014		Y
			Seasonal allergy	01DEC1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2016	30SEP2018	N
			Symphysiolysis	01DEC2016	31DEC2018	N
			Temporomandibular joint syndrome	01JAN2008		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2018	28FEB2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
	C4591001 1254 12541039	Eye disorders	Presbyopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Obsessive-compulsive personality disorder	01JAN1984		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
			Open reduction of fracture	01JAN2013	31DEC2013	N
	C4591001 1254 12541040	Eye disorders	Myopia	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1254 12541041	Congenital, familial and genetic disorders	Craniosynostosis	(b) (6) 1994		Y
		Eye disorders	Myopia	01JAN1995		Y
			Strabismus	(b) (6) 1994	31DEC1996	N
		Infections and infestations	Urinary tract infection	01JAN2012	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Cranial operation	01JAN1996	31DEC1996	N
			Strabismus correction	01JAN2005	31DEC2005	N
	C4591001 1254 12541042	Eye disorders	Myopia	01JAN1980		Y
	C4591001 1254 12541044	Eye disorders	Myopia	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541046	Eye disorders	Myopia	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1254 12541049	Eye disorders	Myopia	01JAN2019		Y
	C4591001 1254 12541050	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1983	31DEC1983	N
		Eye disorders	Myopia	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Synovial sarcoma	01JAN2007	31DEC2017	N
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			Pyloroplasty	01JAN1983	31DEC1983	N
			Sarcoma excision	01JAN2017	31DEC2017	N
	C4591001 1254 12541051	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
		Surgical and medical procedures	Fracture treatment	01JAN2009	31DEC2009	N
	C4591001 1254 12541052	Eye disorders	Myopia	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nervous system neoplasm benign	01JAN2014	31DEC2014	N
		Nervous system disorders	Hydrocephalus	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1992		Y
			Insomnia	01JAN1990		Y
	C4591001 1254 12541053	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	15JUL2020		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	05FEB2012	05FEB2012	N
				24OCT2008	24OCT2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1254 12541054	Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2004		Y
			Alopecia	01JAN2017		Y
			Hand dermatitis	01JAN2015		Y
	C4591001 1254 12541055	Injury, poisoning and procedural complications	Road traffic accident	01APR2003	30APR2003	N
			Skin laceration	01APR2003	30APR2003	N
				01OCT2011	31OCT2011	N
			Skull fracture	01OCT2011	31OCT2011	N
		Psychiatric disorders	Schizophrenia	01JAN2005		Y
		Surgical and medical procedures	Skull fracture treatment	01OCT2011	31OCT2011	N
			Wound closure	01APR2003	30APR2003	N
				01OCT2011	31OCT2011	N
	C4591001 1254 12541056	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Allergy to chemicals	01APR2020		Y
	C4591001 1254 12541057	Gastrointestinal disorders	Dyspepsia	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541058	Eye disorders	Presbyopia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1254 12541061	Ear and labyrinth disorders	Vertigo positional	01JAN2005		Y
		Eye disorders	Myopia	01JAN1983		Y
		Immune system disorders	Allergy to animal	01JAN1995		Y
		Infections and infestations	Pleurisy viral	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2013	31DEC2013	N
			Ulna fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1254 12541062	Eye disorders	Myopia	01JAN1985		Y
			Presbyopia	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Lipoma excision	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1254 12541063	Eye disorders	Myopia	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2009		Y
			Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Mastectomy	01JAN2008	31DEC2008	N
	C4591001 1254 12541064	Injury, poisoning and procedural complications	Tendon rupture	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tenoplasty	01JAN2014	31DEC2014	N
	C4591001 1254 12541066	Eye disorders	Presbyopia	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Endometrial hyperplasia	01JUL2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hot flush	01JAN2019		Y
			Hypertension	01JAN2019		Y
	C4591001 1254 12541067	Eye disorders	Myopia	01JAN1996	31DEC2014	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1994		Y
		Surgical and medical procedures	Keratomileusis	01JAN2014	31DEC2014	N
	C4591001 1254 12541068	Eye disorders	Myopia	01JAN2017		Y
		Injury, poisoning and procedural complications	Limb injury	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Panic disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN2015		Y
	C4591001 1254 12541069	Surgical and medical procedures	Tonsillectomy	01JAN1980	31DEC1980	N
		Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	(b) (6) 1999		Y
		Eye disorders	Myopia	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013	31DEC2017	N
			Androgenetic alopecia	01JAN2015		Y
	C4591001 1254 12541071	Immune system disorders	Drug hypersensitivity	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
			Hypercholesterolaemia	01JAN2014		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31JAN2002	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1254 12541072	Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Surgical and medical procedures	Mammoplasty	01JAN2013	31DEC2013	N
	C4591001 1254 12541073	Cardiac disorders	Arteriosclerosis coronary artery	01DEC2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990	31DEC1990	N
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1254 12541075	Immune system disorders	Drug hypersensitivity	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Perinatal depression	01JAN2002	31DEC2003	N
		Surgical and medical procedures	Ankle operation	01JAN2018	31DEC2018	N
			Caesarean section	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1254 12541077	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2008		Y
		Surgical and medical procedures	Fracture treatment	01JAN2017	31DEC2017	N
	C4591001 1254 12541079	Immune system disorders	Seasonal allergy	01JAN1978		Y
	C4591001 1254 12541080	Eye disorders	Myopia	01JAN1977		Y
			Vitreous detachment	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541081	Eye disorders	Myopia	01JAN2005		Y
		Psychiatric disorders	Depression	01JUL2020		Y
	C4591001 1254 12541082	Injury, poisoning and procedural complications	Ligament rupture	01JAN1999	31DEC2015	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2000	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
			Urinary bladder suspension	01JAN2015	31DEC2015	N
		Vascular disorders	White coat hypertension	01JAN2000		Y
	C4591001 1254 12541083	Eye disorders	Myopia	01JAN1974		Y
		Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Iron deficiency	01JAN2015		Y
			Obesity	01JAN1979		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1985	31DEC2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
			Endometrial ablation	01JAN2019	31DEC2019	N
			Gastric bypass	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541084	Eye disorders	Myopia	01JAN1981		Y
		Gastrointestinal disorders	Gastrointestinal disorder	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541087	Surgical and medical procedures	Keratomileusis	01JAN2002	31DEC2002	N
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1254 12541089	Surgical and medical procedures	Debridement	01JAN2017	31DEC2017	N
			Intervertebral disc operation	01JAN1991	31DEC1991	N
			Ligament operation	01JAN1993	31DEC1993	N
	C4591001 1254 12541090	Cardiac disorders	Atrial fibrillation	01JAN1992		Y
		Eye disorders	Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1254 12541094	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01NOV2019		Y
			Pancreatitis acute	01JUL2019	30NOV2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Plantar fasciitis	01JAN2007	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma of spleen	01JAN1997	31DEC1998	N
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2016	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Splenectomy	01JAN1998	31DEC1998	N
			Tenotomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541099	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2004		Y
	C4591001 1254 12541100	Eye disorders	Myopia	01JAN1988		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1984	31DEC1984	N
	C4591001 1254 12541101	Blood and lymphatic system disorders	Anaemia	01APR2020		Y
		Eye disorders	Myopia	01JAN1985		Y
			Presbyopia	01JAN1977		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01DEC2019		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Surgical and medical procedures	Gastric bypass	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1254 12541102	Eye disorders	Myopia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541104	Injury, poisoning and procedural complications	Ligament sprain	01JAN2010	31DEC2019	N
	C4591001 1254 12541105	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1254 12541107	Eye disorders	Myopia	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1254 12541109	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Urinary tract infection	01OCT2019	31OCT2019	N
		Investigations	Biopsy breast	01SEP2019	30SEP2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasm	01SEP2019	30SEP2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1254 12541110	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Renal and urinary disorders	Nephrotic syndrome	01JAN1981	31DEC1986	N
	C4591001 1254 12541111	Eye disorders	Myopia	01JAN2018		Y
			Presbyopia	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1254 12541112	Eye disorders	Glaucoma	01JAN2017		Y
			Myopia	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1254 12541113	Eye disorders	Myopia	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2015	N
	C4591001 1254 12541114	Eye disorders	Myopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	20NOV2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Intracranial pressure increased	01JAN2012	31DEC2019	N
		Surgical and medical procedures	Gastrectomy	01NOV2019	30NOV2019	N
	C4591001 1254 12541115	Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1254 12541116	Eye disorders	Presbyopia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31JAN2019	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2019	31JAN2019	N
	C4591001 1254 12541117	Eye disorders	Astigmatism	01JAN2007	31AUG2019	N
			Myopia	01JAN2007	31AUG2019	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Genital herpes	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Keratomileusis	01AUG2019	31AUG2019	N
	C4591001 1254 12541119	Infections and infestations	Pneumonia	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Concussion	01AUG2019	30SEP2019	N
					31JAN2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2017	N
		Nervous system disorders	Radiculopathy	01JAN2015	31DEC2015	N
			Syncope	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2005		Y
		Surgical and medical procedures	Spinal fusion surgery	05JUN2015	05JUN2015	N
	C4591001 1254 12541120	Eye disorders	Myopia	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Removal of foreign body from rectum	01JAN2002	31DEC2002	N
	C4591001 1254 12541121	Eye disorders	Myopia	01JAN2007		Y
		Gastrointestinal disorders	Gastritis	01JAN2013		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2015	31DEC2015	N
	C4591001 1254 12541123	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1990		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2013	31DEC2013	N
	C4591001 1254 12541124	Infections and infestations	Rhinitis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1990		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1995	31DEC1995	N
			Turbinectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1254 12541126	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31DEC2015	N
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
			Jaw operation	01JAN2016	31DEC2016	N
	C4591001 1254 12541131	Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1254 12541133	Immune system disorders	Food allergy	01JAN2018		Y
	C4591001 1254 12541134	Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	06APR2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Nasal operation	07APR2015	07APR2015	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1254 12541135	Metabolism and nutrition disorders	Hypoglycaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1254 12541139	Injury, poisoning and procedural complications	Limb injury	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Finger repair operation	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541140	Eye disorders	Presbyopia	01JAN2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2009	31DEC2009	N
	C4591001 1254 12541142	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2016	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1254 12541144	Eye disorders	Presbyopia	01JAN1991		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2005		Y
			Nausea	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Ear infection	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2012		Y
			Spondylitis	01JAN2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
			Depression	01JAN2002		Y
		Surgical and medical procedures	Ear tube insertion	01NOV2019	30NOV2019	N
			Foot operation	01APR2019	30APR2019	N
			Tympanoplasty	01JAN1991	31DEC1991	N
	C4591001 1254 12541145	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2012	N
		Injury, poisoning and procedural complications	Joint injury	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01DEC2012	31DEC2012	N
			Knee operation	01JAN1989	31DEC1989	N
	C4591001 1254 12541147	Ear and labyrinth disorders	Deafness	01AUG2020		Y
			Ear pain	14AUG2020	26SEP2020	N
		Eye disorders	Myopia	01JAN1996		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
	C4591001 1254 12541148	Surgical and medical procedures	Wisdom teeth removal	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Psychiatric disorders	Insomnia	01AUG2020		Y
		Reproductive system and breast disorders	Premenstrual syndrome	01JAN1995		Y
	C4591001 1254 12541150	Hepatobiliary disorders	Hepatic steatosis	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1989		Y
		Social circumstances	Tobacco user	01JAN2000		Y
	C4591001 1254 12541151	Surgical and medical procedures	Foot operation	01JAN2006	31DEC2006	N
		Ear and labyrinth disorders	Ear pain	01JAN2002	31DEC2002	N
	C4591001 1254 12541153	Surgical and medical procedures	Ear operation	01JAN2002	31DEC2002	N
		Cardiac disorders	Palpitations	01MAR2020		Y
		Nervous system disorders	Cerebral cyst	01MAR2020		Y
			Migraine	01MAR2020		Y
	C4591001 1254 12541154	Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
	C4591001 1254 12541155	Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2008	31DEC2008	N
	C4591001 1254 12541157	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Gastric bypass	01JAN2006	31DEC2006	N
	C4591001 1254 12541158	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
	C4591001 1254 12541162	Eye disorders	Myopia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01SEP2019		Y
		Injury, poisoning and procedural complications	Arterial injury	13SEP2019	14SEP2019	N
			Muscle injury	13SEP2019	14SEP2019	N
			Peripheral nerve injury	14SEP2019	14SEP2019	N
			Ulnar nerve injury	13SEP2019	14SEP2019	N
		Psychiatric disorders	Alcoholism	01JAN2006	17AUG2020	N
			Anxiety	01JAN2014		Y
			Panic attack	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Pneumonitis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Muscle operation	14SEP2019	14SEP2019	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541163	Eye disorders	Myopia	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JUL2020		Y
	C4591001 1254 12541164	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2013	31DEC2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1254 12541165	Immune system disorders	Seasonal allergy	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1254 12541167	Eye disorders	Myopia	01JAN2007		Y
		Injury, poisoning and procedural complications	Penis injury	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Surgical and medical procedures	Circumcision	01JAN2016	31DEC2016	N
		Vascular disorders	Orthostatic hypotension	01JAN2018		Y
	C4591001 1254 12541168†	Eye disorders	Myopia	01JAN2002		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Infections and infestations	Appendicitis	01FEB2019	28FEB2019	N
		Investigations	HIV test positive	23FEB2020		Y
		Surgical and medical procedures	Appendicectomy	01FEB2019	28FEB2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541169	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2005		Y
	C4591001 1254 12541170	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2003	31DEC2003	N
		Congenital, familial and genetic disorders	Schmid Fraccaro syndrome	(b) (6) 1966		Y
		Eye disorders	Myopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2004	31DEC2004	N
				01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
			Stress urinary incontinence	01JAN2011	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Bunion operation	01JAN2004	31DEC2004	N
			Caesarean section	05OCT1986	05OCT1986	N
			Mass excision	01JAN2003	31DEC2003	N
			Urethral operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541171	Eye disorders	Myopia	01JAN2019		Y
		Gastrointestinal disorders	Malocclusion	01JAN2013	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN2011		Y
			Seasonal allergy	01JAN2011		Y
		Surgical and medical procedures	Jaw operation	01JAN2015	31DEC2015	N
	C4591001 1254 12541173	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Temporomandibular joint syndrome	01JAN2018		Y
	C4591001 1254 12541174	Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1254 12541175	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1254 12541176	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1254 12541180	Gastrointestinal disorders	Malocclusion	01JAN1998	31DEC2001	N
		Metabolism and nutrition disorders	Gout	11SEP2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Plastic surgery to the face	01JAN2001	31DEC2001	N
	C4591001 1254 12541181	Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1254 12541182	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01FEB2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1254 12541183	Eye disorders	Myopia	01JAN1994		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Immune system disorders	Allergy to arthropod sting	01JAN1991		Y
			Food allergy	01JAN1995		Y
		Infections and infestations	Hepatitis A	01JAN2005	31DEC2005	N
		Investigations	Blood pressure increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1254 12541184	Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2015		Y
	C4591001 1254 12541185	Blood and lymphatic system disorders	Anaemia	01JAN2018	31OCT2019	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2008	N
			Pollakiuria	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2016		Y
			Oligomenorrhoea	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Polycystic ovaries	01JAN2003		Y
		Surgical and medical procedures	Lipoma excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008	31DEC2016	N
	C4591001 1254 12541187	Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31MAR2016	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Hysterectomy	01MAR2016	31MAR2016	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1254 12541189	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y
		Infections and infestations	Eye infection	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2019		Y
	C4591001 1254 12541190	Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1254 12541193	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Prostatitis	01JAN2014	31DEC2015	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541194	Immune system disorders	Allergy to animal	01JAN2002		Y
			Dust allergy	01JAN2002		Y
		Infections and infestations	Urinary tract infection	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018		Y
				01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
			Intervertebral disc degeneration	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Attention deficit hyperactivity disorder	01JAN2001		Y
			Bipolar II disorder	01JAN2001		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2002	31DEC2002	N
			Meniscus operation	01JAN2019	31DEC2019	N
	C4591001 1254 12541199	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2013	31DEC2013	N
	C4591001 1254 12541202	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Spinal cord disorder	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Female sterilisation	13JUL2013	13JUL2013	N
			Spinal cord operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1254 12541204	Eye disorders	Amblyopia	01JAN2003	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2000		Y
		Nervous system disorders	Hypersomnia	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2008		Y
			Generalised anxiety disorder	01JAN2008		Y
		Surgical and medical procedures	Amblyopia therapy	01JAN2003	31DEC2003	N
	C4591001 1254 12541208	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1254 12541210	Injury, poisoning and procedural complications	Ligament rupture	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1254 12541211	Congenital, familial and genetic disorders	Thalassaemia minor	(b) (6) 1985		Y
	C4591001 1258 12581001	Psychiatric disorders	Major depression	14AUG2011	10SEP2015	N
	C4591001 1258 12581002	Gastrointestinal disorders	Gastroesophageal reflux disease	13APR2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2014		Y
			Obesity	18JUN2014		Y
			Type 1 diabetes mellitus	01JAN1990		Y
			Vitamin D deficiency	01MAY2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1995		Y
				06NOV2017		Y
			Spinal osteoarthritis	31JUL2018		Y
			Spinal pain	01JAN1998		Y
		Nervous system disorders	Neuralgia	17MAR2016		Y
			Neuropathy peripheral	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Major depression	15OCT2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1258 12581007	Musculoskeletal and connective tissue disorders	Pain in extremity	20AUG2020		Y
		Psychiatric disorders	Alcohol abuse	22APR2007	22APR2007	N
			Drug abuse	22APR2007	22APR2007	N
	C4591001 1258 12581008	Cardiac disorders	Myocardial infarction	24NOV2016	24NOV2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	23JAN2015		Y
		Infections and infestations	Respiratory tract infection	17AUG2020	17AUG2020	N
		Musculoskeletal and connective tissue disorders	Back pain	14OCT2014		Y
			Pain in extremity	24OCT2014		Y
			Spinal stenosis	10NOV2014		Y
		Psychiatric disorders	Anxiety	10NOV2014		Y
		Vascular disorders	Hypertension	10APR2015		Y
	C4591001 1258 12581013	Endocrine disorders	Hypothyroidism	01SEP2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	23JUL2015		Y
		Metabolism and nutrition disorders	Obesity	20OCT2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	16AUG2010		Y
		Nervous system disorders	Carpal tunnel syndrome	21MAY2012		Y
			Headache	13JUL2011		Y
			Seizure	18JUN2016		Y
		Psychiatric disorders	Anxiety	21SEP2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20AUG2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	05JUN2013		Y
	C4591001 1258 12581014	Congenital, familial and genetic disorders	Type V hyperlipidaemia	08JUN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	27OCT2014		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	06JUL2017		Y
	C4591001 1258 12581016	Respiratory, thoracic and mediastinal disorders	Asthma	15FEB2018		Y
	C4591001 1258 12581018	Hepatobiliary disorders	Cholecystitis	16JUN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01OCT2013		Y
		Vascular disorders	Hypertension	29DEC2016		Y
	C4591001 1258 12581026	Cardiac disorders	Pulmonary valve incompetence	19JAN2017		Y
		Social circumstances	Substance use	01JAN2015	03FEB2017	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1258 12581027	Psychiatric disorders	Bipolar disorder	13MAY2013		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	08APR2020		Y
	C4591001 1258 12581033	Psychiatric disorders	Anxiety	15SEP2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	03MAY2010		Y
	C4591001 1258 12581035	Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
	C4591001 1258 12581043	Nervous system disorders	Carpal tunnel syndrome	07MAR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	03MAY2017		Y
	C4591001 1258 12581044	Musculoskeletal and connective tissue disorders	Arthralgia	13APR2013		Y
		Psychiatric disorders	Depression	13APR2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03MAR2014		Y
			Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	17FEB2019	17FEB2019	N
		Vascular disorders	Hypertension	24MAR2010		Y
	C4591001 1258 12581045	Nervous system disorders	Seizure	18OCT2015	18OCT2015	N
	C4591001 1258 12581046	Cardiac disorders	Coronary artery disease	20OCT2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	20SEP2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	20FEB2013		Y
			Obesity	10SEP2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	17AUG2015		Y
			Rotator cuff syndrome	13MAY2010		Y
			Scoliosis	28MAR2016		Y
		Psychiatric disorders	Anxiety	17JUL2013		Y
			Depression	09AUG2016		Y
			Insomnia	19DEC2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	17APR2013		Y
			Rhinitis allergic	08SEP2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	20FEB2013		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1258 12581048	Cardiac disorders	Cardiac failure congestive	10JUN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10APR2015		Y
		Musculoskeletal and connective tissue disorders	Obesity	10JUN2014		Y
			Arthralgia	11JAN2014		Y
			Back pain	11JUN2014		Y
			Fibromyalgia	10JUN2014		Y
			Rheumatoid arthritis	10JUN2014		Y
		Psychiatric disorders	Anxiety	10JUN2014		Y
			Depression	10JUN2014		Y
		Renal and urinary disorders	Hypertonic bladder	10JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06JUL2015		Y
			Rhinitis allergic	01JAN1980		Y
		Vascular disorders	Hypertension	18JAN2007		Y
	C4591001 1258 12581050	Metabolism and nutrition disorders	Obesity	19JUL2019		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	07DEC2015		Y
		Nervous system disorders	Lumbar radiculopathy	21JUL2020		Y
		Psychiatric disorders	Depression	07DEC2015		Y
		Vascular disorders	Hypertension	14SEP2005		Y
	C4591001 1258 12581053	Musculoskeletal and connective tissue disorders	Arthralgia	23FEB2017		Y
	C4591001 1258 12581054	Endocrine disorders	Hypothyroidism	14NOV2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	03JUN2015		Y
		Metabolism and nutrition disorders	Obesity	23OCT2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	30AUG2013		Y
			Back pain	18JUN2004		Y
			Osteoarthritis	24APR2003		Y
		Psychiatric disorders	Anxiety	23OCT2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	10JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	03JUN2015		Y
	C4591001 1258 12581055	Injury, poisoning and procedural complications	Muscle strain	23SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30APR2007		Y
	C4591001 1258 12581058	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1258 12581060	Surgical and medical procedures	Female sterilisation	13JAN2017	13JAN2017	N
	C4591001 1258 12581062	Gastrointestinal disorders	Irritable bowel syndrome	26NOV2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	30JAN2014		Y
			Obesity	14MAR2013		Y
			Type 2 diabetes mellitus	05MAR2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	21MAY2015		Y
		Psychiatric disorders	Anxiety	08MAY2015		Y
			Schizoaffective disorder	18MAR2009		Y
		Renal and urinary disorders	Hypertonic bladder	20MAY2014		Y
		Vascular disorders	Hypertension	05MAR2013		Y
	C4591001 1258 12581064	Blood and lymphatic system disorders	Anaemia	07NOV2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	06OCT2016		Y
			Back pain	06OCT2016		Y
			Osteoarthritis	19MAY2020		Y
		Nervous system disorders	Transient ischaemic attack	04MAR2017	04MAR2017	N
		Vascular disorders	Hypertension	06OCT2016		Y
	C4591001 1258 12581065	Immune system disorders	Seasonal allergy	01JAN2009		Y
	C4591001 1258 12581066	Musculoskeletal and connective tissue disorders	Back pain	28JAN2020		Y
		Nervous system disorders	Paraesthesia	06MAR2019		Y
	C4591001 1258 12581070	Vascular disorders	Hypertension	09DEC2019		Y
	C4591001 1258 12581074	Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1258 12581075	Psychiatric disorders	Schizophrenia	01JAN2011		Y
	C4591001 1260 12601001	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1260 12601002	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01SEP2010	30SEP2010	N
		Nervous system disorders	Migraine	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Breast conserving surgery	01SEP2010	30SEP2010	N
	C4591001 1260 12601004	Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
	C4591001 1260 12601006	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2019		Y
	C4591001 1260 12601007	Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1260 12601010	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
	C4591001 1260 12601013	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1260 12601014	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1260 12601016	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1260 12601023	Musculoskeletal and connective tissue disorders	Compartment syndrome	01JAN2013	31JAN2013	N
		Nervous system disorders	Migraine with aura	01JAN2005		Y
	C4591001 1260 12601024	Cardiac disorders	Atrial fibrillation	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1260 12601034	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Depression	01JAN2012		Y
	C4591001 1260 12601036	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1260 12601045	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1260 12601048	Surgical and medical procedures	Adenoidectomy	01JAN1988	31DEC1988	N
	C4591001 1260 12601049	Gastrointestinal disorders	Colitis ulcerative	01JAN2017		Y
		Vascular disorders	Hypertension	02SEP2020		Y
	C4591001 1260 12601050	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1260 12601055	Social circumstances	Postmenopause	13JUN2016		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
	C4591001 1260 12601063	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1260 12601065	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	27JAN2020		Y
	C4591001 1260 12601067	Immune system disorders	Food allergy	01JAN2016		Y
	C4591001 1260 12601068	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
	C4591001 1260 12601070	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1260 12601074	Immune system disorders	Food allergy	01JAN2016		Y
			Seasonal allergy	01APR2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Nervous system disorders	Tension headache	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1260 12601075	Immune system disorders	Drug hypersensitivity	13FEB2018		Y
		Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2015		Y
	C4591001 1260 12601076	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
	C4591001 1260 12601077	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1260 12601082	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1260 12601084	Psychiatric disorders	Anxiety	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1260 12601091	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1260 12601092	Renal and urinary disorders	Nephrolithiasis	01FEB2020	29FEB2020	N
	C4591001 1260 12601100	Surgical and medical procedures	Salpingectomy	01JAN1999	31DEC1999	N
	C4591001 1260 12601104	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Surgical and medical procedures	Urinary bladder suspension	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1260 12601106	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2007	31DEC2007	N
	C4591001 1260 12601107	Musculoskeletal and connective tissue disorders	Spondylitis	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01FEB2020		Y
	C4591001 1260 12601108	Endocrine disorders	Basedow's disease	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2000	31DEC2000	N
	C4591001 1260 12601111	Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1260 12601112	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN1985		Y
	C4591001 1260 12601114	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
	C4591001 1260 12601115	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1260 12601117	Metabolism and nutrition disorders	Hypercholesterolaemia	02FEB2018		Y
	C4591001 1260 12601118	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1260 12601119	Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1260 12601123	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1260 12601125	Congenital, familial and genetic disorders	Type V hyperlipidaemia	28SEP2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	24NOV2017		Y
		Vascular disorders	Hypertension	28SEP2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1260 12601126	Psychiatric disorders	Sleep disorder	01JAN2014		Y
	C4591001 1260 12601127	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
			Hyperlipidaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1260 12601129	Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1260 12601130	Congenital, familial and genetic disorders	Ataxia telangiectasia	16JUN2017		Y
			Hereditary pancreatitis	21JUL2018		Y
		Psychiatric disorders	Anxiety	02OCT2015		Y
		Social circumstances	Familial risk factor	21JUL2018		Y
	C4591001 1261 12611001	Congenital, familial and genetic disorders	Thalassaemia	01JAN1971		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978	15JUN1989	N
	C4591001 1261 12611002	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Surgical and medical procedures	Fracture treatment	01JAN2009	31DEC2009	N
	C4591001 1261 12611005	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Surgical and medical procedures	Ligament operation	01JAN2012	31DEC2012	N
	C4591001 1261 12611006	Skin and subcutaneous tissue disorders	Drug eruption	15JUN2017		Y
		Surgical and medical procedures	Hydrocele operation	15JUN2009	15JUN2009	N
			Vasectomy	15JUN2013	15JUN2013	N
	C4591001 1261 12611007	Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1261 12611008	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Urinary tract infection	01JAN2010		Y
		Renal and urinary disorders	Micturition urgency	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	05JAN2010	05JAN2010	N
				20JAN2007	20JAN2007	N
			Tonsillectomy	15NOV1986	15NOV1986	N
		Vascular disorders	Hypertension	15MAR2010		Y
	C4591001 1261 12611009	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Ligament operation	01JAN2012	31DEC2012	N
			Limb operation	01SEP2017	30SEP2017	N
			Scar excision	01APR2018	30APR2018	N
	C4591001 1261 12611010	Surgical and medical procedures	Ankle operation	01JAN1985	31DEC1985	N
			Fracture treatment	01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N
			Ligament operation	15MAY2007	15MAY2007	N
			Peripheral nerve operation	15MAR2010	15MAR2010	N
	C4591001 1261 12611011	Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	28SEP2009	28SEP2009	N
	C4591001 1261 12611013	Congenital, familial and genetic disorders	Gene mutation	15MAY2017	15MAY2017	N
		Ear and labyrinth disorders	Hypoacusis	15OCT2011		Y
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Psychiatric disorders	Bipolar disorder	01JAN1993		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2018	31JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mastectomy	15MAY2017	15MAY2017	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
	C4591001 1261 12611016	Immune system disorders	Seasonal allergy	01JAN1984		Y
		Nervous system disorders	Sinus headache	01JAN1984		Y
	C4591001 1261 12611017	Nervous system disorders	Essential tremor	01JAN1993		Y
	C4591001 1261 12611020	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2005		Y
	C4591001 1261 12611023	Musculoskeletal and connective tissue disorders	Plantar fasciitis	01MAR2019		Y
	C4591001 1261 12611024	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2004		Y
	C4591001 1261 12611027	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	21JUN1991		Y
	C4591001 1261 12611029	Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hirsutism	01JAN2010		Y
	C4591001 1261 12611030	Musculoskeletal and connective tissue disorders	Juvenile idiopathic arthritis	01JAN1997	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1261 12611031	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1261 12611032	Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1261 12611034	Psychiatric disorders	Anxiety	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1261 12611035	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2020		Y
	C4591001 1261 12611038	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Nervous system disorders	Headache	01JAN1982		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2020	29FEB2020	N
	C4591001 1261 12611039	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 1261 12611041	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN2016		Y
	C4591001 1261 12611042	Immune system disorders	Hypersensitivity	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1261 12611046	Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
	C4591001 1261 12611047	Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1261 12611049	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN2017		Y
	C4591001 1261 12611050	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1261 12611051	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1261 12611052	Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1261 12611053	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1261 12611056	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
	C4591001 1261 12611057	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
	C4591001 1261 12611058	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1261 12611059	Blood and lymphatic system disorders	Mast cell activation syndrome	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	29JUN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	29JUN2015		Y
		Renal and urinary disorders	Vesicoureteric reflux	01JAN1980		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01JAN1998	31DEC1998	N
	C4591001 1261 12611060	Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
	C4591001 1261 12611062	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1261 12611063	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1261 12611070	Gastrointestinal disorders	Aphthous ulcer	01JAN2019		Y
	C4591001 1261 12611071	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1264 12641001	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1264 12641002	Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1264 12641004	Blood and lymphatic system disorders	Anaemia	01JAN2006		Y
		Immune system disorders	Allergy to animal	01JAN1992		Y
			Food allergy	01JAN1992		Y
				01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641005	Immune system disorders	Seasonal allergy	01JAN1971		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1976	31DEC1990	N
	C4591001 1264 12641006	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1995		Y
	C4591001 1264 12641008	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1264 12641009	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	24JUN2020	24JUN2020	N
	C4591001 1264 12641011	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Skin and subcutaneous tissue disorders	Eczema	01FEB2020		Y
			Idiopathic urticaria	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Dental implantation	01JAN2019	31DEC2019	N
			Intrauterine contraception	01JAN2018		Y
			Tooth extraction	01JAN2019	31DEC2019	N
	C4591001 1264 12641012	Immune system disorders	Allergy to surgical sutures	01JAN1980		Y
			Drug hypersensitivity	01JAN1971		Y
				01JAN1974		Y
				01JAN1979		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1980		Y
				01JAN1986		Y
				01JAN1999		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1264 12641013	Immune system disorders	Seasonal allergy	01JAN1975		Y
	C4591001 1264 12641014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1979		Y
			Seasonal allergy	01JAN2008		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	01JAN2014	31DEC2014	N
		Psychiatric disorders	Performance fear	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1264 12641015	Psychiatric disorders	Anxiety	01MAY2020		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1998		Y
				01JAN2018		Y
	C4591001 1264 12641017	Immune system disorders	Food allergy	01JAN2005		Y
				01JAN2007		Y
			Rubber sensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2015	31DEC2016	N
			Pregnancy	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641020	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Foot operation	27AUG2018	27AUG2018	N
			Hernia repair	01JAN2013	31DEC2013	N
			Knee operation	01JUN2012	30JUN2012	N
			Shoulder operation	29AUG2017	29AUG2017	N
			Tendon sheath incision	01APR2017	30APR2017	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1264 12641021	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN2012		Y
	C4591001 1264 12641022	Immune system disorders	Allergy to animal	01JAN1985		Y
			Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN1985		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1264 12641023	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1264 12641024	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1264 12641025	Congenital, familial and genetic disorders	Protein S deficiency	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1264 12641026	Surgical and medical procedures	Wisdom teeth removal	01JAN2007	31DEC2007	N
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1264 12641028	Immune system disorders	Sleep apnoea syndrome	01JAN2017		Y
			Seasonal allergy	01JAN1988		Y
		Surgical and medical procedures	Mole excision	01JAN2020	31JAN2020	N
			Wisdom teeth removal	01JAN1999	31DEC1999	N
	C4591001 1264 12641029	Immune system disorders	Allergy to metals	01JAN2000		Y
	C4591001 1264 12641032	Musculoskeletal and connective tissue disorders	Seasonal allergy	01JAN1990		Y
			Back pain	01JAN2015		Y
	C4591001 1264 12641033	Gastrointestinal disorders	Colitis ulcerative	01JAN2004		Y
		Infections and infestations	Osteomyelitis	01JAN1967	31DEC1967	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
	C4591001 1264 12641034	Infections and infestations	Appendicitis perforated	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01AUG2016		Y
			Depression	01AUG2016		Y
	C4591001 1264 12641035	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980	31DEC1990	N
		Surgical and medical procedures	Antidepressant therapy	01JAN2010		Y
			Vasectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1264 12641037	Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2013		Y
		Surgical and medical procedures	Jaw operation	01JAN2013	31DEC2013	N
	C4591001 1264 12641041	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1983		Y
		Surgical and medical procedures	Gastric banding	01JAN2007	31DEC2007	N
			Laparoscopic surgery	01JAN2007	31DEC2007	N
	C4591001 1264 12641042	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	25JUN2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1991	31DEC1991	N
			Photorefractive keratectomy	01JAN2002	31DEC2002	N
	C4591001 1264 12641043	Congenital, familial and genetic disorders	Protein S deficiency	01JAN1982		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
			Tenoplasty	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Deep vein thrombosis	01JAN2005		Y
	C4591001 1264 12641046	Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Investigations	Seasonal allergy	01JAN2019		Y
			Colonoscopy	01FEB2020	29FEB2020	N
			Endoscopy	01FEB2020	29FEB2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1264 12641047	Cardiac disorders	Ventricular extrasystoles	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
			Colonoscopy	01JAN2002	31DEC2002	N
				01JAN2019	31DEC2019	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
		Reproductive system and breast disorders	Vaginal cyst	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Breast cyst excision	01JAN1990	31DEC1990	N
			Caesarean section	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
			Meniscus operation	01JAN2017	31DEC2017	N
			Strabismus correction	01JAN2002	31DEC2002	N
			Wisdom teeth removal	01JAN1986	31DEC1986	N
	C4591001 1264 12641048	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Aortic valve replacement	01JUL2014	31JUL2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01JAN2005	31DEC2005	N
	C4591001 1264 12641049	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1264 12641050	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2013		Y
		Surgical and medical procedures	Mammoplasty	01JAN2011	31DEC2011	N
	C4591001 1264 12641052	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Intervertebral disc protrusion	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1264 12641053	Immune system disorders	Contrast media allergy	01JAN2013		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Chondroplasty	01JAN2009	31DEC2009	N
			Varicose vein operation	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641055	Blood and lymphatic system disorders	Anaemia	01JAN1980	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Gastric bypass	01JAN2016	31DEC2016	N
			Intra-uterine contraceptive device insertion	01JAN2016	31DEC2016	N
	C4591001 1264 12641056	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes zoster	01MAR2020	31DEC2020	N
		Surgical and medical procedures	Jaw operation	01JAN2007	31DEC2007	N
			Liposuction	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1264 12641058	Infections and infestations	Herpes virus infection	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Surgical and medical procedures	Surgery	01JAN2013	31DEC2013	N
	C4591001 1264 12641060	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
			Nasal septal operation	01JAN1996	31DEC1996	N
			Wisdom teeth removal	01JAN1994	31DEC1994	N
	C4591001 1264 12641062	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Rubber sensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2004		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641064	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1984		Y
	C4591001 1264 12641065	Pregnancy, puerperium and perinatal conditions	Delivery	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Psychiatric disorders	Perinatal depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hernia repair	01JAN1994	31DEC1994	N
			Intra-uterine contraceptive device insertion	01JAN2017	31DEC2017	N
	C4591001 1264 12641066	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Rubber sensitivity	01JAN1998		Y
	C4591001 1264 12641069	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN1996		Y
		Infections and infestations	Staphylococcal infection	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1992	31DEC1995	N
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
			Knee operation	01JAN2000	31DEC2000	N
			Ligament operation	01JAN1995	31DEC1995	N
				01JAN1997	31DEC1997	N
			Surgery	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641070	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN1990	31DEC1990	N
	C4591001 1264 12641071	Immune system disorders	Allergy to arthropod bite	01JAN2013		Y
			Seasonal allergy	01JAN2013		Y
		Infections and infestations	Herpes zoster	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
			Dermatitis contact	01JAN2008		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2017	31DEC2017	N
			Wisdom teeth removal	01JAN2009	31DEC2009	N
	C4591001 1264 12641072	Immune system disorders	Allergy to chemicals	01JAN2017		Y
			Drug hypersensitivity	01JAN1991		Y
				01JAN2014		Y
		Injury, poisoning and procedural complications	Post concussion syndrome	01SEP2018	31OCT2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
			Sleep apnoea syndrome	01SEP2018		Y
		Surgical and medical procedures	Wisdom teeth removal	01JUN2011	30JUN2011	N
	C4591001 1264 12641073	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2008		Y
	C4591001 1264 12641075	Metabolism and nutrition disorders	Lactose intolerance	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641078	Immune system disorders	Food allergy	01JAN1999		Y
	C4591001 1264 12641081	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN2017		Y
	C4591001 1264 12641082	Eye disorders	Maculopathy	09MAY2018		Y
				28SEP2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
			Irritable bowel syndrome	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine with aura	01JAN2018		Y
	C4591001 1264 12641083	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2018		Y
		Investigations	Biopsy uterus	24AUG2020	24AUG2020	N
			Colonoscopy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
				01JAN2008	31DEC2008	N
			Intra-uterine contraceptive device insertion	01JAN2016	31DEC2016	N
	C4591001 1264 12641084	Infections and infestations	Urinary tract infection	18AUG2020	25AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2014		Y
			Post-traumatic stress disorder	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN2007	31DEC2007	N
	C4591001 1264 12641086	Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Wrist surgery	01JAN2018	31DEC2018	N
	C4591001 1264 12641087	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Psychiatric disorders	Perinatal depression	01APR2006	31DEC2007	N
		Surgical and medical procedures	Caesarean section	14APR2006	14APR2006	N
			Eye operation	01JAN1983	31DEC1983	N
			Gastric bypass	13JAN2017	13JAN2017	N
			Spinal operation	01JAN1983	31DEC1983	N
			Thyroidectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1264 12641088	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1986		Y
		Investigations	Endoscopy	01JAN2017	31DEC2017	N
			Human papilloma virus test positive	01JUN2020		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 1264 12641089	Surgical and medical procedures	Tonsillectomy	01JAN2001	31DEC2001	N
	C4591001 1264 12641090	Cardiac disorders	Atrial fibrillation	01JAN2019	31DEC2019	N
		Immune system disorders	Food allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641091	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Laparoscopy	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
				01JAN2016		Y
		Surgical and medical procedures	Intrauterine contraception	01JAN2020		Y
	C4591001 1264 12641092	Immune system disorders	Food allergy	01JAN2012		Y
	C4591001 1264 12641093	Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2019		Y
	C4591001 1264 12641094	Metabolism and nutrition disorders	Gout	01JAN2014		Y
	C4591001 1264 12641095	Congenital, familial and genetic disorders	Renal dysplasia	01JAN1996		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2019		Y
		Surgical and medical procedures	Limb operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2015	31DEC2015	N
	C4591001 1264 12641096	Reproductive system and breast disorders	Erectile dysfunction	01OCT2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1264 12641100	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01FEB2015		Y
			Plantar fasciitis	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2019		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Bone graft	01JUN2019	30JUN2019	N
			Cholecystectomy	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Tooth extraction	01JUN2019	30JUN2019	N
			Wisdom teeth removal	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1264 12641103	Nervous system disorders	Migraine	01JAN1991		Y
		Surgical and medical procedures	Appendectomy	01JAN1994	31DEC1994	N
			Caesarean section	01NOV2004	30NOV2004	N
				01NOV2008	30NOV2008	N
			Female sterilisation	01NOV2008	30NOV2008	N
			Lithotripsy	01MAY2017	31MAY2017	N
			Mammoplasty	01MAY2009	31MAY2009	N
	C4591001 1264 12641104	Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1264 12641105	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Ligament operation	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2012	31DEC2012	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1264 12641106	Gastrointestinal disorders	Food poisoning	28JUN2020	03JUL2020	N
		Immune system disorders	Allergy to animal	01JAN1999		Y
			Food allergy	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
	C4591001 1264 12641108	Injury, poisoning and procedural complications	Muscle strain	01AUG2020		Y
		Investigations	X-ray	01AUG2020	31AUG2020	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
			Fibromyalgia	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1264 12641109	Immune system disorders	Iodine allergy	01JAN2006		Y
			Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Mobility decreased	01JAN2006		Y
			Pain in extremity	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2017		Y
			Sensitive skin	01JAN2006		Y
		Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb operation	01JAN2006	31DEC2006	N
	C4591001 1264 12641110	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01MAY2016	31MAY2016	N
			Polypectomy	01JUN2017	30JUN2017	N
	C4591001 1264 12641113	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	28JUL2020	02SEP2020	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Uterine dilation and curettage	24JAN2017	24JAN2017	N
			Wisdom teeth removal	01JAN1998	31DEC1998	N
		Vascular disorders	White coat hypertension	01JAN2000		Y
	C4591001 1264 12641115	Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1264 12641116	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2018	31DEC2018	N
	C4591001 1264 12641118	Social circumstances	Menopause	01JUL2017		Y
	C4591001 1264 12641119	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1264 12641120	Immune system disorders	Food allergy	01JUL2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01MAR2013		Y
			Eczema	01JAN2012		Y
		Surgical and medical procedures	Contraceptive implant	01APR2013	30APR2013	N
				20JAN2020	20JAN2020	N
	C4591001 1264 12641122	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Food allergy	01JAN2016		Y
			Reaction to preservatives	01JAN2016		Y
		Psychiatric disorders	Affective disorder	10JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1264 12641123	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Hiatus hernia	01JAN2016		Y
			Oesophageal ulcer	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Oophorectomy	01JAN2005	31DEC2005	N
			Ostectomy	01JAN1995	31DEC1995	N
			Ovarian cystectomy	01JAN1980	31DEC1980	N
	C4591001 1264 12641124	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal tract adenoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Gastric bypass	01JAN2005	31DEC2005	N
			Intestinal resection	01JAN2016	31DEC2016	N
			Laparoscopic surgery	01FEB2020	29FEB2020	N
	C4591001 1264 12641125	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Intra-uterine contraceptive device insertion	01JAN2016	31DEC2016	N
			Renal stone removal	01JAN2010	31DEC2010	N
			Tenoplasty	01JAN2013	31DEC2013	N
	C4591001 1264 12641126	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01MAR2020		Y
	C4591001 1264 12641129	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1264 12641132	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
	C4591001 1264 12641135	Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN1995		Y
	C4591001 1264 12641140	Immune system disorders	Food allergy	01JAN2008		Y
			Seasonal allergy	01JAN2017		Y
	C4591001 1264 12641141	Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Juvenile idiopathic arthritis	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2012		Y
	C4591001 1264 12641142	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1264 12641143	Reproductive system and breast disorders	Cervical dysplasia	01MAY2012	31MAY2012	N
		Surgical and medical procedures	Hysterectomy	01MAY2012	31MAY2012	N
	C4591001 1264 12641144	Infections and infestations	Genital herpes	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1264 12641145	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Food allergy	01JAN2018		Y
			Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641146	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN2005		Y
	C4591001 1264 12641147	Immune system disorders	Food allergy	01JAN2007		Y
		Nervous system disorders	Radiculopathy	01JAN2017		Y
	C4591001 1264 12641150	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1264 12641151	Gastrointestinal disorders	Inguinal hernia	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2020		Y
	C4591001 1264 12641152	Nervous system disorders	Anosmia	01JAN2019		Y
	C4591001 1264 12641153	Immune system disorders	Allergy to arthropod bite	01JAN2016		Y
			Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
	C4591001 1264 12641154	Immune system disorders	Allergy to animal	01JAN1969		Y
			Seasonal allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Face lift	01JAN2014	31JAN2014	N
	C4591001 1264 12641156	Immune system disorders	Seasonal allergy	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2017		Y
		Surgical and medical procedures	Finger repair operation	01JAN1983	31DEC1983	N
			Foot operation	01JAN1994	31DEC1994	N
			Tenoplasty	01MAY2017	04AUG2017	N
		Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1264 12641157	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1264 12641158	Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Chondroplasty	01JAN2014	31DEC2014	N
			Jaw operation	01JAN2011	31DEC2011	N
	C4591001 1264 12641159	Gastrointestinal disorders	Gastritis	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Fibromyalgia	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Shoulder operation	01JUL2020	31JUL2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1264 12641160	Gastrointestinal disorders	Hiatus hernia	01JAN2018		Y
			Impaired gastric emptying	01NOV2019		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Human papilloma virus test positive	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2010	31DEC2019	N
			Sciatica	01JAN2004		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine cyst	01MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26APR2004		Y
		Surgical and medical procedures	Endometrial ablation	25JUL2019	25JUL2019	N
			Intra-uterine contraceptive device insertion	01DEC2011	25JUL2019	N
	C4591001 1264 12641162	Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1992	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Skin operation	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1976	31DEC1976	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1264 12641165	Investigations	Cardiac murmur	(b) (6) 1973		Y
	C4591001 1264 12641166	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Allergy to plants	01DEC2019		Y
			Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Neuralgia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Joint arthroplasty	01JAN2008		Y
	C4591001 1264 12641167	Gastrointestinal disorders	Coeliac disease	01JAN2009		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1264 12641168	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Knee operation	01JAN1991	31DEC1991	N
			Shoulder operation	01JAN2002	31DEC2002	N
			Skin lesion removal	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1264 12641171	Congenital, familial and genetic disorders	Congenital uterine anomaly	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01MAR1998		Y
		Nervous system disorders	Migraine	01OCT2006		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1264 12641172	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Red blood cell count increased	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	11SEP2020		Y
		Surgical and medical procedures	Hernia hiatus repair	01MAR2020	31MAR2020	N
	C4591001 1264 12641173	Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1997	31DEC2009	N
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Mammoplasty	01JAN2016	31DEC2016	N
	C4591001 1264 12641175	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
	C4591001 1264 12641176	Immune system disorders	Seasonal allergy	01MAR2016		Y
	C4591001 1264 12641177	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN1991		Y
	C4591001 1264 12641179	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Tuberculin test positive	01JAN2019		Y
	C4591001 1264 12641181	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
			Bunion operation	01JAN1997	31DEC1997	N
			Otoplasty	01JAN2009	31DEC2009	N
	C4591001 1264 12641183	Endocrine disorders	Hypothyroidism	01JUN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Biopsy thyroid gland	01AUG2019	31AUG2019	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01AUG2019		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641185	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1264 12641186	Gastrointestinal disorders	Abdominal hernia	01JAN2010	31JUL2014	N
		Immune system disorders	Drug hypersensitivity	17SEP2020		Y
			Food allergy	01JAN1985		Y
			Seasonal allergy	01JAN1992		Y
		Infections and infestations	Bronchitis	01JAN2018	31DEC2018	N
			Herpes zoster	01JUL2018	31JUL2018	N
			Pneumonia	01JAN1985	31DEC1985	N
				01JAN2006	31DEC2006	N
				14DEC2019	31JAN2020	N
			Scarlet fever	01JAN1989	31DEC1989	N
			Urinary tract infection	07SEP2020	16SEP2020	N
			Varicella	01JAN1978	31DEC1978	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
			Type 2 diabetes mellitus	01JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Abdominal hernia repair	01JUL2014	31JUL2014	N
	C4591001 1264 12641187	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Keratomileusis	01JAN2007	31DEC2007	N
			Uterine dilation and curettage	01JAN2010	31DEC2015	N
			Wisdom teeth removal	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641188	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1984		Y
	C4591001 1264 12641189	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Papilloma viral infection	01JAN2020		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2016	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN1996		Y
		Surgical and medical procedures	Caesarean section	04FEB2011	04FEB2011	N
			Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1264 12641190	Immune system disorders	Sarcoidosis	01JAN2002	31DEC2004	N
		Psychiatric disorders	Depression	01JAN2010	31DEC2013	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2004		Y
	C4591001 1264 12641191	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Food allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hyperlipidaemia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Hepatitis B immunisation	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1264 12641192	Vascular disorders	Hypertension	01APR2003		Y
	C4591001 1264 12641193	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641197	Immune system disorders	Dust allergy	01JAN2002		Y
			Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Muscle strain	01SEP2020		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN1990		Y
	C4591001 1264 12641200	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2016	31DEC2016	N
	C4591001 1264 12641201	Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Wisdom teeth removal	01JAN2004	31DEC2004	N
	C4591001 1264 12641202	Injury, poisoning and procedural complications	Road traffic accident	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019	29FEB2020	N
		Surgical and medical procedures	Bone operation	01JAN2002	31DEC2002	N
	C4591001 1264 12641206	Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Facet joint syndrome	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2011	31DEC2011	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2012		Y
			Eating disorder	01JAN2011	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641208	Immune system disorders	Allergy to metals	01JAN1987		Y
		Surgical and medical procedures	Knee operation	01JAN2012	31DEC2012	N
	C4591001 1264 12641209	Cardiac disorders	Left ventricular failure	30NOV2013		Y
			Myocardial infarction	30NOV2013	03DEC2013	N
		Gastrointestinal disorders	Toothache	01OCT2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Coronary artery bypass	03DEC2013	03DEC2013	N
	C4591001 1264 12641210	Immune system disorders	Seasonal allergy	01JAN2014		Y
	C4591001 1264 12641211	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1264 12641212	Gastrointestinal disorders	Colitis	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN2007	31DEC2007	N
	C4591001 1264 12641213	Investigations	Blood cholesterol increased	01OCT2019		Y
	C4591001 1264 12641215	Ear and labyrinth disorders	Tinnitus	01MAY2018		Y
		Psychiatric disorders	Depression	15SEP2015		Y
	C4591001 1264 12641216	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Surgical and medical procedures	Oocyte harvest	01JAN2000	31DEC2002	N
			Peripheral nerve operation	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641218	Ear and labyrinth disorders	Vertigo	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
		Surgical and medical procedures	Bone cyst excision	01JAN2014	31DEC2014	N
	C4591001 1264 12641221	Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Allergy to animal	01JAN1985		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Oral herpes	01JAN2015		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2015		Y
			Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2013	31DEC2014	N
	C4591001 1264 12641226	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01APR2020		Y
	C4591001 1264 12641227	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Vulvovaginal mycotic infection	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN2018	31DEC2018	N
	C4591001 1264 12641228	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Infections and infestations	Helicobacter gastritis	01MAR2020	31MAR2020	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1265 12651004	Surgical and medical procedures	Closed fracture manipulation	22APR2013	22APR2013	N
	C4591001 1265 12651006	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	07JUL2020		Y
		Gastrointestinal disorders	Haemorrhoids	30JUL2019		Y
			Large intestine polyp	01MAR2019		Y
		Infections and infestations	Herpes simplex	10JAN2018		Y
		Nervous system disorders	Circadian rhythm sleep disorder	29SEP2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	19JAN2018		Y
			Major depression	07MAR2019		Y
	C4591001 1265 12651007	Psychiatric disorders	Alcohol abuse	05MAY2018		Y
		Surgical and medical procedures	Tooth extraction	01JAN1995	31DEC1995	N
	C4591001 1265 12651010	Eye disorders	Glaucoma	29APR2008		Y
		Gastrointestinal disorders	Irritable bowel syndrome	03APR2019		Y
		Psychiatric disorders	Generalised anxiety disorder	04OCT2011		Y
		Surgical and medical procedures	Anal sphincterotomy	30MAR2011	30MAR2011	N
			Botulinum toxin injection	02FEB2011	02FEB2011	N
	C4591001 1265 12651013	Infections and infestations	Herpes simplex	23MAY2019		Y
		Metabolism and nutrition disorders	Obesity	07MAY2018		Y
		Psychiatric disorders	Borderline personality disorder	18DEC2015		Y
			Major depression	01FEB2013		Y
		Skin and subcutaneous tissue disorders	Acne	06OCT2014		Y
	C4591001 1265 12651016	Metabolism and nutrition disorders	Obesity	03MAR2020		Y
		Surgical and medical procedures	Vasectomy	18APR2019	18APR2019	N
	C4591001 1265 12651020	Blood and lymphatic system disorders	Microcytic anaemia	10SEP2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastrointestinal haemorrhage	05JAN2011	31JAN2011	N
			Gastroesophageal reflux disease	27DEC2007		Y
			Small intestinal obstruction	15MAY2011	31MAY2011	N
			Upper gastrointestinal haemorrhage	30SEP2010	30SEP2010	N
		Immune system disorders	Drug hypersensitivity	05JUN2014		Y
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	10OCT2004		Y
		Investigations	Laparoscopy	14MAY2011	14MAY2011	N
		Metabolism and nutrition disorders	Obesity	10JUL2012		Y
			Vitamin D deficiency	14JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	04APR2008		Y
			Spinal osteoarthritis	30JUN2015		Y
		Psychiatric disorders	Alcohol use disorder	30SEP2010		Y
			Generalised anxiety disorder	10SEP2011		Y
			Major depression	04APR2012		Y
			Sleep disorder due to general medical condition, insomnia type	10SEP2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	16SEP2005		Y
		Surgical and medical procedures	Abdominal operation	14MAY2011	14MAY2011	N
			Gastric bypass	01MAY2009	31MAY2009	N
			Gastroenterostomy	01MAY2009	31MAY2009	N
		Vascular disorders	Essential hypertension	13JUN2012		Y
	C4591001 1265 12651022	Congenital, familial and genetic disorders	Branchial cyst	01JAN2002	31DEC2002	N
		Endocrine disorders	Thyroid cyst	14SEP2011		Y
			Thyroid mass	01AUG2014		Y
		Infections and infestations	Appendicitis	19JAN2017	20JAN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Herpes simplex	22JUN2012		Y
		Nervous system disorders	Migraine	01AUG2014		Y
		Surgical and medical procedures	Appendicectomy	20JAN2017	20JAN2017	N
			Intrauterine contraception	20JAN2016		Y
			Neck surgery	01JAN2002	31DEC2002	N
	C4591001 1265 12651024	Cardiac disorders	Mitral valve prolapse	01JAN2011		Y
		Congenital, familial and genetic disorders	Thalassaemia alpha	05JAN2011		Y
		Endocrine disorders	Basedow's disease	30MAR2017		Y
		Eye disorders	Strabismus	24JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2006	N
				05JAN2011		Y
		Surgical and medical procedures	Lymphadenectomy	01JAN1992	31DEC1992	N
			Strabismus correction	05DEC2019	05DEC2019	N
			Uterine dilation and curettage	08FEB2011	08FEB2011	N
				19OCT2012	19OCT2012	N
	C4591001 1265 12651025	Metabolism and nutrition disorders	Hyperlipidaemia	10NOV2015		Y
			Type 2 diabetes mellitus	06FEB2018		Y
		Nervous system disorders	Diabetic neuropathy	03FEB2020		Y
		Psychiatric disorders	Major depression	25SEP2018		Y
		Surgical and medical procedures	Toe amputation	01JAN2012	31DEC2012	N
	C4591001 1265 12651027	Psychiatric disorders	Depression	05MAR2018		Y
			Generalised anxiety disorder	05MAR2018		Y
	C4591001 1265 12651030	Surgical and medical procedures	Tenoplasty	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651031	Congenital, familial and genetic disorders	Type V hyperlipidaemia	18AUG2015		Y
		Gastrointestinal disorders	Diverticulum intestinal	23OCT2015		Y
		Infections and infestations	Genital herpes simplex	18AUG2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	18AUG2015		Y
		Nervous system disorders	Diabetic neuropathy	06MAY2016		Y
			Restless legs syndrome	18AUG2015		Y
		Psychiatric disorders	Anxiety disorder	28APR2017		Y
			Attention deficit hyperactivity disorder	18AUG2015		Y
			Insomnia	18AUG2015		Y
			Major depression	18AUG2015		Y
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Small intestinal resection	01JAN2015	31DEC2015	N
	C4591001 1265 12651032	Surgical and medical procedures	Sinus operation	01JAN2014	31DEC2014	N
	C4591001 1265 12651037	Endocrine disorders	Hypothyroidism	02FEB2016		Y
		Metabolism and nutrition disorders	Obesity	02FEB2016		Y
		Musculoskeletal and connective tissue disorders	Soft tissue mass	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Acne	26JUN2013		Y
	C4591001 1265 12651040	Reproductive system and breast disorders	Cervical dysplasia	16JAN2020		Y
	C4591001 1265 12651041	Psychiatric disorders	Anxiety	14OCT2019		Y
			Attention deficit hyperactivity disorder	10FEB2017		Y
			Major depression	14OCT2019		Y
	C4591001 1265 12651042	Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	16FEB2018		Y
	C4591001 1265 12651043	Immune system disorders	Drug hypersensitivity	06MAR2019		Y
				26APR2010		Y
		Infections and infestations	Papilloma viral infection	03FEB2018	06MAR2019	N
		Psychiatric disorders	Anxiety	20MAY2010		Y
			Attention deficit hyperactivity disorder	20MAY2010		Y
			Persistent depressive disorder	12FEB2018		Y
	C4591001 1265 12651044	Investigations	Alanine aminotransferase increased	22OCT2018	19AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	16NOV2016		Y
		Psychiatric disorders	Anxiety	11AUG2016		Y
			Attention deficit hyperactivity disorder	11AUG2016		Y
			Bipolar II disorder	19SEP2016		Y
			Eating disorder	19SEP2016		Y
	C4591001 1265 12651047	Gastrointestinal disorders	Diverticulum intestinal	26MAR2014		Y
			Haemorrhoids	26MAR2014		Y
		Hepatobiliary disorders	Gallbladder polyp	15MAR2018	29MAR2018	N
		Immune system disorders	Drug hypersensitivity	26FEB2019		Y
		Injury, poisoning and procedural complications	Hand fracture	15NOV2015		Y
		Investigations	Biopsy colon	26MAR2014	26MAR2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	23FEB2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	04APR2017		Y
		Surgical and medical procedures	Appendicectomy	30JUL2009	30JUL2009	N
			Cholecystectomy	29MAR2018	29MAR2018	N
		Vascular disorders	Hypertension	26FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651049	Skin and subcutaneous tissue disorders	Acne	09FEB2020		Y
		Surgical and medical procedures	Keratomileusis	01JAN2019	31DEC2019	N
	C4591001 1265 12651053	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1265 12651055	Immune system disorders	Drug hypersensitivity	27JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	27JUL2020		Y
		Skin and subcutaneous tissue disorders	Acne	20JUL2018		Y
			Psoriasis	20FEB2012		Y
		Vascular disorders	Hypertension	01APR2013		Y
	C4591001 1265 12651058	Musculoskeletal and connective tissue disorders	Plantar fasciitis	04JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	25NOV2011	01FEB2012	N
		Renal and urinary disorders	Hypercalciuria	01APR2015		Y
			Nephrolithiasis	24FEB2003	17DEC2018	N
		Surgical and medical procedures	Large intestinal polypectomy	28JAN2019	28JAN2019	N
			Lithotripsy	12JUN2015	12JUN2015	N
			Micrographic skin surgery	01FEB2012	01FEB2012	N
			Ureteral stent insertion	12JUN2015	12JUN2015	N
	C4591001 1265 12651059	Congenital, familial and genetic disorders	Gilbert's syndrome	09NOV2015		Y
		Investigations	Blood bilirubin increased	09NOV2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	14NOV2016		Y
		Psychiatric disorders	Anxiety	09NOV2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09NOV2015		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	30JAN2017	14MAR2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Skin cyst excision	14MAR2017	14MAR2017	N
	C4591001 1265 12651060	Surgical and medical procedures	Intrauterine contraception	18MAR2016		Y
	C4591001 1265 12651062	Gastrointestinal disorders	Inguinal hernia	25MAY2010		Y
		Immune system disorders	Drug hypersensitivity	05AUG2013		Y
				24SEP2007		Y
			Food allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Hand fracture	19NOV2019	30JUL2020	N
		Metabolism and nutrition disorders	Obesity	19NOV2019		Y
		Psychiatric disorders	Adjustment disorder	31JUL2013		Y
			Anxiety	31JUL2013		Y
			Depressed mood	31JUL2013		Y
			Social anxiety disorder	17FEB2014		Y
		Social circumstances	Bereavement	31JUL2013		Y
	C4591001 1265 12651063	Psychiatric disorders	Major depression	28DEC2016		Y
	C4591001 1265 12651064	Metabolism and nutrition disorders	Overweight	20AUG2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	22JAN2013		Y
		Surgical and medical procedures	Intrauterine contraception	11JUN2014		Y
	C4591001 1265 12651065	Surgical and medical procedures	Large intestinal polypectomy	26JUN2018	26JUN2018	N
	C4591001 1265 12651066	Endocrine disorders	Hypothyroidism	30MAY2003		Y
		Infections and infestations	Varicella	01JAN1994	31DEC1994	N
		Psychiatric disorders	Alcohol abuse	01JAN2016	31DEC2016	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1265 12651067	Investigations	Biopsy colon	30APR2019	30APR2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	24FEB2004		Y
		Vascular disorders	Essential hypertension	22SEP2004		Y
	C4591001 1265 12651072	Musculoskeletal and connective tissue disorders	Chondropathy	01MAY2007		Y
	C4591001 1265 12651073	Gastrointestinal disorders	Haemorrhoids	14SEP2018		Y
		Immune system disorders	Drug hypersensitivity	24OCT2016		Y
		Nervous system disorders	Migraine	31OCT2016		Y
		Psychiatric disorders	Insomnia	31OCT2016		Y
		Surgical and medical procedures	Lipoma excision	19NOV2018	19NOV2018	N
	C4591001 1265 12651076	Blood and lymphatic system disorders	Anaemia	11DEC2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12JAN2017		Y
	C4591001 1265 12651079	Endocrine disorders	Hypothyroidism	21NOV2011		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2009	31DEC2009	N
	C4591001 1265 12651081	Immune system disorders	Drug hypersensitivity	23NOV2007		Y
		Investigations	Human papilloma virus test positive	29JAN2007	18AUG2018	N
		Musculoskeletal and connective tissue disorders	Back pain	08OCT2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11MAY2007		Y
			Rhinitis allergic	11MAY2007		Y
		Surgical and medical procedures	Orthopaedic procedure	01JAN1999	31DEC1999	N
	C4591001 1265 12651082	Infections and infestations	Pneumonia	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	26NOV2019		Y
			Attention deficit hyperactivity disorder	02OCT2017		Y
			Depression	26NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	26JUL2011		Y
		Surgical and medical procedures	Appendectomy	12SEP2017	12SEP2017	N
			Circumcision	01JAN1994	31DEC1994	N
	C4591001 1265 12651083	Metabolism and nutrition disorders	Obesity	22OCT2013		Y
	C4591001 1265 12651084	Immune system disorders	Allergy to arthropod sting	19OCT2011		Y
			Drug hypersensitivity	26FEB2014		Y
			Seasonal allergy	19OCT2011		Y
		Injury, poisoning and procedural complications	Meniscus injury	08AUG2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	09AUG2016		Y
		Musculoskeletal and connective tissue disorders	Rhabdomyolysis	06JUN2013	31DEC2013	N
		Psychiatric disorders	Generalised anxiety disorder	18NOV2013		Y
	C4591001 1265 12651086	Renal and urinary disorders	Nephrolithiasis	23APR2016	31DEC2016	N
	C4591001 1265 12651089	Psychiatric disorders	Alcoholism	01APR2014		Y
			Major depression	01AUG2019		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1265 12651090	Gastrointestinal disorders	Diverticulum	15JAN2020		Y
		Infections and infestations	Diverticulitis	15JAN2020		Y
		Metabolism and nutrition disorders	Overweight	13MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	13MAR2018		Y
			Back pain	13MAR2018		Y
		Renal and urinary disorders	Renal cyst	28JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	01JAN2010	31DEC2010	N
	C4591001 1265 12651093	Metabolism and nutrition disorders	Overweight	03JUL2013		Y
		Reproductive system and breast disorders	Infertility male	24NOV2015		Y
		Surgical and medical procedures	Meniscus operation	01JAN2009	31DEC2009	N
	C4591001 1265 12651096	Skin and subcutaneous tissue disorders	Acne cystic	02JUN2010		Y
		Surgical and medical procedures	Tonsillectomy	13MAY2013	13MAY2013	N
	C4591001 1265 12651097	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	15DEC2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1984	31DEC1984	N
	C4591001 1265 12651098	Eye disorders	Binocular eye movement disorder	25JUN2015		Y
		Investigations	Human papilloma virus test positive	06APR2012	07JUN2018	N
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Varicose vein	15JUN2015		Y
	C4591001 1265 12651099	Infections and infestations	Genital herpes simplex	05FEB2020		Y
			Papilloma viral infection	14SEP2016	05SEP2017	N
		Musculoskeletal and connective tissue disorders	Back pain	20APR2017		Y
		Nervous system disorders	Sciatica	20APR2017		Y
		Social circumstances	Postmenopause	01FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651101	Surgical and medical procedures	Bunion operation	14NOV2017	14NOV2017	N
		Cardiac disorders	Sinus tachycardia	05JUN2007	31DEC2007	N
		Eye disorders	Blepharospasm	09OCT2014		Y
		Gastrointestinal disorders	Abdominal pain	17AUG2006		Y
			Gastroesophageal reflux disease	10APR2006		Y
			Impaired gastric emptying	31DEC2014		Y
			Irritable bowel syndrome	17JUN2004		Y
			Pancreatitis chronic	19JAN2017		Y
		Hepatobiliary disorders	Hepatic steatosis	18OCT2006		Y
		Immune system disorders	Drug hypersensitivity	17JAN2008		Y
		Investigations	Biopsy colon	08JUL2014	08JUL2014	N
				15NOV2010	15NOV2010	N
			Laparoscopy	15MAY2015	15MAY2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	27JUN2013		Y
			Obesity	13APR2011		Y
			Type 2 diabetes mellitus	26MAY2011		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	02NOV2007		Y
		Nervous system disorders	Cramp-fasciculation syndrome	30AUG2013		Y
			Neuropathy peripheral	03MAY2013		Y
			Seizure	05JUN2007	05JUN2007	N
			Syncope	07OCT2005	31DEC2005	N
		Psychiatric disorders	Bipolar I disorder	26JAN2010		Y
			Generalised anxiety disorder	28FEB2008		Y
			Major depression	25JAN2007		Y
		Renal and urinary disorders	Chronic kidney disease	11FEB2014		Y
			Hypertonic bladder	06AUG2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Respiratory, thoracic and mediastinal disorders	Asthma	16AUG2016		Y
		Surgical and medical procedures	Adhesiolysis	15MAY2015	15MAY2015	N
			Female sterilisation	01JAN1998	31DEC1998	N
			Hysterectomy	12DEC2013	12DEC2013	N
			Salpingectomy	12DEC2013	12DEC2013	N
		Vascular disorders	Hypertension	19JAN2017		Y
	C4591001 1265 12651104	Metabolism and nutrition disorders	Obesity	09JUL2018		Y
			Vitamin D deficiency	24AUG2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	19AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	16JUN2017		Y
	C4591001 1265 12651106	Immune system disorders	Drug hypersensitivity	14NOV2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	14JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14NOV2013		Y
			Rhinitis allergic	14NOV2013		Y
		Skin and subcutaneous tissue disorders	Acne	14NOV2013		Y
			Eczema	14NOV2013		Y
			Keloid scar	14NOV2013		Y
	C4591001 1265 12651108	Immune system disorders	Drug hypersensitivity	21MAY2009		Y
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	13JAN2017		Y
		Psychiatric disorders	Anxiety disorder	10NOV2014		Y
			Insomnia	19SEP2011		Y
		Skin and subcutaneous tissue disorders	Psoriasis	23JUN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651110	Gastrointestinal disorders	Gastroesophageal reflux disease	22OCT2015		Y
		Hepatobiliary disorders	Cholelithiasis	09JUN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2020		Y
				14SEP2020		Y
			Food allergy	01JAN2020		Y
		Metabolism and nutrition disorders	Gout	21JUL2015		Y
		Psychiatric disorders	Anxiety disorder	21JUL2015		Y
			Insomnia	21JUL2015		Y
		Surgical and medical procedures	Hip arthroplasty	12JUN2020	12JUN2020	N
	C4591001 1265 12651111	Eye disorders	Open angle glaucoma	27FEB2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	27FEB2004		Y
		Nervous system disorders	Lumbosacral radiculopathy	21FEB2019		Y
	C4591001 1265 12651114	Cardiac disorders	Bundle branch block left	12MAY2014		Y
			Mitral valve disease	03MAR2008		Y
			Tricuspid valve disease	07APR2008		Y
		Congenital, familial and genetic disorders	Congenital flat feet	08FEB2011		Y
			Ehlers-Danlos syndrome	08FEB2011		Y
		Immune system disorders	Allergy to animal	28MAR2007		Y
		Infections and infestations	Varicella	13DEC2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	28MAR2007		Y
			Dwarfism	10DEC2004		Y
			Scoliosis	03NOV2003		Y
		Psychiatric disorders	Major depression	07MAY2014		Y
		Reproductive system and breast disorders	Gynaecomastia	08FEB2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	08FEB2011		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1989	31DEC1989	N
			Orchidopexy	01JAN1989	31DEC1989	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
			Tooth extraction	03AUG2011	03AUG2011	N
	C4591001 1265 12651124	Investigations	Human papilloma virus test positive	05MAY2019		Y
		Surgical and medical procedures	Caesarean section	07JAN2015	07JAN2015	N
				20AUG2013	20AUG2013	N
			Intra-uterine contraceptive device insertion	17APR2019		Y
	C4591001 1265 12651126	Psychiatric disorders	Somnambulism	09AUG2012		Y
	C4591001 1265 12651128	Cardiac disorders	Cardiac failure	19JAN2019		Y
			Cardiac ventricular thrombosis	23JAN2019	31DEC2019	N
			Congestive cardiomyopathy	04MAR2020		Y
		Gastrointestinal disorders	Enterovesical fistula	06NOV2019		Y
				14FEB2019		Y
		Immune system disorders	Drug hypersensitivity	11MAR2019		Y
		Infections and infestations	Sepsis	06FEB2019	31DEC2019	N
			Urinary tract infection bacterial	14FEB2019	31DEC2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	24OCT2016		Y
			Malnutrition	28JAN2019		Y
			Type 2 diabetes mellitus	24OCT2016		Y
		Renal and urinary disorders	Microalbuminuria	11OCT2017		Y
	C4591001 1265 12651134	Investigations	Blood pressure increased	10APR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15APR2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Tobacco user	03DEC2009		Y
	C4591001 1265 12651136	Cardiac disorders	Atrial fibrillation	08APR2019		Y
		General disorders and administration site conditions	Chest pain	04MAR2019		Y
		Infections and infestations	Pneumonia	08APR2019	30APR2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	04JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	08APR2019		Y
	C4591001 1265 12651139†	Blood and lymphatic system disorders	Neutropenia	05NOV2017		Y
		Gastrointestinal disorders	Dysphagia	15JUN2018		Y
			Eosinophilic oesophagitis	30JUL2018		Y
		Infections and infestations	Asymptomatic HIV infection	06SEP2012		Y
		Investigations	Biopsy	25JUL2018	25JUL2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	06SEP2012	06SEP2012	N
		Surgical and medical procedures	Anal fistula repair	01MAY2013	01MAY2013	N
	C4591001 1265 12651142	Metabolism and nutrition disorders	Overweight	29JUL2013		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	26MAR2019		Y
		Surgical and medical procedures	Prophylaxis against HIV infection	03APR2020		Y
	C4591001 1265 12651143†	Investigations	HIV test positive	28OCT2013		Y
	C4591001 1265 12651144	Gastrointestinal disorders	Gastroesophageal reflux disease	08DEC2016		Y
		Injury, poisoning and procedural complications	Exposure to communicable disease	11DEC2016		Y
		Investigations	Liver function test increased	11DEC2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	11DEC2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	11DEC2016		Y
			Overweight	08DEC2016		Y
			Vitamin D deficiency	13DEC2016		Y
		Renal and urinary disorders	Chronic kidney disease	07MAR2019		Y
		Social circumstances	High risk sexual behaviour	08DEC2016		Y
		Surgical and medical procedures	Hernia repair	01JAN1981	31DEC1981	N
	C4591001 1265 12651145	Metabolism and nutrition disorders	Hyperlipidaemia	14NOV2017		Y
			Hypokalaemia	15NOV2019		Y
			Obesity	02NOV2017		Y
			Type 2 diabetes mellitus	09NOV2017		Y
		Renal and urinary disorders	Chronic kidney disease	01DEC2017		Y
			Renal cyst	24JUL2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1265 12651146	Endocrine disorders	Goitre	09MAY2017		Y
		Immune system disorders	Drug hypersensitivity	15MAR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	15MAR2017		Y
		Psychiatric disorders	Adjustment disorder	23OCT2017		Y
			Anxiety	15MAR2017		Y
			Major depression	28SEP2017		Y
		Reproductive system and breast disorders	Menorrhagia	15MAR2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	15MAR2017		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Intrauterine contraception	07FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1265 12651147	Metabolism and nutrition disorders	Rhinoplasty	01JAN2000	31DEC2000	N	
			Hyperlipidaemia	17JUN2004		Y	
		Musculoskeletal and connective tissue disorders	Obesity	13MAY2014		Y	
			Type 2 diabetes mellitus	13MAY2014		Y	
			Tendonitis	01JAN1999	31DEC1999	N	
		Nervous system disorders	Neuropathy peripheral	14MAY2010		Y	
			Psychiatric disorders	Insomnia	21FEB2003		Y
		Renal and urinary disorders	Schizoaffective disorder	13FEB2003		Y	
			Haematuria	30JUN2005	31JUL2005	N	
			Microalbuminuria	28JUL2005		Y	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	06NOV2013		Y	
			Vascular disorders	Essential hypertension	17JUN2004		Y
		C4591001 1265 12651148	Gastrointestinal disorders	Abdominal adhesions	30JUN2017		Y
				Abdominal hernia	06APR2020		Y
	Hepatobiliary disorders		Gastroesophageal reflux disease	15JUN2016		Y	
			Intestinal obstruction	30JUN2017		Y	
			Obstruction gastric	26MAR2016		Y	
			Rectal haemorrhage	07APR2014		Y	
			Umbilical hernia	31MAR2014		Y	
			Hepatic steatosis	05JUL2013		Y	
			Chronic sinusitis	26JAN2012		Y	
	Infections and infestations		Diverticulitis	05JUL2013		Y	
			Sinusitis fungal	04JAN2018		Y	
			Injury, poisoning and procedural complications	Muscle strain	17MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendon injury	17MAY2018		Y
		Metabolism and nutrition disorders	Diabetes mellitus	14APR2015	14APR2015	N
			Hyperlipidaemia	09JUL2010		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	23JUN2010		Y
		Nervous system disorders	Nerve compression	31MAY2018		Y
			Paraesthesia	31MAY2018		Y
		Psychiatric disorders	Anxiety	04AUG2017		Y
			Major depression	07SEP2017		Y
			Post-traumatic stress disorder	29APR2011		Y
		Reproductive system and breast disorders	Breast mass	03JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	04JAN2018		Y
			Asthma	14MAR2008		Y
			Nasal septum deviation	13JAN2012		Y
			Rhinitis allergic	04JAN2018		Y
		Surgical and medical procedures	Abdominal hernia repair	15JUN2016	15JUN2016	N
				31AUG2020	31AUG2020	N
			Caesarean section	09APR2011	09APR2011	N
			Carpal tunnel decompression	15AUG2013	15AUG2013	N
			Cholecystectomy	14MAR2017	14MAR2017	N
				16FEB2017	16FEB2017	N
			Fasciotomy	23JUN2010	23JUN2010	N
			Female sterilisation	09AUG2011	09AUG2011	N
			Functional endoscopic sinus surgery	17SEP2012	17SEP2012	N
			Gastrectomy	03DEC2014	03DEC2014	N
				15JUN2016	15JUN2016	N
			Gastric bypass	29JUN2017	29JUN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Incisional hernia repair	29JUN2017	29JUN2017	N
			Intrauterine contraception	07APR2020		Y
			Nasal septal operation	17SEP2012	17SEP2012	N
		Vascular disorders	Varicose vein	14MAR2008		Y
	C4591001 1265 12651149	Blood and lymphatic system disorders	Iron deficiency anaemia	04APR2018		Y
		Investigations	Cystoscopy	07DEC2018	07DEC2018	N
		Metabolism and nutrition disorders	Obesity	11DEC2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	04APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	07APR2019		Y
		Surgical and medical procedures	Hysterectomy	07DEC2018	07DEC2018	N
			Salpingectomy	07DEC2018	07DEC2018	N
			Spinal operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	11DEC2017		Y
	C4591001 1265 12651151	Gastrointestinal disorders	Rectal haemorrhage	22JAN2019	22JAN2019	N
				22JUN2020	22JUN2020	N
		Hepatobiliary disorders	Hepatic steatosis	24SEP2013		Y
		Investigations	Transaminases increased	25JAN2006		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	05FEB2014		Y
			Hypertriglyceridaemia	18JUN2012		Y
			Obesity	05MAY2016		Y
		Psychiatric disorders	Adjustment disorder	07MAR2015		Y
			Depressed mood	07MAR2015		Y
			Insomnia	14MAY2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18APR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis atopic	14JUN2013		Y
		Surgical and medical procedures	Prophylaxis against HIV infection	15JUN2018		Y
	C4591001 1265 12651153	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	17APR2009		Y
		Immune system disorders	Drug hypersensitivity	22APR2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24AUG2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	18FEB2020		Y
			Rotator cuff syndrome	18FEB2020		Y
		Psychiatric disorders	Major depression	08MAY2013		Y
		Renal and urinary disorders	Hypertonic bladder	20JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05JUL2006		Y
			Sleep apnoea syndrome	19JUL2018		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1980	31DEC1980	N
				01JAN2010	31DEC2010	N
			Ostectomy	23JAN2015	23JAN2015	N
				31AUG2020	31AUG2020	N
			Removal of foreign body	02OCT2018	02OCT2018	N
			Turbinectomy	16AUG2008	16AUG2008	N
	C4591001 1265 12651155	Infections and infestations	Rhinitis	13JAN2020		Y
		Psychiatric disorders	Insomnia	18FEB2020		Y
	C4591001 1265 12651159†	Eye disorders	Necrotising retinitis	24APR2015		Y
		Immune system disorders	Drug hypersensitivity	12FEB2018		Y
		Investigations	Colonoscopy	21OCT2019	21OCT2019	N
			HIV test positive	12FEB2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	27OCT2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	27OCT2015		Y
		Social circumstances	Familial risk factor	21OCT2019		Y
		Surgical and medical procedures	Cataract operation	01MAY2018	01MAY2018	N
	C4591001 1265 12651161	Gastrointestinal disorders	Colitis	22FEB2018		Y
		Immune system disorders	Drug hypersensitivity	07AUG2014		Y
		Infections and infestations	Varicella	18JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Back pain	15MAR2018		Y
		Nervous system disorders	Migraine	09DEC2019		Y
			Syncope	12JUL2019	12JUL2019	N
		Psychiatric disorders	Anxiety	09JUN2020		Y
			Generalised anxiety disorder	12JUL2019		Y
		Skin and subcutaneous tissue disorders	Eczema asteatotic	08OCT2012		Y
			Hidradenitis	20FEB2020		Y
	C4591001 1265 12651162	Gastrointestinal disorders	Abdominal pain upper	29AUG2016		Y
		Hepatobiliary disorders	Bile duct stone	29AUG2016		Y
			Cholelithiasis	29AUG2016		Y
		Reproductive system and breast disorders	Cervical dysplasia	18MAY2016		Y
		Surgical and medical procedures	Cholecystectomy	09SEP2016	09SEP2016	N
	C4591001 1265 12651164†	Eye disorders	Conjunctivitis allergic	25JUN2019		Y
		Gastrointestinal disorders	Anogenital dysplasia	23AUG2013		Y
				29MAR2014		Y
			Aphthous ulcer	18APR2014		Y
			Haemorrhoids	21JUN2019		Y
		Immune system disorders	Drug hypersensitivity	23AUG2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Genital herpes simplex	07JAN2014		Y
			Rhinitis	25JUN2019		Y
		Investigations	HIV test positive	19AUG2013		Y
			Hepatitis A antibody positive	19AUG2013		Y
			Hepatitis B antibody positive	10AUG2013		Y
			Mumps antibody test positive	20AUG2018		Y
		Psychiatric disorders	Anxiety disorder	06APR2020		Y
			Substance use disorder	19AUG2013		Y
		Renal and urinary disorders	Dysuria	02JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23MAY2019		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	21JUN2019		Y
		Surgical and medical procedures	Anal fissure excision	01JAN2005	31DEC2005	N
			Anal fistula repair	01JAN2008	31DEC2008	N
			Gingival graft	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
			Temporomandibular joint surgery	01JAN1996	31DEC1996	N
	C4591001 1265 12651165	Investigations	Colonoscopy	17JAN2013	17JAN2013	N
				29NOV2018	29NOV2018	N
		Nervous system disorders	Arachnoid cyst	07JAN2020		Y
			Migraine with aura	19AUG2014		Y
		Psychiatric disorders	Depression	30AUG2018		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	10DEC2008		Y
		Surgical and medical procedures	Appendectomy	14JUL2014	14JUL2014	N
	C4591001 1265 12651166	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1265 12651167	Blood and lymphatic system disorders	Thrombocytopenia	20JUL2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	17SEP2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	03MAR2014		Y
		Reproductive system and breast disorders	Breast mass	25SEP2003		Y
	C4591001 1265 12651170	Injury, poisoning and procedural complications	Hand fracture	05FEB2007	05FEB2007	N
			Upper limb fracture	05FEB2007	05FEB2007	N
		Skin and subcutaneous tissue disorders	Acne	29JUL2011		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2007	31DEC2007	N
	C4591001 1265 12651173	Endocrine disorders	Thyroid mass	28MAY2019		Y
		Investigations	Cystoscopy	14OCT2019	14OCT2019	N
		Metabolism and nutrition disorders	Vitamin D deficiency	02FEB2016		Y
		Psychiatric disorders	Major depression	27DEC2019		Y
		Reproductive system and breast disorders	Infertility female	28JAN2016		Y
		Social circumstances	Tobacco user	28JAN2016		Y
		Surgical and medical procedures	Appendectomy	14NOV2016	14NOV2016	N
			Hysterectomy	14OCT2019	14OCT2019	N
			Salpingectomy	14OCT2019	14OCT2019	N
	C4591001 1265 12651174	Renal and urinary disorders	Hypertonic bladder	15JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	31OCT2003		Y
	C4591001 1265 12651177	Injury, poisoning and procedural complications	Limb injury	09APR2019		Y
		Investigations	Blood pressure increased	09APR2019		Y
		Metabolism and nutrition disorders	Obesity	02MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Alcohol use disorder	09APR2019		Y
		Social circumstances	Substance use	09APR2019		Y
	C4591001 1265 12651180	Gastrointestinal disorders	Gastroesophageal reflux disease	23JAN2019		Y
		Immune system disorders	Drug hypersensitivity	23JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	24SEP2020		Y
		Psychiatric disorders	Anxiety	15JAN2019		Y
			Attention deficit hyperactivity disorder	15JAN2019		Y
			Depression	15JAN2019		Y
			Post-traumatic stress disorder	15JAN2019		Y
	C4591001 1265 12651182†	Surgical and medical procedures	Gastrectomy	15JAN2019	15JAN2019	N
		Endocrine disorders	Hypothyroidism	27NOV2017		Y
		Eye disorders	Refraction disorder	26SEP2005		Y
		Hepatobiliary disorders	Hepatic steatosis	12FEB2011		Y
		Immune system disorders	Drug hypersensitivity	08FEB2010		Y
				19DEC2013		Y
				22AUG2017		Y
		Infections and infestations	Urinary tract infection bacterial	13JUL2020		Y
		Investigations	HIV test positive	01FEB2010		Y
			Tuberculin test positive	08FEB2010		Y
		Metabolism and nutrition disorders	Gout	20JUL2019		Y
			Vitamin D deficiency	12FEB2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	14NOV2018		Y
		Renal and urinary disorders	Pollakiuria	13JUL2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	04MAY2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Mechanical urticaria	20NOV2017		Y
			Urticaria cholinergic	20NOV2017		Y
			Urticaria chronic	20NOV2017		Y
	C4591001 1265 12651186†	Congenital, familial and genetic disorders	Pectus excavatum	04APR2016		Y
			Ear and labyrinth disorders	Vertigo positional	23JAN2020	
		Gastrointestinal disorders	Gastric ulcer	02SEP2020		Y
		Infections and infestations	Asymptomatic HIV infection	13JAN2006		Y
			Chronic sinusitis	14DEC2006		Y
			Hepatitis C	20JUL2006		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	06DEC2017		Y
		Nervous system disorders	Paraesthesia	14DEC2006		Y
		Psychiatric disorders	Drug abuse	04SEP2020		Y
				08APR2020		Y
			31OCT2011		Y	
		Renal and urinary disorders	Renal cyst	10JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	03SEP2009		Y
	C4591001 1269 12691001	Infections and infestations	Onychomycosis	01JAN2015		Y
				Metabolism and nutrition disorders	Gout	01JAN2018
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
				Osteoarthritis	01JAN2018	
		Psychiatric disorders	Insomnia	01JAN2019		Y
	C4591001 1269 12691002	Gastrointestinal disorders	Constipation	01MAR2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1269 12691004	Surgical and medical procedures	Splenectomy	01JAN1977	31DEC1977	N
		Immune system disorders	Allergy to animal	01JAN2000		Y
			Allergy to chemicals	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Vascular disorders	White coat hypertension	01JAN2000		Y
	C4591001 1269 12691006	Surgical and medical procedures	Limb operation	01JAN2008	31DEC2008	N
	C4591001 1269 12691007	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Haemorrhoids	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
	C4591001 1269 12691010	Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2009		Y
	C4591001 1269 12691011	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN1992		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1269 12691013	Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1269 12691014	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Infections and infestations	Urinary tract infection	01JUL2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUL2020		Y
			Insomnia	01JAN2020		Y
	C4591001 1269 12691020	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1269 12691022	Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1269 12691025	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997	31DEC1999	N
		Nervous system disorders	Headache	01JAN2011		Y
	C4591001 1269 12691026	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rash	01JUL2020		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31DEC2011	N
			Mitral valve repair	01JAN1975	31DEC1975	N
	C4591001 1269 12691027	Infections and infestations	Vaginal infection	01JUN2020	31AUG2020	N
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1269 12691030	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
	C4591001 1269 12691031	Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
	C4591001 1269 12691032	Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prophylaxis against HIV infection	01JAN2014		Y
			Spinal fusion surgery	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1989	31DEC1989	N
	C4591001 1269 12691034	Immune system disorders	Allergy to animal	01JAN2000		Y
	C4591001 1269 12691037	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Brain stem stroke	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Jaw operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1269 12691039	Eye disorders	Strabismus	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Infections and infestations	Kidney infection	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1269 12691041	Infections and infestations	Oral herpes	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
		Psychiatric disorders	Alcoholism	01JAN1994		Y
	C4591001 1269 12691045	Immune system disorders	Allergy to synthetic fabric	01JAN2012		Y
			Drug hypersensitivity	01JAN1998		Y
				01JAN2012		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Pneumonia	01FEB2020	29FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Back injury	01JUN2020		Y
			Road traffic accident	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1269 12691047	Infections and infestations	Vulvovaginal candidiasis	01SEP2019	30SEP2019	N
	C4591001 1269 12691048	Ear and labyrinth disorders	Tinnitus	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1269 12691050	Immune system disorders	Contrast media allergy	01JAN2019		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	24AUG2020		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1269 12691051	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1269 12691055	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Nervous system disorders	Headache	01JAN1998		Y
			Migraine	01JAN2018		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2011	31DEC2011	N
			Ovarian cystectomy	01JAN2014	31DEC2014	N
	C4591001 1269 12691056	Immune system disorders	Allergy to animal	01AUG2020		Y
	C4591001 1269 12691057	Psychiatric disorders	Anxiety	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691058	Surgical and medical procedures	Sinus operation	01JAN2014	31DEC2014	N
			Synovial cyst removal	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1269 12691059	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Dermatitis contact	01JAN2017		Y
	C4591001 1269 12691060	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Cataract	01JAN2009	31DEC2009	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Meniscus removal	01JAN2003	31DEC2003	N
			Shoulder operation	01JAN1997	31DEC1997	N
			Toe operation	01JAN2012	31DEC2012	N
	C4591001 1269 12691062	Cardiac disorders	Supraventricular tachycardia	01NOV2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1269 12691063	Surgical and medical procedures	Female sterilisation	01JAN2011	31DEC2011	N
		Gastrointestinal disorders	Constipation	01JAN2008		Y
			Diarrhoea	01JAN2008		Y
			Gastrooesophageal reflux disease	01JAN2008		Y
			Irritable bowel syndrome	01JAN2008		Y
		Immune system disorders	Allergy to animal	01JAN2006		Y
			Dust allergy	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
	C4591001 1269 12691064	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1998	25AUG2020	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1269 12691065	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Chest pain	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1269 12691072	Nervous system disorders	Migraine	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstruation irregular	01JAN1998		Y
	C4591001 1269 12691073	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Urinary tract infection	20MAY2020	31MAY2020	N
		Nervous system disorders	Headache	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN1975		Y
			Depression	01JAN2001		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1269 12691074	Vascular disorders	Deep vein thrombosis	01JAN2017	31DEC2017	N
			Hot flush	01JAN2018		Y
	C4591001 1269 12691075	Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
	C4591001 1269 12691076	Infections and infestations	Papilloma viral infection	01JAN2017		Y
			Vulvovaginal candidiasis	01JUL2020	31JUL2020	N
	C4591001 1269 12691078	Psychiatric disorders	Anxiety	01JAN1999		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Gastric bypass	01JAN2011	31DEC2011	N
			Ligament operation	01JAN2013	31DEC2013	N
	C4591001 1269 12691081	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Tonsillectomy	01JAN1994	31DEC1994	N
	C4591001 1269 12691087	Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Eye operation	01JAN2011	31DEC2011	N
	C4591001 1269 12691088	Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Myomectomy	01JAN2017	31DEC2017	N
	C4591001 1269 12691089	Eye disorders	Keratoconus	01JAN2000		Y
	C4591001 1269 12691091	Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Intervertebral disc operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1269 12691093	Ear and labyrinth disorders	Vertigo	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1269 12691095	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01NOV2019	30NOV2019	N
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Small intestinal resection	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691097	Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1998	31DEC1998	N
	C4591001 1269 12691099	Injury, poisoning and procedural complications	Eye injury	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Vasectomy	01JUN2013	30JUN2013	N
	C4591001 1269 12691103	General disorders and administration site conditions	Chest pain	01JAN2020	31JAN2020	N
		Infections and infestations	Eczema infected	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
		Surgical and medical procedures	Cleft lip repair	01JAN1983	31DEC2001	N
	C4591001 1269 12691104	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
		Surgical and medical procedures	Caesarean section	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1269 12691105	Immune system disorders	Anaphylactic reaction	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
	C4591001 1269 12691106	Immune system disorders	Food allergy	01JAN2008		Y
			Seasonal allergy	01JAN2019		Y
	C4591001 1269 12691107	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
	C4591001 1269 12691108	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2015		Y
	C4591001 1269 12691110	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Eye disorders	Retinal detachment	01JAN2010	31DEC2010	N
		Immune system disorders	Rubber sensitivity	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
	C4591001 1269 12691113	Infections and infestations	Urinary tract infection	01JUN2020	30JUN2020	N
		Psychiatric disorders	Alcoholism	01JAN2015	31MAY2020	N
			Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
			Drug abuse	01JAN1999	31MAY2020	N
	C4591001 1269 12691115	Surgical and medical procedures	Female sterilisation	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1269 12691116	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1991	31DEC1992	N
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2010		Y
		Surgical and medical procedures	Explorative laparotomy	01MAR1992	31MAR1992	N
			Tumour excision	01MAR1992	31MAR1992	N
	C4591001 1269 12691117	Nervous system disorders	Seizure	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691119	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1269 12691121	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1269 12691122	Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Gastrooesophageal reflux disease	01APR2020		Y
		Immune system disorders	Allergy to animal	01JAN1987		Y
			Seasonal allergy	01JAN1992		Y
		Infections and infestations	Urinary tract infection	01MAY2020	31MAY2020	N
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN2015		Y
	C4591001 1269 12691123	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1992		Y
	C4591001 1269 12691126	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
			Cluster headache	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2006		Y
	C4591001 1269 12691127	Surgical and medical procedures	Bone operation	01MAY2020	31MAY2020	N
	C4591001 1269 12691129	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Diarrhoea	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
		Reproductive system and breast disorders	Peyronie's disease	01JAN2012		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2011	31DEC2011	N
	C4591001 1269 12691130	Surgical and medical procedures	Gastrectomy	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1269 12691133	Immune system disorders	Seasonal allergy	01MAY2020		Y
	C4591001 1269 12691136	Infections and infestations	Herpes simplex	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
	C4591001 1269 12691140	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01NOV2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Sciatica	01AUG2020		Y
		Surgical and medical procedures	Hysterectomy	01JUL2007	31JUL2007	N
			Oophorectomy	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
	C4591001 1269 12691143	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1999		Y
		Surgical and medical procedures	Female sterilisation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701003	Metabolism and nutrition disorders	Impaired fasting glucose	24FEB2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	24JAN2017		Y
			Myofascial pain syndrome	24JAN2017		Y
			Spinal osteoarthritis	24JAN2017		Y
	C4591001 1270 12701004	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	11JAN2019		Y
		Renal and urinary disorders	Stress urinary incontinence	18MAY2017		Y
		Reproductive system and breast disorders	Cervical dysplasia	12FEB2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26JUN2017		Y
		Skin and subcutaneous tissue disorders	Acne	28AUG2012		Y
	C4591001 1270 12701007	Endocrine disorders	Hypothyroidism	04SEP2018		Y
		Gastrointestinal disorders	Constipation	09MAR2017		Y
		Injury, poisoning and procedural complications	Muscle strain	03APR2019		Y
		Metabolism and nutrition disorders	Obesity	10JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	03APR2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	16JUN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	29FEB2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12JUL2013		Y
		Vascular disorders	Hypertension	17JAN2017		Y
	C4591001 1270 12701008	Respiratory, thoracic and mediastinal disorders	Asthma	08OCT2012		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1270 12701010	Ear and labyrinth disorders	Vertigo	13SEP2019		Y
		Investigations	Human papilloma virus test positive	04APR2017		Y
		Renal and urinary disorders	Stress urinary incontinence	07APR2017		Y
	C4591001 1270 12701011	Gastrointestinal disorders	Gastrooesophageal reflux disease	09OCT2014		Y
		Immune system disorders	Seasonal allergy	19NOV2015		Y
		Investigations	High density lipoprotein decreased	22JUL2016		Y
			Tuberculin test positive	09OCT2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	22JUL2016		Y
			Hypertriglyceridaemia	22JUL2016		Y
			Metabolic syndrome	22JUL2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	04MAY2015		Y
				10APR2017		Y
		Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	02JUL2018	02JUL2018	N
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	13AUG2020		Y
			Anxiety disorder	29APR2016		Y
		Vascular disorders	Hypertension	08MAY2019		Y
	C4591001 1270 12701013	Musculoskeletal and connective tissue disorders	Arthralgia	30APR2017		Y
		Psychiatric disorders	Anxiety	17SEP2018		Y
	C4591001 1270 12701014	Gastrointestinal disorders	Large intestine polyp	10MAY2010		Y
		Immune system disorders	Drug hypersensitivity	21MAY2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23MAY2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	15JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	23JAN2007		Y
			Neuroma	23JAN2007		Y
			Seborrhoeic keratosis	23JAN2007		Y
		Psychiatric disorders	Insomnia	26JUN2009		Y
		Skin and subcutaneous tissue disorders	Dermatitis	23JAN2007		Y
	C4591001 1270 12701015	Nervous system disorders	Medication overuse headache	15MAY2018		Y
			Migraine with aura	15MAY2018		Y
			Tension headache	15MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07JAN2020		Y
			Rhinitis allergic	20JUL2020		Y
			Sleep apnoea syndrome	21MAY2020		Y
		Skin and subcutaneous tissue disorders	Skin irritation	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	29JAN2015	29JAN2015	N
			Salpingo-oophorectomy	05JUL2018	05JUL2020	N
	C4591001 1270 12701018	Immune system disorders	Drug hypersensitivity	30OCT2006		Y
		Infections and infestations	Genital herpes simplex	03JUN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	17DEC2018		Y
			Rotator cuff syndrome	30OCT2017		Y
			Temporomandibular joint syndrome	08AUG2008		Y
		Nervous system disorders	Migraine	13DEC2007		Y
		Psychiatric disorders	Anxiety	30MAY2014		Y
		Reproductive system and breast disorders	Metrorrhagia	09APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	13APR2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701020	Gastrointestinal disorders	Colitis ulcerative	05MAR2018		Y
	C4591001 1270 12701021	Gastrointestinal disorders	Gastroesophageal reflux disease	07JUN2020		Y
		Metabolism and nutrition disorders	Lactose intolerance	07JUN2020		Y
		Nervous system disorders	Migraine	07JUN2020		Y
		Reproductive system and breast disorders	Menorrhagia	07JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07JUN2020		Y
		Skin and subcutaneous tissue disorders	Acne	07JUN2020		Y
			Urticaria chronic	07JUN2020		Y
	C4591001 1270 12701022	Gastrointestinal disorders	Gastroesophageal reflux disease	30JUL2019		Y
		Immune system disorders	Seasonal allergy	06MAR2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	10NOV2006		Y
			Hyperlipidaemia	30JUL2019		Y
			Hypertriglyceridaemia	30JUL2019		Y
			Type 2 diabetes mellitus	30JUL2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	02SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Cough variant asthma	06MAR2015		Y
		Skin and subcutaneous tissue disorders	Nail bed disorder	04APR2016		Y
	C4591001 1270 12701030	Eye disorders	Presbyopia	06FEB2020		Y
		General disorders and administration site conditions	Peripheral swelling	13JUN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	21DEC2005		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibrous histiocytoma	06AUG2008		Y
			Melanocytic naevus	06AUG2008		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	06AUG2008		Y
	C4591001 1270 12701033	Eye disorders	Astigmatism	05JAN2007		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1993		Y
		Psychiatric disorders	Adjustment disorder	22JUL2019		Y
			Major depression	25JUN2019		Y
	C4591001 1270 12701034	Eye disorders	Myopia	29SEP2009		Y
		Gastrointestinal disorders	Coeliac disease	17NOV2011		Y
			Haemorrhoids	10MAR2010		Y
		Metabolism and nutrition disorders	Gluten sensitivity	24MAR2010		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	17NOV2011		Y
	C4591001 1270 12701035	Musculoskeletal and connective tissue disorders	Back pain	28MAR2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2004		Y
			Rhinitis allergic	01JUN2004		Y
	C4591001 1270 12701037	Metabolism and nutrition disorders	Obesity	27DEC2016		Y
		Vascular disorders	Hypertension	28APR2020		Y
	C4591001 1270 12701045	Gastrointestinal disorders	Diverticulum intestinal	02MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	10DEC2019		Y
		Skin and subcutaneous tissue disorders	Angiokeratoma	08MAY2015		Y
	C4591001 1270 12701046	Immune system disorders	Drug hypersensitivity	24DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	04DEC2015		Y
		Nervous system disorders	Migraine	13OCT2017		Y
		Psychiatric disorders	Major depression	24MAR2015		Y
		Reproductive system and breast disorders	Ovarian cyst	12DEC2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05JAN2016		Y
	C4591001 1270 12701048	Reproductive system and breast disorders	Dysmenorrhoea	15MAY2020		Y
	C4591001 1270 12701051	Gastrointestinal disorders	Gastroesophageal reflux disease	12MAR2019		Y
			Large intestine polyp	29MAR2019	29MAR2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2005		Y
			Obesity	06JUL2015		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	09JUL2015	14MAR2016	N
		Surgical and medical procedures	Large intestinal polypectomy	29MAR2019	29MAR2019	N
		Vascular disorders	Hypertension	01SEP2005		Y
	C4591001 1270 12701056	Eye disorders	Amblyopia	06NOV2007		Y
		Immune system disorders	Drug hypersensitivity	27JAN2003		Y
				29JUL2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	19NOV2007		Y
			Obesity	18SEP2015		Y
		Psychiatric disorders	Major depression	28MAR2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14APR2008		Y
			Rhinitis allergic	20MAY2007		Y
			Sleep apnoea syndrome	29AUG2020		Y
		Surgical and medical procedures	Gastrectomy	12MAR2015	12MAR2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701064	Hepatobiliary disorders	Hepatic steatosis	26JAN2015		Y
		Immune system disorders	Food allergy	01AUG1982		Y
			Seasonal allergy	26JAN2015		Y
		Metabolism and nutrition disorders	Gout	27JUL2011		Y
			Hyperlipidaemia	23FEB2009		Y
			Obesity	13JAN2020		Y
			Type 2 diabetes mellitus	23FEB2009		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	26JAN2015		Y
			Tendonitis	18MAR2020		Y
		Nervous system disorders	Neuropathy peripheral	26JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	26JAN2015		Y
	C4591001 1270 12701065	Endocrine disorders	Hypothyroidism	04JAN2018		Y
		Immune system disorders	Drug hypersensitivity	07JUN2020		Y
		Metabolism and nutrition disorders	Obesity	25JAN2017		Y
			Vitamin D deficiency	21NOV2016		Y
		Musculoskeletal and connective tissue disorders	Joint stiffness	21MAR2019		Y
			Neck pain	21NOV2016		Y
			Plantar fasciitis	23MAY2017		Y
				30APR2018		Y
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	12JUL2019		Y
		Reproductive system and breast disorders	Breast enlargement	12JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	25JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	16MAR2020		Y
	C4591001 1270 12701068	Metabolism and nutrition disorders	Obesity	15APR2009		Y
			Type 2 diabetes mellitus	10MAY2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	12AUG2020		Y
			Osteoarthritis	14JUN2010		Y
		Nervous system disorders	Migraine	14JUN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	14JUN2010		Y
		Surgical and medical procedures	Knee arthroplasty	13FEB2013	13FEB2013	N
	C4591001 1270 12701069	Gastrointestinal disorders	Anal skin tags	21AUG2018		Y
		Infections and infestations	Genital herpes simplex	30JUL2020		Y
		Nervous system disorders	Sinus headache	25OCT2019		Y
		Psychiatric disorders	Cyclothymic disorder	17APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	23MAR2017		Y
			Rhinitis allergic	23MAR2017		Y
		Skin and subcutaneous tissue disorders	Acne	16AUG2019		Y
	C4591001 1270 12701071	Endocrine disorders	Hypothyroidism	08JUN2018		Y
		Immune system disorders	Allergy to arthropod sting	24APR2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	24APR2018		Y
		Psychiatric disorders	Insomnia	24APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	24APR2018		Y
	C4591001 1270 12701074	Metabolism and nutrition disorders	Obesity	12NOV2015		Y
			Type 2 diabetes mellitus	10JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Premature ejaculation	29MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26JUN2014		Y
			Rhinitis allergic	14JUN1996		Y
		Vascular disorders	Hypertension	20SEP2016		Y
	C4591001 1270 12701076	Eye disorders	Myopia	30APR2007		Y
		General disorders and administration site conditions	Drug intolerance	20OCT2014		Y
				29JUL2013		Y
		Infections and infestations	Rhinitis	05OCT2004		Y
		Injury, poisoning and procedural complications	Meniscus injury	02JAN2019	19FEB2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	06OCT2018		Y
			Intervertebral disc degeneration	08APR2013		Y
			Osteopenia	18APR2012		Y
			Spondyloarthropathy	01JUN2016		Y
		Psychiatric disorders	Generalised anxiety disorder	15MAR2018		Y
			Insomnia	08MAR2017		Y
		Reproductive system and breast disorders	Endometriosis	10JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	18APR2012		Y
			Bronchial hyperreactivity	10FEB2014		Y
		Surgical and medical procedures	Meniscus removal	19FEB2019	19FEB2019	N
			Salpingo-oophorectomy bilateral	01JUL2016	01JUL2016	N
	C4591001 1270 12701082	Ear and labyrinth disorders	Deafness bilateral	09MAR2011		Y
		Immune system disorders	Drug hypersensitivity	01NOV2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	High density lipoprotein decreased	09MAR2011		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	09MAR2011		Y
			Obesity	17APR2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	20OCT2017		Y
			Temporomandibular joint syndrome	09MAR2011		Y
		Nervous system disorders	Cervical radiculopathy	14JUL2018		Y
		Psychiatric disorders	Anxiety disorder	08APR2016		Y
			Attention deficit hyperactivity disorder	02FEB2018		Y
			Depression	01NOV2017		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	09MAR2011		Y
	C4591001 1270 12701084	Gastrointestinal disorders	Diverticulum	01JAN2000		Y
			Gastrooesophageal reflux disease	20NOV2017		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	09SEP2020		Y
		Nervous system disorders	Migraine	02NOV2018		Y
		Psychiatric disorders	Anxiety disorder	24OCT2018		Y
			Depression	24OCT2018		Y
			Insomnia	29JUN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15NOV2017		Y
		Vascular disorders	Hypertension	06DEC2019		Y
	C4591001 1270 12701085	Eye disorders	Refraction disorder	19MAY2009		Y
		Immune system disorders	Drug hypersensitivity	08AUG2002		Y
				20DEC2013		Y
		Injury, poisoning and procedural complications	Epicondylitis	27APR2018		Y
		Metabolism and nutrition disorders	Obesity	04AUG2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	26AUG2019		Y
			Tendonitis	13MAY2010		Y
		Nervous system disorders	Migraine	11JUN2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	20MAY2020		Y
			Uterine haemorrhage	10JAN2020		Y
		Vascular disorders	Hypertension	04AUG2009		Y
	C4591001 1270 12701086	Cardiac disorders	Pericarditis	17JAN2013	14MAR2013	N
		Eye disorders	Dry eye	29AUG2019		Y
			Myopia	15JUN2017		Y
			Punctate keratitis	22OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	15NOV2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15NOV2015		Y
			Rhinitis allergic	12NOV2015		Y
		Skin and subcutaneous tissue disorders	Acne	15FEB2011		Y
	C4591001 1270 12701087	Nervous system disorders	Migraine	06AUG2010		Y
	C4591001 1270 12701088	Reproductive system and breast disorders	Varicocele	07DEC2019		Y
	C4591001 1270 12701089	Gastrointestinal disorders	Gastroesophageal reflux disease	11MAR2009		Y
		Immune system disorders	Drug hypersensitivity	11JAN2011		Y
				26DEC2015		Y
				28DEC2001		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Genital herpes simplex	04JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	29APR2016		Y
			Obesity	11APR2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2013		Y
			Osteoarthritis	04JAN2019		Y
	C4591001 1270 12701090	Endocrine disorders	Hypothyroidism	18OCT2018		Y
	C4591001 1270 12701091	Metabolism and nutrition disorders	Hyperlipidaemia	27JAN2016		Y
			Obesity	27JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	13JUN2019		Y
		Nervous system disorders	Restless legs syndrome	27JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	12MAY2014		Y
	C4591001 1270 12701097	Cardiac disorders	Left ventricular hypertrophy	01JUN2007		Y
		Eye disorders	Myopia	05DEC2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	02DEC2004		Y
		Immune system disorders	Drug hypersensitivity	11FEB2008		Y
				13MAR2008		Y
		Investigations	High density lipoprotein decreased	21FEB2007		Y
		Metabolism and nutrition disorders	Obesity	24FEB2006		Y
			Type 2 diabetes mellitus	04JUN2019		Y
		Psychiatric disorders	Bipolar II disorder	12JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20APR2016		Y
			Nasal septum deviation	10JAN2017	10JAN2017	N
			Rhinitis allergic	23MAY2012		Y
			Sleep apnoea syndrome	17MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nasal septal operation	10JAN2017	10JAN2017	N
		Vascular disorders	Hypertension	24FEB2006		Y
	C4591001 1270 12701098	Metabolism and nutrition disorders	Hypertriglyceridaemia	24JUN2012		Y
			Obesity	25AUG2015		Y
		Vascular disorders	Hypertension	25AUG2015		Y
	C4591001 1270 12701099	Gastrointestinal disorders	Gastrooesophageal reflux disease	15SEP2018		Y
		Immune system disorders	Drug hypersensitivity	18AUG2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	30JUN2020		Y
		Musculoskeletal and connective tissue disorders	Joint instability	26AUG2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	23FEB2017		Y
		Surgical and medical procedures	Inguinal hernia repair	05DEC2019	05DEC2019	N
	C4591001 1270 12701100	Congenital, familial and genetic disorders	Neurofibromatosis	01JAN1986		Y
		Hepatobiliary disorders	Cholelithiasis	11AUG2016	31DEC2018	N
		Immune system disorders	Seasonal allergy	30APR2013		Y
	C4591001 1270 12701107	Eye disorders	Corneal scar	01JAN2000		Y
				15NOV2019		Y
			Refraction disorder	15NOV2019		Y
		Infections and infestations	Ophthalmic herpes zoster	01JAN2000		Y
			Urinary tract infection	12SEP2020		Y
		Musculoskeletal and connective tissue disorders	Neck pain	11AUG2020		Y
	C4591001 1270 12701118	Immune system disorders	Drug hypersensitivity	20SEP2007		Y
			Seasonal allergy	22AUG2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Glucose tolerance impaired	14FEB2017		Y
			Hyperlipidaemia	07APR2014		Y
		Nervous system disorders	Migraine	07JUL2016		Y
		Reproductive system and breast disorders	Premenstrual dysphoric disorder	15JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	03DEC2018		Y
		Surgical and medical procedures	Breast cyst excision	10FEB2009	10FEB2009	N
	C4591001 1270 12701119	Gastrointestinal disorders	Irritable bowel syndrome	03JUN2013		Y
		Immune system disorders	Drug hypersensitivity	08JUL2020		Y
		Infections and infestations	Cervicitis human papilloma virus	08DEC2017		Y
		Nervous system disorders	Hypersomnia	20NOV2009		Y
		Psychiatric disorders	Anxiety disorder	20NOV2009		Y
	C4591001 1270 12701121	Nervous system disorders	Migraine	25JUL2017		Y
	C4591001 1270 12701122	Immune system disorders	Drug hypersensitivity	24NOV2018		Y
		Metabolism and nutrition disorders	Obesity	15SEP2015		Y
		Psychiatric disorders	Anxiety	15SEP2015		Y
	C4591001 1270 12701123	Endocrine disorders	Hypothyroidism	24DEC2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	12OCT2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	09APR2009		Y
	C4591001 1270 12701124	Cardiac disorders	Arteriosclerosis coronary artery	14NOV2019		Y
			Ventricular tachycardia	20JUN2017	30SEP2017	N
		Immune system disorders	Drug hypersensitivity	20MAY2003		Y
		Metabolism and nutrition disorders	Obesity	07MAY2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	15APR2010		Y
		Reproductive system and breast disorders	Infertility	07MAY2012		Y
		Surgical and medical procedures	Intervertebral disc operation	20NOV2019	20NOV2019	N
		Vascular disorders	Hypertension	21APR2017		Y
	C4591001 1270 12701125	Psychiatric disorders	Anxiety	28JAN2020		Y
			Insomnia	14JAN2013		Y
	C4591001 1270 12701128	Gastrointestinal disorders	Gastroesophageal reflux disease	11MAR2019		Y
		Immune system disorders	Drug hypersensitivity	02DEC2016		Y
		Psychiatric disorders	Major depression	02DEC2016	30JUN2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	11MAR2019		Y
			Rhinitis allergic	11MAR2019		Y
	C4591001 1270 12701131	Endocrine disorders	Hypothyroidism	12MAY2015		Y
	C4591001 1270 12701132	Blood and lymphatic system disorders	Thrombocytopenia	23MAR2012		Y
		Musculoskeletal and connective tissue disorders	Neck pain	07JAN2019		Y
		Psychiatric disorders	Anxiety disorder	21APR2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	19JUL2018		Y
		Surgical and medical procedures	Hysterectomy	09AUG2018	09AUG2018	N
	C4591001 1270 12701133	Gastrointestinal disorders	Haemorrhoids	29OCT2008		Y
		Immune system disorders	Drug hypersensitivity	10OCT2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Tendonitis	01MAR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	02FEB2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	26MAY2012		Y
		Skin and subcutaneous tissue disorders	Eczema	08NOV2019		Y
	C4591001 1270 12701134	Endocrine disorders	Goitre	29FEB2012		Y
			Thyroid cyst	23AUG2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	04NOV2007		Y
		Immune system disorders	Drug hypersensitivity	02AUG2010		Y
				04NOV2007		Y
				19JUL2010		Y
		Infections and infestations	Rhinitis	01SEP2017		Y
		Metabolism and nutrition disorders	Obesity	04NOV2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2016		Y
			Intervertebral disc degeneration	11APR2008		Y
			Neck pain	11APR2008		Y
			Spinal osteoarthritis	20JUN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	25JAN2012		Y
		Nervous system disorders	Migraine	17AUG2009		Y
		Psychiatric disorders	Adjustment disorder with mixed anxiety and depressed mood	06FEB2018		Y
			Major depression	15JAN2019		Y
			Post-traumatic stress disorder	29JUL2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Menorrhagia	12DEC2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	16AUG2017		Y
			Sleep apnoea syndrome	12JUL2017		Y
		Skin and subcutaneous tissue disorders	Hidradenitis	24DEC2018		Y
			Rosacea	16AUG2017		Y
	C4591001 1270 12701135	Metabolism and nutrition disorders	Obesity	14OCT2016		Y
		Psychiatric disorders	Anxiety	11FEB2020		Y
			Insomnia	11FEB2020		Y
	C4591001 1270 12701136	Respiratory, thoracic and mediastinal disorders	Asthma	25JAN2006		Y
			Rhinitis allergic	25JAN2006		Y
		Skin and subcutaneous tissue disorders	Alopecia areata	15JAN2014		Y
			Dermatitis atopic	11AUG2009		Y
	C4591001 1270 12701142	Eye disorders	Chorioretinopathy	17FEB2009		Y
		Metabolism and nutrition disorders	Dyslipidaemia	06MAR2019		Y
	C4591001 1270 12701146	Skin and subcutaneous tissue disorders	Acne	17NOV2016		Y
	C4591001 1270 12701148	Skin and subcutaneous tissue disorders	Acne	07MAY2020		Y
	C4591001 1270 12701149	Infections and infestations	Rhinitis	15FEB2020		Y
	C4591001 1270 12701150	Congenital, familial and genetic disorders	Imperforate hymen	27OCT2020		Y
		Immune system disorders	Food allergy	30MAR2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	31MAR2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Cold urticaria	23JUL2018		Y
			Dermatitis atopic	17AUG2011		Y
	C4591001 1270 12701151	Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	12MAR2019	12MAR2019	N
		Skin and subcutaneous tissue disorders	Acne	12MAY2017		Y
			Dermatitis atopic	04JUN2012		Y
		Surgical and medical procedures	Thoracic operation	16MAR2019	16MAR2019	N
	C4591001 1270 12701154	Psychiatric disorders	Attention deficit hyperactivity disorder	04SEP2014		Y
	C4591001 1270 12701156	Endocrine disorders	Thyroid mass	04MAY2018	03JUL2018	N
		Surgical and medical procedures	Thyroidectomy	03JUL2018	03JUL2018	N
	C4591001 1270 12701157	Infections and infestations	Oral herpes	24MAY2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	29OCT2020		Y
	C4591001 1270 12701158	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17JUL2015		Y
	C4591001 1270 12701159	Psychiatric disorders	Autism spectrum disorder	31JUL2018		Y
			Depression	15MAY2018		Y
			Generalised anxiety disorder	15MAY2018		Y
	C4591001 1270 12701160	Eye disorders	Astigmatism	28AUG2020		Y
			Myopia	10APR2019		Y
		Immune system disorders	Drug hypersensitivity	21OCT2018		Y
	C4591001 1270 12701162	Metabolism and nutrition disorders	Lactose intolerance	17JAN2012		Y
			Obesity	25FEB2013		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	20MAR2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19APR2010		Y
		Skin and subcutaneous tissue disorders	Acne	20AUG2020		Y
	C4591001 1270 12701164	Immune system disorders	Drug hypersensitivity	29MAY2020		Y
	C4591001 1270 12701165	Injury, poisoning and procedural complications	Cartilage injury	15JAN2019	29JAN2019	N
		Surgical and medical procedures	Chondroplasty	29JAN2019	29JAN2019	N
	C4591001 1270 12701166	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19MAY2020		Y
	C4591001 1270 12701167	Skin and subcutaneous tissue disorders	Acne	10MAR2016		Y
	C4591001 1270 12701168	Musculoskeletal and connective tissue disorders	Arthralgia	30SEP2020		Y
	C4591001 1270 12701169	Nervous system disorders	Central auditory processing disorder	02AUG2017		Y
			Migraine with aura	02AUG2020		Y
	C4591001 1270 12701170	Nervous system disorders	Migraine	07MAR2013		Y
	C4591001 1270 12701171	Immune system disorders	Drug hypersensitivity	04MAR2015		Y
		Infections and infestations	Folliculitis	12NOV2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03MAR2015		Y
			Rhinitis allergic	03MAR2015		Y
		Skin and subcutaneous tissue disorders	Acne	07FEB2019		Y
	C4591001 1270 12701172	Immune system disorders	Drug hypersensitivity	04MAR2015		Y
		Infections and infestations	Folliculitis	12NOV2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	28OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	04MAR2015		Y
		Skin and subcutaneous tissue disorders	Acne	14JUL2016		Y
	C4591001 1270 12701175	Musculoskeletal and connective tissue disorders	Arthralgia	18APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26OCT2007		Y
			Rhinitis allergic	26JAN2007		Y
	C4591001 1270 12701176	Respiratory, thoracic and mediastinal disorders	Asthma	28NOV2006		Y
			Rhinitis allergic	04DEC2013		Y
	C4591001 1270 12701178	Eye disorders	Refraction disorder	05MAR2019		Y
		Metabolism and nutrition disorders	Iron deficiency	24SEP2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	11JUN2008		Y
	C4591001 1270 12701179	Nervous system disorders	Headache	03OCT2019		Y
		Skin and subcutaneous tissue disorders	Acne	03OCT2019		Y
	C4591001 1270 12701182	Immune system disorders	Drug hypersensitivity	28FEB2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	09AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	29JAN2020		Y
	C4591001 1270 12701183	Psychiatric disorders	Social anxiety disorder	21JAN2020		Y
		Skin and subcutaneous tissue disorders	Acne	08AUG2017		Y
			Mechanical urticaria	26OCT2010		Y
	C4591001 1270 12701185	Nervous system disorders	Febrile convulsion	16JUL2006	31DEC2008	N
	C4591001 1270 12701186	Immune system disorders	Food allergy	01JUL2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				28NOV2012		Y
			Seasonal allergy	01JUL2011		Y
	C4591001 1270 12701190	Reproductive system and breast disorders	Dysmenorrhoea	23AUG2018		Y
	C4591001 1270 12701193	Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	12NOV2015		Y
	C4591001 1270 12701196	Eye disorders	Retinoschisis	11AUG2014		Y
	C4591001 1270 12701197	Immune system disorders	Drug hypersensitivity	25OCT2013		Y
		Psychiatric disorders	Adjustment disorder	13OCT2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25OCT2013		Y
	C4591001 4444 44441007	Blood and lymphatic system disorders	Immune thrombocytopenia	01MAR2010	12DEC2010	N
		Reproductive system and breast disorders	Ovarian cyst	10SEP2019	03OCT2020	N
	C4591001 4444 44441008	Immune system disorders	Mite allergy	15FEB2000		Y
	C4591001 4444 44441012	Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 4444 44441015	Endocrine disorders	Hypothyroidism	01SEP2010		Y
		Investigations	Intraocular pressure increased	01SEP2015		Y
	C4591001 4444 44441024	Psychiatric disorders	Depression	02JAN2014		Y
	C4591001 4444 44441028	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2010		Y
	C4591001 4444 44441034	Metabolism and nutrition disorders	Type 2 diabetes mellitus	03JUL2019	02FEB2020	N
		Surgical and medical procedures	Gastric bypass	26FEB2020	28FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441038	Vascular disorders	Hypertension	06DEC2001		Y
	C4591001 4444 44441040	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibrosarcoma	01SEP1990	01SEP1992	N
		Vascular disorders	Hypertension	01SEP2018		Y
	C4591001 4444 44441043	Infections and infestations	Tooth infection	01JAN2017	18NOV2020	N
		Psychiatric disorders	Depression	01AUG2000		Y
	C4591001 4444 44441056	Psychiatric disorders	Initial insomnia	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2000		Y
	C4591001 4444 44441060	Endocrine disorders	Autoimmune thyroiditis	10SEP1998		Y
	C4591001 4444 44441065	Skin and subcutaneous tissue disorders	Acne	02JAN2013		Y
	C4591001 4444 44441068	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2018		Y
	C4591001 4444 44441069	Ear and labyrinth disorders	Deafness bilateral	01JAN1983		Y
		Metabolism and nutrition disorders	Obesity	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
	C4591001 4444 44441071	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
		Psychiatric disorders	Persistent depressive disorder	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 4444 44441072	Metabolism and nutrition disorders	Type 2 diabetes mellitus	03JUN2019		Y
		Vascular disorders	Hypertension	01SEP2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441075	Endocrine disorders	Hypothyroidism	23SEP2010		Y
	C4591001 4444 44441076	Metabolism and nutrition disorders	Dyslipidaemia	01FEB2018		Y
		Vascular disorders	Hypertension	01FEB2017		Y
	C4591001 4444 44441079	Blood and lymphatic system disorders	Anaemia	01AUG2020		Y
	C4591001 4444 44441086	Ear and labyrinth disorders	Meniere's disease	01JAN2003		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 4444 44441094	Vascular disorders	Hypertension	01DEC2018		Y
	C4591001 4444 44441100	Vascular disorders	Hypertension	20DEC2019		Y
	C4591001 4444 44441103	Psychiatric disorders	Anxiety disorder	01OCT2018		Y
		Vascular disorders	Hypertension	01SEP2012		Y
	C4591001 4444 44441108	Endocrine disorders	Hypothyroidism	07JUL2000		Y
	C4591001 4444 44441110	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2015		Y
	C4591001 4444 44441121	Endocrine disorders	Hypothyroidism	10OCT2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	10FEB1989		Y
	C4591001 4444 44441123	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Infections and infestations	Pulmonary tuberculosis	01FEB1997	01JAN2000	N
	C4591001 4444 44441125	Eye disorders	Glaucoma	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441134	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2017	04OCT2017	N
	C4591001 4444 44441135	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 4444 44441138	Endocrine disorders	Hypothyroidism	14JUN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
	C4591001 4444 44441144	Infections and infestations	Pneumonia	22DEC2019	29DEC2019	N
		Reproductive system and breast disorders	Varicocele	01JUN2007	01JUN2007	N
		Surgical and medical procedures	Inguinal hernia repair	01JUN2007	01JUN2007	N
	C4591001 4444 44441147	Psychiatric disorders	Anorexia nervosa	09SEP2016		Y
			Major depression	09SEP2016		Y
	C4591001 4444 44441154	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 4444 44441155	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 4444 44441160	Injury, poisoning and procedural complications	Hand fracture	18DEC2017	18FEB2018	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01MAR2015		Y
	C4591001 4444 44441162	Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 4444 44441166	Reproductive system and breast disorders	Premature menopause	02MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441169	Gastrointestinal disorders	Dyspepsia	20APR2019		Y
	C4591001 4444 44441171	Endocrine disorders	Hypothyroidism	01JUN2006		Y
		Infections and infestations	Pulmonary tuberculosis	01JUL2018	01FEB2019	N
		Skin and subcutaneous tissue disorders	Acne	01AUG2020		Y
	C4591001 4444 44441172	Cardiac disorders	Arrhythmia	03MAR2016		Y
	C4591001 4444 44441173	Metabolism and nutrition disorders	Obesity	01JAN1986		Y
			Type 2 diabetes mellitus	01OCT2012		Y
	C4591001 4444 44441194	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 4444 44441197	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 4444 44441199	Endocrine disorders	Hypothyroidism	01SEP2005		Y
	C4591001 4444 44441205	Metabolism and nutrition disorders	Hypertriglyceridaemia	02SEP2010		Y
			Hyperuricaemia	03SEP2010		Y
			Obesity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	12SEP2018		Y
		Vascular disorders	Hypertension	10SEP2014		Y
	C4591001 4444 44441206	Metabolism and nutrition disorders	Obesity	25OCT2015		Y
	C4591001 4444 44441211	Psychiatric disorders	Insomnia	01MAY2014		Y
	C4591001 4444 44441212	Vascular disorders	Hypertension	01JUN2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441213	Psychiatric disorders	Anorexia nervosa	15JAN2015	20AUG2015	N
	C4591001 4444 44441218	Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT1995		Y
	C4591001 4444 44441220	Musculoskeletal and connective tissue disorders	Osteopenia	22JUN2020		Y
	C4591001 4444 44441224	Cardiac disorders	Sinus bradycardia	01SEP2010		Y
		Vascular disorders	Hypertension	01JUL2005		Y
	C4591001 4444 44441243	Metabolism and nutrition disorders	Gluten sensitivity	01AUG2017		Y
	C4591001 4444 44441245	Musculoskeletal and connective tissue disorders	Scoliosis	01MAR2010		Y
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 4444 44441247	Metabolism and nutrition disorders	Obesity	01FEB1990		Y
			Type 2 diabetes mellitus	01AUG2020		Y
		Vascular disorders	Hypertension	01AUG1989		Y
	C4591001 4444 44441249	Gastrointestinal disorders	Inguinal hernia	01JUL2020	05OCT2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
	C4591001 4444 44441255	Gastrointestinal disorders	Irritable bowel syndrome	01SEP2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP2016	20AUG2019	N
		Surgical and medical procedures	Hysterectomy	20AUG2019	20AUG2019	N
	C4591001 4444 44441257	Eye disorders	Glaucoma	01JAN1990		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 4444 44441261	Metabolism and nutrition disorders	Type 1 diabetes mellitus	07JUL2006		Y
	C4591001 4444 44441265	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	18SEP2005	18SEP2006	N
		Surgical and medical procedures	Radical hysterectomy	18SEP2006		Y
	C4591001 4444 44441268	Eye disorders	Dry eye	01JAN2018		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
	C4591001 4444 44441272	Reproductive system and breast disorders	Amenorrhoea	18MAR2019		Y
	C4591001 4444 44441279	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2012		Y
	C4591001 4444 44441284	Immune system disorders	Drug hypersensitivity	22AUG2005		Y
	C4591001 4444 44441293	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01SEP2016		Y
	C4591001 4444 44441294	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2018		Y
	C4591001 4444 44441297	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2017		Y
		Surgical and medical procedures	Gastric bypass	25MAR2019	25MAR2019	N
			Intra-uterine contraceptive device insertion	01FEB2020	01FEB2020	N
		Vascular disorders	Peripheral venous disease	22AUG2020		Y
	C4591001 4444 44441301	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 4444 44441302	Vascular disorders	Hypertension	01SEP2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441310	Psychiatric disorders	Depression	01MAR2016	01SEP2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 4444 44441311	Congenital, familial and genetic disorders	Phimosis	01JAN2020		Y
	C4591001 4444 44441317	Gastrointestinal disorders	Chronic gastritis	15JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	18MAR2015	13MAR2020	N
		Skin and subcutaneous tissue disorders	Rosacea	08JUN2010		Y
	C4591001 4444 44441321	Vascular disorders	Varicose vein	01JAN2017		Y
	C4591001 4444 44441325	Vascular disorders	Hypertension	05MAY2015		Y
	C4591001 4444 44441326	Endocrine disorders	Goitre	08JAN2019	16DEC2019	N
		Surgical and medical procedures	Thyroidectomy	16DEC2019	16DEC2019	N
	C4591001 4444 44441327	Endocrine disorders	Hypothyroidism	01JUN2010		Y
	C4591001 4444 44441334	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 4444 44441336	Psychiatric disorders	Insomnia	01SEP2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01SEP1983		Y
	C4591001 4444 44441337	Gastrointestinal disorders	Gastroesophageal reflux disease	08SEP2010		Y
	C4591001 4444 44441346	Endocrine disorders	Hypothyroidism	03DEC2010		Y
	C4591001 4444 44441348	Hepatobiliary disorders	Hepatic steatosis	03FEB2020		Y
	C4591001 4444 44441351	Metabolism and nutrition disorders	Obesity	09NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441358	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2017		Y
	C4591001 4444 44441359	Surgical and medical procedures	Cholecystectomy	01JAN2012	01JAN2012	N
	C4591001 4444 44441360	Gastrointestinal disorders	Haemorrhoids	01NOV2019		Y
		Surgical and medical procedures	Knee operation	10JAN2019	10JUN2019	N
			Ligament operation	10JAN2019	10JUN2019	N
			Meniscus operation	10JAN2019	10JUN2019	N
	C4591001 4444 44441366	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01MAR2007		Y
	C4591001 4444 44441376	Psychiatric disorders	Panic attack	01JAN2011	01FEB2011	N
	C4591001 4444 44441378	Respiratory, thoracic and mediastinal disorders	Asthma	25SEP2010		Y
	C4591001 4444 44441379	Infections and infestations	Chronic sinusitis	01JAN2000		Y
	C4591001 4444 44441384	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	03NOV2010		Y
	C4591001 4444 44441386	Endocrine disorders	Hypothyroidism	01SEP2020		Y
	C4591001 4444 44441388	Gastrointestinal disorders	Coeliac disease	11FEB2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	17MAY2017	24MAY2017	N
		Surgical and medical procedures	Knee operation	17MAY2017	24MAY2017	N
	C4591001 4444 44441395	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	01SEP2011	01SEP2012	N
		Surgical and medical procedures	Cholesteatoma removal	01SEP2011	01SEP2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441398	Cardiac disorders	Myocardial infarction	20MAY2014	22MAY2014	N
		Endocrine disorders	Hypothyroidism	01JUN2012		Y
		Social circumstances	Tobacco user	25MAY1990		Y
		Vascular disorders	Hypertension	10OCT2019		Y
	C4591001 4444 44441402	Cardiac disorders	Arteriospasm coronary	11MAR2018	18MAR2018	N
	C4591001 4444 44441404	Reproductive system and breast disorders	Sexual dysfunction	01SEP2019		Y
	C4591001 4444 44441405†	Investigations	HIV test positive	14MAR2007		Y
	C4591001 4444 44441407	Endocrine disorders	Hypothyroidism	01MAR2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01FEB2020		Y
		Surgical and medical procedures	Thyroidectomy	01APR2005	01APR2005	N
	C4591001 4444 44441408	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	14MAY2013		Y
	C4591001 4444 44441425	Social circumstances	Tobacco user	01JUN1985		Y
		Surgical and medical procedures	Caesarean section	18SEP1992	18SEP1992	N
	C4591001 4444 44441432	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	03MAR2018		Y
	C4591001 4444 44441436	Metabolism and nutrition disorders	Obesity	22APR2010		Y
	C4591001 4444 44441438	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	C4591001 4444 44441443	Metabolism and nutrition disorders	Obesity	04DEC2000		Y
	C4591001 4444 44441444	Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441446	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 4444 44441452	Eye disorders	Astigmatism	01JAN1980		Y
			Hypermetropia	01JAN1988		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2012		Y
	C4591001 4444 44441459	Vascular disorders	Hypertension	01APR2019		Y
	C4591001 4444 44441460	Reproductive system and breast disorders	Premature menopause	13AUG2020		Y
	C4591001 4444 44441474	Blood and lymphatic system disorders	Iron deficiency anaemia	01JUN2020		Y
		Endocrine disorders	Hypothyroidism	01SEP2014		Y
		Skin and subcutaneous tissue disorders	Acne	13JUN2002		Y
	C4591001 4444 44441476	Metabolism and nutrition disorders	Dyslipidaemia	01APR2011		Y
		Nervous system disorders	Ischaemic stroke	04APR2017	17JUL2017	N
				10FEB2011	15MAR2011	N
		Vascular disorders	Hypertension	01APR2011		Y
	C4591001 4444 44441482	Vascular disorders	Hypertension	01APR2010		Y
	C4591001 4444 44441483	Nervous system disorders	Migraine	01SEP2015		Y
		Reproductive system and breast disorders	Breast mass	01JAN2010		Y
	C4591001 4444 44441485	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 4444 44441488	Metabolism and nutrition disorders	Hyperuricaemia	01AUG2019	18SEP2019	N
	C4591001 4444 44441491	Cardiac disorders	Angina unstable	15MAY2014	15MAY2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	10JAN2012		Y
		Nervous system disorders	Optic neuritis	01SEP2013	01SEP2014	N
		Surgical and medical procedures	Coronary arterial stent insertion	15MAY2014	15MAY2014	N
		Vascular disorders	Hypertension	01SEP2000		Y
	C4591001 4444 44441494	Gastrointestinal disorders	Abdominal pain upper	01MAR2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 4444 44441498	Congenital, familial and genetic disorders	Microphthalmos	(b) (6) 2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 4444 44441503	Nervous system disorders	Migraine	01OCT2016		Y
	C4591001 4444 44441506	Cardiac disorders	Supraventricular extrasystoles	12APR2017	12APR2019	N
		Gastrointestinal disorders	Dyspepsia	10JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	12APR2019	12APR2019	N
	C4591001 4444 44441510	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 4444 44441515	Nervous system disorders	Tarsal tunnel syndrome	10MAR2020		Y
	C4591001 4444 44441516	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 4444 44441518	Vascular disorders	Hypertension	08JUN2020		Y
	C4591001 4444 44441520	Ear and labyrinth disorders	Deafness unilateral	01JUL2020		Y
		Vascular disorders	Hypertension	15JUL2016		Y
	C4591001 4444 44441523	Eye disorders	Glaucoma	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441524	Surgical and medical procedures	Inguinal hernia repair	14SEP1995	14SEP1995	N
	C4591001 4444 44441528	Blood and lymphatic system disorders	Iron deficiency anaemia	01SEP2009		Y
		Psychiatric disorders	Anxiety disorder	01SEP2017		Y
		Surgical and medical procedures	Myomectomy	01AUG2008		Y
	C4591001 4444 44441530	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	10MAY2016		Y
	C4591001 4444 44441532	Metabolism and nutrition disorders	Dyslipidaemia	11JAN2020		Y
		Vascular disorders	Hypertension	08JAN2020		Y
	C4591001 4444 44441536	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2017	01APR2018	N
		Vascular disorders	Peripheral venous disease	01SEP2019		Y
	C4591001 4444 44441539	Gastrointestinal disorders	Chronic gastritis	01MAY2020		Y
		Hepatobiliary disorders	Cholelithiasis	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	01AUG2013	10AUG2013	N
	C4591001 4444 44441541	Psychiatric disorders	Anxiety	01JUN2018		Y
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 4444 44441542	Endocrine disorders	Hypothyroidism	01MAR2014		Y
	C4591001 4444 44441546	Metabolism and nutrition disorders	Hypercholesterolaemia	15JUL2020		Y
		Vascular disorders	Hypertension	15JUL2020		Y
	C4591001 4444 44441549	Gastrointestinal disorders	Gastric ulcer	01AUG2005		Y
		Reproductive system and breast disorders	Ovarian cyst	15DEC2005	16JAN2006	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Oophorectomy	16JAN2006	17JAN2006	N
	C4591001 4444 44441550	Hepatobiliary disorders	Cholelithiasis	01FEB2020	23DEC2020	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2012		Y
	C4591001 4444 44441553	Surgical and medical procedures	Mammoplasty	13FEB2020	13FEB2020	N
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
	C4591001 4444 44441558	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
	C4591001 4444 44441561	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2014		Y
	C4591001 4444 44441562	Reproductive system and breast disorders	Benign prostatic hyperplasia	12DEC2019		Y
	C4591001 4444 44441563	Skin and subcutaneous tissue disorders	Vitiligo	01JAN2007		Y
	C4591001 4444 44441570	Endocrine disorders	Hypothyroidism	10FEB2000		Y
	C4591001 4444 44441574	Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Nervous system disorders	Epilepsy	01SEP2019		Y
		Surgical and medical procedures	Metabolic surgery	03AUG2010		Y
		Vascular disorders	Hypertension	07NOV2019		Y
	C4591001 4444 44441577	Metabolism and nutrition disorders	Hyperlipidaemia	09SEP2000		Y
	C4591001 4444 44441586	Reproductive system and breast disorders	Uterine polyp	01FEB2020		Y
	C4591001 4444 44441589	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
	C4591001 4444 44441593	Respiratory, thoracic and mediastinal disorders	Asthma	10JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441597	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2015		Y
	C4591001 4444 44441599	Nervous system disorders	Epilepsy	05JAN2000	15NOV2002	N
	C4591001 4444 44441603	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
	C4591001 4444 44441605	Vascular disorders	Hypertension	01SEP2020		Y
	C4591001 4444 44441608	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 4444 44441610	Cardiac disorders	Type 2 diabetes mellitus Arrhythmia	01OCT2019 01SEP2019		Y Y
	C4591001 4444 44441611	Surgical and medical procedures Infections and infestations	Female sterilisation Appendicitis	01FEB2012 04JUL2009	01FEB2012 04JUL2009	N N
	C4591001 4444 44441612	Surgical and medical procedures Congenital, familial and genetic disorders	Peritonitis Laparotomy Arnold-Chiari malformation	04JUL2009 04JUL2009 16APR2017	04JUL2009 04JUL2009	N N Y
	C4591001 4444 44441614	Surgical and medical procedures Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ventriculo-peritoneal shunt Meningioma	20JUL2017 03SEP2018		Y N
	C4591001 4444 44441616	Surgical and medical procedures Metabolism and nutrition disorders	Meningioma surgery Type 2 diabetes mellitus	07JAN2019 10FEB2015	09JAN2019	N Y
	C4591001 4444 44441618	Skin and subcutaneous tissue disorders	Alopecia	13FEB2020		Y
	C4591001 4444 44441628	Gastrointestinal disorders	Haemorrhoids	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	15FEB2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2003		Y
	C4591001 4444 44441629	Nervous system disorders	Seizure	01AUG1980	05JUN2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09SEP2010		Y
	C4591001 4444 44441632	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	12JUN2015		Y
		Social circumstances	Tobacco user	01JAN1979		Y
	C4591001 4444 44441633	Psychiatric disorders	Depression	20AUG2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 4444 44441634	Metabolism and nutrition disorders	Obesity	17MAR2000		Y
		Surgical and medical procedures	Metabolic surgery	09OCT2013	09OCT2013	N
	C4591001 4444 44441643	Nervous system disorders	Migraine	01JAN1984		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2015		Y
	C4591001 4444 44441644	Gastrointestinal disorders	Gastritis	01JAN2015		Y
	C4591001 4444 44441654	Nervous system disorders	Hemiplegia	(b) (6) 1995		Y
	C4591001 4444 44441658	Respiratory, thoracic and mediastinal disorders	Nasal polyps	06JUN2016	06MAR2017	N
		Surgical and medical procedures	Nasal polypectomy	06JUN2016	06MAR2017	N
	C4591001 4444 44441664	Eye disorders	Glaucoma	04SEP2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2015		Y
			Insulin resistance	08MAR2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01OCT1998	01OCT1998	N
			Thyroidectomy	16MAY2012	16MAY2012	N
	C4591001 4444 44441668	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
	C4591001 4444 44441669	Gastrointestinal disorders	Hiatus hernia	10APR2018	10APR2018	N
		Metabolism and nutrition disorders	Obesity	01NOV2016		Y
		Surgical and medical procedures	Hernia repair	10APR2018	10APR2018	N
	C4591001 4444 44441670	Psychiatric disorders	Insomnia	23FEB2016		Y
	C4591001 4444 44441673	Vascular disorders	Hypertension	25OCT2006		Y
	C4591001 4444 44441676	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 4444 44441677	Eye disorders	Chalazion	01APR2020		Y
	C4591001 4444 44441678	Endocrine disorders	Androgen deficiency	01JUN2018		Y
			Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	12NOV2016		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 4444 44441679	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 4444 44441680	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2011	03OCT2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 4444 44441681	Gastrointestinal disorders	Coeliac disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441682	Metabolism and nutrition disorders	Gout	02SEP2020	09SEP2020	N
			Obesity	01NOV2019		Y
	C4591001 4444 44441685	Endocrine disorders	Hypothyroidism	08AUG2020		Y
			Thyroid mass	27JUL2020		Y
	C4591001 4444 44441695	Congenital, familial and genetic disorders	Factor XI deficiency	03MAY2006		Y
		Psychiatric disorders	Generalised anxiety disorder	03MAY2019		Y
	C4591001 4444 44441696	Skin and subcutaneous tissue disorders	Psoriasis	05NOV1993		Y
	C4591001 4444 44441710	Immune system disorders	Seasonal allergy	01SEP2016		Y
	C4591001 4444 44441716	Endocrine disorders	Hypothyroidism	03NOV2000		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01SEP2016		Y
			Vitamin D deficiency	08JUL2020		Y
	C4591001 4444 44441719	Surgical and medical procedures	Peripheral nerve transposition	05MAY2019	05MAY2019	N
	C4591001 4444 44441721	Endocrine disorders	Hypothyroidism	01JUN2008		Y
	C4591001 4444 44441726	Psychiatric disorders	Depression	01AUG2019		Y
	C4591001 4444 44441729	Blood and lymphatic system disorders	Iron deficiency anaemia	01SEP1998		Y
		Immune system disorders	Allergy to chemicals	01SEP1977		Y
			Drug hypersensitivity	01JAN1993		Y
	C4591001 4444 44441738	Immune system disorders	Mite allergy	01MAR2000		Y
		Surgical and medical procedures	Female sterilisation	24NOV2016	24NOV2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441739	Hepatobiliary disorders	Cholecystitis	10JUN2010	10JUN2010	N
	C4591001 4444 44441745	Endocrine disorders	Hypothyroidism	20FEB2013		Y
	C4591001 4444 44441746	Metabolism and nutrition disorders	Hypercholesterolaemia	02JUL2010		Y
	C4591001 4444 44441747	Social circumstances Metabolism and nutrition disorders	Menopause Obesity	10FEB2014 01JUN1995		Y Y
	C4591001 4444 44441748	Psychiatric disorders	Type 2 diabetes mellitus Anxiety disorder	01APR2020 07SEP2017		Y Y
	C4591001 4444 44441751	Vascular disorders Metabolism and nutrition disorders	Hypertension Obesity	03SEP2014 05JUN2017		Y Y
	C4591001 4444 44441752	Neoplasms benign, malignant and unspecified (incl cysts and polyps) Surgical and medical procedures Respiratory, thoracic and mediastinal disorders	Uterine leiomyoma Hysterectomy Asthma	01FEB2018 28SEP2018 05MAY2006	28SEP2018 28SEP2018	N N Y
	C4591001 4444 44441756	Hepatobiliary disorders	Cholelithiasis	01OCT2019	15NOV2019	N
	C4591001 4444 44441764	Metabolism and nutrition disorders Musculoskeletal and connective tissue disorders	Obesity Osteoarthritis	01JAN2014 01JAN2005		Y Y
	C4591001 4444 44441766	Surgical and medical procedures Endocrine disorders	Cholecystectomy Hypothyroidism	15NOV2019 03MAR2017	15NOV2019	N Y
	C4591001 4444 44441766	Vascular disorders	Hypertension	20OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441768	Endocrine disorders	Hypothyroidism	01JUN2005		Y
		Social circumstances	Menopause	14AUG2019		Y
	C4591001 4444 44441770	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	10AUG2016	10AUG2017	N
		Surgical and medical procedures	Cancer surgery	01APR2020	01APR2020	N
			Hysterectomy	10AUG2017	10AUG2017	N
	C4591001 4444 44441771	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN1990		Y
		Ear and labyrinth disorders	Vertigo	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	15FEB2020		Y
			Spinal osteoarthritis	15FEB2020		Y
	C4591001 4444 44441772	Psychiatric disorders	Depression	01SEP2016		Y
	C4591001 4444 44441773	Vascular disorders	Hypertension	15FEB2009		Y
	C4591001 4444 44441778	Endocrine disorders	Hypothyroidism	02SEP2009		Y
	C4591001 4444 44441779	Immune system disorders	Drug hypersensitivity	01SEP2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	02JUL2003		Y
	C4591001 4444 44441780	Ear and labyrinth disorders	Otosclerosis	02SEP2019		Y
		Skin and subcutaneous tissue disorders	Vitiligo	03AUG2015		Y
	C4591001 4444 44441785	Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
	C4591001 4444 44441786	Endocrine disorders	Hypothyroidism	16SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441788	Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 4444 44441795	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 4444 44441796	Gastrointestinal disorders	Irritable bowel syndrome	02JUN2017		Y
		Vascular disorders	Hypertension	03MAR2016		Y
	C4591001 4444 44441797	Endocrine disorders	Hypothyroidism	03MAY2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 4444 44441798	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 4444 44441800	Metabolism and nutrition disorders	Obesity	01JUL2008		Y
		Surgical and medical procedures	Gastric bypass	23DEC2011	25DEC2011	N
	C4591001 4444 44441801	Endocrine disorders	Hypothyroidism	01SEP2008		Y
		Infections and infestations	Dengue fever	30APR2020	06MAY2020	N
		Surgical and medical procedures	Caesarean section	29JUL2015	29JUL2015	N
	C4591001 4444 44441804	Congenital, familial and genetic disorders	Thalassaemia minor	(b) (6) 1981		Y
		Endocrine disorders	Hypothyroidism	01JUN1996		Y
		Nervous system disorders	Headache	01JUN1996		Y
	C4591001 4444 44441810	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2017		Y
			Hyperuricaemia	01FEB2016		Y
	C4591001 4444 44441815	Blood and lymphatic system disorders	Anaemia	01FEB2020		Y
	C4591001 4444 44441824	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	02MAY2018	02JUN2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nephrectomy	02JUN2018	02JUN2018	N
	C4591001 4444 44441825	Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2016		Y
	C4591001 4444 44441826	Congenital, familial and genetic disorders	Thalassaemia minor	02FEB1990		Y
		Psychiatric disorders	Anxiety disorder	01FEB1985		Y
	C4591001 4444 44441827	Vascular disorders	Hypertension	21SEP2012		Y
	C4591001 4444 44441830	Eye disorders	Maculopathy	01JAN2014		Y
	C4591001 4444 44441832	Hepatobiliary disorders	Hepatic steatosis	01JUL2020		Y
	C4591001 4444 44441841	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 4444 44441843	Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 4444 44441850	Congenital, familial and genetic disorders	Poland's syndrome	(b) (6) 1987		Y
	C4591001 4444 44441851	Eye disorders	Glaucoma	10JUN2012		Y
	C4591001 4444 44441852	Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 4444 44441854	Surgical and medical procedures	Female sterilisation	17OCT2017	17OCT2017	N
	C4591001 4444 44441855†	Investigations	HIV test positive	01MAY2013		Y
	C4591001 4444 44441857	Respiratory, thoracic and mediastinal disorders	Asthma	15MAY2008		Y
	C4591001 4444 44441859	Eye disorders	Glaucoma	01FEB2013		Y
		Metabolism and nutrition disorders	Obesity	19FEB2011		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441861	Psychiatric disorders	Panic attack	01JUN2011		Y
	C4591001 4444 44441862	Musculoskeletal and connective tissue disorders	Rhabdomyolysis	01MAR2014	04MAR2014	N
	C4591001 4444 44441868	Psychiatric disorders	Anxiety disorder	01MAR2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2019		Y
	C4591001 4444 44441870	Infections and infestations	Herpes zoster	01SEP1980	11JUL2018	N
	C4591001 4444 44441874	Eye disorders	Retinal disorder	20AUG2004	01SEP2018	N
		Surgical and medical procedures	Preventive surgery	01SEP2018	01SEP2018	N
	C4591001 4444 44441875	Surgical and medical procedures	Appendicectomy	01SEP1997	01SEP1997	N
	C4591001 4444 44441886	Surgical and medical procedures	Fracture treatment	17AUG2017	17SEP2017	N
			Pyloroplasty	(b) (6) 1988	(b) (6) 1988	N
	C4591001 4444 44441887†	Investigations	HIV test positive	01NOV2012		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	15JUN2020		Y
	C4591001 4444 44441891	Endocrine disorders	Hypothyroidism	04JUN2014		Y
		Musculoskeletal and connective tissue disorders	Synovitis	15AUG2019		Y
		Surgical and medical procedures	Arthrotomy	10SEP2020	10SEP2020	N
			Synovectomy	10SEP2020	10SEP2020	N
	C4591001 4444 44441896	Social circumstances	Menopause	01APR2019		Y
	C4591001 4444 44441898	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	06JAN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	06JAN2015	06JAN2015	N
			Salpingectomy	06JAN2015	06JAN2015	N
	C4591001 4444 44441907	Gastrointestinal disorders	Pancreatitis	01AUG2010	15AUG2010	N
		Infections and infestations	Hepatitis A	01OCT1986	01NOV1986	N
	C4591001 4444 44441909	Skin and subcutaneous tissue disorders	Dermatitis atopic	24SEP2020		Y
	C4591001 4444 44441912	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 4444 44441913	Gastrointestinal disorders	Chronic gastritis	30SEP2015		Y
	C4591001 4444 44441917	Cardiac disorders	Bundle branch block right	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 4444 44441918	Cardiac disorders	Arrhythmia	28MAY2019		Y
		Nervous system disorders	Migraine	02SEP1983		Y
	C4591001 4444 44441923	Vascular disorders	Hypertension	21SEP2020		Y
	C4591001 4444 44441929	Infections and infestations	Genital herpes	04MAY2017		Y
			Syphilis	04MAY2017	04JUN2017	N
	C4591001 4444 44441931	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 4444 44441933	Endocrine disorders	Hypothyroidism	02MAR2010		Y
		Psychiatric disorders	Gastrointestinal somatic symptom disorder	01MAR2017		Y
	C4591001 4444 44441934	Psychiatric disorders	Panic disorder	13NOV2017		Y
	C4591001 4444 44441935	Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 4444 44441937	Gastrointestinal disorders	Coeliac disease	09SEP2018		Y
	C4591001 4444 44441938	Respiratory, thoracic and mediastinal disorders	Bronchiectasis	16DEC1990	17DEC1990	N
		Surgical and medical procedures	Lung lobectomy	17DEC1990	17DEC1990	N
	C4591001 4444 44441940	Hepatobiliary disorders	Cholecystitis	01DEC2009	01MAY2010	N
		Surgical and medical procedures	Cholecystectomy	01MAY2010	01MAY2010	N
	C4591001 4444 44441945	Blood and lymphatic system disorders	Iron deficiency anaemia	17APR2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	05FEB2017	05JUL2017	N
		Vascular disorders	Deep vein thrombosis	17APR2018	17MAY2018	N
	C4591001 4444 44441946	Gastrointestinal disorders	Coeliac disease	21AUG2017		Y
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 4444 44441949	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prolactin-producing pituitary tumour	01JAN2010		Y
	C4591001 4444 44441952	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	15FEB2017	14JUN2018	N
		Surgical and medical procedures	Hysterectomy	14JUN2018	14JUN2018	N
	C4591001 4444 44441956	Nervous system disorders	Migraine without aura	01FEB2017		Y
	C4591001 4444 44441964	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	20SEP2016		Y
	C4591001 4444 44441965	Nervous system disorders	Migraine with aura	01JUN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441970	Vascular disorders	Hypertension	02JAN2013		Y
	C4591001 4444 44441972	Endocrine disorders	Hypothyroidism	15JUN2007		Y
		Injury, poisoning and procedural complications	Tooth fracture	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Dental operation	01JAN2019	31DEC2019	N
	C4591001 4444 44441973	Reproductive system and breast disorders	Menstruation irregular	01JAN2011		Y
			Ovarian cyst	01JUL2018		Y
	C4591001 4444 44441974	Surgical and medical procedures	Vasectomy	01JUN2010	30JUN2010	N
		Vascular disorders	Hypertension	13JAN2016		Y
	C4591001 4444 44441975	Infections and infestations	Peritonitis	03DEC1993	06DEC1993	N
		Surgical and medical procedures	Nasal septal operation	03MAR2019	03MAR2019	N
	C4591001 4444 44441982	Nervous system disorders	Paraesthesia	01JUN2010	01MAR2017	N
	C4591001 4444 44441986	Injury, poisoning and procedural complications	Fibula fracture	16JAN2019	05MAY2019	N
			Meniscus injury	08AUG2019		Y
		Nervous system disorders	Migraine	01FEB1998		Y
	C4591001 4444 44441988	Gastrointestinal disorders	Diverticulum	01FEB2010		Y
	C4591001 4444 44441990	Metabolism and nutrition disorders	Obesity	01JUN2020		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 4444 44441995	Social circumstances	Tobacco user	11JUN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441997	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 4444 44442005	Gastrointestinal disorders	Haemorrhoids	01SEP2020		Y
	C4591001 4444 44442008	Blood and lymphatic system disorders	Haemolytic uraemic syndrome	04APR1991	05SEP1992	N
	C4591001 4444 44442009	Psychiatric disorders	Anxiety disorder	13JUN2018		Y
	C4591001 4444 44442014	Reproductive system and breast disorders	Depression Gynaecomastia	25AUG2020 01SEP1995	01JUL2008	Y N
	C4591001 4444 44442016	Surgical and medical procedures Eye disorders	Mammoplasty Astigmatism	01JUL2008 01JAN2011	01JUL2008	N Y
	C4591001 4444 44442018	Infections and infestations Cardiac disorders	Urinary tract infection Atrial fibrillation	01APR2020 01OCT1996	02OCT1996	Y N
	C4591001 4444 44442021	Cardiac disorders	Ventricular extrasystoles	03MAR2015		Y
	C4591001 4444 44442022	Surgical and medical procedures Vascular disorders	Cardiac ablation Hypertension	03APR2015 01JUL2014	03APR2015	N Y
	C4591001 4444 44442025	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
	C4591001 4444 44442029	Cardiac disorders	Arrhythmia	01SEP2010		Y
	C4591001 4444 44442030†	Metabolism and nutrition disorders Investigations	Dyslipidaemia HIV test positive	01SEP1995 15SEP2015		Y Y
		Psychiatric disorders	Generalised anxiety disorder	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442032	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	03APR1992		Y
	C4591001 4444 44442033	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2015		Y
		Vascular disorders	Hypertension	01SEP2008		Y
	C4591001 4444 44442034	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2018		Y
	C4591001 4444 44442035	Endocrine disorders	Hypothyroidism	01SEP2013		Y
	C4591001 4444 44442044	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 4444 44442047	Metabolism and nutrition disorders	Obesity	01FEB2020		Y
	C4591001 4444 44442052	Metabolism and nutrition disorders	Insulin resistance	02JAN2008		Y
	C4591001 4444 44442054	Endocrine disorders	Hypothyroidism	01SEP2000		Y
		Surgical and medical procedures	Female sterilisation	10DEC2019	10DEC2019	N
	C4591001 4444 44442055	Infections and infestations	American trypanosomiasis	01MAR1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01OCT2012	05OCT2013	N
		Surgical and medical procedures	Hysterectomy	05OCT2013	05OCT2013	N
	C4591001 4444 44442059	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01MAR2019		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2008	03NOV2008	N
			Thyroidectomy	01JAN2013	03JAN2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442060	Surgical and medical procedures	Ligament operation	02JAN2013	03JAN2013	N
	C4591001 4444 44442064	Infections and infestations	Peritonsillar abscess	01MAR2014	10MAR2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	10SEP2014	11NOV2014	N
		Psychiatric disorders	Depression	08JUL2002		Y
		Surgical and medical procedures	Hysterectomy	11NOV2014	11NOV2014	N
			Tonsillectomy	10MAR2014	10MAR2014	N
	C4591001 4444 44442065	Cardiac disorders	Atrial tachycardia	15FEB2020		Y
		Eye disorders	Myopia	10JUN2019		Y
	C4591001 4444 44442069	Endocrine disorders	Hypothyroidism	01APR2020		Y
	C4591001 4444 44442070	Metabolism and nutrition disorders	Type 2 diabetes mellitus	15SEP2018		Y
	C4591001 4444 44442071	Infections and infestations	Tuberculosis	03MAY1999	09NOV1999	N
	C4591001 4444 44442073	Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2015	N
	C4591001 4444 44442080	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 4444 44442084	Musculoskeletal and connective tissue disorders	Back pain	01APR2020		Y
	C4591001 4444 44442087	Respiratory, thoracic and mediastinal disorders	Asthma	01MAR1990		Y
	C4591001 4444 44442088	Nervous system disorders	Seizure	04FEB2014	04MAR2014	N
		Psychiatric disorders	Anxiety disorder	17JUN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442090	Surgical and medical procedures	Varicose vein operation	11MAY2015	13MAY2015	N
		Vascular disorders	Peripheral venous disease	20OCT2014	23OCT2014	N
	C4591001 4444 44442094	Respiratory, thoracic and mediastinal disorders	Asthma	15APR2014	13MAY2014	N
	C4591001 4444 44442095	Psychiatric disorders	Anxiety disorder	17SEP2015		Y
	C4591001 4444 44442100	Infections and infestations	Onychomycosis	01MAY2013		Y
	C4591001 4444 44442101	Metabolism and nutrition disorders	Obesity	01NOV2019		Y
	C4591001 4444 44442102	Congenital, familial and genetic disorders	Thalassaemia	01JUL2000		Y
	C4591001 4444 44442104	Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Metabolism and nutrition disorders	Obesity	03FEB1993		Y
		Surgical and medical procedures	Metabolic surgery	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2012	31DEC2012	N
	C4591001 4444 44442107	Endocrine disorders	Hypothyroidism	05JUN1993		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Rhinoplasty	01SEP2000	02SEP2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 4444 44442113	Eye disorders	Conjunctivitis allergic	01FEB2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442115	Endocrine disorders	Hypothyroidism	08DEC2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	04APR2017		Y
	C4591001 4444 44442117	Endocrine disorders	Hypothyroidism	03MAY2000		Y
		Vascular disorders	Hypertension	23JUN2012		Y
	C4591001 4444 44442118	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	12JUL2017		Y
		Reproductive system and breast disorders	Endometriosis	11NOV2000	06NOV2013	N
	C4591001 4444 44442119	Musculoskeletal and connective tissue disorders	Articular calcification	01JAN2016		Y
			Intervertebral disc protrusion	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01SEP2010	30SEP2010	N
		Surgical and medical procedures	Gastric bypass	17SEP2018	17SEP2018	N
			Hysterectomy	30SEP2010	30SEP2010	N
	C4591001 4444 44442122	Infections and infestations	Meningitis	01MAR1987	05MAR1987	N
		Musculoskeletal and connective tissue disorders	Neck pain	15SEP2020	20SEP2020	N
		Nervous system disorders	Migraine	01SEP1990		Y
		Surgical and medical procedures	Caesarean section	22NOV2013	22NOV2013	N
	C4591001 4444 44442123	Gastrointestinal disorders	Gastroesophageal reflux disease	27JUL2020		Y
	C4591001 4444 44442129	Gastrointestinal disorders	Gastroesophageal reflux disease	12DEC2019		Y
		Immune system disorders	Drug hypersensitivity	12SEP2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	05NOV1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442133	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN2005		Y
	C4591001 4444 44442135	Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	28MAR2020		Y
	C4591001 4444 44442138	Metabolism and nutrition disorders	Hypokalaemia	01SEP2004	02SEP2004	N
			Obesity	06FEB2019		Y
		Psychiatric disorders	Insomnia	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP1989		Y
			Nasal turbinate hypertrophy	01DEC2019		Y
	C4591001 4444 44442140	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2017		Y
	C4591001 4444 44442142	Endocrine disorders	Hypothyroidism	01JUN2005		Y
	C4591001 4444 44442146	Musculoskeletal and connective tissue disorders	Spondylolisthesis	11MAR2015	20OCT2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	09SEP2010	06OCT2011	N
		Surgical and medical procedures	Hysterectomy	06OCT2011	06OCT2011	N
			Vertebroplasty	20OCT2015	20OCT2015	N
	C4591001 4444 44442147	Cardiac disorders	Acute myocardial infarction	05MAR2014	05MAR2014	N
		Surgical and medical procedures	Angioplasty	05MAR2014	05MAR2014	N
			Vascular stent insertion	05MAR2014	05MAR2014	N
	C4591001 4444 44442148	Nervous system disorders	Epilepsy	24SEP2002	25SEP2006	N
	C4591001 4444 44442151	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2015		Y
			Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spinal flattening	01JAN2004		Y
		Surgical and medical procedures	Scoliosis surgery	27JUL1983	27JUL1983	N
	C4591001 4444 44442152	Gastrointestinal disorders	Gastrooesophageal reflux disease	11SEP2015		Y
	C4591001 4444 44442155	Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	14SEP2010	27SEP2010	N
				22MAR2011	05APR2011	N
	C4591001 4444 44442156	Surgical and medical procedures	Varicose vein operation	09SEP2017	09SEP2017	N
		Vascular disorders	Peripheral venous disease	02JAN2010		Y
	C4591001 4444 44442160	Surgical and medical procedures	Caesarean section	05JUL2017	05JUL2017	N
	C4591001 4444 44442162	Nervous system disorders	Migraine	01SEP2008		Y
		Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 4444 44442163	Respiratory, thoracic and mediastinal disorders	Asthma	27SEP1991		Y
	C4591001 4444 44442167	Gastrointestinal disorders	Oesophagitis	03JUN2019		Y
		Infections and infestations	Tinea versicolour	01FEB2020		Y
	C4591001 4444 44442168	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 4444 44442170	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG2020	02SEP2020	N
	C4591001 4444 44442172	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2010		Y
	C4591001 4444 44442190	Immune system disorders	Drug hypersensitivity	01SEP1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442193	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	09JAN2019		Y
	C4591001 4444 44442196	Musculoskeletal and connective tissue disorders	Scoliosis	01MAR2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 4444 44442197	Reproductive system and breast disorders	Polycystic ovaries	01FEB2020		Y
	C4591001 4444 44442198	Blood and lymphatic system disorders	Anaemia	02JUN2014		Y
		Endocrine disorders	Hypothyroidism	10JUN2014		Y
	C4591001 4444 44442201	Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 1971	18DEC1988	N
		Endocrine disorders	Hypothyroidism	01JUL2012		Y
		Surgical and medical procedures	Atrial septal defect repair	18DEC1988	18DEC1988	N
	C4591001 4444 44442210	Nervous system disorders	Headache	01MAR2010		Y
		Psychiatric disorders	Anxiety disorder	07MAR2018		Y
	C4591001 4444 44442212	Metabolism and nutrition disorders	Type 2 diabetes mellitus	30OCT2015		Y
		Vascular disorders	Hypertension	28OCT2015		Y
	C4591001 4444 44442215	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 4444 44442217	Endocrine disorders	Hypothyroidism	27SEP2017		Y
	C4591001 4444 44442219	Surgical and medical procedures	Adenoidectomy	09JUL2002	09JUL2002	N
	C4591001 4444 44442221	Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
		Renal and urinary disorders	Hypercalciuria	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442226	Metabolism and nutrition disorders	Metabolic syndrome	15JUL2014	15DEC2017	N
			Obesity	01JAN1998		Y
	C4591001 4444 44442227	Surgical and medical procedures	Female sterilisation	16JUN2015	16JUN2015	N
	C4591001 4444 44442232	Cardiac disorders	Arrhythmia	01SEP1993	01DEC1993	N
	C4591001 4444 44442233	Reproductive system and breast disorders	Menorrhagia	01JAN2007	15NOV2007	N
		Surgical and medical procedures	Hysterectomy	15NOV2007	15NOV2007	N
	C4591001 4444 44442235	Congenital, familial and genetic disorders	Ventricular septal defect	03OCT1976		Y
	C4591001 4444 44442236	Respiratory, thoracic and mediastinal disorders	Asthma	01APR2004		Y
	C4591001 4444 44442237	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	20FEB2015		Y
	C4591001 4444 44442241	Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Investigations	Sleep study	01JAN2020		Y
		Vascular disorders	Hypertension	28JUN2020		Y
	C4591001 4444 44442248	Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Vascular disorders	Hypertension	08NOV2018		Y
	C4591001 4444 44442253	Skin and subcutaneous tissue disorders	Lichen planus	01JAN2015		Y
	C4591001 4444 44442256	Musculoskeletal and connective tissue disorders	Scoliosis	15JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 4444 44442262	Psychiatric disorders	Anxiety disorder	22SEP2011		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442269	Injury, poisoning and procedural complications	Lower limb fracture	01MAR2010	01MAR2010	N
		Skin and subcutaneous tissue disorders	Vitiligo	01SEP2019		Y
		Surgical and medical procedures	Internal fixation of fracture	01MAR2010	01MAR2010	N
	C4591001 4444 44442270	Skin and subcutaneous tissue disorders	Skin exfoliation	01APR2020		Y
	C4591001 4444 44442273	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	05OCT2018		Y
	C4591001 4444 44442274	Metabolism and nutrition disorders	Obesity	01JUN2020		Y
	C4591001 4444 44442275	Gastrointestinal disorders	Gastritis erosive	01JAN2016		Y
		Infections and infestations	Hepatitis A	01SEP1997	30SEP1997	N
	C4591001 4444 44442277	Cardiac disorders	Arrhythmia	01MAR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01SEP2015	01DEC2015	N
		Surgical and medical procedures	Prostatectomy	07SEP2015	07SEP2015	N
	C4591001 4444 44442278	Metabolism and nutrition disorders	Obesity	10JAN2018		Y
		Vascular disorders	Hypertension	01SEP2013		Y
	C4591001 4444 44442279	Metabolism and nutrition disorders	Obesity	01MAR2015		Y
	C4591001 4444 44442280	Blood and lymphatic system disorders	Anaemia	01FEB2019	01APR2019	N
	C4591001 4444 44442283	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12FEB2010		Y
	C4591001 4444 44442291	Respiratory, thoracic and mediastinal disorders	Asthma	02SEP1998		Y
	C4591001 4444 44442292	Congenital, familial and genetic disorders	Congenital ectodermal dysplasia	(b) (6)	1986	Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Lactose intolerance	15JUN2017		Y
	C4591001 4444 44442294	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 4444 44442300	Musculoskeletal and connective tissue disorders	Fibromyalgia	01AUG2009		Y
	C4591001 4444 44442301	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2004	01MAR2004	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Breast conserving surgery	01MAR2004	01MAR2004	N
	C4591001 4444 44442304	Metabolism and nutrition disorders	Obesity	01NOV2019		Y
	C4591001 4444 44442305	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 4444 44442306	Metabolism and nutrition disorders	Metabolic syndrome	03JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01DEC2007		Y
	C4591001 4444 44442307	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	01NOV2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	01NOV2014	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 4444 44442310	Congenital, familial and genetic disorders	Cataract congenital	(b) (6) 1967		Y
		Eye disorders	Retinal detachment	10NOV2006		Y
		Metabolism and nutrition disorders	Gout	07OCT2018		Y
		Musculoskeletal and connective tissue disorders	Rheumatic fever	05JUN1978	12JUN1979	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01AUG2020		Y
	C4591001 4444 44442314	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	07MAY2020	03JUN2020	N
		Surgical and medical procedures	Spinal operation	03JUN2020	03JUN2020	N
	C4591001 4444 44442315	Nervous system disorders	Epilepsy	01MAR1980	01OCT2005	N
		Reproductive system and breast disorders	Breast cyst	01FEB2000	01FEB2000	N
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JUN2005	01JUL2005	N
		Surgical and medical procedures	Breast cyst excision	01MAR2003	01MAR2003	N
			Caesarean section	01JAN1998	01JAN1998	N
				10SEP2006	10SEP2006	N
				21AUG2008	21AUG2008	N
			Vocal cord polypectomy	01JUL2005	01JUL2005	N
	C4591001 4444 44442317	Psychiatric disorders	Generalised anxiety disorder	01JUN2018		Y
	C4591001 4444 44442318	Skin and subcutaneous tissue disorders	Dermatitis atopic	01SEP2001		Y
	C4591001 4444 44442319	Psychiatric disorders	Panic attack	01JAN2015		Y
>55	C4591001 1001 10011037^	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
			Migraine	01JAN1965	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2013	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
			Joint resurfacing surgery	01JAN2009	31DEC2009	N
				01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1001 10011039^	Ear and labyrinth disorders	Tinnitus	01DEC2019		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Muscle spasms	01JAN2005		Y
		Nervous system disorders	Spinal cord disorder	01JUN2019	31JUL2019	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2014		Y
	C4591001 1001 10011040^	General disorders and administration site conditions	Hernia	01SEP2019	31DEC2019	N
		Injury, poisoning and procedural complications	Ligament rupture	01MAR2013	31MAR2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2012	31DEC2013	N
		Surgical and medical procedures	Hernia repair	01DEC2019	31DEC2019	N
			Ligament operation	01MAR2003	31MAR2003	N
			Prostatectomy	01MAR2013	31MAR2013	N
	C4591001 1001 10011041^	Immune system disorders	Drug hypersensitivity	05APR2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Renal and urinary disorders	Atonic urinary bladder	01APR2020		Y
	C4591001 1001 10011042^	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN1987	31DEC1987	N
	C4591001 1001 10011043^	Infections and infestations	Herpes simplex	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN2016		Y
	C4591001 1001 10011044^	Cardiac disorders	Ventricular extrasystoles	01APR2020		Y
		Congenital, familial and genetic disorders	Heart disease congenital	01JAN1957		Y
		Eye disorders	Glaucoma	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1953	31DEC1953	N
	C4591001 1001 10011045^	Immune system disorders	Seasonal allergy	01JUN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2006		Y
		Nervous system disorders	Restless legs syndrome	01JUN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Tonsillectomy	01JUN1955	01JUN1955	N
	C4591001 1001 10011046^	Immune system disorders	Drug hypersensitivity	03MAY2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01MAY2019	29MAY2019	N
		Surgical and medical procedures	Skin neoplasm excision	29MAY2019	29MAY2019	N
	C4591001 1001 10011048^	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2012		Y
	C4591001 1001 10011049^	Gastrointestinal disorders	Reflux gastritis	01JAN1990		Y
		General disorders and administration site conditions	Adhesion	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998		Y
			Bowen's disease	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990		Y
			Pulmonary embolism	01JAN1974	31DEC1975	N
	C4591001 1001 10011050^	Injury, poisoning and procedural complications	Hip fracture	01MAY2018	31MAY2020	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2016	31JAN2016	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Hip surgery	01MAY2018	31MAY2018	N
	C4591001 1001 10011052^	Cardiac disorders	Bundle branch block left	01JAN2018		Y
		Congenital, familial and genetic disorders	Developmental hip dysplasia	(b) (6) 1954	31DEC2015	N
		Eye disorders	Cataract	01JAN2010	30NOV2018	N
			Macular fibrosis	01NOV2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1990		Y
			Ovarian cyst	01JAN2000	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2019		Y
	C4591001 1001 10011053^	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
			Oral herpes	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 1001 10011055^	Immune system disorders	Drug hypersensitivity	11JUN2013		Y
		Injury, poisoning and procedural complications	Hand fracture	17MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus injury	01JAN1997	31DEC1997	N
		Investigations	Arthroscopy	01JAN1997	31DEC1997	N
			Hysteroscopy	01AUG2005	31AUG2005	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2018		Y
		Nervous system disorders	Nerve compression	01JUL2012	31JUL2012	N
		Renal and urinary disorders	Haematuria	01JUL2019	31JUL2019	N
		Surgical and medical procedures	Bunion operation	01JAN1996	31DEC1996	N
			Peripheral nerve operation	01JUL2012	31JUL2012	N
	C4591001 1001 10011057^	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1001 10011058^	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
			Sinus node dysfunction	01JAN2014		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y
			Vertigo	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	07FEB2020		Y
			Seasonal allergy	01JAN1966		Y
		Psychiatric disorders	Sleep disorder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1966		Y
		Surgical and medical procedures	Foraminotomy	01JAN2010	31DEC2010	N
			Joint injection	07FEB2020	07FEB2020	N
			Spinal laminectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1001 10011059^	Ear and labyrinth disorders	Deafness	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb injury	20MAY2006	20AUG2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	26MAR2019	17JUN2019	N
			Osteoporosis	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	20MAY2006	31DEC2006	N
			Bunion operation	26MAR2019	31DEC2019	N
	C4591001 1001 10011061^	Endocrine disorders	Goitre	01JAN2005		Y
		Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	31JAN2017		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
			Cystitis	01JAN1970		Y
			Gonorrhoea	01JAN1971	31DEC1971	N
			Tonsillitis	01JAN1956	31DEC1956	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUL2010		Y
			Synovial cyst	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990		Y
		Psychiatric disorders	Sleep disorder	01JAN2005		Y
		Reproductive system and breast disorders	Breast mass	01JAN2005	31DEC2005	N
			Ovarian cyst	01JAN1973	31DEC1973	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1961		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011063^	Endocrine disorders	Hypothyroidism	10MAR2020		Y
		Infections and infestations	Hepatitis B	01JAN1993	29NOV2017	N
			Tonsillitis	01JAN1952	31DEC1952	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01DEC2019	10MAR2020	N
		Nervous system disorders	Migraine	01JAN1990	31DEC1995	N
		Skin and subcutaneous tissue disorders	Drug eruption			Y
			Urticaria			Y
		Surgical and medical procedures	Laparotomy	16JUN2018	16JUN2018	N
			Salpingo-oophorectomy	16JUN2018	16JUN2018	N
			Thyroidectomy	10MAR2020	10MAR2020	N
			Tonsillectomy			N
	C4591001 1001 10011064^	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
	C4591001 1001 10011081	Cardiac disorders	Coronary artery disease	01JAN2011	31DEC2011	N
		Eye disorders	Glaucoma	01JAN1964		Y
		Gastrointestinal disorders	Large intestine polyp	01SEP2012	30SEP2012	N
		Infections and infestations	Herpes zoster	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Eye injury	01JAN1964	31DEC1964	N
			Humerus fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2015		Y
		Nervous system disorders	Facial paralysis	01JAN1991	31DEC1991	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Neuropathy peripheral	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
			Prostatitis	01JAN2005		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011	31DEC2011	N
			Eyelid operation	16DEC2016	16DEC2016	N
			Hernia repair	01JAN1952	31DEC1952	N
			Trabeculectomy	01JAN2008	31DEC2008	N
	C4591001 1001 10011082	Cardiac disorders	Myocardial infarction	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010	31DEC2010	N
	C4591001 1001 10011084	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2005	31DEC2005	N
		Investigations	Biopsy prostate	13JUN2016	13JUN2016	N
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2006		Y
					31DEC2008	N
			Spondylitis	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014		Y
			Renal cyst	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ankle operation	01JAN2005	31DEC2007	N
			Hernia repair	01JAN1968	31DEC1968	N
			Hip surgery	01JUN2019	30JUN2019	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
			Therapeutic embolisation	01SEP2014	30SEP2014	N
				01SEP2018	30SEP2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1001 10011090	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
		Psychiatric disorders	Alcoholism	01JAN2005		Y
	C4591001 1001 10011093	Congenital, familial and genetic disorders	Pectus excavatum	01JAN1964	(b) (6) 1964	N
		Eye disorders	Cataract	01JAN2013	31DEC2020	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1979	31DEC1979	N
				01JAN1997	31DEC1997	N
		Infections and infestations	Appendicitis	01JUN2004	30JUN2004	N
		Injury, poisoning and procedural complications	Ligament rupture	01DEC2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y
	C4591001 1001 10011094	Endocrine disorders	Goitre	01JAN2002	31DEC2002	N
			Hypothyroidism	01JAN2002		Y
		Eye disorders	Cataract cortical	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Tendon injury	01JAN1990	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010	31DEC2019	N
			Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N
			Thyroidectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Arteriosclerosis	01JAN2014	31DEC2014	N
	C4591001 1001 10011097	Eye disorders	Dry eye	01JAN2019		Y
		Gastrointestinal disorders	Crohn's disease	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1001 10011098	Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Glaucoma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1001 10011099	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Ear and labyrinth disorders	Vertigo	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
	C4591001 1001 10011100	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011103	Gastrointestinal disorders	Constipation	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1001 10011104	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1001 10011108	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	21JUN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Monoclonal gammopathy	01JAN2010		Y
		Nervous system disorders	Dysgeusia	01JAN2019		Y
			Parosmia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2018	31DEC2018	N
			Dysphonia	01JAN2019	31DEC2019	N
			Nasal polyps	01JAN2019		Y
			Nasal septum deviation	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1001 10011109	Infections and infestations	Sinusitis	01JAN2010	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011110	Eye disorders	Macular degeneration	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Kaposi's sarcoma	01JAN2012		Y
			Prostate cancer	01JAN2003	31DEC2003	N
		Nervous system disorders	Syncope	01JAN2009		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2019		Y
	C4591001 1001 10011111	Eye disorders	Cataract	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Periarthritis	01JAN2011	31DEC2011	N
	C4591001 1001 10011112	Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Infections and infestations	Herpes simplex	01JAN1974		Y
		Psychiatric disorders	Anxiety	01DEC1990		Y
	C4591001 1001 10011114	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Infections and infestations	Latent tuberculosis	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
			Osteoporosis	01JAN2000		Y
			Spondylitis	01JAN2017		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast mass	01AUG2017	31AUG2017	N
				01FEB2017	28FEB2017	N
	C4591001 1001 10011115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Nervous system disorders	Migraine with aura	01JAN1990		Y
	C4591001 1001 10011116	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Giant cell tumour of tendon sheath	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	31DEC2019	N
	C4591001 1001 10011118	Ear and labyrinth disorders	Vertigo	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1962		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1001 10011119	Endocrine disorders	Hyperaldosteronism	01JAN2011		Y
			Hypothyroidism	01JAN2005		Y
		Investigations	Tuberculin test positive	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma stage 0	01JAN1977	31DEC1997	N
			Meningioma	01JAN1996	31DEC2011	N
			Uterine leiomyoma	21NOV2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1001 10011120	Congenital, familial and genetic disorders	Congenital lymphoedema	(b) (6) 1949		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2010		Y
	C4591001 1001 10011121	Endocrine disorders	Hypothyroidism	01SEP2015		Y
		Eye disorders	Glaucoma	01JAN2015		Y
	C4591001 1001 10011122	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	03MAR2014	31DEC2019	N
			Foot deformity	03MAR2014	03MAR2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
			Endometrial cancer	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1960	31DEC1967	N
			Actinic keratosis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1001 10011123	Psychiatric disorders	Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1001 10011124	Cardiac disorders	Mitral valve incompetence	01JAN2013		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Macular degeneration	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Overweight	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1974	31DEC1974	N
				01JAN1987	31DEC1987	N
			Breast cancer	01FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					28FEB2019	N
			Neuroma	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2012		Y
		Surgical and medical procedures	Oestrogen therapy	01AUG2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1001 10011127	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007	31DEC2017	N
		Psychiatric disorders	Depression	01JAN1997		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2008	31DEC2008	N
	C4591001 1001 10011133	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1965		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive lobular breast carcinoma	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1001 10011134	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1001 10011137	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963	31DEC2010	N
	C4591001 1001 10011139	Vascular disorders	Hypertension	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1001 10011141	Cardiac disorders	Atrioventricular block first degree	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Prostatomegaly	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1948		Y
	C4591001 1001 10011142	Eye disorders	Vitreous floaters	02AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1001 10011144	Eye disorders	Macular degeneration	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	26JUL2017	21AUG2017	N
	C4591001 1001 10011147	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Eye disorders	Open angle glaucoma	01JAN2005		Y
		Infections and infestations	Staphylococcal infection	26JUL2013	28AUG2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1975	31DEC2017	N
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	19OCT2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1001 10011148	Immune system disorders	Seasonal allergy	01JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1002 10021042^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteoporosis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01DEC2002		Y
			Depression	01JAN2002		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
	C4591001 1002 10021043^	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Eye disorders	Myopia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1985	31DEC1985	N
			Concussion	01JUL1975	31JUL1975	N
			Joint dislocation	01JAN1968	31DEC1968	N
			Lower limb fracture	01JUL1975	31JUL1975	N
			Skin laceration	01JUL1975	31JUL1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Lipoma excision	01JAN2009	31DEC2009	N
	C4591001 1002 10021044^	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Thyroidectomy	01JAN1985	31DEC1985	N
	C4591001 1002 10021045^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Infections and infestations	Urinary tract infection	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01FEB2018		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1973	31DEC2010	N
		Surgical and medical procedures	Cataract operation	01MAR2015	31MAR2015	N
			Face lift	01DEC2017	31DEC2017	N
	C4591001 1002 10021047^	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Immune system disorders	Hypersensitivity	01JAN1977		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1988		Y
	C4591001 1002 10021049^	Congenital, familial and genetic disorders	Tourette's disorder	01JAN1947		Y
		Eye disorders	Dry eye	01JAN2014		Y
			Eyelid ptosis	01JAN2009	31DEC2017	N
			Hypermetropia	01JAN1980		Y
		Immune system disorders	Food allergy	01JAN1949		Y
			Seasonal allergy	01APR1947		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
			Malignant melanoma	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Oophorectomy	01JAN1990	31DEC1990	N
			Ptosis repair	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
	C4591001 1002 10021050^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016		Y
	C4591001 1002 10021052^	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Dry eye	01JAN2016		Y
			Myopia	01JAN1994	31DEC1994	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Skin laceration	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970	31DEC1972	N
		Surgical and medical procedures	Limb operation	01JAN1978	31DEC1978	N
	C4591001 1002 10021053^	Eye disorders	Cataract	01JAN2015	12JUN2018	N
			Dry eye	01JAN2000		Y
			Myopia	01JAN1958	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Constipation	01JAN2002		Y
			Volvulus	01JAN2002		Y
		Infections and infestations	Chronic sinusitis	01JAN2002	31DEC2003	N
		Injury, poisoning and procedural complications	Chillblains	01JAN2015	31DEC2019	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	12JUN2018	12JUN2018	N
				23MAY2018	23MAY2018	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Nasal operation	01JAN2003	31DEC2003	N
			Sclerotherapy	01JAN2018	31DEC2018	N
			Varicose vein operation	01JAN2019	31DEC2019	N
	C4591001 1002 10021054^	Cardiac disorders	Bundle branch block right	01JAN1980		Y
		Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Eye disorders	Glaucoma	01JAN1998		Y
		Immune system disorders	Allergy to animal	01JAN1992		Y
			Mycotic allergy	01JAN1992		Y
			Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Joint injury	01NOV2018	28FEB2019	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spinal instability	01JAN2016	30APR2017	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Reproductive system and breast disorders	Pelvic discomfort	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	11AUG1992	11AUG1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01FEB2019	28FEB2019	N
			Spinal fusion surgery	01APR2017	30APR2017	N
	C4591001 1002 10021060^	Ear and labyrinth disorders	Hypoacusis	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2007	31DEC2007	N
	C4591001 1002 10021062^	Eye disorders	Prostate cancer	01JAN2016	31DEC2016	N
			Uveitis	01MAY2020	02JUN2020	N
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
			Hyperchlorhydria	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Sleep disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Diaphragmatic paralysis	01JAN2010		Y
	C4591001 1002 10021063^	Gastrointestinal disorders	Abdominal hernia	01JAN2014	31DEC2017	N
		Infections and infestations	Gingivitis	01JAN2014	31DEC2014	N
			Osteomyelitis	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2011	31DEC2013	N
			Limb injury	01JAN2011	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1976	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
	C4591001 1002 10021064^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Bronchitis	01FEB2020	29FEB2020	N
			Helicobacter gastritis	01JAN2019	31DEC2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2016	31DEC2016	N
	C4591001 1002 10021067^	Eye disorders	Myopia	01JAN1961		Y
		Renal and urinary disorders	Nocturia	01JAN2020		Y
		Surgical and medical procedures	Hernia repair	01MAY2019	31MAY2019	N
			Vasectomy	01JAN1972	31DEC1972	N
	C4591001 1002 10021068^	Gastrointestinal disorders	Diarrhoea	01MAY2020	31MAY2020	N
		Injury, poisoning and procedural complications	Sciatic nerve injury	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Hysteroscopy	01OCT2014	31OCT2014	N
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2012		Y
		Nervous system disorders	Radiculopathy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal disorder	01FEB2017	30APR2017	N
		Surgical and medical procedures	Ankle arthroplasty	01OCT2015	31OCT2015	N
			Arthrodesis	01MAY2010	31MAY2010	N
			Cataract operation	01DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01NOV2019	30NOV2019	N
			Intervertebral disc operation	01FEB2012	29FEB2012	N
			Joint arthroplasty	01FEB2013	28FEB2013	N
			Sinus operation	01APR2017	30APR2017	N
	C4591001 1002 10021069^	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JUL2016	31JUL2016	N
		Surgical and medical procedures	Lymphoma operation	01JUL2016	31JUL2016	N
	C4591001 1002 10021071^	Eye disorders	Hypermetropia	01JAN1989		Y
			Myopia	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
	C4591001 1002 10021072^	Eye disorders	Myopia	01JAN1973	31DEC1995	N
		Infections and infestations	Urinary tract infection	01NOV2017	30NOV2017	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1983	31MAR1991	N
		Pregnancy, puerperium and perinatal conditions	Delivery	24OCT1990	24OCT1990	N
		Surgical and medical procedures	Intervertebral disc operation	01MAR1991	31MAR2020	N
			Keratomileusis	01JAN1995	31DEC1995	N
			Skin neoplasm excision	01JAN2000	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1002 10021073^	Ear and labyrinth disorders	Deafness unilateral	01MAR2020		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Glaucoma	01JUN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Alcohol intolerance	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Shoulder arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1002 10021074^	Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2007		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Infections and infestations	Lyme disease	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2008		Y
	C4591001 1002 10021075^	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01AUG2018	31AUG2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2019		Y
		Surgical and medical procedures	Skin neoplasm excision	01AUG2018	31AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1002 10021077^	Cardiac disorders	Supraventricular tachycardia	01JUN2017	31JAN2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31JAN2019	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Mammoplasty	01JAN2012	31DEC2012	N
	C4591001 1003 10031031^	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Anosmia	01JAN2010		Y
		Social circumstances	Familial risk factor	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Oophorectomy	01JAN1970		Y
		Vascular disorders	Deep vein thrombosis	01JAN2017		Y
	C4591001 1003 10031035^	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Cataract	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
			Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1003 10031036^	Infections and infestations	Rhinitis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JUN2020		Y
			Seborrhoeic dermatitis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nasal septal operation	01JAN2017	31DEC2017	N
	C4591001 1003 10031037^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1003 10031043^	Immune system disorders	Contrast media allergy	01JAN2000		Y
	C4591001 1003 10031046^	Endocrine disorders	Hypothyroidism	01MAR2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1993		Y
	C4591001 1003 10031047^	Ear and labyrinth disorders	Deafness unilateral	01JAN1962		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
		Social circumstances	Corrective lens user	01JAN1955		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2000	31DEC2000	N
	C4591001 1003 10031051^	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1967		Y
		Surgical and medical procedures	Knee operation	01JAN1993	31DEC1993	N
	C4591001 1003 10031053^	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1992		Y
	C4591001 1003 10031054^	Surgical and medical procedures	Varicose vein operation	01JAN2018	31DEC2018	N
	C4591001 1003 10031055^	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
				01JAN2010		Y
			Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Hand fracture	10AUG2018	31OCT2018	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
	C4591001 1003 10031056^	Endocrine disorders	Hypothyroidism	01JAN2011		Y
	C4591001 1003 10031058^	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Chondrocalcinosis pyrophosphate	01JAN2012		Y
			Muscle spasms	01JAN1975		Y
			Osteopenia	01JAN2019		Y
		Nervous system disorders	Arachnoiditis	01JAN2000		Y
			Migraine	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
	C4591001 1003 10031063^	Ear and labyrinth disorders	Aural polyp	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Perfume sensitivity	01JAN2000		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1998		Y
	C4591001 1003 10031067^	Investigations	Blood cholesterol increased	01DEC2018		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1953		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1003 10031069^	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1975		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Mole excision	01JAN1995		Y
			Skin lesion removal	01JAN2005	31DEC2005	N
	C4591001 1003 10031076^	Investigations	Blood cholesterol increased	01JAN1985		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
	C4591001 1003 10031077^	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1974		Y
	C4591001 1003 10031078^	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1961	31DEC1961	N
		Social circumstances	Corrective lens user	01JAN1950		Y
		Surgical and medical procedures	Knee operation	01JAN2005		Y
	C4591001 1003 10031079^	Immune system disorders	Drug hypersensitivity	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				24JUN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1003 10031080^	Immune system disorders	Contrast media allergy	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1964		Y
				01JAN1969		Y
	C4591001 1003 10031083^	Ear and labyrinth disorders	Deafness bilateral	01SEP2015		Y
		Eye disorders	Retinal tear	01SEP2015	30SEP2015	N
		Investigations	White blood cell count decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1965		Y
			Radiculopathy	01SEP2015		Y
	C4591001 1003 10031087^	Congenital, familial and genetic disorders	Spine malformation	01JAN1954		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Epididymitis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Epididymectomy	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN1982	31DEC2003	N
			Spinal laminectomy	01JAN1982	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031089	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1003 10031091	Cardiac disorders	Aortic valve stenosis	01JAN2013	31DEC2013	N
		Eye disorders	Hypermetropia	01JAN1993		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2016	31DEC2016	N
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2012	N
		Social circumstances	Corrective lens user	01JAN1993		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2013	31DEC2013	N
				01JAN2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1003 10031092	Congenital, familial and genetic disorders	Congenital cystic kidney disease	(b) (6) 1951		Y
		Eye disorders	Retinal detachment	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Nervous system disorders	Nerve compression	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1995	31DEC1995	N
				01JAN1996	31DEC1996	N
			Dupuytren's contracture operation	01JAN2012	31DEC2012	N
			Tenoplasty	01JAN2009	31DEC2009	N
				01JAN2016	31DEC2016	N
			Tenotomy	01JAN1998	31DEC1998	N
				01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031093	Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN1980		Y
		Infections and infestations	Onychomycosis	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1003 10031095	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Writer's cramp	01JAN2017		Y
		Surgical and medical procedures	Prostatectomy	01JAN2012	28JUL2012	N
	C4591001 1003 10031098	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal stromal tumour	01JAN2010	31DEC2010	N
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2000	31DEC2000	N
	C4591001 1003 10031099	Immune system disorders	Seasonal allergy	01JAN1956		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2004		Y
			Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Shoulder operation	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN1995	31DEC1995	N
	C4591001 1003 10031103	Immune system disorders	Allergy to animal	01JAN1958		Y
			Seasonal allergy	01JAN1958		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
			Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
	C4591001 1003 10031105	Eye disorders	Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1994	31DEC1994	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2001	31DEC2001	N
		Social circumstances	Corrective lens user	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1003 10031106	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Persistent depressive disorder	01JAN1999		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1003 10031107	Immune system disorders	Drug hypersensitivity	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Epilepsy	01JAN1991		Y
			Migraine	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1003 10031108	Gastrointestinal disorders	Crohn's disease	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1974		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
	C4591001 1003 10031109	Surgical and medical procedures	Colostomy	01JAN2000		Y
		Eye disorders	Amblyopia	01JAN1937		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
			Transurethral prostatectomy	01JAN2000	31DEC2000	N
	C4591001 1003 10031110	Eye disorders	Myopia	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2006		Y
		Social circumstances	Corrective lens user	01JAN1970		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2010	31DEC2010	N
			Intervertebral disc operation	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031113	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	01JAN2017		Y
	C4591001 1003 10031114	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2008	31DEC2008	N
		Investigations	Blood cholesterol increased	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2019	31DEC2019	N
	C4591001 1003 10031117	Eye disorders	Retinal vein thrombosis	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1003 10031118	Investigations	Blood cholesterol increased	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1003 10031119	Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2020		Y
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1003 10031120	Cardiac disorders	Ventricular extrasystoles	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1003 10031121	Cardiac disorders	Ventricular extrasystoles	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1003 10031123	Eye disorders	Retinal detachment	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1003 10031126	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01OCT2017	31OCT2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031127	Eye disorders	Myopia	01JAN1969		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Staphylococcal bacteraemia	01JAN2017	31DEC2017	N
		Investigations	Blood pressure increased	01JAN2017		Y
	C4591001 1003 10031128	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN1982		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2012	31DEC2012	N
	C4591001 1003 10031129	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Myopia	01JAN1969		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN2009		Y
	C4591001 1003 10031130	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1003 10031131	Cardiac disorders	Ventricular extrasystoles	01JAN2019	31DEC2019	N
		Infections and infestations	Diverticulitis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031132	Eye disorders	Hypermetropia	01JAN1978		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1003 10031133	Investigations	Blood cholesterol increased	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1003 10031134	Vascular disorders	Hypertension	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1003 10031135	Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
		General disorders and administration site conditions	Chronic fatigue syndrome	01JAN2017		Y
		Infections and infestations	Encephalitis	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1003 10031136	Social circumstances	Orthosis user	(b) (6) 1956		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1003 10031139	Surgical and medical procedures	Fascial operation	01JAN2020	31DEC2020	N
		Ear and labyrinth disorders	Vertigo positional	01JAN2013		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Surgical and medical procedures	Meniscus operation	01JAN2008	31DEC2008	N
			Renal surgery	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1003 10031142	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31JAN1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31JAN1994	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
	C4591001 1003 10031145	Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Immune system disorders	Allergy to chemicals	01JAN1996		Y
			Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
			Spondylitis	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Pityriasis rosea	01JAN1991	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Intraocular lens implant	01JAN2010	31DEC2010	N
			Limb operation	01JAN2018	31DEC2018	N
			Pelvic operation	01JAN1996	31DEC1996	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Toe operation	01JAN2003	31DEC2003	N
				01JAN2005	31DEC2005	N
			Urinary bladder suspension	01JAN1996	31DEC1996	N
	C4591001 1003 10031148	Investigations	Blood cholesterol increased	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Seborrhoeic keratosis	01JAN2015		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2013	31DEC2013	N
	C4591001 1003 10031149	Eye disorders	Cataract	01FEB2019	28FEB2019	N
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1959	31DEC1959	N
			Cataract operation	01FEB2019	28FEB2019	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1003 10031150	Infections and infestations	Diverticulitis	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Scoliosis	01JAN1980		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1003 10031152	Eye disorders	Myopia	01JAN1957		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Sinusitis fungal	01JAN2016	23DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01AUG2007	31MAR2008	N
			Prostate cancer	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Hearing aid user	01JAN2012		Y
		Surgical and medical procedures	Acoustic neuroma removal	01MAR2008	31MAR2008	N
			Finger amputation	01JAN1994	31DEC1994	N
			Hernia repair	01JUN2000	30JUN2000	N
			Prostatectomy	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1003 10031153	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1003 10031154	Eye disorders	Age-related macular degeneration	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1003 10031157	Cardiac disorders	Cardiac failure congestive	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Cellulitis	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Reproductive system and breast disorders	Breast cyst	29JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Transgender hormonal therapy	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1003 10031159	Endocrine disorders	Basedow's disease	01JAN2001		Y
		Eye disorders	Cataract	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Intraocular lens implant	01JAN2019	31DEC2019	N
			Ligament operation	01JAN2002	31DEC2002	N
			Thyroidectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031163	Cardiac disorders	Atrial fibrillation	01DEC2018	31DEC2018	N
			Cardiac flutter	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	16JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1003 10031164	Eye disorders	Visual impairment	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1980		Y
			Hearing aid user	01JAN2005		Y
			Hearing aid user	01JAN2016		Y
	C4591001 1003 10031165	Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
		Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	01JAN1970		Y
			Thalassaemia minor	01JAN1970		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Astigmatism	01JAN1956		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1995		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1989		Y
		Surgical and medical procedures	Thyroglossal cyst excision	01JAN1973	31DEC1973	N
	C4591001 1003 10031167	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Contrast media allergy	01JAN1975		Y
			Drug hypersensitivity	01JAN1980		Y
				01JAN2016		Y
				01JAN2017		Y
		Infections and infestations	Diverticulitis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Deafness traumatic	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Lactose intolerance	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1980		Y
			Transient ischaemic attack	01JAN2018	31DEC2018	N
		Psychiatric disorders	Drug dependence	01JAN1977	31DEC1997	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Chronic obstructive pulmonary disease	01JAN1980		Y
		Social circumstances	Alcoholic	01JAN1977	31DEC1997	N
			Corrective lens user	01JAN2015		Y
			Hearing aid user	01JAN2020		Y
			Tobacco user	01JAN1977		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016		Y
			Glaucoma surgery	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031168	Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
			Hepatic steatosis	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Renal stone removal	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1003 10031169	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Social circumstances	Ex-tobacco user	01JAN1972	31DEC1980	N
		Surgical and medical procedures	Prostatectomy	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1003 10031172	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2013		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2013	31DEC2013	N
	C4591001 1003 10031173	Immune system disorders	Hypersensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1003 10031176	Eye disorders	Cataract	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1003 10031178	Eye disorders	Hypermetropia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2009	31DEC2009	N
			Hip surgery	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1003 10031181	Psychiatric disorders	Depression	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1003 10031182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990	31DEC1995	N
			Inguinal hernia	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1003 10031185	Eye disorders	Astigmatism	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Mite allergy	01JAN2015		Y
			Mycotic allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Shoulder arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1003 10031188	Eye disorders	Myopia	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y
			Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1003 10031189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2016		Y
			Upper-airway cough syndrome	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
	C4591001 1003 10031192	Infections and infestations	Diverticulitis	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
			Jaw operation	01JAN1980	31DEC1980	N
			Knee operation	01JAN1981	31DEC1981	N
			Tenoplasty	01JAN1986	31DEC1986	N
	C4591001 1003 10031193	Social circumstances	Corrective lens user	01JAN1975		Y
				01JAN2008		Y
			Postmenopause	01JAN2010		Y
	C4591001 1003 10031195	Gastrointestinal disorders	Diverticulum	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1962		Y
			Transient ischaemic attack	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN1998	31DEC1998	N
			Shoulder arthroplasty	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1003 10031200	Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Myopia	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Seasonal allergy	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gluten sensitivity	01DEC2010		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JAN1963	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1984	31DEC2002	N
			Childhood asthma	01JAN1962	31DEC1966	N
			Nasal septum deviation	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Eczema	01MAR2020		Y
		Social circumstances	Corrective lens user	01JAN1994		Y
				01JAN2012		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN1996	31DEC1996	N
			Gastric stapling	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Intestinal polypectomy	01JAN2014	31DEC2014	N
				01JAN2019	31DEC2019	N
			Renal stone removal	01JAN2015	31DEC2015	N
			Rhinoplasty	01JAN2003	31DEC2003	N
			Thyroidectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Raynaud's phenomenon	01JAN2004		Y
	C4591001 1003 10031202	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1003 10031208	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2013	31DEC2016	N
		Cardiac disorders	Arrhythmia	01JAN2017		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Contrast media allergy	01JAN2005		Y
			Drug hypersensitivity	01JAN1957		Y
				01JAN2012		Y
		Infections and infestations	Fungal infection	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1003 10031209	Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Menopause	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1005 10051005	Cardiac disorders	Atrial fibrillation	01JAN2000	31DEC2010	N
		Ear and labyrinth disorders	Deafness	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tinnitus	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Trigger finger	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
			Uterine leiomyoma	01JAN1989	31DEC1989	N
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Mastectomy	01JAN2012	31DEC2012	N
			Myomectomy	01JAN1989	31DEC1989	N
			Tendon sheath incision	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051006	Ear and labyrinth disorders	Deafness	01JAN2005		Y
		Eye disorders	Macular degeneration	01JAN2014		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2013	31DEC2013	N
			Hip fracture	01JAN2007	31DEC2007	N
			Wrist fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Osteopenia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2013		Y
		Surgical and medical procedures	Fracture treatment	01JAN2007	31DEC2007	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
				01JAN2012	31DEC2012	N
			Medical device removal	01JAN2009	31DEC2009	N
			Rhinoplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1005 10051009	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
				01JAN2018		Y
			Hypersensitivity	01JAN1965		Y
		Infections and infestations	Oral herpes	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1005 10051010	Ear and labyrinth disorders	Deafness	01JAN1990		Y
			Tinnitus	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Overweight	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051011	Ear and labyrinth disorders	Tinnitus	01JAN1973		Y
		Immune system disorders	Hypersensitivity	01JAN1960		Y
		Infections and infestations	Oral herpes	01JAN1950		Y
		Metabolism and nutrition disorders	Overweight	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Insomnia	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
			Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Inguinal hernia repair	01JAN2016	31DEC2016	N
			Joint surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1005 10051012	Ear and labyrinth disorders	Vertigo	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1988	31DEC1988	N
		Psychiatric disorders	Depression	01JAN1999	31DEC2001	N
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014	31DEC2019	N
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN1974	31DEC1974	N
			Keratomileusis	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051013	Congenital, familial and genetic disorders	Hydrocele	01JAN2012	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAY2020		Y
			Overweight	01JAN1987		Y
		Surgical and medical procedures	Appendectomy	01JAN2002	31DEC2002	N
	C4591001 1005 10051014	Cardiac disorders	Bradycardia	01JAN2006		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Investigations	Biopsy prostate normal	01JAN2001	31DEC2001	N
			Prostatic specific antigen increased	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2006	31DEC2006	N
			Cardiac pacemaker replacement	01JAN2014	31DEC2014	N
			Cataract operation	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2006	31DEC2006	N
			Muscle operation	01JAN2009	31DEC2009	N
	C4591001 1005 10051018	Ear and labyrinth disorders	Deafness	01JAN2015		Y
			Tinnitus	01JAN2015		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
			Blood triglycerides increased	01JAN2012		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Tendon sheath incision	01JAN2017	31DEC2017	N
	C4591001 1005 10051019	Ear and labyrinth disorders	Deafness	01JAN1990		Y
			Tinnitus	01JAN2010		Y
			Vertigo	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Insulin resistance	01JUL2020		Y
			Overweight	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Meniscus operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1005 10051020	Eye disorders	Glaucoma	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1975		Y
			Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Migraine with aura	01JAN1967		Y
		Psychiatric disorders	Anxiety	01JAN1960		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2010		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051021	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2015		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
	C4591001 1005 10051022	Ear and labyrinth disorders	Deafness	01JAN2016		Y
			Tinnitus	01JAN2016		Y
			Vertigo	01MAY2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Osteoarthritis	01JAN2020		Y
			Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2019	31DEC2019	N
		Renal and urinary disorders	Urinary incontinence	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN1979		Y
		Surgical and medical procedures	Bladder repair	01JAN2017	31DEC2017	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Shoulder arthroplasty	01JAN2010	31DEC2010	N
	C4591001 1005 10051023	Ear and labyrinth disorders	Deafness	01JAN2016	31DEC2016	N
			Tinnitus	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2009	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051025	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1005 10051032	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Hypersensitivity	01JAN1963	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
	C4591001 1005 10051033	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
	C4591001 1005 10051034	Cardiac disorders	Coronary artery disease	01JAN2008		Y
			Myocardial infarction	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051037	Immune system disorders	Hypersensitivity	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN1980	31DEC1980	N
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN1982	31DEC1982	N
				01JAN1984	31DEC1984	N
			Oophorectomy	01JAN1980	31DEC1980	N
			Parathyroidectomy	01JAN2019	31DEC2019	N
			Urinary bladder suspension	01JAN2019	31DEC2019	N
	C4591001 1005 10051038	Ear and labyrinth disorders	Deafness	01JAN2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010	31DEC2012	N
			Trigger finger	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Caesarean section	01JAN1969	31DEC1969	N
				01JAN1971	31DEC1971	N
			Spinal operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1005 10051039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Hypersensitivity	01JAN1955		Y
		Infections and infestations	Oral herpes	01JAN2000	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955	31DEC1970	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Fracture treatment	01JAN1986	31DEC1986	N
				01JAN2012	31DEC2012	N
			Hip arthroplasty	01JUN2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1005 10051040	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
	C4591001 1005 10051042	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1981		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
			Spinal osteoarthritis	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rotator cuff repair	01JAN2002	31DEC2002	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
			Tenoplasty	01JAN2002	31DEC2002	N
				01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1005 10051043	Ear and labyrinth disorders	Deafness	01JAN2006		Y
		Immune system disorders	Hypersensitivity	01JAN1950		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2019	31DEC2019	N
			Uterine leiomyoma	01JAN1991	31DEC1991	N
		Nervous system disorders	Cerebrovascular accident	01JAN1945	31DEC1956	N
		Psychiatric disorders	Depression	01JAN1991	31DEC2000	N
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Knee arthroplasty	01JAN1993	31DEC1993	N
				01JAN2008	31DEC2008	N
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1005 10051044	Ear and labyrinth disorders	Vertigo	01JAN2002	31DEC2003	N
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Investigations	Arthroscopy	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Overweight	01JAN2004	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine without aura	01JAN2003	31DEC2004	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Caesarean section	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1975	31DEC1975	N
			Uterine dilation and curettage	01JAN2003	31DEC2003	N
	C4591001 1005 10051045	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
	C4591001 1005 10051046	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051047	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
			Hiatus hernia	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Vitamin B12 deficiency	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2019	31DEC2019	N
			Appendicectomy	01JAN1990	31DEC1990	N
			Female sterilisation	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1005 10051049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Migraine with aura	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051050	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
	C4591001 1005 10051053	Cardiac disorders	Atrial flutter	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1005 10051056	Immune system disorders	Hypersensitivity	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Menopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051058	Eye disorders	Glaucoma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1005 10051060	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Nervous system disorders	Essential tremor	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1005 10051061	Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Cardiac disorders	Ventricular extrasystoles	01JAN2015		Y
		Investigations	Arthroscopy	01JAN1994	31DEC1994	N
	C4591001 1005 10051062	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1978	31DEC1978	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
			Transurethral prostatectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051063	Cardiac disorders	Mitral valve prolapse	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1965		Y
		Nervous system disorders	Migraine without aura	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051064	Cardiac disorders	Mitral valve prolapse	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN1986		Y
		Renal and urinary disorders	Micturition urgency	01JAN2002		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
				01JAN2009	31DEC2009	N
	C4591001 1005 10051065	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2009		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1994	31DEC1994	N
		Social circumstances	Menopause	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015	31DEC2015	N
	C4591001 1005 10051069	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2010	N
			Squamous cell carcinoma of skin	01JAN1993		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1005 10051072	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1005 10051074	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1956		Y
		Social circumstances	Menopause	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051078	Ear and labyrinth disorders	Deafness	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
		Surgical and medical procedures	Neuroprosthesis implantation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1005 10051080	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Onychomycosis	01JAN2020		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1005 10051083	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1977	31DEC1977	N
				01JAN1982	31DEC1982	N
				01JAN1986	31DEC1986	N
				01JAN1994	31DEC1994	N
	C4591001 1005 10051086	Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1005 10051088	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Surgical and medical procedures	Venous ligation	06FEB2020	06FEB2020	N
		Vascular disorders	Deep vein thrombosis	01JAN2016		Y
			Hypertension	01JAN1990		Y
	C4591001 1005 10051089	Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Migraine without aura	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Sexual dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1005 10051090	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1005 10051091	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051092	Metabolism and nutrition disorders	Overweight	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1005 10051095	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2016	31DEC2016	N
	C4591001 1005 10051096	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1005 10051097	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1964		Y
		Social circumstances	Menopause	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1005 10051098	Cardiac disorders	Coronary artery disease	01JAN2008		Y
			Myocardial infarction	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
		Renal and urinary disorders	Urinary retention	01JAN2014		Y
		Reproductive system and breast disorders	Sexual dysfunction	01JAN2005		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2008	31DEC2008	N
			Coronary artery bypass	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051102	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Social circumstances	Menopause	01JAN1997		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1997	31DEC1997	N
	C4591001 1005 10051103	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2000		Y
				01JAN2010		Y
			Hypersensitivity	01JAN2015		Y
		Infections and infestations	Oral herpes	01JAN1984		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1005 10051104	Ear and labyrinth disorders	Tinnitus	01JAN1994		Y
		Endocrine disorders	Hypothyroidism	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1978		Y
		Social circumstances	Menopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1005 10051109	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1990		Y
			Hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN1997	31DEC1997	N
		Psychiatric disorders	Insomnia	01JAN1997		Y
	C4591001 1005 10051111	Infections and infestations	Tuberculosis	01JAN1975	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1005 10051114	Surgical and medical procedures	Cholecystectomy	01JAN2015		Y
	C4591001 1005 10051116	Cardiac disorders	Supraventricular tachycardia	01JAN1990	31DEC2005	N
		Ear and labyrinth disorders	Deafness	01JAN1995		Y
			Tinnitus	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Hypersensitivity	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Gastric bypass	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Mammoplasty	01JAN1997	31DEC1997	N
	C4591001 1005 10051120	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Hypersensitivity	01JAN1970		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Metabolism and nutrition disorders	Overweight	01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2012		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
	C4591001 1005 10051121	Blood and lymphatic system disorders	Hypercoagulation	01JAN2018		Y
		Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018	31DEC2018	N
		Vascular disorders	Deep vein thrombosis	01JAN2012	31DEC2012	N
	C4591001 1005 10051122	Endocrine disorders	Thyroid mass	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1005 10051124	Social circumstances	Menopause	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
	C4591001 1005 10051126	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	17JUL2020		Y
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Bladder repair	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1005 10051127	Immune system disorders	Hypersensitivity	01JAN1972		Y
		Infections and infestations	Oral herpes	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1005 10051128	Cardiac disorders	Coronary artery disease	01JAN2007		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2006		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1005 10051130	Reproductive system and breast disorders	Prostatomegaly	01FEB2020		Y
			Sexual dysfunction	01JAN2015		Y
	C4591001 1005 10051131	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
			Rosacea	01JAN2010		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N
				01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051132	Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC2019		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051136	Gastrointestinal disorders	Dry mouth	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1005 10051137	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN1976		Y
		Nervous system disorders	Migraine without aura	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Sexual dysfunction	01MAR2020		Y
	C4591001 1005 10051138	Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1005 10051139	Social circumstances	Menopause	01JAN2006		Y
		Ear and labyrinth disorders	Deafness	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1983		Y
	C4591001 1005 10051141		Erectile dysfunction	01JAN2000		Y
		Cardiac disorders	Atrial fibrillation	01JAN2001		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1005 10051143	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine with aura	01JAN2000		Y
		Surgical and medical procedures	Cystocele repair	01JAN2003	31DEC2003	N
			Meniscus operation	01JAN2014	31DEC2014	N
	C4591001 1005 10051149	Ear and labyrinth disorders	Deafness	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051152	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1968		Y
		Investigations	Blood cholesterol increased	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2005	31DEC2005	N
	C4591001 1005 10051154	Immune system disorders	Seasonal allergy	01JAN1969		Y
		Investigations	Blood cholesterol increased	01JUN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Phlebectomy	01AUG2019	31AUG2019	N
				01FEB2020	29FEB2020	N
	C4591001 1005 10051155	Immune system disorders	Allergy to animal	01JAN1953		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1953		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2012		Y
			Dry skin	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051156	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Hypersensitivity	01JAN1980		Y
		Infections and infestations	Genital herpes	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1005 10051157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2019		Y
		Surgical and medical procedures	Bunion operation	01JAN2020	31DEC2020	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Meniscus removal	01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
	C4591001 1005 10051158	Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2003		Y
	C4591001 1005 10051159	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051160	Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1005 10051162	Hepatobiliary disorders	Cholelithiasis	01JAN1973	31DEC1973	N
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	04AUG2020		Y
			Osteoporosis	04AUG2020		Y
		Nervous system disorders	Headache	01JAN1980		Y
			Migraine with aura	01JAN1980		Y
		Social circumstances	Menopause	01JAN1998		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN1973	31DEC1973	N
	C4591001 1005 10051163	Ear and labyrinth disorders	Deafness bilateral	01JAN2003		Y
			Tinnitus	01JAN2003		Y
		Endocrine disorders	Thyroid mass	01JAN2019		Y
		Investigations	Hysteroscopy	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1005 10051172	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1985		Y
			Insomnia	01JAN2005		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
	C4591001 1005 10051173	Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1005 10051174	Cardiac disorders	Mitral valve prolapse	01JAN1978		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine without aura	01JAN1985		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1005 10051176	Immune system disorders	Hypersensitivity	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051177	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Infections and infestations	Herpes simplex meningitis	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1005 10051180	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1977	31DEC1977	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2001	31DEC2001	N
		Social circumstances	Menopause	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1977	31DEC1977	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051184	Eye disorders	Glaucoma	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine with aura	01JAN1985		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1998		Y
		Surgical and medical procedures	Meniscus removal	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051185	General disorders and administration site conditions	Oedema peripheral	01JAN2007		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2005	31DEC2005	N
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
			Bipolar disorder	01JAN1992		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Sexual dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Colectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051186	Cardiac disorders	Coronary artery disease	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myocardial infarction	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2007	31DEC2007	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Contusion	11AUG2020		Y
			Post concussion syndrome	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Gastric bypass	01JAN2008	31DEC2008	N
	C4591001 1005 10051191	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2011	31DEC2011	N
				01JAN2017	31DEC2017	N
	C4591001 1005 10051193	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine without aura	01JAN2000		Y
		Social circumstances	Menopause	01JAN2003		Y
		Surgical and medical procedures	Mastectomy	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051194	Cardiac disorders	Coronary artery disease	01JAN2006		Y
			Myocardial infarction	01JAN2006	31DEC2006	N
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1005 10051195	Cardiac disorders	Atrial tachycardia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Immune system disorders	Hypersensitivity	01JAN1988		Y
		Investigations	Catheterisation cardiac	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine with aura	01JAN1990	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN1982		Y
			Depression	01JAN1982		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1951	31DEC1951	N
			Caesarean section	01JAN1972	31DEC1972	N
				01JAN1978	31DEC1978	N
			Cataract operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN1982	31DEC1982	N
			Tendon sheath incision	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1951	31DEC1951	N
	C4591001 1005 10051196	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Hypersensitivity	01JAN1986		Y
		Infections and infestations	Oral herpes	01JAN1970		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2011		Y
			Overweight	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Surgical and medical procedures	Ligament operation	01JAN2011	31DEC2011	N
			Meniscus operation	01JAN2009	31DEC2009	N
	C4591001 1005 10051197	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1005 10051201	Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y
	C4591001 1005 10051202	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1005 10051204	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Hypersensitivity	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2001		Y
			Rosacea	01JAN1985		Y
	C4591001 1005 10051205	Surgical and medical procedures	Prostatectomy	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Hypersensitivity	01JAN2000		Y
	C4591001 1005 10051206	Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Menopause	01JAN2011		Y
	C4591001 1005 10051207	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Mastectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1005 10051208	Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Familial risk factor	01JAN1990		Y
	C4591001 1005 10051209	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1005 10051211	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Reproductive system and breast disorders	Sexual dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1005 10051213	Immune system disorders	Hypersensitivity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999	31DEC1999	N
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN1999	31DEC1999	N
	C4591001 1005 10051214	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Menopause	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051227	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Knee operation	01JAN2008	31DEC2008	N
			Oophorectomy	01JAN2004	31DEC2004	N
	C4591001 1005 10051229	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Infections and infestations	Oral herpes	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
	C4591001 1005 10051230	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN1980		Y
		Immune system disorders	Hypersensitivity	01FEB1987		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2013		Y
		Surgical and medical procedures	Breast conserving surgery	10JAN2007	10JAN2007	N
	C4591001 1005 10051231	Ear and labyrinth disorders	Vertigo	01FEB2020		Y
		Immune system disorders	Hypersensitivity	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Metabolism and nutrition disorders	Overweight	01JAN1958		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051234	Immune system disorders	Hypersensitivity	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	03FEB2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1970		Y
	C4591001 1005 10051239	Immune system disorders	Hypersensitivity	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Overweight	01JAN1993		Y
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1998	31DEC1998	N
	C4591001 1005 10051247	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Surgical and medical procedures	Meniscus operation	01JAN2012	31DEC2012	N
	C4591001 1005 10051249	Infections and infestations	Herpes simplex	01MAR2020		Y
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	01JAN2015		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
	C4591001 1005 10051250	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Overweight	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051252	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN1956		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Lithotripsy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1005 10051253	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1961	31DEC1961	N
	C4591001 1005 10051255	Infections and infestations	Oral herpes	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051256	Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Ear and labyrinth disorders	Vertigo	01JAN2018		Y
	C4591001 1005 10051258	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Hypersensitivity	01JAN2012		Y
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Blood cholesterol increased	01JAN1999		Y
			Back pain	01JAN2010		Y
		Psychiatric disorders	Osteoarthritis	01JAN2009		Y
			Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Muscle operation	01JAN2010	31DEC2010	N
	Open reduction of fracture		01JAN2020	31JAN2020	N	
	Spinal fusion surgery		01JAN2011	31DEC2011	N	
	Spinal operation		01JAN2016	31DEC2016	N	
	Toe operation		01JAN2009	31DEC2009	N	
	Vascular disorders	Hypertension	01JAN2005		Y	
	Immune system disorders	Hypersensitivity	01JAN2000		Y	
		Investigations	Blood cholesterol increased	01JAN2008		Y
	Metabolism and nutrition disorders	Overweight	01JAN2005		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1005 10051261	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1983	31DEC1983	N
	C4591001 1005 10051262	Cardiac disorders	Tachycardia	01JAN2004		Y
		Ear and labyrinth disorders	Deafness	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1963		Y
		Immune system disorders	Hypersensitivity	01JAN1963		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Dehydration	01JAN2004		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2001		Y
		Surgical and medical procedures	Cervical conisation	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1005 10051263	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
	C4591001 1005 10051265	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1992	31DEC1992	N
			Thyroid cancer	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Mastectomy	01JAN1992	31DEC1992	N
				01JAN2004	31DEC2004	N
			Thyroidectomy	01JAN2007	31DEC2007	N
	C4591001 1005 10051266	Ear and labyrinth disorders	Deafness	01JAN2010		Y
			Tinnitus	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Strabismus correction	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1957	31DEC1957	N
			Vasectomy	19JUN2020	19JUN2020	N
	C4591001 1005 10051269	Immune system disorders	Hypersensitivity	01JAN2008		Y
		Infections and infestations	Onychomycosis	01JAN2015		Y
		Investigations	Arthroscopy	01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Overweight	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
			Ligament operation	01JAN2008		Y
			Meniscus operation	01JAN2011	31DEC2011	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1005 10051271	Ear and labyrinth disorders	Otosclerosis	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Nervous system disorders	Migraine with aura	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN1995	31DEC1995	N
			Keratomileusis	01JAN2001	31DEC2001	N
			Spinal laminectomy	01JAN1994	31DEC1994	N
			Stapedectomy	01JAN1974	31DEC1974	N
	C4591001 1005 10051272	Immune system disorders	Contrast media allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1005 10051275	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Overweight	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
			Tenoplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1005 10051278	Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1993		Y
			Breast cancer	01JAN2011	31DEC2016	N
	C4591001 1005 10051282	Eye disorders	Glaucoma	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Overweight	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051284	Immune system disorders	Hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
	C4591001 1005 10051286	Investigations	Blood cholesterol increased	01JAN1995		Y
	C4591001 1005 10051287	Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Intervertebral disc operation	01JAN2012	31DEC2012	N
	C4591001 1005 10051293	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Alcohol use disorder	01JAN1973		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1005 10051296	Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051298	Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2005		Y
		Surgical and medical procedures	Eye prosthesis insertion	01JAN2005		Y
	C4591001 1005 10051299	Ear and labyrinth disorders	Tinnitus	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2008		Y
		Surgical and medical procedures	Colectomy	01JAN1977	31DEC1977	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051300	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2011	31DEC2011	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Renal stone removal	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051303	Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Infections and infestations	Fungal skin infection	01JAN2001		Y
		Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Renal surgery	01JAN2019	31DEC2019	N
	C4591001 1005 10051304	Immune system disorders	Hypersensitivity	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1005 10051306	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2017	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051307	Ear and labyrinth disorders	Hypoacusis	01JAN1984		Y
			Tinnitus	01JAN1984		Y
		Gastrointestinal disorders	Coeliac disease	01JAN1995		Y
			Hiatus hernia	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
			Prostatomegaly	01JAN1990		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2006	31DEC2006	N
				01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
			Spinal laminectomy	01JAN1999	31DEC1999	N
	C4591001 1005 10051309	Investigations	Blood cholesterol increased	01JAN1980		Y
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Open reduction of fracture	01JAN1994	31DEC1994	N
	C4591001 1005 10051312	Immune system disorders	Hypersensitivity	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1957	31DEC1957	N
	C4591001 1005 10051313	Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Immune system disorders	Hypersensitivity	01JAN1975		Y
		Infections and infestations	Herpes simplex	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1005 10051319	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1977		Y
		Infections and infestations	Oral herpes	01JAN2006		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Migraine without aura	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN1977		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1005 10051320	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1950		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2001	N
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Social circumstances	Menopause	01JAN1987		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
			Cataract operation	01JAN2006	31DEC2006	N
	C4591001 1005 10051321	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
			Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Social circumstances	Menopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1005 10051324	Investigations	Arthroscopy	01JAN2001	31DEC2007	N
			Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1005 10051325	Investigations	Blood cholesterol increased	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Transurethral prostatectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051327	Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Overweight	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2004	31DEC2004	N
	C4591001 1005 10051329	Cardiac disorders	Supraventricular tachycardia	01JAN1987		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Hypersensitivity	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1005 10051330	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine without aura	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1985		Y
		Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1005 10051333	Immune system disorders	Hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Overweight	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	21OCT2019		Y
	C4591001 1005 10051334	Surgical and medical procedures	Gastric bypass	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Hypersensitivity	01JAN1982		Y
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2011		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2014		Y
			Overweight	01JAN1960		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2011	31DEC2011	N
		Nervous system disorders	Migraine without aura	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
			Urinary incontinence	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
			Sleep apnoea syndrome	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1982		Y
		Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Gastric bypass	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1005 10051336	Metabolism and nutrition disorders	Gout	01JAN2001		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
	C4591001 1005 10051337	Cardiac disorders	Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2005	31DEC2005	N
		Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
			Ovarian cancer	01JAN1997	31DEC1997	N
		Nervous system disorders	Migraine without aura	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Artificial menopause	01JAN1997		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2005	31DEC2005	N
			Coronary artery bypass	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
				01MAR2020	31DEC2020	N
			Mastectomy	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1005 10051338	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Stomatitis	10SEP2020		Y
		Immune system disorders	Hypersensitivity	01JAN2006		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Social circumstances	Menopause	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Spinal decompression	01JAN2016	31DEC2016	N
	C4591001 1005 10051342	Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1960		Y
		Surgical and medical procedures	Hydrocele operation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1005 10051344	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2010	31DEC2010	N
			Ovarian cystectomy	01JAN1995	31DEC1995	N
	C4591001 1005 10051347	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN1993	31DEC1993	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2008	31DEC2008	N
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2018	31DEC2018	N
			Endometrial ablation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1005 10051348	Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1005 10051351	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Investigations	Cardiac murmur	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1005 10051353	Injury, poisoning and procedural complications	Splenic rupture	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Overweight	01JAN1975		Y
		Surgical and medical procedures	Splenectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051355	Immune system disorders	Hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1005 10051360	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
			Coronary artery disease	01JAN2019		Y
			Myocardial infarction	01JAN2019	31JAN2019	N
		Gastrointestinal disorders	Diarrhoea	01OCT2020		Y
		Infections and infestations	Tinea pedis	01JAN2016		Y
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Mitral valve replacement	01JAN2019	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1005 10051367	Eye disorders	Glaucoma	01JAN1975		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN1964		Y
		Metabolism and nutrition disorders	Overweight	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Menopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1005 10051372	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	28AUG2020	28AUG2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051373	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2000		Y
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1005 10051374	Cardiac disorders	Mitral valve prolapse	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2000	N
		Social circumstances	Menopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Mastectomy	01JAN2000	31DEC2000	N
	C4591001 1005 10051375	Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Gastrectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1005 10051379	Immune system disorders	Hypersensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1005 10051382	Metabolism and nutrition disorders	Overweight	01JAN1970		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1005 10051387	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Immune system disorders	Hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN1999	31DEC1999	N
			Oophorectomy	01JAN2006	31DEC2006	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1005 10051389	Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Back pain	01FEB2020		Y
		Nervous system disorders	Migraine with aura	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1999		Y
	C4591001 1005 10051391	Nervous system disorders	Essential tremor	01JAN2018		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1005 10051392	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
	C4591001 1005 10051395	Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1005 10051399	Cardiac disorders	Mitral valve prolapse	01JAN2005		Y
		Eye disorders	Glaucoma	01JAN2015		Y
	C4591001 1005 10051402	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
	C4591001 1005 10051403	Endocrine disorders	Hypothyroidism	01JAN1968		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Overweight	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Social circumstances	Menopause	01JAN2005		Y
	C4591001 1005 10051405	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN1995		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1005 10051406	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1006 10061001	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	09MAY2011		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	17MAY2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	24OCT2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	23OCT2019		Y
		Psychiatric disorders	Anxiety	01JAN1967		Y
			Depression	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Actinic keratosis	12SEP2012		Y
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
	C4591001 1006 10061002	General disorders and administration site conditions	Drug intolerance	01JAN1994		Y
		Immune system disorders	Seasonal allergy	07MAY2002		Y
		Infections and infestations	Chronic sinusitis	01JAN2014		Y
		Injury, poisoning and procedural complications	Accident at work	01JAN2003	31DEC2003	N
		Investigations	Prostatic specific antigen increased	23OCT2013		Y
		Metabolism and nutrition disorders	Gout	01SEP2015		Y
			Hyperlipidaemia	07MAY2002		Y
			Vitamin B12 deficiency	01JAN2019		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Intervertebral disc compression	01JAN2003	31DEC2003	N
		Nervous system disorders	Neuropathy peripheral	01JAN2003		Y
		Psychiatric disorders	Insomnia	07OCT2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07JAN2006		Y
			Epididymal enlargement	26APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	24OCT2014		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2012		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2003	31DEC2003	N
	C4591001 1006 10061003	Ear and labyrinth disorders	Cerumen impaction	13JAN2014		Y
		Hepatobiliary disorders	Hepatic lesion	25AUG2017		Y
		Immune system disorders	Seasonal allergy	01APR2018		Y
		Infections and infestations	Genital herpes simplex	12JUN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	18APR2012		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01DEC2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	28JUN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2015	31DEC2015	N
	C4591001 1006 10061004	Endocrine disorders	Hypothyroidism	01MAY1994		Y
		Gastrointestinal disorders	Umbilical hernia	05SEP2014	28DEC2018	N
		General disorders and administration site conditions	Drug intolerance	01JAN1971		Y
				01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1987		Y
		Infections and infestations	Tinea cruris	01APR2020		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01MAY1994		Y
			Testis cancer	01JUL1998	04SEP1998	N
		Nervous system disorders	Paraesthesia	01JUN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN1998		Y
		Surgical and medical procedures	Orchidectomy	04SEP1998	04SEP1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061006	Congenital, familial and genetic disorders	Factor XI deficiency	01JAN1984		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN1980		Y
			Meniere's disease	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Hiatus hernia	18DEC2017		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Genital herpes	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	18DEC2017		Y
			Fibromyalgia	01JAN1980		Y
			Foot deformity	14DEC2016		Y
			Intervertebral disc degeneration	10APR2012		Y
			Osteoarthritis	10DEC2009		Y
			Osteopenia	01JAN1980		Y
			Sacroiliitis	01JAN1970		Y
			Scoliosis	12APR2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	18DEC2017		Y
			Colon adenoma	01MAY2012	01MAY2012	N
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1006 10061010	Eye disorders	Cataract	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1976		Y
			Intervertebral disc degeneration	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2000	31DEC2019	N
		Nervous system disorders	Lumbar radiculopathy	01JAN1976		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Neurogenic bladder	01JAN1997		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1972		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
			Eczema	01JAN1959		Y
	C4591001 1006 10061016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Oesophagitis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Low density lipoprotein increased	21MAY2018		Y
		Metabolism and nutrition disorders	Obesity	10JUN2020	10AUG2020	N
			Overweight	10AUG2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
	C4591001 1006 10061017	Endocrine disorders	Hypogonadism	01JUN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2019		Y
			Intervertebral disc degeneration	01MAY2019		Y
			Musculoskeletal chest pain	01JAN2017		Y
			Spondylitis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	03DEC2014		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2000		Y
	C4591001 1006 10061020	Cardiac disorders	Arteriosclerosis coronary artery	01DEC1989		Y
			Bundle branch block right	01JAN2017		Y
			Cardiovascular disorder	06MAR2019	31MAR2019	N
			Coronary artery disease	01JAN1989		Y
			Mitral valve prolapse	01JAN1989	27AUG2020	N
			Myocardial infarction	01DEC1989	31DEC1989	N
				01MAR2017	31MAR2017	N
				25MAR2004	31MAR2004	N
		Gastrointestinal disorders	Anal fissure	01JAN2018		Y
			Flatulence	01JAN2008		Y
			Intestinal obstruction	01APR2008	01APR2008	N
			Peptic ulcer	01JAN1980		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Investigations	Coagulation factor V level	(b) (6) 1944		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	21AUG1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Plantar fasciitis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
			Transient ischaemic attack	01JAN2016	31DEC2016	N
				01JUL2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01AUG2010	31AUG2010	N
			Coronary arterial stent insertion	01MAR2017	31MAR2017	N
				25MAR2004	25MAR2004	N
			Duodenal ulcer repair	09FEB2008	09FEB2020	N
			Intestinal operation	01APR2008	01APR2008	N
		Vascular disorders	Deep vein thrombosis	01JAN1983		Y
			Hypertension	01JAN2018		Y
	C4591001 1006 10061025	Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 1955	31DEC2008	N
		Eye disorders	Cataract	01JAN2019	31MAR2020	N
					31MAY2020	N
		Gastrointestinal disorders	Coeliac artery stenosis	01JAN1956		Y
			Constipation	01JAN2010		Y
			Large intestine polyp	01JAN2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Exostosis of jaw	01JAN1999		Y
			Morphoea	01JAN2016	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2008	31DEC2008	N
			Cataract operation	01MAR2020	31MAR2020	N
				01MAY2020	31MAY2020	N
	C4591001 1006 10061027	Ear and labyrinth disorders	Deafness	02FEB2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	27JUL2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	23NOV2009		Y
			Pain in extremity	23NOV2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	05MAY2011	05MAY2011	N
			Seborrhoeic keratosis	12NOV2015	12NOV2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Vascular disorders	Hypertension	10DEC2015		Y
	C4591001 1006 10061029	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Lactose intolerance	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019		Y
			Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2015		Y
			Sinus tarsi syndrome	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer stage 0, with cancer in situ	01JAN2010	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1960		Y
			Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Cancer surgery	01JAN2011	31DEC2011	N
	C4591001 1006 10061030	Infections and infestations	Clostridium difficile infection	13MAY2010	15MAY2010	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
			Osteoarthritis	01JAN1988		Y
		Psychiatric disorders	Insomnia	06JUL2010		Y
	C4591001 1006 10061034	Cardiac disorders	Palpitations	01JAN2020		Y
		Gastrointestinal disorders	Haemorrhoids	18APR2014		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	27JUN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	22JUN2015		Y
			Intervertebral disc protrusion	25SEP2015		Y
			Mixed connective tissue disease	06OCT2015		Y
		Nervous system disorders	Neuropathy peripheral	27JUN2013		Y
			Restless legs syndrome	01JUN2013		Y
		Psychiatric disorders	Anxiety	22JUN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Raynaud's phenomenon	02JUL2015		Y
	C4591001 1006 10061035	Ear and labyrinth disorders	Hypoacusis	01JAN2009		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Drug intolerance	01JAN1980		Y
			Fatigue	04SEP2019		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1999		Y
			Drug hypersensitivity	01JAN1967		Y
				01JAN1999		Y
				01MAR2019		Y
			Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	03JAN2013		Y
			Back pain	03NOV2015		Y
			Intervertebral disc degeneration	01JAN1975		Y
			Intervertebral disc protrusion	01JAN1980		Y
			Kyphosis	03NOV2015		Y
			Neck pain	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1006 10061039	Cardiac disorders	Bradycardia	01JAN2000		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Normal tension glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN1980		Y
			Haemorrhoids	01JAN2012		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
			Spinal osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1990		Y
		Surgical and medical procedures	Prostatectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1006 10061044	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1992	31DEC1992	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01NOV2018		Y
			Depression	01JAN1990		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Nephropathy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1006 10061045	Blood and lymphatic system disorders	Iron deficiency anaemia	30APR2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01MAY2019		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JUN2020		Y
			Pain in extremity	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Eczema	01MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2000	31DEC2000	N
			Mammoplasty	01JUN2019	30JUN2019	N
	C4591001 1006 10061046	General disorders and administration site conditions	Device intolerance	01JAN1986	31DEC1987	N
		Hepatobiliary disorders	Cholecystitis	01JUN2012	14JUN2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	14JUN2012	14JUN2012	N
			Female sterilisation	01JAN1987	31DEC1987	N
	C4591001 1006 10061047	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01AUG1990	31OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01OCT2019	31OCT2019	N
		Vascular disorders	Varicose vein	01JAN1990		Y
	C4591001 1006 10061049	Infections and infestations	Sinusitis	17AUG1990		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1006 10061051	Gastrointestinal disorders	Diverticulum	01JAN2015		Y
			Haemorrhoids	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	26NOV2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff syndrome	19JUN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN2013		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01MAY2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1006 10061059	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01NOV2011		Y
		Ear and labyrinth disorders	Cerumen impaction	07FEB2012		Y
			Deafness	13JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	30NOV2017		Y
		Immune system disorders	Drug hypersensitivity	13JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	18JAN2013		Y
			Obesity	22JAN2013		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	10NOV2015		Y
			Musculoskeletal pain	12SEP2019		Y
			Osteoarthritis	01JAN2000		Y
			Pain in extremity	06NOV2019		Y
			Spinal stenosis	26NOV2019		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1006 10061060	Blood and lymphatic system disorders	Iron deficiency anaemia	20DEC2014		Y
		Cardiac disorders	Aortic valve stenosis	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Arteriosclerosis coronary artery	01JAN2002		Y
			Bradycardia	23OCT2009		Y
			Coronary artery disease	01JAN2002		Y
		Ear and labyrinth disorders	Deafness bilateral	27MAR2018		Y
			Tinnitus	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Duodenal stenosis	03MAR2014	15MAY2018	N
			Duodenal ulcer	03MAR2014	15MAY2019	N
			Gastric ulcer	14JAN2019		Y
			Gastroesophageal reflux disease	20DEC2014		Y
			Hiatus hernia	03MAR2014		Y
			Umbilical hernia	09NOV2010		Y
		General disorders and administration site conditions	Ulcer haemorrhage	21JAN2019	24JAN2019	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Helicobacter infection	01JAN2019	01FEB2019	N
		Injury, poisoning and procedural complications	Wrist fracture	25MAR2019	06MAY2019	N
		Investigations	Blood glucose increased	27MAY2020		Y
			Cardiac murmur	(b) (6) 1939		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13DEC2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1955		Y
				07JAN2020		Y
			Muscle spasms	01JAN2018		Y
			Osteoarthritis	01JAN1979		Y
			Plantar fasciitis	10OCT2019		Y
			Synovial cyst	10JUL2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Dizziness	27MAY2020		Y
			Neuropathy peripheral	16JAN2013		Y
			Tension headache	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	19SEP2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	26SEP2016		Y
			Testicular atrophy	31DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	22APR2011		Y
			Sleep apnoea syndrome	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1972		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2002	31DEC2002	N
			Prostatectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	02JUN2010		Y
			Peripheral venous disease	31DEC2018		Y
	C4591001 1006 10061063	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN1970		Y
				01JAN2017		Y
		Investigations	Glycosylated haemoglobin increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2005	31MAY2005	N
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	08JAN2018		Y
		Nervous system disorders	Paraesthesia	01NOV2019		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2017	31JAN2017	N
				01JAN2018	31DEC2018	N
			Spinal fusion surgery	01MAY2005	31MAY2005	N
	C4591001 1006 10061064	Eye disorders	Glaucoma	01JAN1971		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1006 10061065	Eye disorders	Dry eye	01JAN2016		Y
			Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	23JAN2004		Y
			Large intestine polyp	01JAN2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2012		Y
				01JAN2015		Y
			Fatigue	01JAN2009		Y
		Immune system disorders	Allergy to plants	01JAN2018		Y
			Mycotic allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	05JUL2019	05JUL2019	N
			Oesophageal candidiasis	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2000		Y
		Injury, poisoning and procedural complications	Hand fracture	28APR2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01JAN2014		Y
			Pain in extremity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	01OCT2004	31DEC2004	N
		Nervous system disorders	Blood brain barrier defect	01JAN2018		Y
		Psychiatric disorders	Terminal insomnia	01JAN2010		Y
		Renal and urinary disorders	Nocturia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Acoustic neuroma removal	01JAN2004		Y
			Appendectomy	05JUL2019	05JUL2019	N
			Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1006 10061069	Congenital, familial and genetic disorders	Malformation venous	31MAR2006		Y
		Endocrine disorders	Hypothyroidism	29OCT1993		Y
		Eye disorders	Cataract	01JAN2018	02JUL2020	N
		Gastrointestinal disorders	Diverticulum	30NOV2016		Y
			Haemorrhoids	05JUN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Infections and infestations	Oral herpes	18MAY2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	30DEC2018		Y
			Hypercholesterolaemia	30NOV2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	29OCT1993		Y
			Osteoporosis	09JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	17JUN2019		Y
			Seborrhoeic keratosis	12NOV2013		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Cataract operation	02JUL2020	02JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061076	Psychiatric disorders	Insomnia	25JUN2020	25JUN2020	N
		Social circumstances	Postmenopause	01APR2019		Y
	C4591001 1006 10061077	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2005		Y
		Investigations	Arthroscopy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1982	31DEC2006	N
		Social circumstances	Postmenopause	18SEP2013		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1982	31DEC1982	N
	C4591001 1006 10061080	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
			Coronary artery disease	01JAN1987		Y
			Myocardial infarction	01JAN2005	31DEC2005	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN1945		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2010		Y
	C4591001 1006 10061082	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061083	Gastrointestinal disorders	Gastritis erosive	03DEC2008		Y
		Infections and infestations	Genital herpes simplex	02JUL2009		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	25AUG2015		Y
			Hyperlipidaemia	18JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
			Bursitis	01MAY2020		Y
			Cervical spinal stenosis	01JAN1990		Y
			Intervertebral disc degeneration	01JAN1996		Y
			Neck pain	01JAN1980		Y
			Spinal stenosis	01JAN1996		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980	31DEC1999	N
			Migraine with aura	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2009		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	06JUN2018		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1986	31DEC1986	N
				29JUN1999	29JUN1999	N
	C4591001 1006 10061086	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1006 10061097	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	02MAY2017		Y
		Endocrine disorders	Hypogonadism	25JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	14MAY2015		Y
			Hiatus hernia	08MAY2015		Y
			Irritable bowel syndrome	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01AUG2016	18AUG2016	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Infections and infestations	Sinusitis	14DEC2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15APR2011		Y
			Metabolic syndrome	19MAR2012		Y
			Type 2 diabetes mellitus	15APR2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	02MAR2012		Y
		Nervous system disorders	Polyneuropathy	28JUN2018		Y
		Psychiatric disorders	Insomnia	30AUG2011		Y
			Major depression	07APR2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	07APR2016		Y
		Surgical and medical procedures	Cholecystectomy	18AUG2016	18AUG2016	N
			Gastrectomy	01NOV2011	01NOV2011	N
	C4591001 1006 10061098	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN1966		Y
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN1966		Y
		Ear and labyrinth disorders	Tinnitus	12MAR2015		Y
		Eye disorders	Cataract	20OCT2016	16FEB2017	N
		Gastrointestinal disorders	Gastrointestinal haemorrhage	27NOV2017	31DEC2017	N
		General disorders and administration site conditions	Chronic fatigue syndrome	14AUG2012		Y
		Immune system disorders	Hypersensitivity	01JAN1969		Y
		Infections and infestations	Sinusitis	01JAN1980	31DEC2017	N
			Urinary tract infection	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	14AUG2014		Y
			Muscle spasms	10MAR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	11SEP2011	11SEP2011	N
		Nervous system disorders	Migraine with aura	01JAN1979		Y
			Restless legs syndrome	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Postpartum haemorrhage	01JAN1989	31DEC1989	N
		Psychiatric disorders	Anxiety	19MAY2014		Y
			Attention deficit hyperactivity disorder	01FEB1989		Y
			Insomnia	13SEP2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	06SEP2011		Y
			Rosacea	12SEP2011		Y
			Urticaria	01JAN1989		Y
				01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Urinary bladder suspension	01JAN2018		Y
	C4591001 1006 10061101	Eye disorders	Eye allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Investigations	Blood testosterone decreased	01FEB2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Sciatica	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seizure	01JAN1974		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN1976		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
			Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1006 10061105	Eye disorders	Cataract	01JAN2005		Y
		Gastrointestinal disorders	Diverticulum	16MAR2010		Y
			Eosinophilic oesophagitis	01JAN2008		Y
			Hiatus hernia	18OCT2011		Y
		General disorders and administration site conditions	Drug intolerance	04JUL2017		Y
		Investigations	Cardiac murmur	01JAN1978		Y
			Hepatic enzyme increased	29JUN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11FEB2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	06NOV2018		Y
			Uterine leiomyoma	06DEC2012		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1998		Y
			Ovarian cyst	26OCT2012	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	06NOV2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	29JUN2017		Y
	C4591001 1006 10061115	Eye disorders	Cataract	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JUN2019		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1006 10061119	Cardiac disorders	Ventricular extrasystoles	13MAR2001		Y
		Congenital, familial and genetic disorders	Hereditary haemochromatosis	01JAN1960		Y
		Gastrointestinal disorders	Chronic gastritis	19JUL2002		Y
			Gastroesophageal reflux disease	19JUL2002		Y
		Hepatobiliary disorders	Hepatomegaly	01JAN1990		Y
		Immune system disorders	Seasonal allergy	17NOV2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	30MAR2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
				01OCT2011		Y
			Osteopenia	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1006 10061120	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2014		Y
		Ear and labyrinth disorders	Cerumen impaction	01JAN2011		Y
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
			Inguinal hernia	05NOV2012	05NOV2012	N
			Large intestine polyp	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Investigations	Blood pressure increased	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Back pain	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1980		Y
		Surgical and medical procedures	Inguinal hernia repair	05NOV2012	05NOV2012	N
	C4591001 1006 10061121	Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007	23DEC2017	N
			Osteoporosis	25JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	30NOV2017		Y
		Psychiatric disorders	Grief reaction	20AUG2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	30JUN2002		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01DEC2017	31DEC2017	N
			Knee arthroplasty	23DEC2017	23DEC2017	N
		Vascular disorders	Hypertension	31MAR2004		Y
	C4591001 1006 10061123	Gastrointestinal disorders	Coeliac disease	01JAN1979		Y
			Diverticulum	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1995		Y
			Oedema peripheral	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990		Y
			Squamous cell carcinoma	01JAN2007		Y
		Nervous system disorders	Narcolepsy	02JUN2020		Y
		Renal and urinary disorders	Nocturia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1006 10061125	Eye disorders	Dry eye	01JAN2006		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	09SEP2016		Y
		Renal and urinary disorders	Stress urinary incontinence	14MAR2014		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	04SEP2009		Y
			Menorrhagia	01JAN1997	12JUL2006	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	03MAY2020	03MAY2020	N
			Endometrial ablation	12JUL2016	12JUL2016	N
	C4591001 1006 10061132	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Fungal infection	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
				01JAN2019		Y
			Osteoporosis	01FEB2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1006 10061135	Blood and lymphatic system disorders	Anaemia	01JAN2001		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Chest discomfort	01JAN2016		Y
			Fatigue	01JAN1991		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Infections and infestations	Oral herpes	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2002		Y
			Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01AUG2017		Y
		Psychiatric disorders	Depression	01JAN1991		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Venous operation	01APR2017	30APR2017	N
		Vascular disorders	Hot flush	01JAN2001		Y
			Peripheral venous disease	01JAN2016		Y
	C4591001 1006 10061139	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN1992		Y
		Ear and labyrinth disorders	Tinnitus	19DEC2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	20AUG2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061143	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2020		Y
			Periarthritis	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1006 10061145	Ear and labyrinth disorders	Deafness bilateral	01JUL2005		Y
			Tinnitus	01JUL2005		Y
		Eye disorders	Borderline glaucoma	17MAY2012		Y
			Conjunctivochalasis	17MAY2012		Y
			Retinal degeneration	17MAY2012		Y
		Gastrointestinal disorders	Diverticulum	02APR2015		Y
			Dysphagia	01JAN2017		Y
			Gastroesophageal reflux disease	30JAN2003		Y
			Nausea	01JAN2010		Y
		Hepatobiliary disorders	Hepatic steatosis	08SEP2011		Y
			Liver disorder	07OCT2014		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08SEP2011		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	08SEP2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15JAN2020		Y
				27FEB2020		Y
		Nervous system disorders	Diabetic neuropathy	17AUG2017		Y
		Psychiatric disorders	Anxiety	30OCT2009		Y
			Major depression	17AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Chronic obstructive pulmonary disease	30JAN2003		Y
			Sleep apnoea syndrome	23JAN2011		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1006 10061146	General disorders and administration site conditions	Drug intolerance	01JAN1975		Y
			Oedema peripheral	30SEP2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1985		Y
			Drug hypersensitivity	01JAN1975		Y
				03DEC2012		Y
		Metabolism and nutrition disorders	Gout	30SEP2010		Y
			Hypercholesterolaemia	07OCT2010		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	30SEP2010		Y
		Psychiatric disorders	Depression	28JUL2020		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1984	31DEC1984	N
			Ovarian rupture	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	11AUG2006		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
			Oophorectomy bilateral	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	30APR2020		Y
	C4591001 1006 10061147	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Genital herpes	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
			Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1979		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JUN2020		Y
			Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1006 10061149	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc degeneration	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2010	19OCT2010	N
			Osteoporosis	03JUN2019		Y
			Spinal stenosis	01JAN2010	19OCT2010	N
		Nervous system disorders	Disturbance in attention	01JAN1980		Y
			Hypoaesthesia	01JAN2017		Y
		Psychiatric disorders	Anxiety	03JUN2019		Y
			Depression	03JUN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Foraminotomy	19OCT2010	19OCT2010	N
			Intervertebral disc operation	19OCT2010	19OCT2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061150	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Gastrointestinal disorders	Umbilical hernia	21MAY2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Hallucination	10MAR2016		Y
		Vascular disorders	Hypertension	23JAN2017		Y
	C4591001 1006 10061157	Cardiac disorders	Arrhythmia	01JAN2017		Y
			Supraventricular tachycardia	01JAN2017		Y
		Eye disorders	Dry eye	01JAN2020		Y
		Gastrointestinal disorders	Hiatus hernia	01MAR2020	03MAR2021	N
			Oral lichen planus	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986		Y
			Osteopenia	01JAN2000		Y
		Nervous system disorders	Amnesia	01JAN2017		Y
			Sciatica	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN2016		Y
			Nail psoriasis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1006 10061158	Congenital, familial and genetic disorders	Congenital spinal stenosis	01JAN1995		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2013		Y
			Pain	01JAN1972		Y
		Immune system disorders	Food allergy	01JAN2009		Y
				01JAN2010		Y
			Hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN1995		Y
			Osteoarthritis	01JAN2010		Y
			Osteoporosis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN1991		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1974	31DEC2008	N
			Ovarian cyst	01JAN1974	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1006 10061168	Ear and labyrinth disorders	Hypoacusis	01JAN2005		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2008		Y
		Hepatobiliary disorders	Hepatitis	01JAN1980	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Cervical spinal stenosis	01JAN2000		Y
			Osteoarthritis	01JAN2000	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
			Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Nervous system disorders	Monoplegia	01JAN2000		Y
			Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1006 10061177	Gastrointestinal disorders	Diverticulum	07JUN2016		Y
			Gingival disorder	01JAN1975		Y
			Haemorrhoids	07JUN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Plantar fasciitis	01JAN2018		Y
			Scoliosis	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Dental implantation	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1006 10061178	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2013		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1007 10071031^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
	C4591001 1007 10071032^	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1007 10071034^	Immune system disorders	Seasonal allergy	01JAN1971		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1007 10071035^	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1966	31DEC1981	N
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
	C4591001 1007 10071037^	Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb injury	01JAN2018	31DEC2018	N
			Meniscus injury	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Shoulder operation	01JAN2018	31DEC2018	N
	C4591001 1007 10071038^	Ear and labyrinth disorders	Tinnitus	01JAN2019	31DEC2019	N
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Musculoskeletal pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Social circumstances	Hearing aid user	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Intraocular lens implant	01JAN2019	31DEC2019	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1007 10071039^	Eye disorders	Corneal erosion	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1956		Y
		Surgical and medical procedures	Corneal transplant	01JAN2017	31DEC2017	N
	C4591001 1007 10071042^	Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2009		Y
	C4591001 1007 10071043^	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Nervous system disorders	Sciatica	01JAN1990		Y
		Psychiatric disorders	Sleep disorder	01JAN2015		Y
	C4591001 1007 10071044^	Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Uterine polypectomy	01JAN2017	31DEC2017	N
	C4591001 1007 10071045^	Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2000	31DEC2000	N
	C4591001 1007 10071049^	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1007 10071051^	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN1974		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
			Meniscus injury	01JAN1998	31DEC2012	N
		Reproductive system and breast disorders	Breast cyst	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vulvovaginal dryness	01JAN2004		Y
		Surgical and medical procedures	Breast cyst excision	01JAN2012	31DEC2012	N
			Ligament operation	01JAN1998	31DEC1998	N
	C4591001 1007 10071052^	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Infections and infestations	Diverticulitis	01JAN2019	31MAR2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2002		Y
	C4591001 1007 10071053^	Surgical and medical procedures	Transurethral prostatectomy	01NOV2019	30NOV2019	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Exposure to communicable disease	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Prostatectomy	01JAN2007	31DEC2007	N
	C4591001 1007 10071056^	Immune system disorders	Seasonal allergy	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Ovarian cystectomy	01JAN1977	31DEC1977	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071057^	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Gastrointestinal disorders	Anal incontinence	01JAN2019	30JUN2019	N
			Hiatus hernia	01APR2019	30APR2019	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Osteoporosis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019	30JUN2019	N
		Reproductive system and breast disorders	Uterine cyst	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hernia repair	01APR2019	30APR2019	N
			Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1007 10071071^	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1987	31DEC2006	N
			Neck pain	01JAN1987		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
	C4591001 1007 10071073^	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1007 10071074^	Congenital, familial and genetic disorders	Duchenne muscular dystrophy gene carrier	(b) (6) 1946		Y
		Hepatobiliary disorders	Cholelithiasis	01NOV1975	30JUN1976	N
		Surgical and medical procedures	Cholecystectomy	01JUN1976	30JUN1976	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071075^	Eye disorders	Cataract	01JAN2018	31MAY2020	N
		Infections and infestations	Oral herpes	01JAN2010		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Tooth fracture	01APR2020	12JUL2020	N
			Arthritis	01JAN2012		Y
			Plantar fasciitis	01JAN1999	31DEC2000	N
		Psychiatric disorders	Rapid eye movement sleep behaviour disorder	01NOV2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01MAY2020	31MAY2020	N
			Tenoplasty	01JAN2000	31DEC2000	N
	C4591001 1007 10071077^	Immune system disorders	Rubber sensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2018	16JUL2018	N
		Surgical and medical procedures	Vertebroplasty	16JUL2018	16JUL2018	N
	C4591001 1007 10071079	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01APR2016	31AUG2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2019		Y
		Surgical and medical procedures	Ureteral stent insertion	01APR2016	30APR2016	N
			Ureteral stent removal	01AUG2016	31AUG2016	N
	C4591001 1007 10071081	Eye disorders	Dry eye	01JUL2008		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071084	Nervous system disorders	Facial paralysis	01DEC2007	31JUL2008	N
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1007 10071085		Knee arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1007 10071086	Reproductive system and breast disorders	Benign prostatic hyperplasia	01DEC2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2002	31DEC2002	N
			Trabeculectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
		Cardiac disorders	Atrial fibrillation	01JAN2017	31DEC2018	N
	C4591001 1007 10071088	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2012	N
		Nervous system disorders	Complex regional pain syndrome	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
			Erectile dysfunction	01JAN2010		Y
	C4591001 1007 10071090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
	C4591001 1007 10071091	Cardiac disorders	Coronary artery occlusion	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUL2013	31JUL2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01SEP2013		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2007	31DEC2007	N
			Rotator cuff repair	01JUL2013	31JUL2013	N
	C4591001 1007 10071094	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JUN2015		Y
			Exostosis	01JAN2015	31DEC2015	N
			Rotator cuff syndrome	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Uterine cyst	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Cheilectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
	C4591001 1007 10071098	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1007 10071099	Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Glaucoma traumatic	01JAN1967		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
	C4591001 1007 10071101	Cardiac disorders	Supraventricular tachycardia	08OCT2019		N
		Endocrine disorders	Hypothyroidism	01NOV2007		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
			Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Gastrectomy	01SEP2019	30SEP2019	N
	C4591001 1007 10071103	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1007 10071104	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2015		Y
	C4591001 1007 10071105	Psychiatric disorders	Depression	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Bronchitis	04JUL2020	12JUL2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013		Y
	C4591001 1007 10071113	Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Congenital, familial and genetic disorders	Atrial septal defect	01JAN2016	31JAN2016	N
	C4591001 1007 10071114	Surgical and medical procedures	Cardiac operation	01JAN2016	31JAN2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1998		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN2000		Y
	C4591001 1007 10071115	Cardiac disorders	Myocardial infarction	01AUG2010	31AUG2010	N
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2010	31DEC2010	N
			Gastrooesophageal reflux disease	01JAN1995		Y
			Inguinal hernia	01JAN2006	31DEC2006	N
			Umbilical hernia	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Synovial cyst	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1953		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2006	31DEC2006	N
			Umbilical hernia repair	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Infections and infestations	Appendicitis perforated	01JAN1973	31DEC1973	N
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN1973	31DEC1973	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Renal stone removal	01JAN2014	31DEC2014	N
	C4591001 1007 10071120	Immune system disorders	Seasonal allergy	01JAN1975		Y
	C4591001 1007 10071121	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071122	Cardiac disorders	Angina pectoris	31MAR2017		Y
		Investigations	Angiogram	31MAR2017	31MAR2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colorectal cancer metastatic	01DEC1990	31DEC1991	N
	C4591001 1007 10071124	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
			Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN1993	31DEC1998	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1993	31DEC1993	N
	C4591001 1007 10071126	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1007 10071127	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Endocrine hypertension	01JAN2015		Y
	C4591001 1007 10071128	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1007 10071134	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
	C4591001 1007 10071135	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1007 10071136	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
			Myocardial ischaemia	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071139	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1007 10071140	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1978		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma stage I	01JAN1981	31DEC1981	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1007 10071142	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1007 10071144	Gastrointestinal disorders	Diverticulum	01JAN2003	31MAY2003	N
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1975		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y
		Surgical and medical procedures	Colostomy closure	01MAY2003	31MAY2003	N
	C4591001 1007 10071147	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1007 10071149	Injury, poisoning and procedural complications	Lower limb fracture	04JUL2018	04JUL2018	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Fracture treatment	07JUL2018		Y
	C4591001 1007 10071156	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071160	Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1007 10071161	Cardiac disorders	Arrhythmia	01JAN2013	31DEC2013	N
		Immune system disorders	Food allergy	01JAN1954		Y
			Hypersensitivity	01JAN1948		Y
			Rubber sensitivity	01JAN1983		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of the tongue	01JAN1997	31DEC1997	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1991	31DEC1991	N
		Social circumstances	Menopause	01JAN1997	31DEC1998	N
		Surgical and medical procedures	Cancer surgery	01JAN1997	31DEC1997	N
			Cardiac ablation	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip arthroplasty	01JAN1995	31DEC1995	N
			Oophorectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1007 10071163	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN1982		Y
	C4591001 1007 10071164	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1999		Y
	C4591001 1007 10071165	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1007 10071166	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Urinary tract infection	22JUL2020	29JUL2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
	C4591001 1007 10071167	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1942		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071168	Cardiac disorders	Supraventricular tachycardia	01JAN2004	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cardiac ablation	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Metabolic surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071169	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1947		Y
		Injury, poisoning and procedural complications	Concussion	03JUL2020	04JUL2020	N
			Ligament sprain	03JUL2020		Y
			Limb injury	03JUL2020		Y
		Investigations	Heart rate irregular	01JAN1972	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1997	31DEC1997	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1951		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2005	31DEC2005	N
			Prostatectomy	01JAN1997	31DEC1997	N
	C4591001 1007 10071173	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01APR2015	31DEC2015	N
			Wrist fracture	01APR2015	30JUN2015	N
		Surgical and medical procedures	Wrist surgery	01MAY2015	31MAY2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071174	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1973		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Menopause	01JAN2014	31DEC2015	N
	C4591001 1007 10071176	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
	C4591001 1007 10071177	Cardiac disorders	Arrhythmia	01JAN1962		Y
			Cardiac disorder	01JAN2018		Y
		Social circumstances	Menopause	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Percutaneous coronary intervention	01NOV2018		Y
	C4591001 1007 10071180	Cardiac disorders	Mitral valve prolapse	01JAN1993		Y
		Endocrine disorders	Hypothyroidism	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	05AUG2020		Y
		Surgical and medical procedures	Mastectomy	01JAN2003	31DEC2003	N
	C4591001 1007 10071183	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN2005		Y
			Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071187	Eye disorders	Cataract	01JAN2015	31DEC2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Colectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1007 10071188	Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071189	Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer metastatic	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Hysterectomy	01JAN1973	31DEC1973	N
			Nephrectomy	01JAN1973	31DEC1973	N
	C4591001 1007 10071190	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1951		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	18OCT2018		Y
		Nervous system disorders	Cerebrovascular accident	19FEB2019	30JUN2019	N
			Neuropathy peripheral	07AUG2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1951		Y
		Vascular disorders	Hypertension	03FEB2019		Y
	C4591001 1007 10071191	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN2005		Y
			Rubber sensitivity	01JAN2017		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1007 10071192	Cardiac disorders	Left ventricular hypertrophy	27FEB2019		Y
		Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Gastrointestinal disorders	Barrett's oesophagus	17MAR2017	09AUG2019	N
			Chronic gastritis	17MAR2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010		Y
				01OCT2019	31OCT2019	N
		Renal and urinary disorders	Bladder prolapse	01JAN2006	31DEC2006	N
			Chronic kidney disease	01JAN2019		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Cystocele repair	01JAN2006	31DEC2006	N
			Hysterectomy	01DEC1992	31DEC1992	N
			Otoplasty	01OCT2019	31OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071198	Eye disorders	Retinal vein occlusion	01JAN2011		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2012		Y
		Immune system disorders	Allergy to plants	01JAN1965		Y
		Infections and infestations	Herpes zoster	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1007 10071199	Psychiatric disorders	Insomnia	01JAN2019		Y
		Social circumstances	Menopause	01JAN2013	31DEC2013	N
	C4591001 1007 10071200	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Hormone replacement therapy	01JUL1988		Y
			Hysterectomy	01JUL1988	31JUL1988	N
	C4591001 1007 10071201	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anogenital warts	23MAY2020	05JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Menopause	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Papilloma excision	05JUN2020	05JUN2020	N
	C4591001 1007 10071205	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	23NOV2012	23NOV2012	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1007 10071209	Immune system disorders	Hypersensitivity	01JAN1958		Y
	C4591001 1007 10071210	Immune system disorders	Seasonal allergy	01JAN1955		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Prostatectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1007 10071213	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1007 10071215	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071216	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071220	General disorders and administration site conditions	Drug intolerance	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1007 10071222	Immune system disorders	Seasonal allergy	01JAN1959		Y
		Investigations	Bone density abnormal	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2012		Y
		Nervous system disorders	Sciatica	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1007 10071223	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Ataxia	01JAN2017		Y
		Renal and urinary disorders	Hydronephrosis	31MAR1969	31DEC1969	N
		Surgical and medical procedures	Nephrectomy	01JAN1969	31DEC1969	N
			Spinal fusion surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071224	Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Menopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071226	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1007 10071234	Nervous system disorders	Transient global amnesia	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2015		Y
	C4591001 1007 10071237	Immune system disorders	Rubber sensitivity	01JAN1995		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN2000		Y
	C4591001 1007 10071239	Immune system disorders	Seasonal allergy	01JAN1967		Y
		Injury, poisoning and procedural complications	Skin laceration	15AUG2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071241	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Drug hypersensitivity	01JAN1988		Y
			Hypersensitivity	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2003	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Cholecystostomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071242	Congenital, familial and genetic disorders	Factor V deficiency	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1007 10071244	Cardiac disorders	Tachycardia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1007 10071245	Ear and labyrinth disorders	Vertigo positional	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	01JUN2019	30JUN2019	N
	C4591001 1007 10071248	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071249	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Genital herpes	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1007 10071254	Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN1966		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
	C4591001 1007 10071255	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Chronic inflammatory demyelinating polyradiculoneuropathy	01JAN1998	31DEC2010	N
	C4591001 1007 10071257	Surgical and medical procedures	Micrographic skin surgery	01JAN2014	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Eyelid ptosis	01JAN2014	22AUG2020	N
			Glaucoma	01APR2020		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Iodine allergy	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005	31DEC2015	N
		Surgical and medical procedures	Blepharoplasty	22AUG2020	22AUG2020	N
			Inguinal hernia repair	01JAN2012	31DEC2012	N
	C4591001 1007 10071259	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Cubital tunnel syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Peripheral nerve decompression	28JUN2019	28JUN2019	N
	C4591001 1007 10071260	Eye disorders	Glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2018	30APR2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2000	31MAR2000	N
		Nervous system disorders	Neuralgia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Menopause	01JAN1986		Y
		Surgical and medical procedures	Breast conserving surgery	01MAR2000	31MAR2000	N
			Hysterectomy	01JAN1986	31JAN1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder arthroplasty	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071261	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2018	N
			Morton's neuralgia	01JAN2005	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC1999	N
			Pelvic floor muscle weakness	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Neurectomy	01JAN2018	31DEC2018	N
					31JAN2019	N
			Pelvic floor repair	01JAN2011	31DEC2011	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1007 10071262	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
			Serum sickness	01JAN1953		Y
		Investigations	Blood uric acid increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071263	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
			Carpal tunnel decompression	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1007 10071265	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1007 10071267	Cardiac disorders	Atrial fibrillation	12SEP2012		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31DEC2019	N
				01MAY2020	31MAY2020	N
			Continuous positive airway pressure	01JAN2017		Y
	C4591001 1007 10071268	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Hyperlipidaemia	01JAN2005		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010		Y
	C4591001 1007 10071271	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Plantar fasciitis	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Hip arthroplasty	01MAY2019	31MAY2019	N
				01OCT2019	31OCT2019	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
			Tenoplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071273	Cardiac disorders	Coronary artery disease	14SEP2013	31DEC2013	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1979	31DEC1979	N
			Meniscus injury	01JAN1992	31DEC1992	N
				01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG1996	31DEC1997	N
			Arthritis	01JAN1991		Y
			Osteoarthritis	01JAN2011	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal stenosis	01JAN1959		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1996		Y
		Surgical and medical procedures	Coronary artery bypass	15SEP2013	15SEP2013	N
			Hip arthroplasty	01JAN2012	31JAN2012	N
			Joint dislocation reduction	01JAN1979	31DEC1979	N
			Lithotripsy	01JAN2009	31DEC2009	N
			Meniscus operation	01JAN1992	31DEC1992	N
				01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN1997	31DEC1997	N
	C4591001 1007 10071274	Immune system disorders	Allergy to animal	01JAN2018		Y
			Food allergy	01JAN1961		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1007 10071277	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Menopause	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071279	Cardiac disorders	Cardiac disorder	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071283	Immune system disorders	Allergy to animal	01JAN1982		Y
			Dust allergy	01JAN1982		Y
			Mycotic allergy	01JAN1982		Y
			Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Social circumstances	Menopause	01JAN1989	31DEC1989	N
	C4591001 1007 10071287	Eye disorders	Macular degeneration	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Immune system disorders	Iodine allergy	01JAN2000		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1959	31DEC1959	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1968	31DEC1968	N
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoarthritis	01JAN1968		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	01JAN1997	31DEC1997	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Mastectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN1971	31DEC1971	N
			Tendon graft	01JAN1968	31DEC1968	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1007 10071288	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2018	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1957	31DEC1957	N
			Hernia repair	01JAN2015	31DEC2015	N
			Prostatectomy	17JAN2018	17JAN2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071291	Cardiac disorders	Atrial fibrillation	01MAR2020		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071292	Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Hip arthroplasty	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1974	31DEC1974	N
			Tonsillectomy	01JAN1952	31DEC1952	N
	C4591001 1007 10071293	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Allergy to animal	01JAN1963		Y
			Seasonal allergy	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1007 10071294	Eye disorders	Cataract	01JUL2020		Y
					26AUG2020	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2017	31DEC2017	N
			Jaw fracture	01JAN2017	31DEC2017	N
			Pelvic fracture	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cataract operation	26AUG2020	26AUG2020	N
			Intramedullary rod insertion	01JAN2017	31DEC2017	N
			Jaw operation	01JAN2017	31DEC2017	N
	C4591001 1007 10071297	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Hysterectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Essential hypertension	01JAN2012		Y
	C4591001 1007 10071298	Gastrointestinal disorders	Diverticulum intestinal	01APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071299	Endocrine disorders	Hypothyroidism	01JAN1995		Y
			Thyroid mass	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1997	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
			Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1007 10071300	Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1962		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Menopause	01JAN1995		Y
	C4591001 1007 10071301	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2018		Y
		Nervous system disorders	Headache	01JAN1970		Y
			Intracranial aneurysm	01MAR2018	31MAR2018	N
		Surgical and medical procedures	Intra-cerebral aneurysm operation	01MAR2018	31MAR2018	N
	C4591001 1007 10071302	Cardiac disorders	Mitral valve incompetence	09AUG2013	23AUG2013	N
		Congenital, familial and genetic disorders	Bicuspid aortic valve	20AUG2013		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Surgical and medical procedures	Mitral valve repair	23AUG2013	23AUG2013	N
			Nasal septal operation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1007 10071303	Blood and lymphatic system disorders	Lymphadenopathy	01JAN1985	31DEC1985	N
			Neutropenia	01JAN1980		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Epstein-Barr virus infection	01JAN1988	31DEC1990	N
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Sleep disorder	01JAN1983		Y
		Renal and urinary disorders	Hypertonic bladder	01MAY2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015	31MAY2020	N
			Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Eye irrigation	11OCT2020		Y
			Prostatectomy	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1007 10071304	Ear and labyrinth disorders	Vertigo positional	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Investigations	Arthroscopy	01JUL2018	31JUL2018	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
			Spinal osteoarthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Knee arthroplasty	01JUN2019	30JUN2019	N
			Spinal fusion surgery	01JAN1990	31DEC1990	N
				01JAN2004	31DEC2004	N
	C4591001 1007 10071305	Cardiac disorders	Acute cardiac event	01OCT2019	31OCT2019	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JUL2018	31JUL2018	N
		Nervous system disorders	Neuropathy peripheral	01JUL2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Arterial stent insertion	01OCT2019	31OCT2019	N
			Spinal laminectomy	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1007 10071306	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Salpingo-oophorectomy unilateral	01JAN2003	31DEC2003	N
	C4591001 1007 10071308	Immune system disorders	Seasonal allergy	01JAN1957		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Skin graft	01AUG2020	31AUG2020	N
			Tenoplasty	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071310	Ear and labyrinth disorders	Deafness unilateral	01JAN1969		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Myositis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
	C4591001 1007 10071311	Immune system disorders	Allergy to animal	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2016	N
			Uterine leiomyoma	01JAN1976	31DEC1980	N
		Psychiatric disorders	Depression	01JAN2009		Y
			Sleep disorder	01JAN1974		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071312	Cardiac disorders	Ventricular extrasystoles	01JAN2017		Y
		Eye disorders	Cataract	01JAN2003	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Peptic ulcer	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2018		Y
			Sleep apnoea syndrome	01JUN2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Prostatectomy	01JAN2014	31DEC2014	N
	C4591001 1007 10071313	Eye disorders	Cataract	01JAN2014	31DEC2016	N
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01FEB2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	08DEC2008	31JAN2009	N
			Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2014	31DEC2016	N
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Cholecystostomy	01FEB2000	29FEB2000	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Knee arthroplasty	01MAR2018	31MAR2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal laminectomy	01JAN2009	31JAN2009	N
			Varicose vein operation	01JAN2003	31DEC2003	N
		Vascular disorders	Varicose vein	01JAN1970	31DEC2003	N
	C4591001 1007 10071314	Eye disorders	Cataract	01MAR2019	30APR2019	N
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1007 10071315	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1978		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN1986		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Ethmoid sinus surgery	01JAN1988	31DEC1988	N
				01JAN1991	31DEC1991	N
			Intervertebral disc operation	01JAN1996	31DEC1996	N
			Nasal septal operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1007 10071316	Blood and lymphatic system disorders	Anaemia	01JAN2006		Y
		Ear and labyrinth disorders	Deafness	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1007 10071317	Hepatobiliary disorders	Cholelithiasis	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Endometrial disorder	01JAN1965	31DEC1998	N
		Surgical and medical procedures	Cholecystectomy	01JAN1978	31DEC1978	N
			Gastric bypass	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1007 10071318	Eye disorders	Cataract	01JAN2017	31DEC2018	N
		Gastrointestinal disorders	Reflux gastritis	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1973		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN1973		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1997	31DEC1999	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2018	31DEC2018	N
			Hysterosalpingo-oophorectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071319	Eye disorders	Dry eye	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1007 10071320	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
			Osteopenia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Vascular graft	01JAN1986	31DEC1986	N
				01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071321	Eye disorders	Cataract	01JUN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2014	30SEP2014	N
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Psychiatric disorders	Anxiety	01SEP2017		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Mastectomy	01SEP2014	30SEP2014	N
	C4591001 1007 10071322	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Angioplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1007 10071323	Social circumstances	Menopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071324	Cardiac disorders	Cardiomyopathy	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Cataract	01JAN2000	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2000	31DEC2000	N
				01JAN2018	31DEC2018	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1007 10071325	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Anosmia	01JAN2005		Y
		Social circumstances	Menopause	01JAN1985	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1007 10071326	Cardiac disorders	Cardiac failure	01JAN2013		Y
			Myocardial infarction	01JAN2013	31DEC2013	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2006		Y
		Investigations	Catheterisation cardiac	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1007 10071327	Immune system disorders	Seasonal allergy	01JAN1975		Y
	C4591001 1007 10071328	Immune system disorders	Allergy to animal	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2007	N
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Uterine leiomyoma embolisation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071329	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1958		Y
			Seasonal allergy	01JAN1958		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal cancer stage III	01JAN2011	31DEC2017	N
		Nervous system disorders	Carotid artery occlusion	01JAN2018		Y
			Toxic neuropathy	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1967		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Surgical and medical procedures	Ileostomy closure	01MAY2012	31MAY2012	N
			Intestinal resection	01JAN2011	31DEC2011	N
			Nephrectomy	01JAN1972	31DEC1972	N
				01JAN1973	31DEC1973	N
			Pulmonary resection	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071330	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1997	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1007 10071332	Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01MAY2010		Y
		Investigations	Biopsy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Knee arthroplasty	01JAN2007	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1007 10071333	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2005	31DEC2019	N
		Social circumstances	Menopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071335	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament injury	11APR2020	03JUN2020	N
			Meniscus injury	11APR2020	03JUN2020	N
			Tibia fracture	11APR2020	03JUN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Knee operation	03JUN2020	03JUN2020	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071336	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2000	31DEC2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Foraminotomy	01JAN2013	31DEC2013	N
			Shoulder operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071338	Gastrointestinal disorders	Appendicitis noninfective	01JAN1969	31DEC1969	N
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	30JUN2002	N
		Nervous system disorders	Migraine	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN1997	31DEC2000	N
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
			Oophorectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071343	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Menopause	01JAN2005	31DEC2007	N
	C4591001 1007 10071344	Nervous system disorders	Migraine	01JAN1969		Y
	C4591001 1007 10071345	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN2008		Y
			Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2012		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Allergy to plants	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN1975	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071346	Hepatobiliary disorders	Cholelithiasis	01OCT2014	31OCT2014	N
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
			Food allergy	01JAN2000		Y
			Rubber sensitivity	01JAN2000		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1993		Y
		Social circumstances	Menopause	01JAN2012	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1007 10071347	Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Food allergy	01JAN1952		Y
			Iodine allergy	01JAN2006		Y
		Infections and infestations	Hepatitis B	01JAN1970	31DEC1973	N
			Hepatitis C	01JAN1999	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	25NOV2011		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2016	31DEC2016	N
			Tobacco abuse	01JAN1975		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	25APR2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990	31DEC2000	N
			Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Cardiac operation	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oesophagogastric fundoplasty	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1007 10071348	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2020	31OCT2020	N
	C4591001 1007 10071349	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Social circumstances	Menopause	01JAN1998	31DEC2000	N
	C4591001 1007 10071351	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1983		Y
		Infections and infestations	Appendicitis	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	14OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Cough	28SEP2020		Y
			Oropharyngeal pain	28SEP2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1007 10071354	Immune system disorders	Allergy to animal	01JAN1970		Y
			Drug hypersensitivity	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN1973	31DEC1973	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Social circumstances	Menopause	01JAN1995	31DEC2015	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1973	31DEC1973	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endometrial ablation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071355	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Corneal oedema	01JAN2010		Y
			Glaucoma	01JAN2006		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1971	31DEC1971	N
			Cholecystectomy	01JAN2000	31DEC2000	N
	C4591001 1007 10071356	Eye disorders	Ocular hypertension	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1007 10071357	Cardiac disorders	Coronary artery disease	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Barrett's oesophagus	01JUN2020		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Angioplasty	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071359	Injury, poisoning and procedural complications	Femur fracture	04JUL2001	06JUL2001	N
			Hip fracture	04JUL2001	06JUL2001	N
			Upper limb fracture	04JUL2001	06JUL2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Bursitis	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01AUG2010		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	08OCT2020	08OCT2020	N
		Surgical and medical procedures	Fracture treatment	06JUL2001	06JUL2001	N
			Hip surgery	06JUL2001	06JUL2001	N
			Limb operation	06JUL2001	06JUL2001	N
			Medical device removal	01JAN2016	31DEC2016	N
			Skin cryotherapy	08OCT2020	08OCT2020	N
	C4591001 1007 10071360	Immune system disorders	Allergy to vaccine	01JAN1965		Y
			Drug hypersensitivity	01JAN1955		Y
		Infections and infestations	Sinusitis	01JAN1965		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01MAR1990	31DEC1990	N
	C4591001 1007 10071364	Congenital, familial and genetic disorders	Developmental hip dysplasia	(b) (6) 1949		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2007	31DEC2009	N
		Immune system disorders	Allergy to animal	01JAN2015		Y
			Hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01MAR2020		Y
			Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2009	31DEC2009	N
			Hip arthroplasty	01AUG2019	31AUG2019	N
				01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1007 10071371	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Psychiatric disorders	Cyclothymic disorder	01JAN2010		Y
		Surgical and medical procedures	Rehabilitation therapy	01JAN2015		Y
	C4591001 1007 10071372	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1962		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2005		Y
			Raynaud's phenomenon	01JAN2018		Y
	C4591001 1007 10071375	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
			Reflux laryngitis	01JAN1975		Y
		Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1007 10071379	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1985		Y
			Food allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
	C4591001 1007 10071383	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Food allergy	01MAY2019		Y
			Rubber sensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1007 10071384	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Vaginal infection	01JAN2012		Y
		Social circumstances	Menopause	01JAN2018	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071393	Immune system disorders	Allergy to animal	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2016	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1983	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071396	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1007 10071411	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1007 10071412	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2000	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary sarcoidosis	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1007 10071430	Immune system disorders	Seasonal allergy	01APR2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1007 10071432	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN1990	31DEC1996	N
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1008 10081001	Cardiac disorders	Supraventricular tachycardia	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1008 10081002	Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1008 10081003	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1008 10081004	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081005	Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081008	Cardiac disorders	Coronary artery disease	01JUN2007		Y
			Myocardial infarction	01JUN2007	30JUN2007	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JUN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUN2007	30JUN2007	N
	C4591001 1008 10081009	Eye disorders	Dry eye	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
	C4591001 1008 10081010	Gastrointestinal disorders	Gastric ulcer	01JAN2018	31DEC2018	N
			Irritable bowel syndrome	01JAN1995		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Investigations	Blood cholesterol increased	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1008 10081014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Food allergy	01JAN2005		Y
			Seasonal allergy	01JAN1950		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2015		Y
	C4591001 1008 10081016	Endocrine disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
			Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN1970		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081017	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1008 10081020	Gastrointestinal disorders	Haemorrhoids	01JAN2018	31DEC2018	N
		General disorders and administration site conditions	Precancerous condition	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1961		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2019	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2004	31DEC2004	N
			Skin neoplasm excision	01DEC2019	31DEC2019	N
			Vasectomy	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081021	Eye disorders	Macular degeneration	01OCT2019		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hot flush	01JAN2002		Y
			Hypertension	01JUL2019		Y
	C4591001 1008 10081023	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN1996	31DEC1996	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
	C4591001 1008 10081026	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1008 10081027	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Immune system disorders	Allergy to animal	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1008 10081034	Gastrointestinal disorders	Diverticulum	01JAN2000		Y
			Irritable bowel syndrome	01JAN2014		Y
			Pancreatic cyst	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2002		Y
				01JAN2015		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Human papilloma virus test positive	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Costochondritis	01JAN2019		Y
			Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic neoplasm	01JAN2019		Y
		Nervous system disorders	Small fibre neuropathy	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1008 10081035	Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Skin neoplasm excision	01JUL2020	31JUL2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081038	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
			Large intestine polyp	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Extremity contracture	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Polypectomy	01JAN2014	31DEC2014	N
	C4591001 1008 10081039	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Onychomycosis	01JUN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Insomnia	01JUN2019		Y
		Social circumstances	Postmenopause	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081041	Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1008 10081044	Endocrine disorders	Hypothyroidism	01MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Infections and infestations	Endometritis	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1008 10081045	Cardiac disorders	Myocardial infarction	01JAN2008	31DEC2008	N
		Endocrine disorders	Hypogonadism	01JAN2020		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01AUG2020		Y
		Nervous system disorders	Parkinson's disease	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN1998		Y
			Insomnia	01JAN1998		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2008		Y
		Surgical and medical procedures	Coronary artery bypass	26DEC2008	26DEC2008	N
		Vascular disorders	Hypertension	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081050	Cardiac disorders	Cardiac failure congestive	01JAN2006		Y
			Cardiac valve disease	01JAN2006		Y
			Coronary artery disease	01JAN2006		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2006		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Tinea cruris	01JAN2017		Y
			Tinea pedis	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Ataxia	01JAN2019		Y
			Diabetic neuropathy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2006		Y
			Emphysema	01JAN2006		Y
			Sleep apnoea syndrome	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1008 10081055	Vascular disorders	Hypertension	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081056	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin B12 deficiency	01JAN2019		Y
		Nervous system disorders	Epilepsy	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1008 10081057	Infections and infestations	Herpes simplex	01JAN1990		Y
	C4591001 1008 10081058	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1008 10081060	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Osteoarthritis	01JAN2003		Y
		Nervous system disorders	Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1008 10081061	Infections and infestations	Herpes simplex	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
	C4591001 1008 10081062	Ear and labyrinth disorders	Hypoacusis	01JAN1995		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1968		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN1980		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1008 10081063	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1008 10081069	Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1008 10081070	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2013	31DEC2013	N
			Fall	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rhinoplasty	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1008 10081073	Immune system disorders	Seasonal allergy	01JAN2011		Y
	C4591001 1008 10081074	Ear and labyrinth disorders	Hypoacusis	01JAN1992		Y
			Meniere's disease	01JAN1992		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Diarrhoea	01JAN2007		Y
			Umbilical hernia	01JAN2007	31DEC2007	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Investigations	Blood cholesterol increased	01JAN1996		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1008 10081075	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081076	Investigations	Hormone level abnormal	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1008 10081081	Gastrointestinal disorders	Gingival disorder	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1008 10081082	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081083	Infections and infestations	Large intestine infection	01JAN1976	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1008 10081084	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Psychiatric disorders	Insomnia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1008 10081085	Cardiac disorders	Sinus node dysfunction	01JAN2008		Y
		Eye disorders	Glaucoma	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Gravitational oedema	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2008	31DEC2008	N
			Prostatectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1008 10081090	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastritis	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
			Osteoarthritis	01JAN2010		Y
	C4591001 1008 10081092	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081093	Eye disorders	Dry eye	01JAN2018		Y
		Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1966		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1008 10081094	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1008 10081096	Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1008 10081097	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2020		Y
			Osteoporosis	01DEC2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Spinal laminectomy	01NOV2019	30NOV2019	N
	C4591001 1008 10081098	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081100	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
			Irritable bowel syndrome	01JUL2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Scoliosis	01JAN1992		Y
			Temporomandibular joint syndrome	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1982		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1008 10081104	Cardiac disorders	Cardiac valve disease	01JAN1995	31DEC2009	N
			Supraventricular tachycardia	01JAN2009		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN1995		Y
		Hepatobiliary disorders	Gallbladder hypofunction	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Heart valve replacement	01JAN2009	31DEC2009	N
			Implantable defibrillator replacement	01JAN2009	31DEC2009	N
			Knee arthroplasty	01FEB2019	28FEB2019	N
	C4591001 1008 10081106	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1008 10081107	Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Allergy to metals	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081108	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastric ulcer	01FEB2019		Y
			Gastroesophageal reflux disease	01JAN2007		Y
		General disorders and administration site conditions	Pain	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2013		Y
			Osteoarthritis	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
			Sleep apnoea syndrome	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1008 10081109	Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood testosterone decreased	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081110	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1008 10081111	Immune system disorders	Contrast media allergy	01JAN2008		Y
			Drug hypersensitivity	01JAN1955		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081112	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2018	31DEC2018	N
			Myomectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1008 10081114	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Vulvovaginal dryness	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	25AUG2020		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1008 10081115	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2015		Y
			Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1985		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
			Parkinson's disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Urinary hesitation	01JAN2018		Y
		Surgical and medical procedures	Renal surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1955		Y
	C4591001 1008 10081117	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1008 10081118	Cardiac disorders	Heart valve incompetence	01JAN2019		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1986	31DEC1986	N
		Nervous system disorders	Tremor	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Large intestinal polypectomy	01JAN2009	31DEC2009	N
			Skin neoplasm excision	01JAN1986	31DEC1986	N
	C4591001 1008 10081119	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Rubber sensitivity	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081120	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081123	Gastrointestinal disorders	Constipation	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN2010		Y
			Large intestine polyp	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Cluster headache	01JAN2014		Y
		Psychiatric disorders	Bipolar II disorder	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Large intestinal polypectomy	01JAN2014	31DEC2014	N
	C4591001 1008 10081126	Gastrointestinal disorders	Diarrhoea	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2017	31DEC2017	N
			Poliomyelitis	01JAN1951		Y
		Nervous system disorders	Neuralgia	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Placenta accreta	01JAN1960	31DEC1960	N
		Surgical and medical procedures	Hysterectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Lymphoedema	01JAN2010		Y
	C4591001 1008 10081127	Eye disorders	Glaucoma	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1977		Y
	C4591001 1008 10081128	Cardiac disorders	Myocardial infarction	21APR2010	21APR2010	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN1977	31DEC1977	N
				01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Cancer surgery	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN1999	31DEC1999	N
	C4591001 1008 10081131	Nervous system disorders	Cerebrovascular accident	01DEC2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1008 10081132	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081133	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
			Cardiac failure congestive	01JAN2016		Y
			Coronary artery disease	01JAN2016		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN1975		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urinary incontinence	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
			Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Vasectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081134	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Cardiac failure congestive	01JAN2014		Y
			Coronary artery disease	01JAN2009		Y
		Gastrointestinal disorders	Constipation	01JAN2004		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1945		Y
				01JAN2014		Y
			Seasonal allergy	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
			Cardiac murmur	01JAN1950		Y
		Metabolism and nutrition disorders	Obesity	01JAN1978		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
				01JAN2007		Y
			Spinal stenosis	01JAN2013		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
			Restless legs syndrome	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2018		Y
			Insomnia	01JAN2009		Y
			Stress	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
			Hypertonic bladder	01JAN2017		Y
			Urinary incontinence	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01MAY2019		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1008 10081135	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1008 10081139	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1008 10081141	Immune system disorders	Drug hypersensitivity	01MAR2003		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
	C4591001 1008 10081144	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
				01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2008		Y
			Osteoarthritis	01JAN2008		Y
			Polymyalgia rheumatica	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1992		Y
	C4591001 1008 10081145	Surgical and medical procedures	Shoulder arthroplasty	01JAN2019	31JAN2019	N
		Cardiac disorders	Cardiac aneurysm	01JAN1942		Y
		Congenital, familial and genetic disorders	Atrial septal defect	01JAN1942		Y
		Endocrine disorders	Goitre	01JAN2000		Y
			Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2001		Y
			Orthostatic hypotension	01JAN2001		Y
	C4591001 1008 10081146	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN2007		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2007	31DEC2007	N
			Fall	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cutaneous lymphoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Infusion	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081154	Eye disorders	Glaucoma	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1008 10081157	Renal and urinary disorders	Urinary hesitation	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1008 10081161	Immune system disorders	Seasonal allergy	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y
			Chronic obstructive pulmonary disease	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081162	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal osteoarthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
	C4591001 1008 10081163	Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
			Thyroid mass	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Cognitive disorder	01JAN2017		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2008	31DEC2008	N
			Spinal decompression	01JAN2014	31DEC2014	N
			Spinal nerve stimulator implantation	25OCT2018	25OCT2018	N
			Thyroid nodule removal	01JAN1995	31DEC1995	N
			Vasectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081164	Psychiatric disorders	Anxiety	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081165	Endocrine disorders	Hypothyroidism	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1008 10081167	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2018		Y
	C4591001 1008 10081168	General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1008 10081169	Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081170	General disorders and administration site conditions	Pain	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUL2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Mastectomy	01DEC2008	31DEC2008	N
	C4591001 1008 10081171	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Seasonal allergy	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1008 10081172	Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2010		Y
	C4591001 1008 10081173	Congenital, familial and genetic disorders	Arteriovenous malformation	01JAN2012		Y
		Gastrointestinal disorders	Oesophageal spasm	18NOV2015		Y
		Nervous system disorders	Seizure	01JUN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
	C4591001 1008 10081174	Surgical and medical procedures	Vasectomy	01JAN1984	31DEC1984	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081175	Immune system disorders	Drug hypersensitivity	01JAN1957		Y
			Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01FEB2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1008 10081176	Surgical and medical procedures	Breast conserving surgery	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Diarrhoea	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN1998		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1008 10081177	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Prostatomegaly	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081178	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Psychiatric disorders	Major depression	01JAN1995		Y
		Renal and urinary disorders	Dysuria	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1008 10081179	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1008 10081180	Endocrine disorders	Hypothyroidism	01JAN2012	31DEC2012	N
		Eye disorders	Glaucoma	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Rubber sensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2012	31DEC2012	N
			Vascular graft	01JAN2002	31DEC2002	N
	C4591001 1008 10081181	Gastrointestinal disorders	Inguinal hernia	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1988	31DEC1988	N
	C4591001 1008 10081182	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081184	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
			Prostatic specific antigen increased	01JAN2019		Y
	C4591001 1008 10081185	Investigations	Blood cholesterol increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
	C4591001 1008 10081186	Vascular disorders	Hypertension	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Infections and infestations	Appendicitis perforated	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Affect lability	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1008 10081188	Vascular disorders	Hypertension	01FEB2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
	C4591001 1008 10081189	Vascular disorders	Hypertension	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Neck pain	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2009		Y
			Insomnia	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1008 10081190	Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1008 10081192	Congenital, familial and genetic disorders	Polycystic liver disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Prostatectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081195	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
			Drug eruption	01JAN1956		Y
		Social circumstances	Postmenopause	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1008 10081196	Investigations	Blood cholesterol increased	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2003		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2003	31DEC2003	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1008 10081201	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081203	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1008 10081204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1957		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020	31JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma stage II	01JAN2003	31DEC2003	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ostectomy	01JAN2003	31DEC2003	N
	C4591001 1008 10081205	Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1008 10081206	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1008 10081207	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2000	N
		Social circumstances	Organ donor	01JAN2006	31DEC2006	N
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1008 10081208	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Tremor	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081209	Cardiac disorders	Coronary artery dissection	01OCT2016	31OCT2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1008 10081210	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081211	Cardiac disorders	Bradycardia	01JAN1992		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Skin neoplasm excision	01JAN1994	31DEC1994	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081213	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tinea versicolour	01JAN1971		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1008 10081214	Investigations	Blood cholesterol increased	01JAN2019		Y
		Nervous system disorders	Essential tremor	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081216	Cardiac disorders	Atrial flutter	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2011	31DEC2011	N
			Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081219	Ear and labyrinth disorders	Hypoacusis	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081222	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Herpes simplex	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2012		Y
			Rosacea	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01OCT2017	31OCT2017	N
			Mastectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081223	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1008 10081226	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hot flush	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN2000		Y
	C4591001 1008 10081227	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1988		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081228	Cardiac disorders	Myocardial infarction	01NOV2014	30NOV2014	N
		Investigations	Blood cholesterol increased	01NOV2014		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Surgical and medical procedures	Aortic stent insertion	01JAN2019	31JAN2019	N
			Coronary arterial stent insertion	01NOV2014	30NOV2014	N
			Knee arthroplasty	01NOV2011	30NOV2011	N
			Surgery	01JAN2019	31JAN2019	N
		Vascular disorders	Aortic aneurysm	01JAN2019		Y
			Hypertension	01NOV2014		Y
	C4591001 1008 10081229	Immune system disorders	Seasonal allergy	01JAN1976		Y
	C4591001 1008 10081230	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081231	Eye disorders	Glaucoma	01JAN2014		Y
		Investigations	Cardiac murmur	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1008 10081236	Congenital, familial and genetic disorders	Gilbert's syndrome	01FEB2020		Y
	C4591001 1008 10081237	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
	C4591001 1008 10081241	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Haemorrhoids	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081242	Immune system disorders	Allergy to metals	01JAN2010		Y
			Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Herpes ophthalmic	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Corneal transplant	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1008 10081243	Immune system disorders	Seasonal allergy	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
	C4591001 1008 10081245	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Cataract	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1978	31DEC1978	N
		Social circumstances	Postmenopause	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
			Coronary arterial stent insertion	01MAY2019	31MAY2019	N
			Hysterectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081246	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081247	Gastrointestinal disorders	Inguinal hernia	01JAN2002	31DEC2002	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2002	31DEC2002	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081248	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1008 10081249	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081250	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081252	Cardiac disorders	Tachycardia	01JAN2007		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Gastrointestinal disorders	Diarrhoea	08SEP2020	09SEP2020	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2007	31DEC2007	N
	C4591001 1008 10081254	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Smear cervix abnormal	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
					31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1008 10081255	Eye disorders	Dry eye	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Hypokalaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
		Nervous system disorders	Cognitive disorder	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1966		Y
	C4591001 1008 10081259	Gastrointestinal disorders	Constipation	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1008 10081262	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Investigations	Blood cholesterol increased	01JUL2020		Y
	C4591001 1008 10081264	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1008 10081266	Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1008 10081267	Investigations	Blood cholesterol increased	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2013	31DEC2013	N
	C4591001 1008 10081268	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
				01JAN2019		Y
			Iodine allergy	01JAN1990		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1008 10081270	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1008 10081272	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1008 10081273	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081275	Congenital, familial and genetic disorders	Atrial septal defect	01JAN1958		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
			Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01AUG2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1008 10081276	Gastrointestinal disorders	Diarrhoea	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081277	Congenital, familial and genetic disorders	Hereditary spherocytosis	01JAN1952		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081278	Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		Eye disorders	Dry eye	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Social circumstances	Hearing aid user	01JAN2019		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1990	31DEC1990	N
	C4591001 1008 10081279	Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Sarcoidosis	01JAN2004		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2004	31DEC2004	N
		Social circumstances	Hearing aid user	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01AUG2010	31AUG2010	N
			Salpingo-oophorectomy bilateral	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1008 10081280	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Shoulder arthroplasty	27JAN2020	27JAN2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081282	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1008 10081283	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2017		Y
	C4591001 1008 10081284	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1008 10081285	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2010	31DEC2011	N
		Nervous system disorders	Migraine	01JAN1975		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31JAN2011	N
			Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1008 10081287	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
	C4591001 1008 10081288	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2012		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1008 10081291	Eye disorders	Dry eye	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1008 10081296	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Ear and labyrinth disorders	Vertigo	01MAY2020		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020		Y
			Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1008 10081298	Investigations	Blood cholesterol increased	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081299	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		General disorders and administration site conditions	Chronic fatigue syndrome	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JUL2020		Y
			Depression	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1008 10081301	Ear and labyrinth disorders	Otosclerosis	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
	C4591001 1008 10081302	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN2006		Y
			Seasonal allergy	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hot flush	01JAN2006		Y
	C4591001 1008 10081303	Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2019		Y
	C4591001 1008 10081305	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Surgical and medical procedures	Exeresis	01JAN1983		Y
	C4591001 1008 10081307	Endocrine disorders	Hypothyroidism	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081308	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
	C4591001 1008 10081309	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1008 10081311	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Essential tremor	01JAN2019		Y
		Surgical and medical procedures	Gastric bypass	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081317	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081318	Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal lipoma	01JAN2013		Y
		Nervous system disorders	Syncope	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1008 10081319	Eye disorders	Dry eye	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN2016		Y
			Seasonal allergy	01JAN1975		Y
		Investigations	Blood cholesterol increased	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JUL2020	20OCT2020	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
				01JUN2020	20OCT2020	N
	C4591001 1008 10081322	Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
	C4591001 1008 10081323	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081324	Investigations	Blood cholesterol increased	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC1992	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1992	31DEC1992	N
	C4591001 1008 10081329	Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081330	Eye disorders	Myopic chorioretinal degeneration	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1008 10081331	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081332	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1008 10081334	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081335	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1008 10081339	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2004		Y
			Spinal osteoarthritis	01JAN1996		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
			Major depression	01JAN1995		Y
		Renal and urinary disorders	Renal cyst	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1008 10081340	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1008 10081342	Eye disorders	Cataract	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081345	Cardiac disorders	Atrial fibrillation	01NOV2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Renal and urinary disorders	Urinary retention	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081353	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Spinal osteoarthritis	01JAN2004		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1008 10081355	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081356	Investigations	Blood cholesterol increased	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081362	Investigations	Blood cholesterol increased	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081363	Cardiac disorders	Myocarditis	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Genital herpes	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1008 10081369	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Rotator cuff syndrome	01MAY2020	31MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081371	Cardiac disorders	Coronary artery disease	01JAN2018		Y
			Myocardial infarction	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1008 10081373	Renal and urinary disorders	Nocturia	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1008 10081375	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal stenosis	01JAN2012	31DEC2016	N
		Psychiatric disorders	Abnormal dreams	01JAN2013		Y
			Anxiety	01JAN2015		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1008 10081376	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	14SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1008 10081377	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN1993		Y
	C4591001 1008 10081378	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Organ donor	14MAY2020	14MAY2020	N
		Vascular disorders	Deep vein thrombosis	01JAN1996	31DEC1996	N
			Hypertension	01JAN2015		Y
	C4591001 1008 10081380	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
	C4591001 1008 10081386	Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Hearing aid user	01JAN2018		Y
	C4591001 1008 10081387	Ear and labyrinth disorders	Hypoacusis	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Social circumstances	Hearing aid user	01JAN2010		Y
	C4591001 1008 10081389	Endocrine disorders	Hypothyroidism	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1987		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1008 10081390	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2010		Y
		Surgical and medical procedures	Sebaceous cyst excision	12SEP2020	12SEP2020	N
	C4591001 1008 10081399	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081400	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
			Seasonal allergy	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1976		Y
	C4591001 1008 10081403	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081405	Cardiac disorders	Myocardial infarction	01MAY2019	31MAY2019	N
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081406	Cardiac disorders	Arrhythmia	01JUL2020		Y
			Mitral valve prolapse	01JAN1953		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1008 10081409	Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1008 10081412	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1008 10081414	Cardiac disorders	Supraventricular extrasystoles	01JAN2013		Y
			Ventricular extrasystoles	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1008 10081415	Investigations	Blood cholesterol increased	01JAN2017		Y
			Blood testosterone decreased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081424	Cardiac disorders	Mitral valve prolapse	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1985		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia areata	01JAN2010		Y
	C4591001 1008 10081428	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1008 10081431	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
	C4591001 1008 10081434	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081443	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1008 10081446	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01MAY2020		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1008 10081448	Cardiac disorders	Atrial fibrillation	01JAN2020		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Throat cancer	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Radiotherapy	01JAN2011	31DEC2011	N
	C4591001 1008 10081451	Immune system disorders	Seasonal allergy	01MAY2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1008 10081454	Ear and labyrinth disorders	Vertigo	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1008	Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
	10081455	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN1984		Y
			Seasonal allergy	01JAN2013		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008	Eye disorders	Macular degeneration	01JAN2019		Y
	10081458					
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1992		Y
	C4591001 1008	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
	10081459					
		Immune system disorders	Rubber sensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cervical conisation	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081460	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008 10081461	Cardiac disorders	Coronary artery disease	01JUN2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Constipation	01JAN1964		Y
			Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Renal and urinary disorders	Urethral stenosis	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1995		Y
	C4591001 1008 10081465	Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081478	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081482	Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1008 10081483	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Glaucoma	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Body tinea	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081484	Psychiatric disorders	Depression	10JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	10JUL2020		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	10JUL2020		Y
	C4591001 1008 10081486	Gastrointestinal disorders	Gastrooesophageal reflux disease	01DEC2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081488	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
			Spinal osteoarthritis	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1008 10081489	Immune system disorders	Iodine allergy	01JAN1981		Y
	C4591001 1008 10081491	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1008 10081494	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1008 10081495	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Eye disorders	Dry eye	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081498	Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1008 10081501	Immune system disorders	Drug hypersensitivity	01JAN1952		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081502	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1008 10081503	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081508	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1008 10081510	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1008 10081511	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1008 10081515	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1008 10081516	Cardiac disorders	Angina pectoris	01JAN2014		Y
			Coronary artery disease	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
			Diverticulum	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1964		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1008 10081517	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1008 10081519	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1008 10081522	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Gastrointestinal disorders	Eosinophilic oesophagitis	01MAR2020		Y
			Oesophageal dilatation	01MAR2020	31MAR2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
				01JAN1979		Y
				01JAN1984		Y
			Seasonal allergy	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081526	Investigations	Blood cholesterol increased	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1988	31DEC1988	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1988		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1008 10081530	Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081531	Cardiac disorders	Supraventricular extrasystoles	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081535	Immune system disorders	Drug hypersensitivity	01JAN1949		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
	C4591001 1008 10081536	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Placenta accreta	01JAN1978	31DEC1978	N
	C4591001 1008 10081537	Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Glaucoma	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1008 10081538	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1972		Y
		Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1008 10081539	Eye disorders	Dry eye	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
				01JAN2009		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1008 10081540	Gastrointestinal disorders	Diarrhoea	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Onychomycosis	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1988	31DEC1990	N
	C4591001 1008	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	10081545	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1008	Vascular disorders	Hypertension	01JAN1990		Y
	10081546					
	C4591001 1008	Immune system disorders	Seasonal allergy	01JAN1983		Y
	10081550					
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Prostatectomy	01JAN2009	31DEC2009	N
	C4591001 1008	Endocrine disorders	Hypothyroidism	01JAN1994		Y
	10081560					
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1008	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	10081562					
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1008	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	10081563					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1008 10081564	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1008 10081565	Investigations	Blood cholesterol increased	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
	C4591001 1008 10081566	Investigations	Blood cholesterol increased	01OCT2006		Y
	C4591001 1008 10081569	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2000		Y
		Gastrointestinal disorders	Proctalgia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
			Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1008 10081570	Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Nervous system disorders	Carotid artery disease	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1008 10081571	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1008 10081585	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1008 10081586	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Peroneal nerve palsy	01SEP2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081587	Endocrine disorders	Hypothyroidism	01JAN1971		Y
		Immune system disorders	Seasonal allergy	01JAN1956		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1008 10081588	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1008 10081589	Endocrine disorders	Hypothyroidism	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081591	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1008 10081592	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1008 10081593	Cardiac disorders	Angina pectoris	01JAN2000		Y
			Coronary artery disease	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Iodine allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081597	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1008 10081599	Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Renal and urinary disorders	Pollakiuria	01JAN2018		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2017	31DEC2017	N
		Vascular disorders	Aortic stenosis	01JAN2017	31DEC2017	N
	C4591001 1008 10081601	Infections and infestations	Hepatitis C	01JAN2000	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081602	Cardiac disorders	Bundle branch block left	01JAN2012		Y
			Cardiomyopathy	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1979		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1008 10081603	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01SEP2020		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1008 10081609	Eye disorders	Dry eye	01JAN2007		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1008 10081610	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Renal failure	01JAN2017		Y
		Surgical and medical procedures	Prostatectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1008 10081613	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JUL2020		Y
			Seasonal allergy	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081614	Eye disorders	Cataract	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1008 10081615	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Blood triglycerides increased	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1008 10081616	Ear and labyrinth disorders	Hypoacusis	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1984		Y
		Social circumstances	Hearing aid user	01JAN2012		Y
			Postmenopause	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1008 10081619	Ear and labyrinth disorders	Hypoacusis	01JAN1966		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1008 10081621	Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2019		Y
	C4591001 1008 10081622	Eye disorders	Cataract	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1957		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
	C4591001 1008 10081624	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
	C4591001 1008 10081625	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN1995		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2014		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1988	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
	C4591001 1008 10081626	Immune system disorders	Seasonal allergy	01JAN1954		Y
		Surgical and medical procedures	Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1008 10081634	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Infections and infestations	Herpes simplex	01JAN1984		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1008 10081636	Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1974		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1008 10081639	Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
			Spinal pain	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1008 10081640	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081641	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1008 10081644	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1008 10081645	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1008 10081646	Gastrointestinal disorders	Constipation	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1008 10081650	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1008 10081651	Cardiac disorders	Coronary artery disease	01JAN2017		Y
			Wolff-Parkinson-White syndrome	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2020		Y
	C4591001 1008 10081652	Investigations	Blood cholesterol increased	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1008 10081656	Investigations	Blood cholesterol increased	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1008 10081658	Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081660	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	31DEC2009	N
				01JAN2019	31DEC2019	N
	C4591001 1008 10081661	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01OCT2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
			Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2004	31DEC2004	N
			Breast cancer	01JAN1999	31DEC2000	N
				01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN2004	31DEC2004	N
			Breast conserving surgery	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2014	31DEC2014	N
			Chemotherapy	01JAN2000	31DEC2000	N
			Mastectomy	01JAN2014	31DEC2014	N
			Radiotherapy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1008 10081662	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1968		Y
	C4591001 1008 10081666	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01AUG2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1949		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081667	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
				01JAN2014		Y
		Infections and infestations	Rhinitis	01JAN1945		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1008 10081671	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081679	Investigations	Blood cholesterol increased	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1008 10081681	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1008 10081684	Psychiatric disorders	Attention deficit hyperactivity disorder	01AUG2020		Y
			Depression	01JAN2000		Y
	C4591001 1008 10081685	Injury, poisoning and procedural complications	Gun shot wound	01JAN1997	31DEC1997	N
			Nerve injury	01JAN1997		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1008 10081686	Cardiac disorders	Coronary artery disease	01JAN2017		Y
			Myocardial infarction	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Herpes zoster	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Seizure	01JAN2007		Y
			Tremor	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1971		Y
			Insomnia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Hysterosalpingo-oophorectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1008 10081687	Investigations	Blood cholesterol increased	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1008 10081689	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1008 10081690	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1008 10081691	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2011	31DEC2011	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081694	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
			Chemotherapy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Radiotherapy	01JAN2010	31DEC2010	N
	C4591001 1008 10081697	Eye disorders	Dry eye	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1008 10081699	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Parkinson's disease	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1986	31DEC1986	N
	C4591001 1008 10081701	Immune system disorders	Seasonal allergy	01JAN1962		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1008 10081702	Immune system disorders	Seasonal allergy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1008 10081705	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2005		Y
				01JAN2018		Y
			Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN1984		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1008 10081707	Congenital, familial and genetic disorders	Gene mutation	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2011		Y
			Lymphoedema	01JAN1972		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081708	Eye disorders	Cataract	01JAN2017		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1982		Y
	C4591001 1008 10081709	Reproductive system and breast disorders	Erectile dysfunction	01APR2020		Y
	C4591001 1008 10081711	Eye disorders	Dry eye	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1008 10081714	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
	C4591001 1008 10081718	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1008 10081723	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
	C4591001 1008 10081724	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
				01JAN1990		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Diverticulitis	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01MAY2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1008 10081725	Ear and labyrinth disorders	Hypoacusis	01JAN2016		Y
		Social circumstances	Hearing aid user	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1008 10081726	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Nervous system disorders	Headache	01JAN1970		Y
	C4591001 1008 10081729	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
			Tendonitis	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2010	31DEC2010	N
			Renal cancer	01JAN1996	31DEC1996	N
		Reproductive system and breast disorders	Endometriosis	01JAN1979	31DEC1979	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2009		Y
		Surgical and medical procedures	Exeresis	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1979	31DEC1979	N
			Nephrectomy	01JAN1996	31DEC1996	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1008 10081730	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1008 10081732	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1008 10081735	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1008 10081740	Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1009 10091001	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Rubber sensitivity	01JAN2005		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2009		Y
		Nervous system disorders	Horner's syndrome	03DEC2014		Y
		Psychiatric disorders	Anxiety	14MAR2017		Y
			Insomnia	21JUN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	27OCT2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	09JUN2011		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1009 10091003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
				01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN1995		Y
			Osteopenia	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1995		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2005	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1009 10091004	Blood and lymphatic system disorders	Macrocytosis	01JAN2008		Y
		Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Haemorrhoids	07NOV2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	10SEP2019		Y
			Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1009 10091007	Ear and labyrinth disorders	Deafness neurosensory	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Hiatus hernia	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN1998	31DEC1998	N
			Tongue neoplasm malignant stage unspecified	01JAN2016	07DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091008	Immune system disorders	Seasonal allergy	01JAN1950		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2020		Y
		Vascular disorders	Aortic aneurysm	01JUL2019		Y
	C4591001 1009 10091009	Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1989		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1975	31DEC1976	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
			Implantable defibrillator replacement	01JAN2005	31DEC2005	N
	C4591001 1009 10091010	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2017		Y
	C4591001 1009 10091011	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1009 10091013	Congenital, familial and genetic disorders	Type V hyperlipidaemia	08OCT2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	03OCT2012		Y
		Nervous system disorders	Neuropathy peripheral	10DEC2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	30MAY2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	30NOV2015		Y
	C4591001 1009 10091014	Cardiac disorders	Atrial fibrillation	01JUL2019		Y
			Coronary artery disease	01JUL2019		Y
			Myocardial infarction	01JUL2019	31JUL2019	N
		Investigations	Cardiac murmur	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JUL2019	31JUL2019	N
			Shoulder arthroplasty	01NOV2019	30NOV2019	N
			Vasectomy	01JAN2010	31DEC2011	N
	C4591001 1009 10091015	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Perennial allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN1999		Y
		Nervous system disorders	Essential tremor	01JAN1960		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1009 10091016	Endocrine disorders	Hypogonadism	01JAN1990		Y
			Hypothyroidism	01JAN2012		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1969		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
			Erectile dysfunction	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN1995		Y
			Sleep apnoea syndrome	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1975		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1009 10091017	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1009 10091018	Endocrine disorders	Hypogonadism	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091019	Hepatobiliary disorders	Biliary tract disorder	12MAR2012		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1009 10091020	Immune system disorders	Seasonal allergy	01JAN1950		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1009 10091022	Gastrointestinal disorders	Constipation	31JAN2015		Y
			Inguinal hernia	01NOV2019		Y
		Infections and infestations	Herpes simplex	01JAN1991		Y
		Investigations	Blood pressure increased	11AUG2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
	C4591001 1009 10091024	Gastrointestinal disorders	Diverticulum intestinal	19NOV1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Cardiac murmur	28DEC2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	21AUG2012		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091025	Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2012		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1972		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Limb traumatic amputation	01JAN1972	31DEC1972	N
		Nervous system disorders	Migraine	01JAN1965		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Surgical and medical procedures	Hand repair operation	01JAN1972	31DEC1972	N
			Hip arthroplasty	01APR2017	01APR2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1009 10091026	Congenital, familial and genetic disorders	Type V hyperlipidaemia	04OCT2017		Y
		Endocrine disorders	Hypogonadism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	25MAR2014		Y
			Insomnia	18APR2013		Y
	C4591001 1009 10091027	Congenital, familial and genetic disorders	Congenital renal disorder	(b) (6) 1947		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2010	31MAR2010	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast hyperplasia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	14MAY2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01MAR2017	31MAR2017	N
				17JAN2008	17JAN2008	N
		Vascular disorders	Aortic disorder	11SEP2018		Y
	C4591001 1009 10091029	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Investigations	Blood pressure increased	12AUG2020		Y
		Psychiatric disorders	Anxiety	01MAR2008		Y
			Depression	01NOV2005		Y
			Insomnia	01NOV2009		Y
	C4591001 1009 10091034	Eye disorders	Cataract	02AUG2018		Y
			Dry eye	02AUG2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	12MAR2020		Y
			Vitamin B12 deficiency	21DEC2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Back pain	01JAN1980		Y
			Polyarthritits	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Sleep apnoea syndrome	21DEC2018		Y
	C4591001 1009 10091035	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Investigations	Blood pressure increased	13AUG2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Foot deformity	01JAN2016		Y
			Osteopenia	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Photodermatitis	18FEB2015		Y
		Social circumstances	Menopause	01JAN1998	31DEC1998	N
		Vascular disorders	Raynaud's phenomenon	01JAN1978		Y
	C4591001 1009 10091036	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Urinary retention	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091037	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1009 10091038	Cardiac disorders	Bundle branch block right	01JAN2000		Y
			Mitral valve disease	01JAN2005		Y
			Tricuspid valve disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Vertigo positional	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2005		Y
				01JAN2010		Y
		Immune system disorders	Contrast media allergy	01JAN1960		Y
			Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Post concussion syndrome	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Vitamin B complex deficiency	22APR2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Foot deformity	27DEC2017		Y
			Intervertebral disc degeneration	01JAN1990		Y
			Muscle spasms	01JAN1990		Y
			Osteoarthritis	18OCT2010		Y
			Osteoporosis	01JAN2010		Y
		Nervous system disorders	Memory impairment	01JAN1990		Y
			Migraine	01JAN1990		Y
			Post-traumatic headache	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1965		Y
			Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1009 10091039	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05OCT2016		Y
	C4591001 1009 10091040	Infections and infestations	Type 2 diabetes mellitus Sinusitis	01MAR2020 01JAN2010		Y Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	14OCT2019		Y
	C4591001 1009 10091041	Social circumstances General disorders and administration site conditions	Postmenopause Drug intolerance	01APR2019 10MAY2018		Y Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Osteoporosis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1009 10091043	Cardiac disorders	Bundle branch block left	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Polyarthritits	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1009 10091044	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1999		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteopenia	01FEB2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2004	N
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN1999		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1009 10091047	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Hepatic cyst	01JAN2010		Y
		Investigations	Low density lipoprotein increased	01AUG2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Lumbar spinal stenosis	01JAN2018		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Lumbosacral radiculopathy	01JAN2017		Y
		Renal and urinary disorders	Renal cyst	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1990		Y
	C4591001 1009 10091048	Endocrine disorders	Hypothyroidism	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019		Y
		Nervous system disorders	Psychomotor hyperactivity	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2011		Y
			Seasonal affective disorder	01JAN2008		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2017	31DEC2017	N
			Hypertonic bladder	01JAN2017		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bladder repair	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091051	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2004		Y
		Gastrointestinal disorders	Malabsorption	01JAN2011		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2011		Y
			Vitamin D deficiency	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
			Small intestine carcinoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1956		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1009 10091052	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
			Pain in extremity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1009 10091054	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	10DEC2018		Y
			Obesity	01JAN2010		Y
	C4591001 1009 10091055	Congenital, familial and genetic disorders	Hereditary motor and sensory neuropathy	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1009 10091057	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2015		Y
			Hyperlipidaemia	29OCT2009		Y
		Nervous system disorders	Hypoaesthesia	01JAN2015		Y
		Surgical and medical procedures	Sclerotherapy	01JAN2015	31DEC2015	N
	C4591001 1009 10091060	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Retinal oedema	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	26JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	22FEB2012		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2010	31DEC2010	N
			Cardiac ablation	01JAN2005	31DEC2005	N
	C4591001 1009 10091062	Blood and lymphatic system disorders	Neutropenia	18MAY2016		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Osteoarthritis	30SEP2010		Y
		Psychiatric disorders	Anxiety	04DEC2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	08JAN2013		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1009 10091064	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JUN2016	30JUN2016	N
	C4591001 1009 10091065	Endocrine disorders	Androgen deficiency	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Infections and infestations	Sinusitis	15AUG2020	18AUG2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
	C4591001 1009 10091067	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091069	Cardiac disorders	Supraventricular tachycardia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Osteoarthritis	01JAN2005		Y
			Pain in extremity	01JAN2017		Y
		Nervous system disorders	Essential tremor	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1009 10091071	General disorders and administration site conditions	Oedema peripheral	19AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1974		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1009 10091072	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01MAR2010		Y
		Vascular disorders	Hypertension	01OCT2009		Y
	C4591001 1009 10091074	Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Erectile dysfunction	05JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	12NOV2015		Y
			Psoriasis	01JAN1960		Y
		Surgical and medical procedures	Prostatectomy	01MAR1993	31MAR1993	N
	C4591001 1009 10091076	Ear and labyrinth disorders	Deafness unilateral	01JAN2007		Y
		Eye disorders	Dry eye	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2007		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1009 10091077	Cardiac disorders	Coronary artery disease	01MAY2020		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Lactose intolerance	01DEC2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
	C4591001 1009 10091078	Cardiac disorders	Atrial fibrillation	01JAN2003	30NOV2015	N
		Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 1955		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2006	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Sinusitis	01JAN2000	31DEC2018	N
		Injury, poisoning and procedural complications	Blindness traumatic	01JAN1962		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2018	N
		Surgical and medical procedures	Cardiac ablation	01NOV2015	30NOV2015	N
			Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN2009	31DEC2009	N
			Orbit plastic repair	01JAN1983	31DEC1983	N
			Sinus operation	01JAN2018	31DEC2018	N
	C4591001 1009 10091087	Congenital, familial and genetic disorders	Type V hyperlipidaemia	25JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	16JUL2015		Y
	C4591001 1009 10091089	Ear and labyrinth disorders	Deafness neurosensory	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Astigmatism	01JAN2010		Y
			Cataract	01JAN2012		Y
			Dry eye	01JAN2012		Y
			Glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1964		Y
				01JAN1980		Y
			Oedema peripheral	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2019		Y
			Osteoarthritis	01JAN2017		Y
			Osteoporosis	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1963	31DEC2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y
			Depression	01JAN1962		Y
			Generalised anxiety disorder	01JAN2019		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2017		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1009 10091090	Cardiac disorders	Tricuspid valve incompetence	01JAN1958		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
				01JAN2000		Y
				01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
				01JAN2003		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091093	Endocrine disorders	Hypogonadism male	19DEC2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	04MAY2019		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1009 10091094	Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN1975		Y
			Gastrooesophageal reflux disease	01JAN2016		Y
		General disorders and administration site conditions	Pain	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1957		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Injury, poisoning and procedural complications	Fall	01JAN2010		Y
			Upper limb fracture	01MAR2020	31MAY2020	N
		Investigations	Blood pressure increased	21AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Neck pain	01JAN1990		Y
			Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2015		Y
		Renal and urinary disorders	Bladder prolapse	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1009 10091096	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01MAY2020		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1009 10091099	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Onychomycosis	01AUG2020		Y
		Investigations	Heart rate irregular	24AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Overweight	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Urinary hesitation	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1995		Y
			Raynaud's phenomenon	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1009 10091100	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1976		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1009 10091101	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Investigations	Hepatic enzyme increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Rotator cuff syndrome	01JAN2010		Y
	C4591001 1009 10091104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	08JUL2020		Y
			Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1009 10091107	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Cardiac murmur	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982		Y
	C4591001 1009 10091111	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	29JUL2016		Y
			Hyperlipidaemia	29JUN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin B12 deficiency	12FEB2013		Y
		Renal and urinary disorders	Chronic kidney disease	02MAY2018		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Gastric banding	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1009 10091114	Ear and labyrinth disorders	Deafness bilateral	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN1995		Y
		Social circumstances	Hearing aid user	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1009 10091115	Cardiac disorders	Atrial fibrillation	01JAN1990	31DEC1990	N
			Atrioventricular block complete	01JAN2013		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN1999	31DEC2000	N
		Infections and infestations	Onychomycosis	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN1995		Y
			Vitamin B12 deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN1990		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2013		Y
			Cataract operation	01JAN2000	31DEC2000	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2013		Y
			Hypertension	01JAN1980		Y
	C4591001 1009 10091119	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2005		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Gastrointestinal disorders	Inguinal hernia	11JAN2012		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
				01JAN2000		Y
				01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Food allergy	01JAN1960		Y
			Seasonal allergy	01JAN1979		Y
		Infections and infestations	Onychomycosis	16NOV2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	17AUG2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	13APR2011		Y
			Tremor	01JAN2016		Y
		Psychiatric disorders	Depression	19AUG2016		Y
		Renal and urinary disorders	Chronic kidney disease	07MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14DEC2017		Y
			Sleep apnoea syndrome	02MAR2012		Y
		Surgical and medical procedures	Prostatectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
			Peripheral venous disease	08FEB2017		Y
	C4591001 1009 10091120	Blood and lymphatic system disorders	Thrombocytosis	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1953		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1969	31DEC1970	N
		Psychiatric disorders	Bipolar disorder	01JAN1970		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2020		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1009 10091121	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2016		Y
			Spinal stenosis	01SEP2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Spinal laminectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2010		Y
			Hypertension	01JAN2015		Y
	C4591001 1009 10091122	Blood and lymphatic system disorders	Hypercoagulation	01JAN2016		Y
		Cardiac disorders	Atrial flutter	01JAN2016		Y
			Atrioventricular block first degree	01JAN2016		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2015		Y
		Eye disorders	Macular degeneration	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2006	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1009 10091123	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1975		Y
			Colon adenoma	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN1987		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Cervical discharge	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
			Nasal septal operation	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1009 10091125	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
			Type 2 diabetes mellitus	01SEP2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Osteoarthritis	01JAN2014		Y
			Spinal stenosis	01JAN2014		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2000		Y
			Ovarian cyst	01JAN1999	31DEC2000	N
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1009 10091126	Ear and labyrinth disorders	Deafness bilateral	01JAN1995		Y
		Eye disorders	Dry eye	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Perennial allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1997		Y
			Osteoarthritis	01JAN1990		Y
			Pain in extremity	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JUL2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1009 10091127	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1965		Y
		Investigations	Electrocardiogram PR shortened	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
			Foot deformity	01JAN2010		Y
			Intervertebral disc degeneration	01JAN1990		Y
			Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Insomnia	01DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	17SEP2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1009 10091130	Gastrointestinal disorders	Gastroesophageal reflux disease	13MAR2012		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1952		Y
		Infections and infestations	Sinusitis	01JAN1958		Y
		Metabolism and nutrition disorders	Gout	12JUN2016		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1962		Y
				01JAN1985		Y
			Pain in extremity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1952		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	20MAR2012		Y
			Skin exfoliation	01JAN2010		Y
	C4591001 1009 10091132	Gastrointestinal disorders	Irritable bowel syndrome	01DEC2012		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2016		Y
			Menopausal disorder	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1009 10091135	Congenital, familial and genetic disorders	Methylenetetrahydrofolate reductase gene mutation	(b) (6) 1957		Y
		Endocrine disorders	Hypothyroidism	01JUN2011		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1986		Y
		Immune system disorders	Hypersensitivity	01JAN1958		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2003		Y
			Lactose intolerance	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2019		Y
		Psychiatric disorders	Anxiety	01JUN2011		Y
			Depression	01JUN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1009 10091139	General disorders and administration site conditions	Drug intolerance	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05OCT2011		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015		Y
			Osteoarthritis	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Vascular disorders	Deep vein thrombosis	01JAN2013		Y
			Hypertension	01JAN2006		Y
			Varicose vein	01JAN2000		Y
	C4591001 1009 10091141	Congenital, familial and genetic disorders	Gilbert's syndrome	19MAR2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteosclerosis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Organic erectile dysfunction	01JAN2010		Y
	C4591001 1009 10091143	Skin and subcutaneous tissue disorders	Actinic keratosis	20MAR2013		Y
		Eye disorders	Cataract	01JAN2017		Y
			Dry eye	06SEP2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood pressure increased	12NOV2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	30NOV2016		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2019		Y
			Osteopenia	18JUN2009		Y
		Renal and urinary disorders	Dysuria	10AUG2020	14OCT2020	N
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
	C4591001 1009 10091144	Congenital, familial and genetic disorders	Familial tremor	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Hypoacusis	01JAN2017		Y
		Immune system disorders	Contrast media allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Back pain	01JAN2000		Y
				01JAN2008		Y
		Nervous system disorders	Headache	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Renal and urinary disorders	Micturition urgency	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Deep brain stimulation	01JAN2011		Y
				01JAN2017		Y
	C4591001 1009 10091145	Immune system disorders	Hypersensitivity	05MAY2020		Y
		Infections and infestations	Oral herpes	01JAN2009		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1009 10091146	Gastrointestinal disorders	Gastroesophageal reflux disease	14JUL2011		Y
		Infections and infestations	Meningitis	01OCT2003	31OCT2003	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2014		Y
			Hyperlipidaemia	19JAN2010		Y
			Obesity	21AUG2014		Y
		Musculoskeletal and connective tissue disorders	Back disorder	11JAN2012		Y
			Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	19JAN2010		Y
			Spondylolisthesis	11JAN2012		Y
		Nervous system disorders	Hypoaesthesia	22MAY2019		Y
			Migraine	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Knee arthroplasty	01NOV2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1009 10091148	Immune system disorders	Allergy to animal	01JAN1970		Y
			Drug hypersensitivity	11SEP2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
		Vascular disorders	Hypertension	11FEB2010		Y
	C4591001 1009 10091149	Cardiac disorders	Coronary artery disease	23APR2019		Y
			Myocardial infarction	23APR2019	23APR2019	N
		Ear and labyrinth disorders	Cerumen impaction	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Oscillopsia	01JAN2017		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN1995		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Infections and infestations	Clostridium difficile infection	10APR2019	31MAY2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diverticulitis	01JAN2010		Y
			Meningitis	01JAN2014	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
				19AUG2011		Y
			Arthritis	01JAN2019		Y
			Back pain	01JAN2015		Y
			Trigger finger	01JAN2019	31JAN2020	N
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	31MAR2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Vascular disorders	Aortic arteriosclerosis	23APR2019		Y
	C4591001 1009 10091151	Cardiac disorders	Atrial fibrillation	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tonsil cancer	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Neck dissection	01JAN2013	31DEC2013	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1009 10091153	Cardiac disorders	Bradycardia	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Nerve injury	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
			Back pain	01JAN1986		Y
			Intervertebral disc protrusion	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN1985		Y
	C4591001 1009 10091154	Cardiac disorders	Supraventricular tachycardia	01JAN2012		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
			Tinnitus	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Uterine cyst	01JAN1994	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1009 10091155	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood pressure increased	04SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2018		Y
			Osteoarthritis	01JAN2010		Y
			Pain in extremity	01JAN2017		Y
	C4591001 1009 10091156	Cardiac disorders	Cardiovascular disorder	01NOV2006		Y
		Immune system disorders	Seasonal allergy	01JUL1953		Y
		Injury, poisoning and procedural complications	Rib fracture	08AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Surgical and medical procedures	Stent placement	01NOV2006		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1009 10091157	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1009 10091160	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Hiatus hernia	29JUL2020		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
			Obesity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Osteopenia	01JAN2017		Y
		Renal and urinary disorders	Dysuria	01JAN2017		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Essential hypertension	01JAN1993		Y
	C4591001 1009 10091161	Endocrine disorders	Autoimmune thyroiditis	01JAN1960		Y
		Gastrointestinal disorders	Diverticulum intestinal	01AUG2006		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1961		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
			Osteoporosis	01AUG2006		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1969	31DEC1969	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1009 10091162	Infections and infestations	Herpes simplex	01JAN1985		Y
		Reproductive system and breast disorders	Uterine cyst	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1009 10091165	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1009 10091167	Cardiac disorders	Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2005	31DEC2005	N
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1980		Y
		Eye disorders	Cataract	01JAN2016		Y
			Macular fibrosis	01JAN2017		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2005		Y
			Diverticulum	01JAN2005		Y
			Gastrooesophageal reflux disease	01JAN1960		Y
			Haemorrhoids	01JAN1981		Y
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	01JAN2005	31DEC2016	N
			Seborrhoeic keratosis	01JAN2010		Y
		Nervous system disorders	Hypoaesthesia	01JAN2005		Y
			Tremor	01JAN1980		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
			Upper-airway cough syndrome	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Pancreaticoduodenectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1009 10091168	Eye disorders	Cataract	01JAN2017		Y
			Dry eye	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Muscle spasms	01JAN2018		Y
			Muscular weakness	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
			Seborrhoeic keratosis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
			Alopecia	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01MAR1975	31DEC1975	N
			Micrographic skin surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1009 10091169	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1009 10091170	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	13MAR2014		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN1974		Y
			Sleep apnoea syndrome	12OCT2001		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
			Shoulder arthroplasty	13JUL2020	13JUL2020	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1009 10091173	Ear and labyrinth disorders	Tinnitus	01JAN2013		Y
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Dysphagia	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Skin laceration	07AUG2020	01SEP2020	N
		Investigations	Prostatic specific antigen increased	14JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN1995		Y
			Pain in extremity	01JAN2009		Y
			Trigger finger	24JUN2020		Y
	C4591001 1009 10091176	Musculoskeletal and connective tissue disorders	Arthralgia	01AUG1987		Y
			Back pain	01JAN1977		Y
			Osteoarthritis	01JAN2005		Y
	C4591001 1009 10091179	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian enlargement	01JAN1995	31DEC1995	N
			Uterine haemorrhage	01JAN1994	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1009 10091180	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 1 diabetes mellitus	01JAN2000		Y
	C4591001 1009 10091181	Blood and lymphatic system disorders	Anaemia	21DEC2010		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	13MAY2016		Y
		Endocrine disorders	Testicular failure	21DEC2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	09JUL2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	23SEP2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	18OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tonsil cancer	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1009 10091182	Vascular disorders	Hypertension	01JAN2005		Y
		Gastrointestinal disorders	Diverticulum	01JAN2012		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
			Psoriasis	01JAN2000		Y
			Urticaria	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1009 10091189	Vascular disorders	Hypertension	01JAN2005		Y
		Endocrine disorders	Autoimmune thyroiditis	01MAY2013		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteopenia	17OCT2011		Y
		Nervous system disorders	Dizziness	29JUN2019		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
			Uterine haemorrhage	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Essential hypertension	14JUN2018		Y
	C4591001 1009 10091190	Cardiac disorders	Coronary artery disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1978		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUL2017	31JUL2017	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1009 10091191	Cardiac disorders	Atrioventricular block first degree	01JAN2011		Y
		Eye disorders	Glaucoma	01JAN2015		Y
			Macular degeneration	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08OCT2012		Y
			Hyponatraemia	09OCT2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Spondylolisthesis	05NOV2010		Y
		Nervous system disorders	Sciatica	05NOV2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	22OCT2013		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	09OCT2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1009 10091193	Congenital, familial and genetic disorders	Carpus curvus	03JAN2012		Y
		Immune system disorders	Seasonal allergy	01NOV1992		Y
		Investigations	Low density lipoprotein increased	07JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV1992		Y
	C4591001 1009 10091195	Endocrine disorders	Autoimmune thyroiditis	18SEP2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
			Large intestine polyp	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Herpes simplex	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2017		Y
	C4591001 1009 10091196	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Infections and infestations	Sinusitis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2016		Y
		Investigations	Hormone level abnormal	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1974	13SEP2018	N
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acanthoma	01JAN1980		Y
			Dysplastic naevus	01JAN1969		Y
			Seborrhoeic keratosis	01JAN1975		Y
		Nervous system disorders	Morton's neuralgia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN1994		Y
	C4591001 1009 10091199	Cardiac disorders	Ventricular extrasystoles	01MAR2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1950		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1011 10111002	Blood and lymphatic system disorders	Anaemia	01JAN2009		Y
		Gastrointestinal disorders	Intestinal obstruction	01JAN1989	31DEC1989	N
			Intussusception	01JAN1986	31DEC1986	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Cellulitis	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Epicondylitis	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1990	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign gastrointestinal neoplasm	01JAN1986	31DEC1986	N
		Reproductive system and breast disorders	Uterine leiomyoma	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Bunion operation	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Intestinal adhesion lysis	01JAN1989	31DEC1989	N
	C4591001 1011 10111007	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017	31OCT2018	N
		Surgical and medical procedures	Spinal stenosis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JUN2010	30JUN2010	N
		Surgical and medical procedures	Intervertebral disc operation	01DEC2017	31DEC2017	N
		Surgical and medical procedures	Intervertebral disc operation	01OCT2018	31OCT2018	N
		Surgical and medical procedures	Spinal laminectomy	01DEC2007	31DEC2007	N
		Surgical and medical procedures	Spinal laminectomy	01MAR2017	31MAR2017	N
		Surgical and medical procedures	Spinal laminectomy	01MAY2002	31MAY2002	N
		Surgical and medical procedures	Spinal laminectomy	01OCT2014	31OCT2014	N
		Surgical and medical procedures	Spinal operation	01JAN2010	31JAN2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1011 10111011	Blood and lymphatic system disorders	Anaemia	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Goitre	01JAN1999	31DEC2002	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1998		Y
		Surgical and medical procedures	Thyroidectomy	01DEC2002	31DEC2002	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1011 10111012	Cardiac disorders	Bundle branch block right	01JAN1991		Y
			Coronary artery disease	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN1993		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1011 10111014	Cardiac disorders	Cardiac failure congestive	01JUN2017		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN2001		Y
			Obesity	01JAN1989		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1011 10111015	Cardiac disorders	Bradycardia	01DEC2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Hernia repair	01JAN2000	31DEC2000	N
			Tenolysis	01JAN2007	31DEC2007	N
	C4591001 1011 10111018	Cardiac disorders	Mitral valve prolapse	01JAN1998	31DEC2015	N
		Eye disorders	Amblyopia	01JAN1965	31DEC1965	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1972	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1972		Y
			Rotator cuff syndrome	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2016	31MAR2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
			Morton's neuralgia	01APR2020		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2019	31DEC2019	N
			Haematuria	01JAN1991		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2008		Y
		Surgical and medical procedures	Bladder repair	01MAR2019	31MAR2019	N
			Endometrial ablation	01JAN2006	31DEC2006	N
			Hysterectomy	01MAR2019	31MAR2019	N
			Mitral valve replacement	01JAN2015	31DEC2015	N
			Strabismus correction	01JAN1965	31DEC1965	N
			Tenoplasty	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111019	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Elbow operation	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
	C4591001 1011 10111020	Ear and labyrinth disorders	Hyperacusis	01JAN2014		Y
			Superior semicircular canal dehiscence	01JAN2014	31MAY2015	N
		Endocrine disorders	Goitre	01JAN2006	31DEC2006	N
			Hypothyroidism	01JAN2005	30JUN2005	N
		Gastrointestinal disorders	Volvulus	01AUG2019		Y
		General disorders and administration site conditions	Ulcer	01APR1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01OCT2006	30NOV2006	N
		Surgical and medical procedures	Hysterectomy	01NOV2006	30NOV2006	N
			Inner ear operation	01MAY2015	31MAY2015	N
			Thyroidectomy	01JUN2006	30JUN2006	N
	C4591001 1011 10111022	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1011 10111023	Endocrine disorders	Hyperthyroidism	01JAN2009		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Obesity	01JAN1990	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
			Osteoarthritis	01JAN2018	31DEC2018	N
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1970	31DEC1984	N
		Surgical and medical procedures	Appendectomy	01JAN1973	31DEC1973	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Foot operation	01JAN2018	31DEC2018	N
			Gastric bypass	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
	C4591001 1011 10111025	Cardiac disorders	Myocardial infarction	02OCT2006	02OCT2006	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2013		Y
			Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Aortic stent insertion	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1011 10111026	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1011 10111027	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	31DEC2019	N
				01NOV1990	30APR2019	N
		Reproductive system and breast disorders	Endometriosis	01NOV1975	31JAN1989	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Knee arthroplasty	01APR2019	30APR2019	N
				01JAN2019	31DEC2019	N
			Nasal septal operation	01JAN1978	31DEC1978	N
			Oestrogen replacement therapy	01JAN1989		Y
	C4591001 1011 10111028	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1011 10111029	Infections and infestations	Herpes zoster	01APR2020	30APR2020	N
		Nervous system disorders	Post herpetic neuralgia	10APR2020		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1998	31DEC1998	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Face lift	01JAN2001	31DEC2001	N
			Uterine dilation and curettage	01JAN1998	31DEC1998	N
	C4591001 1011 10111030	Gastrointestinal disorders	Dyspepsia	01JAN1998		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Intervertebral disc protrusion	01JAN1994	31DEC1994	N
				01JAN1997	31DEC1997	N
			Osteoarthritis	01JAN1990		Y
				01JAN2004		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN1994	31DEC1994	N
				01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1011 10111033	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1011 10111036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		General disorders and administration site conditions	Oedema	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1011 10111037	Blood and lymphatic system disorders	Anaemia	01JAN1985	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Cardiac disorders	Mitral valve prolapse	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000	31DEC2008	N
			Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Caesarean section	11OCT1977	11OCT1977	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Nephrectomy	01JAN2005	31DEC2005	N
			Hypertension	01JAN2015		Y
	C4591001 1011 10111040	Vascular disorders				
	C4591001 1011 10111041	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2005		Y
		Surgical and medical procedures	Finger amputation	01JAN1988	31DEC1988	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1011 10111045	Cardiac disorders	Mitral valve incompetence	01JAN2000	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Surgical and medical procedures	Mitral valve replacement	01JAN2009	31DEC2009	N
	C4591001 1011 10111047	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
			Intervertebral disc protrusion	01JAN1988	31DEC1993	N
			Scoliosis	01JAN1977		Y
			Spinal osteoarthritis	01JAN1998		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1954		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2014	31DEC2014	N
			Spinal laminectomy	01JAN1988	31DEC1988	N
				01JAN1993	31DEC1993	N
	C4591001 1011 10111048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1011 10111049	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007	31AUG2017	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Knee arthroplasty	01AUG2017	31AUG2017	N
	C4591001 1011 10111050	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2000		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1011 10111051	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1011 10111054	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1992	31DEC1994	N
			Osteoarthritis	01JAN2000	31DEC2007 31DEC2008	N N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01JAN2011		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1990	31DEC1999	N
		Surgical and medical procedures	Bunion operation	01JAN1994	31DEC1994	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
			Urinary bladder suspension	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1011 10111055	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1011 10111056	Injury, poisoning and procedural complications	Wrist fracture	01SEP2015	30SEP2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	22OCT1975	22OCT1975	N
			Fracture treatment	01SEP2015	30SEP2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1011 10111057	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1011 10111058	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1011 10111059	Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1011 10111060	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1011 10111061	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1011 10111062	Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1011 10111063	Metabolism and nutrition disorders	Obesity	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1011 10111064	Investigations	Blood cholesterol increased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017	31DEC2017	N
			Osteoarthritis	01JAN1975		Y
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1011 10111065	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1011 10111066	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Muscle strain	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2011		Y
	C4591001 1011 10111067	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1991		Y
	C4591001 1011 10111068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989		Y
		Infections and infestations	Appendicitis	01JAN1946	31DEC1946	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Appendicectomy	01JAN1946	31DEC1946	N
			Female sterilisation	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1011 10111069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JUN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	12MAR2000	N
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	12MAR2000	12MAR2000	N
	C4591001 1011 10111073	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1011 10111075	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
			Knee arthroplasty	01JAN1985	31DEC2015	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1011 10111076	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Lyme disease	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC2001	N
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1956		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1011 10111080	Ear and labyrinth disorders	Meniere's disease	01JAN1991		Y
		Nervous system disorders	Dizziness	01JAN1991		Y
	C4591001 1011 10111081	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1983	31DEC1983	N
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1990	31DEC1990	N
			Ligament sprain	02JUL2020		Y
			Meniscus injury	01JAN2001	31DEC2001	N
		Investigations	Arthroscopy	01JAN1999	31DEC1999	N
				01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2011		Y
		Reproductive system and breast disorders	Breast mass	01JAN1985	31DEC1985	N
		Social circumstances	Postmenopause	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Breast conserving surgery	01JAN1985	31DEC1985	N
			Caesarean section	19OCT1979	19OCT1979	N
			Cholecystectomy	01JAN1983	31DEC1983	N
			Female sterilisation	01JAN1979	31DEC1979	N
			Ligament operation	01JAN1990	31DEC1990	N
			Meniscus operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1011 10111083	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2006		Y
			Psoriatic arthropathy	01JAN1993		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1011 10111084	Cardiac disorders	Mitral valve incompetence	01JAN1960	31DEC2016	N
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Mantle cell lymphoma	01JAN2008	31DEC2009	N
		Nervous system disorders	Neuropathy peripheral	01JAN2008		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2016	31DEC2016	N
			Spinal fracture treatment	01JAN2012	31DEC2012	N
	C4591001 1011 10111085	Endocrine disorders	Hyperthyroidism	01JAN2006		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Nasal septal operation	01JAN2015	31DEC2015	N
	C4591001 1011 10111086	Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1011 10111096	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1011 10111099	Cardiac disorders	Coronary artery disease	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Psychiatric disorders	Bipolar disorder	01JAN1985		Y
	C4591001 1011 10111100	Infections and infestations	Lyme disease	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2004	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1011 10111101	Metabolism and nutrition disorders	Obesity	01JAN1999		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
	C4591001 1011 10111105	Cardiac disorders	Ventricular extrasystoles	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Gastric banding	01JAN2008	31DEC2008	N
			Mammoplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1011 10111108	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
			Osteoarthritis	01JAN2006	31DEC2006	N
				01JAN2011	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	18JUL1986	18JUL1986	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1011 10111109	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Diverticulitis	01MAY2001		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
			Nasal septal operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Stab wound	01OCT1990	31OCT1990	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Intestinal resection	01OCT1990	31OCT1990	N
			Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1011 10111114	Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1011 10111120	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1011 10111121	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1011 10111126	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1011 10111127	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1011 10111128	Metabolism and nutrition disorders	Histamine intolerance	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1011 10111132	Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Renal and urinary disorders	Bladder prolapse	01OCT2018	31OCT2018	N
		Reproductive system and breast disorders	Cystocele	01OCT2018	31OCT2018	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01OCT2018	31OCT2018	N
			Meniscus removal	01JAN2014	31DEC2014	N
	C4591001 1011 10111133	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1011 10111136	Investigations	Blood calcium abnormal	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1011 10111137	Investigations	Blood cholesterol increased	01MAR2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1011 10111138	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111139	Psychiatric disorders	Anxiety	01JAN2010		Y
			Intermittent explosive disorder	01JAN2018		Y
	C4591001 1011 10111140	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1011 10111145	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Cardiovascular event prophylaxis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1011 10111146	Investigations	Blood cholesterol increased	01JAN2003		Y
	C4591001 1011 10111147	Eye disorders	Cataract	01JAN2018	31MAR2020	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01MAR2020	31MAR2020	N
	C4591001 1011 10111149	Investigations	Blood cholesterol increased	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Surgical and medical procedures	Face lift	01JAN2015	31DEC2015	N
	C4591001 1011 10111152	Eye disorders	Cataract	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1968	31DEC1968	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1968		Y
				01JAN1971		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Meniscus removal	01JAN1968	31DEC1968	N
			Umbilical hernia repair	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1971		Y
		Cardiac disorders	Tachycardia	01JAN2005		Y
	C4591001 1011 10111153	Gastrointestinal disorders	Rectal prolapse	01JAN2000	31DEC2003	N
		Infections and infestations	Diverticulitis	01JAN2018		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2000	31DEC2003	N
		Reproductive system and breast disorders	Cystocele	01JAN2003	31DEC2003	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Rectal prolapse repair	01JAN2003	31DEC2003	N
	C4591001 1011 10111155	General disorders and administration site conditions	Hernia	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Tibia fracture	01AUG2019	31AUG2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Hernia repair	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1011 10111156	Eye disorders	Cataract	01JAN2009	31DEC2009	N
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2014	31DEC2019	N
			Depression	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Cataract operation	01JAN2009	31DEC2009	N
			Endocrine gland operation	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1950	31DEC1950	N
	C4591001 1011 10111157	Cardiac disorders	Cardiomyopathy	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01DEC1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1011 10111158	Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1011 10111162	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Obesity	01JAN1985		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111167	Endocrine disorders	Hyperthyroidism	01JAN1983		Y
		Metabolism and nutrition disorders	Vitamin B complex deficiency	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1011 10111171	Social circumstances	Postmenopause	01DEC2004		Y
	C4591001 1011 10111172	Gastrointestinal disorders	Gastroesophageal reflux disease	15MAY2017		Y
		General disorders and administration site conditions	Hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Herpes virus infection	01APR2015		Y
		Investigations	Blood cholesterol increased	01DEC2014	30APR2015	N
		Metabolism and nutrition disorders	Gout	01JAN2008		Y
			Obesity	01JAN1991		Y
			Type 2 diabetes mellitus	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2017		Y
			Sleep apnoea syndrome	15MAY2017		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1011 10111177	Investigations	Blood cholesterol increased	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rheumatoid arthritis	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1011 10111178	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011	31JAN2013	N
			Osteoarthritis	01JAN2000		Y
				01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Psychiatric disorders	Depression	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1011 10111180	Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1011 10111185	Cardiac disorders	Atrial fibrillation	01FEB2019		Y
		Congenital, familial and genetic disorders	Protein S deficiency	01JAN1990		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2002	31DEC2017	N
	C4591001 1011 10111187	Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1977	31DEC1977	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1988		Y
	C4591001 1011 10111188	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1011 10111189	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1011 10111191	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2001	31DEC2003	N
				01JAN2008	31DEC2008	N
			Osteoarthritis	01JAN2005		Y
				01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1993		Y
			Insomnia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1011 10111192	General disorders and administration site conditions	Hernia	01JAN1965	31DEC1967	N
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
			Lyme disease	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1011 10111194	Gastrointestinal disorders	Inguinal hernia	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2001	31DEC2001	N
	C4591001 1011 10111196	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1011 10111198	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1011 10111201	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
	C4591001 1011 10111202	Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1011 10111204	Gastrointestinal disorders	Small intestinal obstruction	01JAN2002	31DEC2003	N
		Infections and infestations	Sinusitis	01JAN1999	31DEC2005	N
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intestinal operation	01JAN2002	31DEC2002	N
			Sinus operation	01JAN2015	31DEC2015	N
	C4591001 1011 10111206	Immune system disorders	Seasonal allergy	01MAY2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2017		Y
			Intervertebral disc protrusion	01MAR2000	31MAR2000	N
			Rotator cuff syndrome	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Intervertebral disc operation	01MAR2000	31MAR2000	N
			Rotator cuff repair	01JAN2001	31DEC2001	N
	C4591001 1011 10111208	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin B12 deficiency	01JAN2016		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1998		Y
				01JUN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1011 10111209	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1011 10111217	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
	C4591001 1011 10111218	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1997	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	03DEC1998	03DEC1998	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
	C4591001 1011 10111221	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Injury, poisoning and procedural complications	Jaw fracture	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	31DEC2010	N
	C4591001 1011 10111223	Endocrine disorders	Hyperthyroidism	01JAN1995		Y
			Hypothyroidism	01JAN1995		Y
		Eye disorders	Dry eye	01JUN2020		Y
		Psychiatric disorders	Depression	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1011 10111225	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1011 10111226	Cardiac disorders	Tachycardia	01JAN1990		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2015		Y
		Infections and infestations	Sinusitis	07SEP2020	17SEP2020	N
		Investigations	Cardiac murmur	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Bipolar disorder	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1011 10111230	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1011 10111231	Psychiatric disorders	Depression	01JAN2013		Y
	C4591001 1012 10121002	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Cataract	01JAN2016		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN2019		Y
			Dyspepsia	01JAN2019		Y
			Nausea	01JAN2019		Y
			Vomiting	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2015		Y
			Osteoarthritis	01JAN2003	31DEC2003	N
			Spinal osteoarthritis	01JAN2000		Y
				01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2016		Y
			Eczema	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1012 10121004	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal papilloma of breast	01JUN2020	25JUN2020	N
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	25JUN2020	25JUN2020	N
	C4591001 1012 10121007	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Myalgia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1012 10121008	Eye disorders	Blepharitis	01JAN1966		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Nervous system disorders	Dizziness	01APR2000	30APR2000	N
			Lumbar radiculopathy	16APR2000		Y
			Migraine with aura	01JAN2015		Y
			Syncope	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1966		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1012 10121009	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1012 10121010	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
			Tinnitus	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2008		Y
			Osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1994	31DEC1994	N
			Benign neoplasm of thyroid gland	01JAN2014		Y
			Colon cancer	01JUN2011	30JUN2011	N
			Malignant melanoma	01JAN1990	31DEC1990	N
		Nervous system disorders	Migraine	01JAN1981		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1954		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Colectomy	01SEP2011	30SEP2011	N
			Skin neoplasm excision	01JAN1990	31DEC1990	N
	C4591001 1012 10121015	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Chronic sinusitis	01JAN1972		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1980		Y
			Spondylitis	01JAN1990		Y
				01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1970		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01SEP2019	30SEP2019	N
	C4591001 1012 10121018	Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Essential tremor	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1012 10121023	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1012 10121026	Gastrointestinal disorders	Periodontal disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
				01JAN2017		Y
			Arthritis	01JAN2016		Y
				01JAN2017		Y
			Exostosis	01JAN2016		Y
			Spinal osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cough	01JAN2016		Y
			Dyspnoea	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN1960		Y
	C4591001 1012 10121029	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
	C4591001 1012 10121031	Nervous system disorders	Headache	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1012 10121033	Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2020		Y
		Psychiatric disorders	Alcoholism	01JAN1992	31DEC2017	N
	C4591001 1012 10121034	Cardiac disorders	Supraventricular extrasystoles	01JAN2015		Y
		Eye disorders	Macular degeneration	01JAN2001		Y
			Retinal dystrophy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1970		Y
	C4591001 1012 10121035	Gastrointestinal disorders	Large intestine polyp	01FEB2017	28FEB2017	N
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2015		Y
		Nervous system disorders	Tremor	01JUL2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1988		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Large intestinal polypectomy	01FEB2017	28FEB2017	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1012 10121038	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Nervous system disorders	Dizziness	01JAN2020	31MAR2020	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Gastric bypass	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2020	31MAR2020	N
			Hypertension	01JAN2014		Y
	C4591001 1012 10121039	Immune system disorders	Seasonal allergy	01JAN1946		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1012 10121040	Cardiac disorders	Atrial tachycardia	01JAN2011		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2016	31DEC2016	N
			Urinary bladder suspension	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1012 10121041	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Infections and infestations	Tooth abscess	14AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121042	Infections and infestations	Diverticulitis	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1012 10121044	Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1012 10121047	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05AUG2020		Y
			Malabsorption	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Infections and infestations	Bronchitis	01FEB2019	28FEB2019	N
				01MAY2019	31MAY2019	N
			Urinary tract infection	01JAN2008	31DEC2018	N
		Metabolism and nutrition disorders	Insulin resistance	01JAN2017		Y
			Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1012 10121048	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Impaired fasting glucose	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1012 10121049	Ear and labyrinth disorders	Vertigo	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
			Keratomileusis	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1012 10121054	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1012 10121056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1012 10121057	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Vitamin B12 deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Arthritis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Muscle spasms	01JAN2019		Y
			Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Caesarean section	01JAN1968	31DEC1968	N
				01JAN1972	31DEC1972	N
			Female sterilisation	01JAN1988	31DEC1988	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1012 10121060	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Epididymitis	01JAN2020	31JAN2020	N
			Urosepsis	01JAN2020	31JAN2020	N
		Injury, poisoning and procedural complications	Ligament sprain	01AUG2019	31AUG2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01MAR2020	31MAR2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1982		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Surgical and medical procedures	Renal tumour excision	01MAR2020	31MAR2020	N
	C4591001 1012 10121062	Gastrointestinal disorders	Small intestinal obstruction	14JUN2020	14JUN2020	N
		Infections and infestations	Oral herpes	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1012 10121063	Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1012 10121064	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1979		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1012 10121067	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019	31MAR2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	23JUL2014	N
		Surgical and medical procedures	Breast tumour excision	23JUL2014	23JUL2014	N
			Knee arthroplasty	01MAR2019	31MAR2019	N
	C4591001 1012 10121068	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1012 10121069	Congenital, familial and genetic disorders	Cryptorchism	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01APR2019	30APR2019	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01APR2019	30APR2019	N
		Surgical and medical procedures	Orchidectomy	01JAN1979	31DEC1979	N
	C4591001 1012 10121070	Cardiac disorders	Mitral valve prolapse	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1984	31DEC1984	N
		Nervous system disorders	Migraine	01JAN1963		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1995		Y
				01JAN2008		Y
			Insomnia	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2007		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
			Urinary bladder suspension	01JAN2007	31DEC2007	N
	C4591001 1012 10121071	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1983	31DEC1996	N
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1012 10121075	Eye disorders	Cataract	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
	C4591001 1012 10121077	Cardiac disorders	Arrhythmia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder polyp	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercalcaemia	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1990		Y
			Osteoarthritis	01JAN1997	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2000	31DEC2000	N
			Breast neoplasm	01JAN1999	31DEC1999	N
			Thyroid cancer	01JAN2019	31DEC2019	N
			Uterine leiomyoma	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Social circumstances	Postmenopause	01JUN1993	30JUN1993	N
		Surgical and medical procedures	Adenoidectomy	01JAN1960	31DEC1960	N
			Breast conserving surgery	01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N
			Hip arthroplasty	01JUN2018	30JUN2018	N
				01MAR2018	31MAR2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1993	31DEC1993	N
			Parathyroidectomy	01JAN2019	31DEC2019	N
			Thyroidectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1012 10121080	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1012 10121081	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1012 10121084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Gastrectomy	01JAN2015	31DEC2015	N
	C4591001 1012 10121086	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	11JUN2000	11JUN2000	N
			Nephrectomy	01JAN2003	31DEC2003	N
	C4591001 1012 10121088	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		General disorders and administration site conditions	Chest pain	01JAN2009		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Nervous system disorders	Dizziness	01JAN2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Syncope	01JAN2006		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1991	N
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
			Sclerotherapy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2020		Y
			Peripheral venous disease	01JAN2019	31DEC2019	N
		Cardiac disorders	Ventricular extrasystoles	01JAN1990		Y
	C4591001 1012 10121093					
	C4591001 1012 10121094	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
	C4591001 1012 10121097	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2017	N
			Osteoporosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1012 10121098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Urinary retention	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
			Sinuplasty	01JAN2019	31DEC2019	N
			Spinal operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1012 10121099	Endocrine disorders	Basedow's disease	01JAN1995		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1993	31DEC1993	N
	C4591001 1012 10121100	Gastrointestinal disorders	Hiatus hernia	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
			Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
		Nervous system disorders	Dizziness	01JAN2000		Y
		Renal and urinary disorders	Haematuria	01JAN2010		Y
			Proteinuria	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01FEB2019		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1012 10121106	Cardiac disorders	Atrioventricular block first degree	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Intestinal obstruction	01JAN2018		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Fungal skin infection	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2015		Y
				01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
			Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2010		Y
		Renal and urinary disorders	Nephropathy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Corneal transplant	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1012 10121109	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Glaucoma	27APR2017		Y
			Macular fibrosis	16MAY2014	16MAY2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2013		Y
			Breast cyst	01JAN1972	31DEC1972	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1972	31DEC1972	N
			Cataract operation	01JAN2010	31DEC2020	N
			Muscle operation	01FEB2019	28FEB2019	N
			Retinal operation	16MAY2014	16MAY2014	N
			Sinuplasty	01FEB2019	28FEB2019	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1012 10121112	Cardiac disorders	Arrhythmia	01JAN2019		Y
			Mitral valve prolapse	01JAN2017		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1964		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Electrocardiogram ambulatory	01OCT2019	31OCT2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC1987	31DEC1987	N
			Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
			Prostatectomy	01DEC1987	31DEC1987	N
			Vasectomy	01JAN1977	31DEC1977	N
	C4591001 1012 10121113	Gastrointestinal disorders	Large intestine polyp	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Aortic disorder	01JAN2020		Y
			Hypertension	01JAN1990		Y
	C4591001 1012 10121114	Congenital, familial and genetic disorders	Factor XIII deficiency	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JAN2014		Y
			Lipoma	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pleurisy	01JAN2013	31DEC2013	N
			Pulmonary embolism	01JAN2014	31DEC2014	N
				01JAN2019	31DEC2019	N
	C4591001 1012 10121115	Ear and labyrinth disorders	Vertigo	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01JAN2007	31DEC2007	N
	C4591001 1012 10121122	Vascular disorders	Deep vein thrombosis	01JAN2015	31DEC2015	N
	C4591001 1012 10121123	Gastrointestinal disorders	Gastritis	01JAN1980		Y
		Immune system disorders	Anaphylactic reaction	01JAN1983		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JUL2020		Y
	C4591001 1012 10121125	Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
		Cardiac disorders	Arrhythmia	01JAN2008		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN2020	31MAR2020	N
		Nervous system disorders	Hypoaesthesia	01MAR2020		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Reproductive system and breast disorders	Fallopian tube disorder	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Breast conserving surgery	10MAR2020	10MAR2020	N
			Oophorectomy	01JAN2005	31DEC2005	N
	C4591001 1012 10121126	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin B12 deficiency	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121127	Cardiac disorders	Myocardial infarction	01JAN2001	31DEC2001	N
		Immune system disorders	Amyloidosis	01JAN2005		Y
		Injury, poisoning and procedural complications	Subdural haematoma	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN1997	31DEC1998	N
		Renal and urinary disorders	Hypertonic bladder	01JUL2020		Y
		Surgical and medical procedures	Colostomy	01JAN2017	31DEC2017	N
			Colostomy closure	01JAN2017	31DEC2017	N
			Spinal operation	01JAN2017	31DEC2017	N
	C4591001 1012 10121128	Psychiatric disorders	Insomnia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1012 10121129	Endocrine disorders	Autoimmune thyroiditis	01SEP2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1012 10121135	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1012 10121139	Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121140	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	31DEC2015	31DEC2015	N
		Surgical and medical procedures	Fulguration	01JAN2017	31DEC2017	N
			Prostatectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1012 10121142	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Headache	01JAN1977		Y
		Psychiatric disorders	Depression	01JAN1977		Y
		Social circumstances	Postmenopause	01JAN1999		Y
			Tobacco user	01JAN2005		Y
	C4591001 1012 10121147	Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1012 10121148	Endocrine disorders	Autoimmune thyroiditis	01JAN1999		Y
		Infections and infestations	Hepatitis C	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Lipoedema	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
				01JAN2019		Y
			Fibromyalgia	01JAN1999		Y
			Myofascial pain syndrome	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01FEB2020		Y
			Spinal pain	01JAN2016		Y
				01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
	C4591001 1012 10121150	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2019		Y
		Nervous system disorders	Epilepsy	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01SEP2020		Y
			Drug eruption	01JAN1990		Y
	C4591001 1012 10121152	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1012 10121159	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1012 10121160	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Diverticulitis	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1012 10121161	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Chronic sinusitis	01JAN2000	31MAY2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Sinus operation	01MAY2020	31DEC2020	N
	C4591001 1012 10121165	Ear and labyrinth disorders	Meniere's disease	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1012 10121167	Congenital, familial and genetic disorders	Pseudoxanthoma elasticum	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1012 10121168	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1012 10121169	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Urinary retention	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	01JAN2017	31DEC2017	N
	C4591001 1012 10121170	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01FEB2020		Y
				01JAN2019	31AUG2019	N
		Surgical and medical procedures	Knee arthroplasty	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1012 10121171	Ear and labyrinth disorders	Vertigo	28JUL2020	28JUL2020	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1012 10121175	Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1012 10121176	Injury, poisoning and procedural complications	Meniscus injury	01MAY2020	19MAY2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Meniscus operation	19MAY2020	19MAY2020	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1012 10121177	Infections and infestations	Oral herpes	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1012 10121179	Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1012 10121184	Cardiac disorders	Coronary artery disease	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Investigations	Heart rate decreased	29JUL2020	30JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN1975		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1993		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	30JUL2020	30JUL2020	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1012 10121186	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1012 10121189	Endocrine disorders	Hypogonadism	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1013 10131001	Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01MAR1991		Y
		Nervous system disorders	Diabetic neuropathy	01MAR2007		Y
			Migraine	01MAR2008		Y
		Vascular disorders	Hypertension	01MAR2000		Y
	C4591001 1013 10131004	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1013 10131028	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Colectomy	01JAN2014	31DEC2014	N
	C4591001 1013 10131029	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	11JAN1987	11JAN1987	N
				20JUL1981	20JUL1981	N
			Knee arthroplasty	01JUN2006	30JUN2006	N
	C4591001 1013 10131037	Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
	C4591001 1013 10131041	Injury, poisoning and procedural complications	Foot fracture	01JAN2016	31JAN2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2003	31JUL2004	N
		Surgical and medical procedures	Fracture treatment	01JAN2016	31JAN2016	N
			Mastectomy	01JAN2004	31JAN2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131043	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Investigations	Biopsy breast	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2012		Y
		Reproductive system and breast disorders	Breast cyst	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Oophorectomy bilateral	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1013 10131053	Cardiac disorders	Mitral valve prolapse	01JAN1960		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Meniscus operation	01JAN2009	31DEC2009	N
			Skin operation	01JAN2009	31DEC2009	N
	C4591001 1013 10131061	Gastrointestinal disorders	Inguinal hernia	01JAN1968	31DEC1968	N
		Immune system disorders	Smoke sensitivity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1013 10131065	Surgical and medical procedures	Inguinal hernia repair	01JAN1968	31DEC1968	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Psychiatric disorders	Major depression	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131069	Immune system disorders	Allergy to arthropod bite	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01NOV2018		Y
	C4591001 1013 10131070	Cardiac disorders	Coronary artery disease	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131073	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1979		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Major depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131080	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2016		Y
			Obesity	01JAN1966		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01DEC2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	28FEB2002	N
		Surgical and medical procedures	Oophorectomy bilateral	01FEB2002	28FEB2002	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131085	Ear and labyrinth disorders	Hypoacusis	01JAN1965		Y
		Endocrine disorders	Hypothyroidism	01JUN2019		Y
		Reproductive system and breast disorders	Azoospermia	(b) (6) 1961		Y
			Benign prostatic hyperplasia	01JUN2019		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1013 10131086	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1013 10131091	Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2019		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1013 10131092	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Carotid artery stent insertion	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131095	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN1979	31DEC1979	N
			Myomectomy	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131096	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer in situ	01JAN2018	31MAR2018	N
		Surgical and medical procedures	Breast conserving surgery	01APR2018	30APR2018	N
				01MAR2018	31MAR2018	N
			Female sterilisation	01JUN1977	30JUN1977	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131097	Surgical and medical procedures	Intervertebral disc operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1013 10131099	Psychiatric disorders	Major depression	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1013 10131100	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Cognitive disorder	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131101	Infections and infestations	Hepatitis A	01DEC1965	31DEC1965	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018	12OCT2019	N
			Osteoarthritis	01JAN2017	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2020		Y
			Restless legs syndrome	01FEB2020		Y
		Surgical and medical procedures	Fracture treatment	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Spinal fusion surgery	12OCT2019	12OCT2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN1980		Y
			Iodine allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01AUG2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Scoliosis	01JAN1960		Y
		Psychiatric disorders	Insomnia	01APR2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01DEC1989	31DEC2005	N
		Surgical and medical procedures	Oophorectomy	01DEC1989	31DEC1989	N
				01DEC2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JUN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2015		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Renal stone removal	01JAN2010	31DEC2010	N
	C4591001 1013 10131114	Eye disorders	Cataract	04AUG2011	04AUG2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Nervous system disorders	Carotid arteriosclerosis	01JAN2018	05JAN2018	N
			Facial paralysis	01JUN2012	31JUL2012	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01DEC2015		Y
		Surgical and medical procedures	Carotid artery stent insertion	05JAN2018	05JAN2018	N
				18MAR2019	18MAR2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131123	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2016	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2016	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Coronary artery bypass	01JAN2018	31DEC2018	N
			Spinal fracture treatment	01JAN2017	31DEC2017	N
	C4591001 1013 10131129	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2013	31DEC2013	N
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1013 10131130	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
	C4591001 1013 10131133	Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
		Psychiatric disorders	Major depression	01JAN2013		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN1989	31DEC1989	N
			Mammoplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1013 10131140	Immune system disorders	Seasonal allergy	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Meniscus operation	01JAN2012	31DEC2012	N
		Vascular disorders	Angiopathy	01JAN2008		Y
	C4591001 1013 10131141	Congenital, familial and genetic disorders	Amniotic band syndrome	01JAN1954		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2019		Y
			Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN1971		Y
		Psychiatric disorders	Depression	01JAN1993		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN1972	31DEC1972	N
			Ligament operation	01JAN2005	31DEC2005	N
			Meniscus operation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131142	Gastrointestinal disorders	Diverticulum	01JAN2005		Y
		Infections and infestations	Diverticulitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131144	Gastrointestinal disorders	Haemorrhoids	01JAN1970	31DEC1972	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Infections and infestations	Infection	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1988	31DEC1988	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
			Haemorrhoid operation	01JAN1972	31DEC1972	N
			Spinal fusion surgery	01JAN1972	31DEC1972	N
				01JAN1988	31DEC1988	N
			Vasectomy	01JAN1978	31DEC1978	N
	C4591001 1013 10131150	Cardiac disorders	Supraventricular tachycardia	01JAN1999		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1980		Y
		Infections and infestations	Genital herpes	01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2010		Y
			Protein intolerance	01JAN2005		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2010		Y
	C4591001 1013 10131151	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131152	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131153	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1013 10131154	Investigations	Blood cholesterol increased	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1013 10131157	Cardiac disorders	Coronary artery disease	01JAN2010		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016	31DEC2018	N
	C4591001 1013 10131161	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1998		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Sebaceous cyst excision	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131162	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar disorder	01JAN2015		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2013	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
				01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1996	31DEC1996	N
			Hip arthroplasty	01NOV2019	30NOV2019	N
			Urinary bladder suspension	01JAN2016		Y
	C4591001 1013 10131168	Cardiac disorders	Bundle branch block right	01JAN2015		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN1969		Y
			Tinnitus	01JAN1969		Y
		Gastrointestinal disorders	Constipation	01JAN2011	31DEC2016	N
			Inguinal hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Hypersensitivity	01JAN1950		Y
		Infections and infestations	Sinusitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
		Nervous system disorders	Migraine without aura	01JAN1997		Y
			Tension headache	01JAN1997		Y
		Surgical and medical procedures	Ear tube insertion	01APR2015	30APR2015	N
			Inguinal hernia repair	01JAN2014	31DEC2014	N
			Myringotomy	01APR2015	30APR2015	N
			Sinus operation	01APR2015	30APR2015	N
			Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1013 10131170	Endocrine disorders	Hypothyroidism	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2012	31DEC2018	N
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Ligament operation	01JAN1996	31DEC1996	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Goitre	01JAN1996	31DEC1997	N
	C4591001 1013 10131175	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1976	31DEC1979	N
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
			Thyroidectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1013 10131176	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2005		Y
			Hiatus hernia	01JAN2005		Y
			Inguinal hernia	01JAN2016	31DEC2017	N
			Small intestinal perforation	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31DEC2009	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2000	31DEC2000	N
				01JAN2009	31DEC2009	N
			Small intestinal resection	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131178	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131181	Immune system disorders	Iodine allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1998	31DEC2000	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
			Major depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131183	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1013 10131184	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1979	31DEC1979	N
	C4591001 1013 10131186	Eye disorders	Astigmatism	01JAN1966		Y
			Myopia	01JAN1966		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1976		Y
			Intestinal obstruction	01JAN1982	31DEC1982	N
				01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1976		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2013		Y
			Osteoarthritis	01JAN2005	31MAR2019	N
				01JAN2015	31JUL2019	N
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1985	31DEC2015	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1972		Y
		Surgical and medical procedures	Hip arthroplasty	01JUL2019	31JUL2019	N
				01MAR2019	31MAR2019	N
			Intestinal operation	01JAN1982	31DEC1982	N
			Penile prosthesis insertion	01JAN2015	31DEC2015	N
	C4591001 1013 10131189	Injury, poisoning and procedural complications	Tendon rupture	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Varicose vein operation	01FEB2014	28FEB2014	N
	C4591001 1013 10131191	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2010	31DEC2011	N
		Reproductive system and breast disorders	Menorrhagia	01APR2009	30APR2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Cancer surgery	01JAN2011	31DEC2011	N
			Hysterectomy	01OCT2009	31OCT2009	N
			Oophorectomy bilateral	01OCT2009	31OCT2009	N
			Salpingectomy	01OCT2009	31OCT2009	N
	C4591001 1013 10131193	Endocrine disorders	Basedow's disease	01JAN1992	31DEC1998	N
			Hypothyroidism	01JAN1997		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
			Umbilical hernia	01JAN1992	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
			Osteoporosis	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2002	31DEC2002	N
			Caesarean section	01JAN1992	31DEC1992	N
				01JAN1995	31DEC1995	N
				01JAN2000	31DEC2000	N
			Endometrial ablation	01JAN2008	31DEC2008	N
			Radioactive iodine therapy	01JAN1998	31DEC1998	N
			Umbilical hernia repair	01JAN2002	31DEC2002	N
	C4591001 1013 10131194	Psychiatric disorders	Major depression	01JAN1999		Y
		Surgical and medical procedures	Gastric bypass	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131198	Immune system disorders	Food allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Diabetic neuropathy	01FEB2018		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Nightmare	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1013 10131201	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Wrist surgery	01FEB1990	28FEB1990	N
	C4591001 1013 10131202	Gastrointestinal disorders	Pancreatitis	01JAN2017	31DEC2019	N
		Infections and infestations	Septic arthritis staphylococcal	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN1997		Y
			Tendon rupture	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
		Psychiatric disorders	Alcohol abuse	01JAN1990	31DEC2019	N
		Renal and urinary disorders	Pollakiuria	01JAN2017	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131203	Surgical and medical procedures	Finger amputation	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1991	31DEC1991	N
				01JAN2018	31DEC2018	N
				01SEP2019	30SEP2019	N
			Squamous cell carcinoma	01JAN1991	31DEC1991	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2009	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN1960	31DEC1967	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cancer surgery	01JAN1991	31DEC1991	N
			01JAN2018	31DEC2018	N	
		Skin neoplasm excision	01JAN1991	31DEC1991	N	
			01JAN2018	31DEC2018	N	
			01SEP2019	30SEP2019	N	
	C4591001 1013 10131206	Gastrointestinal disorders	Volvulus	01MAR2007	31MAR2007	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
		Surgical and medical procedures	Colectomy	01MAR2007	31MAR2007	N
	C4591001 1013 10131212	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1990		Y
		Surgical and medical procedures	Aortic valve repair	01JAN2018	31JAN2018	N
			Carotid artery stent insertion	01JUN2018	30JUN2018	N
			Carotid revascularisation	01AUG2018	31AUG2018	N
	C4591001 1013 10131213	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01OCT2018	31OCT2018	N
		Surgical and medical procedures	Otoplasty	01OCT2018	31OCT2018	N
			Skin neoplasm excision	01OCT2018	31OCT2018	N
	C4591001 1013 10131217	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Psychiatric disorders	Major depression	01JAN2006	31DEC2006	N
	C4591001 1013 10131222	Gastrointestinal disorders	Umbilical hernia	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1989	31DEC1989	N
				01JAN1992	31DEC1992	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Arthroscopic surgery	01JAN1989	31DEC1989	N
			Cervical conisation	01JAN1976	31DEC1976	N
			Shoulder operation	01JAN1992	31DEC1992	N
			Umbilical hernia repair	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131226	Gastrointestinal disorders	Umbilical hernia	01MAY2014	31MAY2014	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast prosthesis removal	01APR2018	30APR2018	N
			Cholecystectomy	01MAY2014	31MAY2014	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01MAY1988	31MAY1988	N
			Umbilical hernia repair	01MAY2014	31MAY2014	N
			Uterine dilation and curettage	01SEP1986	30SEP1986	N
	C4591001 1013 10131227	Musculoskeletal and connective tissue disorders	Spinal stenosis	01JUN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JUN2019		Y
		Psychiatric disorders	Alcohol abuse	01JAN1978	31JUL2019	N
			Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1013 10131230	Gastrointestinal disorders	Diverticulum	01JUN2010		Y
			Inguinal hernia	01JUN1980	30JUN1980	N
		General disorders and administration site conditions	Therapeutic response unexpected	01JAN2018	31JUL2018	N
		Immune system disorders	Food allergy	01JAN1975		Y
			Hypersensitivity	01JAN1961		Y
		Infections and infestations	Diverticulitis	01JUN2020	31JUL2020	N
		Psychiatric disorders	Anxiety	01JUN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JUN2012	30JUN2012	N
		Surgical and medical procedures	Inguinal hernia repair	01JUN1980	30JUN1980	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131232	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Peripheral nerve injury	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1013 10131234	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2000	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JUL2019	30SEP2019	N
		Investigations	Arthroscopy	01SEP2019	30SEP2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2009		Y
	C4591001 1013 10131235	Surgical and medical procedures	Haemorrhoid operation	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
		Surgical and medical procedures	Bunion operation	01JAN2003	31DEC2003	N
			Joint arthroplasty	01DEC2017	31DEC2017	N
	C4591001 1013 10131236	Hepatobiliary disorders	Cholecystitis	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2009		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01SEP2019	30SEP2019	N
			Uterine leiomyoma	01JAN1995	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Micrographic skin surgery	01SEP2019	30SEP2019	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Uterine dilation and curettage	01JAN1998	31DEC1998	N
				01JAN2000	31DEC2000	N
	C4591001 1013 10131240	Cardiac disorders	Aortic valve incompetence	01JAN2014		Y
			Ventricular extrasystoles	01JAN2014		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1986	31DEC1986	N
				01JAN2008	31DEC2008	N
		Immune system disorders	Allergy to venom	01JAN1970		Y
			Drug hypersensitivity	01JAN1962		Y
				01JAN1980		Y
			Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1979	31DEC1979	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
			Scoliosis	01JAN2008		Y
		Surgical and medical procedures	Appendectomy	01JAN1979	31DEC1979	N
			Inguinal hernia repair	01JAN1986	31DEC1986	N
				01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131242	Endocrine disorders	Hypothyroidism	01JAN2019		Y
			Thyroid mass	01DEC2018	31DEC2018	N
		Hepatobiliary disorders	Hepatic cyst	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Uterine cyst	01JAN2008	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Salpingo-oophorectomy bilateral	01JAN2010	31DEC2010	N
			Thyroidectomy	01DEC2018	31DEC2018	N
	C4591001 1013 10131243	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Sciatica	01FEB2017		Y
		Reproductive system and breast disorders	Prostatitis	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2000		Y
		Surgical and medical procedures	Prostatic operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1013 10131244	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
				01JAN2013		Y
				01JAN2015		Y
			Spinal osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2000		Y
			Major depression	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1013 10131247	Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Prostatic urethral lift procedure	01FEB2019		Y
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1013 10131248	Infections and infestations	Appendicitis	01MAY2007	31MAY2007	N
		Investigations	Precancerous cells present	01APR2015	30APR2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2018		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JUL2008		Y
		Surgical and medical procedures	Appendicectomy	01MAY2007	31MAY2007	N
			Colectomy	01APR2015	30APR2015	N
			Polypectomy	01APR2015	30APR2015	N
		Vascular disorders	Hypertension	01APR2018		Y
	C4591001 1013 10131249	Infections and infestations	Chronic tonsillitis	01JAN1966	31DEC1966	N
		Surgical and medical procedures	Mammoplasty	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1013 10131253	Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2003		Y
			Generalised anxiety disorder	01JAN2003		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
			Mammoplasty	01JAN2000	31DEC2000	N
	C4591001 1013 10131257	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc protrusion	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131260	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2003	31DEC2003	N
			Tendon rupture	01JAN2004	31DEC2004	N
		Investigations	Arthroscopy	01JAN2004	31DEC2004	N
				01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Articular calcification	01JAN2011	31DEC2011	N
			Osteoarthritis	01JAN2003	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2003	31DEC2003	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131261	Eye disorders	Cataract	01JAN1957	31DEC2001	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2009	31DEC2009	N
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Tenoplasty	01JAN2009	31DEC2009	N
				01JAN2017	31DEC2017	N
	C4591001 1013 10131265	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2019		Y
			Vitamin B complex deficiency	01FEB2019		Y
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1013 10131270	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Infections and infestations	Herpes zoster	01AUG2020	15AUG2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1984	31DEC1984	N
		Psychiatric disorders	Major depression	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Lichen planopilaris	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1013 10131273	Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
	C4591001 1013 10131274	Endocrine disorders	Hypothyroidism	01JAN1965		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007	31DEC2017	N
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
			Knee arthroplasty	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131277	Eye disorders	Angle closure glaucoma	01SEP2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN1995		Y
		Surgical and medical procedures	Cataract operation	01JUL2015	31JUL2015	N
	C4591001 1013 10131278	Metabolism and nutrition disorders	Iron deficiency	01JUN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUN2017		Y
		Social circumstances	Postmenopause	01DEC2015		Y
		Surgical and medical procedures	Female sterilisation	01DEC1981	31DEC1981	N
	C4591001 1013 10131279	Gastrointestinal disorders	Hiatus hernia	01JAN2015	31JUL2015	N
		Social circumstances	Postmenopause	01AUG2019		Y
		Surgical and medical procedures	Caesarean section	14JUN1995	14JUN1995	N
			Hernia hiatus repair	01JUL2015	31JUL2015	N
	C4591001 1013 10131282	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003	31DEC2008	N
				01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Knee operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131284	Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
			Spinal fusion surgery	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131286	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1985	31DEC1990	N
			Tendon rupture	01JAN2005		Y
		Investigations	Arthroscopy	01JAN1990	31DEC1990	N
				01JAN2001	31DEC2001	N
				01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
	C4591001 1013 10131289	Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1995	31DEC1995	N
	C4591001 1013 10131294	Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1013 10131295	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131297	Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
		Endocrine disorders	Hyperthyroidism	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2016		Y
			Trigger finger	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2014		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1013 10131298	Surgical and medical procedures	Tendon sheath incision	01JAN2003	31DEC2003	N
			Urinary bladder suspension	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1013 10131300	Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131300	Gastrointestinal disorders	Intestinal obstruction	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rickets	01JAN1945	31DEC1948	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Intestinal operation	01JAN2016	31DEC2016	N
		Spinal corpectomy	01FEB2020	29FEB2020	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131301	Blood and lymphatic system disorders	Pseudolymphoma	01MAR2018		Y
		Metabolism and nutrition disorders	Obesity	01AUG2008		Y
			Type 2 diabetes mellitus	01AUG2006		Y
		Psychiatric disorders	Alcohol use disorder	01JUN1981	28FEB2010	N
			Depression	01AUG2006		Y
		Vascular disorders	Hypertension	01AUG2006		Y
	C4591001 1013 10131310	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Renal stone removal	01JAN2019	31DEC2019	N
			Skin lesion removal	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
	C4591001 1013 10131314	Cardiac disorders	Angina pectoris	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Post procedural infection	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018		Y
			Spinal stenosis	01JAN2015	31DEC2018	N
		Nervous system disorders	Nystagmus	01JAN1960		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131320	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Surgical and medical procedures	Chondroplasty	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1013 10131323	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Mastectomy	01JAN1982	31DEC1982	N
	C4591001 1013 10131324	Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131326	Immune system disorders	Food allergy	01JAN2011		Y
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Bone cyst	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myalgia	01JAN2000		Y
			Osteolysis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1013 10131327	Infections and infestations	Herpes simplex	01MAR2010		Y
			Tonsillitis	01MAR1956	31MAR1956	N
		Injury, poisoning and procedural complications	Ligament rupture	01MAR1999	31MAR1999	N
		Metabolism and nutrition disorders	Gout	01MAR2010	31MAR2010	N
			Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Coccydynia	01MAR1982	31MAR1982	N
		Surgical and medical procedures	Coccygectomy	01MAR1982	31MAR1982	N
			Ligament operation	01MAR1999	31MAR1999	N
			Rhinoplasty	01MAR1990	31MAR1990	N
			Tonsillectomy	01MAR1956	31MAR1956	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1013 10131328	Cardiac disorders	Aortic valve incompetence	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN1972		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131329	Immune system disorders	Hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Nasal septum deviation	01JAN2016	31DEC2016	N
			Sinus congestion	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Bone cyst excision	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2020	31JAN2020	N
			Sinus operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1013 10131330	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31OCT2013 31OCT2015	N N
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31OCT2007	N
		Social circumstances	Postmenopause	01OCT2007		Y
		Surgical and medical procedures	Caesarean section	02JAN1992	02JAN1992	N
			Carpal tunnel decompression	01OCT2013	31OCT2013	N
				01OCT2015	31OCT2015	N
			Endometrial ablation	01OCT2007	31OCT2007	N
			Hip arthroplasty	01OCT2018	31OCT2018	N
	C4591001 1013 10131331	Endocrine disorders	Hypothyroidism	01APR1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Skin neoplasm excision	01JUL2017	31JUL2017	N
	C4591001 1013 10131333	Investigations	Bone density decreased	01AUG2008		Y
		Nervous system disorders	Migraine	01AUG2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2008		Y
	C4591001 1013 10131334	Surgical and medical procedures	Debridement	01OCT2007	31OCT2007	N
	C4591001 1013 10131335	Cardiac disorders	Coronary artery disease	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1975		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2017		Y
			Fibromyalgia	01JAN2016		Y
			Rotator cuff syndrome	01JAN2015		Y
		Nervous system disorders	Cognitive disorder	01JAN2016		Y
			Diabetic neuropathy	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1988	31DEC1988	N
			Knee arthroplasty	01JAN1969	31DEC1969	N
				01JAN2016	31DEC2016	N
			Toe amputation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1013 10131336	Eye disorders	Retinopathy	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 1 diabetes mellitus	01JAN1966		Y
		Musculoskeletal and connective tissue disorders	Neuropathic arthropathy	01JAN2011		Y
		Psychiatric disorders	Major depression	01JAN2000		Y
		Surgical and medical procedures	Exeresis	01JAN1991	31DEC1991	N
			Limb operation	01JAN2011	31DEC2011	N
			Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131337	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	16JUL2020	N
			Breast cancer	01JAN2006	06JUN2006	N
			Uterine leiomyoma	01JAN2004	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Intraocular lens implant	01MAR2020	31MAR2020	N
			Ligament operation	01JAN1982	31DEC1982	N
			Mastectomy	06JUN2006	06JUN2006	N
			Skin neoplasm excision	16JUL2020	16JUL2020	N
		Vascular disorders	Lymphoedema	01JAN2008		Y
	C4591001 1013 10131341	Injury, poisoning and procedural complications	Joint dislocation	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	08AUG1990	08AUG1990	N
				17MAR1987	17MAR1987	N
			Cartilage graft	01JAN2010	31DEC2010	N
			Osteotomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131342	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2012	31DEC2012	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
		Surgical and medical procedures	Tenoplasty	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131344	Infections and infestations	Tonsillitis	29APR1997	29APR1997	N
		Renal and urinary disorders	Nephrolithiasis	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	29APR1997	29APR1997	N
		Surgical and medical procedures	Cholecystectomy	22JAN2020	22JAN2020	N
			Duodenal switch	20JAN2020	20JAN2020	N
			Gastrectomy	22OCT2010	22OCT2010	N
				23JAN2020	23JAN2020	N
			Hernia hiatus repair	21JAN2020	21JAN2020	N
			Neurectomy	31JUL2013	31JUL2013	N
			Tonsillectomy	29APR1997	29APR1997	N
			Turbinectomy	29APR1997	29APR1997	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1013 10131345	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1013 10131346	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Varicocele	01JAN1979	31DEC2017	N
		Social circumstances	Testicular prosthesis user	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Nerve block	01JAN2020	31JAN2020	N
			Orchidectomy	01JAN2017	31DEC2017	N
	C4591001 1013 10131347	Infections and infestations	Sinusitis	01JUL2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131350	Eye disorders	Cataract	01JAN2018	31DEC2020	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
				01JAN2016	31DEC2016	N
			Prostate cancer	01JAN2017	31DEC2017	N
			Squamous cell carcinoma	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cancer surgery	01JAN2016	31DEC2016	N
			Cataract operation	01FEB2020	29FEB2020	N
			Chondroplasty	01JAN1990	31DEC1990	N
			Radiotherapy to prostate	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1013 10131354	Cardiac disorders	Coronary artery disease	01JAN1990	31DEC2011	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatomyositis	01FEB2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Coronary artery bypass	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1013 10131356	Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1013 10131358	Gastrointestinal disorders	Abdominal hernia	01AUG2018	31AUG2018	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2011	N
		Surgical and medical procedures	Abdominal hernia repair	01AUG2018	31AUG2018	N
			Radical prostatectomy	01JAN2011	31DEC2011	N
	C4591001 1013 10131359	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUL2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Benign tumour excision	01JAN2009	31DEC2009	N
			Mammoplasty	01JAN2005	31DEC2005	N
	C4591001 1013 10131360	Cardiac disorders	Aortic valve incompetence	01MAR2018	31MAY2018	N
		Gastrointestinal disorders	Inguinal hernia	01JUN2013	22JUN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
			Compartment syndrome	01JAN2008	31DEC2012	N
				01JAN2009	31DEC2013	N
			Intervertebral disc protrusion	01JAN1991	31DEC1991	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01AUG2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAY2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1991		Y
		Surgical and medical procedures	Aortic valve replacement	01MAY2018	31MAY2018	N
			Coronary artery bypass	01MAY2018	31MAY2018	N
			Inguinal hernia repair	22JUN2020	22JUN2020	N
			Tendon sheath incision	04DEC2013	04DEC2013	N
			Wrist surgery	07SEP2012	07SEP2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131362	Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
	C4591001 1013 10131363	Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1013 10131367	Endocrine disorders	Open reduction of fracture	01JAN2002	31DEC2002	N
			Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2005	31DEC2005	N
	C4591001 1013 10131368	Surgical and medical procedures	Oophorectomy bilateral	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Investigations	Blood triglycerides increased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01MAR2014	31MAR2014	N
		Product issues	Stent malfunction	09NOV2015	09NOV2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2003		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Coronary arterial stent insertion	01JAN2004	31DEC2004	N
				01JAN2010	31DEC2010	N
			Haemorrhoid operation	28FEB2017	28FEB2017	N
			Knee operation	01JAN1990	31DEC1990	N
				01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131369	Gastrointestinal disorders	Rotator cuff repair	01MAR2014	31MAR2014	N
			Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Hernia	01JAN1952	31DEC1952	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Erectile dysfunction	01JAN2005		Y
			Chronic obstructive pulmonary disease	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Fasciotomy	01JAN2014	31DEC2014	N
			Hernia repair	01JAN1952	31DEC1952	N
			Vasectomy	01JAN1992	31DEC1992	N
			Umbilical hernia	01JAN2017	31DEC2017	N
		C4591001 1013 10131372	Gastrointestinal disorders			
	Infections and infestations		Appendicitis	01JAN1982	31DEC1982	N
	Injury, poisoning and procedural complications		Meniscus injury	01JAN1988	31DEC1988	N
						31DEC1998
	Musculoskeletal and connective tissue disorders	Investigations	Arthroscopy	01JAN1998	31DEC1998	N
			Osteoarthritis	01JAN1998		Y
	Psychiatric disorders		Spinal osteoarthritis	01JAN1998		Y
			Bipolar disorder	01JAN2000		Y
			Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1013 10131374	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Back pain	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1013 10131378	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	08MAR1985	08MAR1985	N
				10DEC2001	10DEC2001	N
				28DEC2002	28DEC2002	N
			Female sterilisation	28DEC2002	28DEC2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131380	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1013 10131382	Investigations	Cardiac murmur	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1990	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1013 10131384	Cardiac disorders	Bradycardia	01JAN2000		Y
			Sinus arrhythmia	01JAN2015	31JAN2015	N
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2013	31DEC2016	N
			Myxoid cyst	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2015	31JAN2015	N
			Synovial cyst removal	01JAN2004	31DEC2004	N
	C4591001 1013 10131386	Injury, poisoning and procedural complications	Ligament rupture	01JAN1978	31DEC1980	N
		Surgical and medical procedures	Ligament operation	01JAN1980	31DEC1980	N
	C4591001 1013 10131387	Cardiac disorders	Mitral valve prolapse	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01AUG2000		Y
		Gastrointestinal disorders	Inguinal hernia	01AUG1980	31AUG1980	N
		Investigations	Blood triglycerides increased	01AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1948		Y
			Chronic obstructive pulmonary disease	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01AUG1989	31AUG1989	N
			Inguinal hernia repair	01AUG1980	31AUG1980	N
		Vascular disorders	Hypertension	01AUG2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131390	Injury, poisoning and procedural complications	Foot fracture	16AUG2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2002	31DEC2002	N
	C4591001 1013 10131393	Vascular disorders	Hypertension	01AUG1993		Y
	C4591001 1013 10131399	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013	31DEC2016	N
		Immune system disorders	Mite allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
			Wrist fracture	01FEB2019	28FEB2019	N
		Investigations	Catheterisation cardiac	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
			Foot deformity	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Bunion operation	01JAN2015	31DEC2015	N
			Fracture treatment	01FEB2019	28FEB2019	N
			Intraocular lens implant	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
				01JAN2016	31DEC2016	N
			Ligament operation	01JAN2011	31DEC2011	N
			Oesophagogastric fundoplasty	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Renal stone removal	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131402	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN2001		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2009	31DEC2014	N
		Surgical and medical procedures	Fallopian tube operation	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Meniscus operation	01JAN1988	31DEC1988	N
				01JAN2008	31DEC2008	N
			Oophorectomy bilateral	01JAN2014	31DEC2014	N
	C4591001 1013 10131404	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Foot operation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131410	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	05JUL1982	05JUL1982	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				10APR1986	10APR1986	N
				19SEP1989	19SEP1989	N
	C4591001 1013 10131414	Immune system disorders	Drug hypersensitivity	01JAN1949		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2012	31DEC2015	N
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2018	15JAN2020	N
		Reproductive system and breast disorders	Endometriosis	01AUG1989		Y
			Ovarian cyst	01JAN1986	31DEC1989	N
		Surgical and medical procedures	Bunion operation	01AUG2015	31AUG2015	N
			Craniotomy	15JAN2020	15JAN2020	N
			Oophorectomy	01AUG1989	31AUG1989	N
		Vascular disorders	Hypertension	15JAN2020		Y
	C4591001 1013 10131415	Cardiac disorders	Atrial fibrillation	01AUG2016		Y
			Supraventricular tachycardia	01AUG2003		Y
		Eye disorders	Blepharitis	01MAY2020		Y
		Immune system disorders	Seasonal allergy	01AUG2014		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2014		Y
			Periarthritis	01AUG2003	31AUG2003	N
		Psychiatric disorders	Insomnia	01AUG2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac ablation	01APR2020	30APR2020	N
			Rotator cuff repair	01AUG2003	31AUG2003	N
	C4591001 1013 10131428	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1013 10131429	Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01JAN2011	31DEC2011	N
	C4591001 1013 10131431	Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Cardiac disorders	Cardiac failure congestive	01JAN2018	31DEC2018	N
			Coronary artery disease	01JAN1995		Y
			Myocardial infarction	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
			Ventricular tachycardia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN1980		Y
			Hypercholesterolaemia	01JAN1995		Y
			Obesity	01MAR2020		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
				01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017	31DEC2017	N
			Implantable defibrillator replacement	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1013 10131433	Eye disorders	Glaucoma	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN1958	31DEC1958	N
	C4591001 1013 10131434	Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Seasonal allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Meniscus injury	07JUL1999	07JUL1999	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1997		Y
			Morton's neuralgia	01JAN2007	01FEB2008	N
		Reproductive system and breast disorders	Ovarian cyst	24APR1997	24APR1997	N
		Surgical and medical procedures	Hysterectomy	24APR1997	24APR1997	N
			Meniscus operation	07JUL1999	07JUL1999	N
			Neurectomy	01FEB2008	01FEB2008	N
	C4591001 1013 10131435	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Neck dissection	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN2000	31DEC2000	N
	C4591001 1013 10131443	Psychiatric disorders	Anxiety	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Salpingo-oophorectomy bilateral	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131450	Gastrointestinal disorders	Haemorrhoids	01JAN1999	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	15OCT1989	15OCT1989	N
				28JAN1992	28JAN1992	N
			Female sterilisation	28JAN1992	28JAN1992	N
			Haemorrhoid operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1013 10131453	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Myomectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131455	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2005		Y
			Migraine	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	25SEP1990	25SEP1990	N
			Rhinoplasty	01JAN1985	31DEC1985	N
			Tendon sheath incision	01JAN2018	31DEC2018	N
	C4591001 1013 10131456	Eye disorders	Strabismus	01JAN1967	31DEC1967	N
		Injury, poisoning and procedural complications	Skin laceration	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Strabismus correction	01JAN1967	31DEC1967	N
			Wound closure	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131457	Cardiac disorders	Palpitations	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
	C4591001 1013 10131460	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine carcinoma in situ	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fallopian tube operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
	C4591001 1013 10131461	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Psychiatric disorders	Insomnia	01MAY2020		Y
			Major depression	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131462	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1956		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
	C4591001 1013 10131465	General disorders and administration site conditions	Pelvic mass	01JAN1999	31DEC1999	N
		Infections and infestations	Herpes simplex	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Eosinophilic cellulitis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Fallopian tube operation	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Oophorectomy	01JAN1999	31DEC1999	N
	C4591001 1013 10131466	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
	C4591001 1013 10131479	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN1972		Y
	C4591001 1013 10131480	Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
			Blood testosterone decreased	01JAN2020		Y
		Surgical and medical procedures	Liposuction	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131481	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
	C4591001 1013 10131482	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Glaucoma	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1013 10131483	Cardiac disorders	Sinus arrhythmia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2010	31DEC2010	N
			Caesarean section	01FEB1988	01FEB1988	N
				15AUG1983	15AUG1983	N
				16APR1982	16APR1982	N
	C4591001 1013 10131485	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypersensitivity	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1013 10131488	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1991		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2016	31DEC2016	N
			Meniscus injury	01JAN2003	31DEC2003	N
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	30NOV2000	N
			Spondylitis	01JAN2017		Y
			Trigger finger	01JAN2015	31DEC2016	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Bunion operation	01NOV2000	30NOV2000	N
				01SEP2000	30SEP2000	N
			Ligament operation	01JAN1996	31DEC1996	N
			Meniscus operation	01JAN2003	31DEC2003	N
				01JAN2015	31DEC2015	N
			Tendon sheath incision	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1013 10131489	Ear and labyrinth disorders	Otosclerosis	01JAN2001	31DEC2017	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2017	31DEC2017	N
			Lower limb fracture	01JAN2017	31DEC2017	N
			Spinal compression fracture	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tibia fracture	01JAN2017	31DEC2017	N
			Wrist fracture	01JAN2017	31DEC2017	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
			Bone operation	01JAN2017	31DEC2017	N
			Stapedectomy	01JAN2001	31DEC2001	N
				01JAN2017	31DEC2017	N
	C4591001 1013 10131490	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Infections and infestations	Tonsillitis	01JAN1961	31DEC1961	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1961	31DEC1961	N
	C4591001 1013 10131491	Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131494	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1013 10131495	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chronic tonsillitis	01JAN1988	31DEC1988	N
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Spinal laminectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1013 10131496	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
	C4591001 1013 10131497	Endocrine disorders	Basedow's disease	01JAN1993		Y
		Eye disorders	Glaucoma	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Large intestine polyp	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Cellulitis	01JAN2014	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
			Hypomagnesaemia	01JAN2010		Y
			Vitamin B12 deficiency	01JAN2010		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
			Uterine cancer	01JAN2013	31DEC2013	N
		Nervous system disorders	Essential tremor	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Mastectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131505	Gastrointestinal disorders	Haemorrhoids	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Food allergy	01JAN1981		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1984	31DEC2004	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1013 10131506	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131508	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2012	31DEC2012	N
			Osteoporosis	01MAY2020		Y
			Spinal stenosis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Bunion operation	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
	C4591001 1013 10131509	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131510	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
			Polyuria	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1013 10131511	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131512	Endocrine disorders	Hypothyroidism	01JAN2010		Y
			Thyroid cyst	01JAN2010		Y
		Reproductive system and breast disorders	Uterine cyst	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Uterine cystectomy	01JAN1998	31DEC1998	N
	C4591001 1013 10131516	Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Allergy to chemicals	01JAN2000		Y
			Rubber sensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Vascular disorders	Aortic aneurysm	01JAN2010		Y
			Hypertension	01JAN2010		Y
	C4591001 1013 10131517	Cardiac disorders	Coronary artery disease	01JAN2005		Y
			Myocardial infarction	14FEB2016	14FEB2016	N
		Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1951		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1978		Y
	C4591001 1013 10131519	Surgical and medical procedures	Coronary arterial stent insertion	14FEB2016	14FEB2016	N
		Injury, poisoning and procedural complications	Ligament injury	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Ligament operation	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1013 10131520	Infections and infestations	Cellulitis	01AUG2020	31AUG2020	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2014		Y
		Surgical and medical procedures	Arterial stent insertion	01JAN2014		Y
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
	C4591001 1013 10131521	Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Spinal compression fracture	01NOV2014	30NOV2014	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Finger amputation	01JAN1989	31DEC1989	N
			Inguinal hernia repair	01JAN1990	31DEC1990	N
			Spinal laminectomy	01NOV2014	30NOV2014	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131523	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
			Major depression	01JAN1985		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31JAN2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	16JUL2007	16JUL2007	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131525	Eye disorders	Ocular hypertension	01JAN2008		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1975	31DEC1975	N
			Inguinal hernia	01JAN1984	31DEC1984	N
			Umbilical hernia	01JAN2004	31DEC2004	N
		Investigations	Arthroscopy	01JAN1994	31DEC1994	N
				01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1993	31DEC1994	N
				01JAN2013	31DEC2013	N
			Tenosynovitis stenosans	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2013		Y
		Surgical and medical procedures	Cartilage operation	01JAN1987	31DEC1987	N
			Haemorrhoid operation	01JAN1975	31DEC1975	N
				01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN1984	31DEC1984	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Tendon sheath incision	01JAN2016	31DEC2016	N
			Umbilical hernia repair	01JAN2004	31DEC2004	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1013 10131527	Eye disorders	Angle closure glaucoma	01JAN2006		Y
			Cataract	01JAN2015	31DEC2016	N
			Retinal detachment	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
			Cataract operation	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Retinopexy	01JAN2000	31DEC2000	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Tendon sheath incision	01JAN2011	31DEC2011	N
	C4591001 1013 10131528	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1986		Y
			Type 2 diabetes mellitus	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2003		Y
	C4591001 1013 10131536	Vascular disorders	Hypertension	01JAN2003		Y
		Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Infections and infestations	Fungal skin infection	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Psychiatric disorders	Major depression	01JAN2006		Y
		Surgical and medical procedures	Meniscus operation	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1013 10131537	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1013 10131539	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Vulvovaginal mycotic infection	01AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131540	Eye disorders	Cataract	01JAN2004	31AUG2005	N
			Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Abdominal hernia	10MAR2009	10SEP2009	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	09JAN2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Abdominal hernia repair	10SEP2009	10SEP2009	N
			Cataract operation	01AUG2005	31AUG2005	N
				01JUL2005	31JUL2005	N
			Hip arthroplasty	09JAN2018	09JAN2018	N
				21FEB2017	21FEB2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131543	Psychiatric disorders	Major depression	01JAN2014		Y
		Social circumstances	Tobacco user	01JAN2012		Y
	C4591001 1013 10131548	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2019		Y
	C4591001 1013 10131549	Infections and infestations	Cervicitis human papilloma virus	01MAY2013	31MAY2013	N
		Investigations	Precancerous cells present	01MAY2013	31MAY2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Hypertriglyceridaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31AUG2018	N
		Nervous system disorders	Tension headache	01JAN2015		Y
		Psychiatric disorders	Major depression	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Surgical and medical procedures	Fallopian tube operation	01MAY2013	31MAY2013	N
			Hip arthroplasty	01AUG2018	31AUG2018	N
			Hysterectomy	01MAY2013	31MAY2013	N
			Oophorectomy bilateral	01MAY2013	31MAY2013	N
		Vascular disorders	Aortic aneurysm	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1013 10131551	Metabolism and nutrition disorders	Gout	01AUG2020		Y
			Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
			Vitamin D deficiency	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	11SEP2020		Y
		Surgical and medical procedures	Caesarean section	14MAR1985	14MAR1985	N
				17FEB1983	17FEB1983	N
				21JUL1981	21JUL1981	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131554	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2003	31DEC2003	N
			Rheumatoid arthritis	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2009	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy bilateral	01JAN2009	31DEC2009	N
			Salpingectomy	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131555	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JAN2002	31DEC2002	N
			Intervertebral disc operation	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131558	Cardiac disorders	Coronary artery occlusion	01JUL2020	29JUL2020	N
		Hepatobiliary disorders	Cholecystitis	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01DEC2018		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
			Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Coronary arterial stent insertion	29JUL2020	29JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131560	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Iron deficiency	01APR2020		Y
			Vitamin B12 deficiency	01APR2020		Y
		Nervous system disorders	Migraine with aura	01JAN1992		Y
		Psychiatric disorders	Major depression	01JAN1982		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1976	29FEB2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N
			Urinary bladder suspension	01FEB2020	29FEB2020	N
	C4591001 1013 10131561	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2017		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1013 10131566	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Hypertriglyceridaemia	01JAN2014		Y
			Obesity	01JAN1993		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lobular breast carcinoma in situ	01JAN2019	31JAN2019	N
		Nervous system disorders	Migraine without aura	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Granuloma annulare	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131574	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007	31DEC2012	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2007		Y
			Major depression	01JAN2007		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2012	31DEC2012	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1013 10131578	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1965		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131579	Cardiac disorders	Coronary artery occlusion	01JAN2010	31DEC2015	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2006		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	31DEC2015	31DEC2015	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131583	Blood and lymphatic system disorders	Anaemia	01JAN1968		Y
		Surgical and medical procedures	Mammoplasty	01JAN1984	31DEC1984	N
	C4591001 1013 10131590	Endocrine disorders	Basedow's disease	01JAN2002		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2003	31DEC2003	N
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Surgical and medical procedures	Jaw operation	01JAN2003	31DEC2003	N
			Radioactive iodine therapy	01JAN2002	31DEC2002	N
			Umbilical hernia repair	01JAN2003	31DEC2003	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1013 10131596	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2009	31DEC2009	N
	C4591001 1013 10131602	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Hepatobiliary disorders	Cholecystitis	01APR1995	30APR1995	N
		Immune system disorders	Food allergy	01JAN1995		Y
		Infections and infestations	Chronic tonsillitis	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Caesarean section	05APR1980	05APR1980	N
			Cancer surgery	01JAN2009	31DEC2009	N
			Cholecystectomy	01APR1995	30APR1995	N
			Female sterilisation	01JAN1982	31DEC1982	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1013 10131604	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Atrial appendage closure	01JUN2020	30JUN2020	N
			Cardiac ablation	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1013 10131609	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1013 10131615	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Tongue discomfort	01JAN2008		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Intervertebral disc degeneration	01JAN2017		Y
			Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1994	31DEC1995	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1992	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
			Endometrial ablation	01JAN1995	31DEC1995	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1013 10131617	Cardiac disorders	Atrial fibrillation	01FEB2020		Y
				01JAN2016	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1013 10131618	Eye disorders	Cataract	01JAN2006	31DEC2006	N
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2006		Y
					31DEC2006	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131620	Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1013 10131623†	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	HIV infection	01JAN1993		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN1996	31DEC1996	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Cancer surgery	01JAN1996	31DEC1996	N
			Fracture treatment	01JAN1998	31DEC1998	N
			Peripheral artery bypass	01JAN2017	31DEC2017	N
			Shoulder operation	01JAN1999	31DEC1999	N
			Vascular stent insertion	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131646	Cardiac disorders	Cardiovascular disorder	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Chest pain	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2012		Y
		Surgical and medical procedures	Angioplasty	01JAN2018	31DEC2018	N
			Atrial septal defect repair	01JAN1965		Y
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131648	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Major depression	01JAN2010	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131650	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN2009	31DEC2009	N
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131655	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1980		Y
			Drug hypersensitivity	01JAN1967		Y
			Food allergy	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1013 10131661	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131662	Ear and labyrinth disorders	Deafness	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Iodine allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Cochlea implant	01JAN2019	31DEC2019	N
			Splenectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131672	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131679	Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1013 10131684	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1955		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1013 10131686	Gastrointestinal disorders	Pancreatitis acute	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Metabolism and nutrition disorders	Food intolerance	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31JAN2015	N
	C4591001 1013 10131687	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2011	31DEC2011	N
		Endocrine disorders	Hypothyroidism	01JUL2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN1967		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1995	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01APR2020	31MAY2020	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Joint arthroplasty	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
			Transurethral prostatectomy	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2020	30JUN2020	N
		Psychiatric disorders	Binge eating	01JAN1989	31DEC2018	N
		Surgical and medical procedures	Gastric bypass	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc operation	01JUN2020	30JUN2020	N
	C4591001 1013 10131702	Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1013 10131706	Hepatobiliary disorders	Cholelithiasis	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Cholecystectomy	01FEB2020	29FEB2020	N
			Vasectomy	01JAN1976	31DEC1976	N
	C4591001 1013 10131707	Endocrine disorders	Hypothyroidism	01OCT2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Iodine allergy	01JAN1977		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131712	Immune system disorders	Food allergy	01JAN1985		Y
			Hypersensitivity	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
	C4591001 1013 10131714	Eye disorders	Arcus lipoides	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131715	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Spinal osteoarthritis	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131725	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01MAY2020		Y
		Psychiatric disorders	Insomnia	01APR2020		Y
	C4591001 1013 10131726	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1013 10131727	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Gout	01JAN2015	31DEC2016	N
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2011		Y
			Generalised anxiety disorder	01JAN2011		Y
			Post-traumatic stress disorder	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Renal stone removal	01JAN2015	31DEC2015	N
	C4591001 1013 10131728	Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131735	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1013 10131741	Metabolism and nutrition disorders	Gout	01JAN2011		Y
			Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1975		Y
		Surgical and medical procedures	Vasectomy	01JAN1976	31DEC1976	N
	C4591001 1013 10131742	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
		Psychiatric disorders	Major depression	01JAN1970		Y
	C4591001 1013 10131743	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2000		Y
	C4591001 1013 10131747	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Nerve compression	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1013 10131750	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01OCT2019	31OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1013 10131751	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1013 10131753	Immune system disorders	Drug hypersensitivity	01JAN1954		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
					31DEC2016	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2020		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131754	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
			Varicose vein operation	01JAN1981	31DEC1981	N
	C4591001 1013 10131755	Eye disorders	Glaucoma	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2011		Y
	C4591001 1013 10131758	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1013 10131764	Surgical and medical procedures	Knee arthroplasty	01NOV2019	30NOV2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131765	Eye disorders	Cataract	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JUL2020	31JUL2020	N
			Cholecystectomy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1013 10131766	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
	C4591001 1013 10131768	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Rubber sensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006	31OCT2007	N
				01JAN2007	31DEC2007	N
			Osteoarthritis	01JAN2005	31DEC2015	N
				01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2019	31DEC2019	N
				01JAN1980		Y
		Surgical and medical procedures	Female sterilisation	01JAN1972	31DEC1972	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Lithotripsy	01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
			Spinal laminectomy	01OCT2007	31OCT2007	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1013 10131773	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1998		Y
		Nervous system disorders	Anosmia	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Rhinoplasty	01JAN2007	31DEC2007	N
	C4591001 1013 10131775	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
				01JAN2000		Y
			Rubber sensitivity	01JAN1986		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Sinusitis	12OCT2020	12OCT2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cataract operation	23SEP2020	23SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1986	31DEC1986	N
			Oophorectomy bilateral	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1013 10131776	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Nervous system disorders	Multiple sclerosis	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1013 10131781	Cardiac disorders	Atrial fibrillation	01JAN2006		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N
				01JAN2004	31DEC2004	N
		Injury, poisoning and procedural complications	Tendon injury	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN1981	31DEC1981	N
				01JAN2006	31DEC2006	N
			Tenoplasty	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1013 10131782	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131784	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
	C4591001 1013 10131786	Cardiac disorders	Myocardial infarction	23JUN2019	23JUN2019	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN1999		Y
			Obesity	01JAN1965		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Psychiatric disorders	Generalised anxiety disorder	01JUL2016		Y
			Major depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2018	01MAY2018	N
			Percutaneous coronary intervention	01MAY2018	01MAY2018	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1013 10131787	Cardiac disorders	Heart valve incompetence	01JAN2008	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon injury	01JAN2015	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Heart valve replacement	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
			Tenoplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1013 10131789	Congenital, familial and genetic disorders	Hereditary spherocytosis	01JAN1959		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1013 10131795	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2008	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2010		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1013 10131798	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1013 10131799	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Reproductive system and breast disorders	Prostatomegaly	02JUL2020	02JUL2020	N
		Surgical and medical procedures	Prostatectomy	02JUL2020	02JUL2020	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1013 10131805	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Reproductive system and breast disorders	Prostatomegaly	01JUL2019		Y
	C4591001 1013 10131814	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
	C4591001 1013 10131816	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Intervertebral disc protrusion	01JAN1994	31DEC2005	N
			Sjogren's syndrome	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Surgical and medical procedures	Bunion operation	01FEB2020	29FEB2020	N
			Intervertebral disc operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1015 10151002	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1015 10151003	Endocrine disorders	Hypothyroidism	04SEP2016		Y
		Vascular disorders	Hypertension	26AUG2015		Y
	C4591001 1015 10151019	Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	21JAN2020		Y
	C4591001 1015 10151024	Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1015 10151025	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1015 10151032	Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1015 10151036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2011	31DEC2011	N
		Nervous system disorders	Paraparesis	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151037	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1015 10151040	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
	C4591001 1015 10151042	Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1015 10151043	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
	C4591001 1015 10151059	Surgical and medical procedures	Hernia hiatus repair	01FEB2020	29FEB2020	N
	C4591001 1015 10151060	Infections and infestations	Herpes simplex	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1015 10151065	Injury, poisoning and procedural complications	Post procedural hypothyroidism	01DEC1994	31DEC1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1015 10151078	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1015 10151079	Immune system disorders	Seasonal allergy	01JAN1969		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN1997	31DEC1997	N
		Nervous system disorders	Headache	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2017		Y
	C4591001 1015 10151090	Infections and infestations	Herpes simplex	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
	C4591001 1015 10151091	Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1015 10151095	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
	C4591001 1015 10151096	Congenital, familial and genetic disorders	Atrial septal defect	01JAN1957		Y
		Nervous system disorders	Migraine	01JAN1982		Y
	C4591001 1015 10151109	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1015 10151114	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151127	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN2017	31DEC2017	N
	C4591001 1015 10151129	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1982		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2003	31DEC2003	N
	C4591001 1015 10151140	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2020		Y
	C4591001 1015 10151141	Endocrine disorders	Basedow's disease	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JUN2019		Y
			Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	12MAR2020		Y
	C4591001 1015 10151142	Eye disorders	Astigmatism	01JAN1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1015 10151144	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
	C4591001 1015 10151155	Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1015 10151156	Cardiac disorders	Atrial fibrillation	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151168	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
	C4591001 1015 10151173	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1015 10151178	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Pneumonia	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
	C4591001 1015 10151181	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
	C4591001 1015 10151186	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
	C4591001 1015 10151190	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1977		Y
			Neuropathy peripheral	01JAN2005		Y
	C4591001 1015 10151194	Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Menopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN1956		Y
	C4591001 1015 10151213	Investigations	Seroconversion test positive	01JAN1983		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1957		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151215	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1990		Y
	C4591001 1015 10151219	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1015 10151237	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1015 10151238†	Cardiac disorders	Cardiac failure congestive	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Hepatobiliary disorders	Cirrhosis alcoholic	01JAN2015		Y
		Investigations	HIV test positive	01JAN1991		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2002	31DEC2003	N
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2005		Y
			Insomnia	01JAN1990		Y
		Renal and urinary disorders	Polyuria	01JAN1955		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
			Chronic obstructive pulmonary disease	01JAN2009		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1015 10151244	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1015 10151247	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Nervous system disorders	Sciatica	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1015 10151251	Investigations	Intraocular pressure increased	01JAN2015		Y
		Social circumstances	Menopause	01JAN1992		Y
	C4591001 1015 10151253	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2012	31DEC2012	N
	C4591001 1015 10151258	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Vascular disorders	Aneurysm	01JUL2019		Y
	C4591001 1016 10161001	Cardiac disorders	Angina pectoris	01MAY2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2005		Y
			Type 2 diabetes mellitus	01JUN1996		Y
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1016 10161002	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2000		Y
			Type 2 diabetes mellitus	17JUN2004		Y
		Reproductive system and breast disorders	Prostatomegaly	01NOV2019		Y
		Vascular disorders	Hypertension	01JUL2000		Y
	C4591001 1016 10161007	Musculoskeletal and connective tissue disorders	Osteopenia	05FEB2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161011	Endocrine disorders	Hypothyroidism	01OCT2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2010		Y
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1016 10161012	Ear and labyrinth disorders	Vertigo	01AUG2015		Y
		Endocrine disorders	Hypothyroidism	01DEC1990		Y
		Immune system disorders	Seasonal allergy	01JUL2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC1999		Y
		Nervous system disorders	Migraine	01DEC1969		Y
		Psychiatric disorders	Depression	01JUL2005		Y
	C4591001 1016 10161013	Endocrine disorders	Hyperthyroidism	01JUL2010		Y
		Immune system disorders	Seasonal allergy	01APR1964		Y
		Investigations	Vitamin D decreased	01JUL2014		Y
		Psychiatric disorders	Anxiety	01JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01APR2015		Y
		Social circumstances	Postmenopause	01JUL2014		Y
	C4591001 1016 10161015	Musculoskeletal and connective tissue disorders	Arthritis	01JUL2018		Y
		Vascular disorders	Deep vein thrombosis	01JUN2019	31AUG2019	N
			Hypertension	01JUN2000		Y
	C4591001 1016 10161016	Cardiac disorders	Atrial fibrillation	01AUG2018		Y
		Immune system disorders	Seasonal allergy	01APR1995		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2018		Y
		Vascular disorders	Hypertension	01JUL1988		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161022	Immune system disorders	Drug hypersensitivity	01AUG1972		Y
			Seasonal allergy	01APR2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	02APR2020		Y
	C4591001 1016 10161023	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2017		Y
		Nervous system disorders	Migraine	01AUG2010		Y
		Psychiatric disorders	Anxiety	01JUL2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2009	30JUN2009	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2018		Y
		Surgical and medical procedures	Vasectomy	01APR1995	30APR1995	N
		Vascular disorders	Deep vein thrombosis	01JAN2019		Y
			Hypertension	01JAN1990		Y
	C4591001 1016 10161024	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP1999	30SEP1999	N
		Psychiatric disorders	Depression	01SEP1999		Y
		Surgical and medical procedures	Hysterectomy	01SEP1999	30SEP1999	N
	C4591001 1016 10161025	Metabolism and nutrition disorders	Gout	01AUG2014		Y
			Hypercholesterolaemia	01AUG2017		Y
	C4591001 1016 10161026	Gastrointestinal disorders	Gastric ulcer	01MAY2013	31MAY2017	N
		Immune system disorders	Drug hypersensitivity	01MAY1994		Y
				01OCT1960		Y
			Iodine allergy	01MAY1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01OCT2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2005		Y
		Nervous system disorders	Transient ischaemic attack	01SEP2016	30SEP2016	N
		Psychiatric disorders	Insomnia	01SEP2016		Y
	C4591001 1016 10161027	Ear and labyrinth disorders	Vertigo	01MAR2018		Y
		Endocrine disorders	Hyperthyroidism	01JUN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	19SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2007	31DEC2007	N
		Nervous system disorders	Aura	01AUG1983		Y
			Cerebrovascular accident	01JAN2007	31DEC2007	N
			Trigeminal neuralgia	01MAR1984		Y
		Psychiatric disorders	Anxiety	01MAR2005		Y
		Vascular disorders	Hypertension	01MAR1984		Y
	C4591001 1016 10161032	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2019		Y
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982		Y
	C4591001 1016 10161035	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01SEP2004		Y
		Nervous system disorders	Seizure	01JUN2006	31JUL2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01SEP1983	30SEP1983	N
	C4591001 1016 10161036	Cardiac disorders	Spinal nerve stimulator implantation	01SEP2004		Y
			Supraventricular tachycardia	01JUN1995		Y
		Immune system disorders	Hypersensitivity	01MAR1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2010		Y
		Vascular disorders	Hot flush	01APR2008		Y
			Hypertension	01JUN2000		Y
	C4591001 1016 10161037	Immune system disorders	Seasonal allergy	01JUN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2000		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
	C4591001 1016 10161039	Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2010		Y
	C4591001 1016 10161040	Hepatobiliary disorders	Gallbladder disorder	01JUN1990	30JUN1990	N
		Immune system disorders	Drug hypersensitivity	01JUN1989		Y
			Hypersensitivity	01APR2010		Y
		Investigations	Cardiac murmur	27JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01APR2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN1982	30JUN1982	N
		Surgical and medical procedures	Cholecystectomy	01JUN1990	30JUN1990	N
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1016 10161041	Congenital, familial and genetic disorders	Congenital vas deferens absence	(b) (6) 1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Glaucoma	01AUG2010		Y
		Immune system disorders	Seasonal allergy	01MAY1993		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
	C4591001 1016 10161042	Metabolism and nutrition disorders	Vitamin B12 deficiency	01SEP2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01SEP2010		Y
	C4591001 1016 10161044	Endocrine disorders	Hypothyroidism	01JUL2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JUL2016		Y
	C4591001 1016 10161050	Cardiac disorders	Coronary artery disease	01FEB2012		Y
		Ear and labyrinth disorders	Meniere's disease	01OCT2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2012		Y
		Nervous system disorders	Nerve compression	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Coronary arterial stent insertion	01FEB2012	29FEB2012	N
		Vascular disorders	Arteriosclerosis	01FEB2012	29FEB2012	N
	C4591001 1016 10161052	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR1992		Y
	C4591001 1016 10161053	Immune system disorders	Seasonal allergy	01APR2000		Y
		Surgical and medical procedures	Meniscus operation	30JUN2020	30JUN2020	N
			Mole excision	25JUL2020	25JUL2020	N
	C4591001 1016 10161059	Immune system disorders	Hypersensitivity	01APR2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2010		Y
				01JUL2007		Y
		Psychiatric disorders	Depression	01OCT2011		Y
		Reproductive system and breast disorders	Menorrhagia	01JUL1992	31JUL1992	N
		Surgical and medical procedures	Hysterectomy	01JUL1992	31JUL1992	N
		Vascular disorders	Hypertension	01JUN1976		Y
	C4591001 1016 10161061	Gastrointestinal disorders	Constipation	01JUL2016		Y
		Immune system disorders	Hypersensitivity	01DEC1978		Y
		Nervous system disorders	Restless legs syndrome	01APR2010		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2015		Y
		Surgical and medical procedures	Hysterectomy	01AUG1996	31AUG1996	N
	C4591001 1016 10161062	Blood and lymphatic system disorders	Iron deficiency anaemia	01OCT2018	30APR2020	N
		Injury, poisoning and procedural complications	Optic nerve injury	01OCT2018		Y
		Reproductive system and breast disorders	Uterine prolapse	01JUN2000	30JUN2000	N
		Surgical and medical procedures	Hysterectomy	01JUN2000	30JUN2000	N
	C4591001 1016 10161063	Gastrointestinal disorders	Inguinal hernia	01FEB1992	29FEB1992	N
		Surgical and medical procedures	Hernia repair	01FEB1992	29FEB1992	N
			Vasectomy	01FEB1992	29FEB1992	N
	C4591001 1016 10161066	Endocrine disorders	Hyperthyroidism	01JUL2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JUN2000	30JUN2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01APR1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2010	31AUG2010	N
		Psychiatric disorders	Anxiety	01AUG2000		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2000	30JUN2000	N
			Hysterectomy	01AUG2010	31AUG2010	N
	C4591001 1016 10161067	Immune system disorders	Seasonal allergy	01JUL2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2019		Y
			Osteoarthritis	01AUG2017		Y
		Nervous system disorders	Essential tremor	01JUL2017		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1016 10161068	Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2018		Y
		Psychiatric disorders	Anxiety	01JUL2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2020		Y
		Vascular disorders	Hypertension	01JUL2010		Y
	C4591001 1016 10161070	Immune system disorders	Drug hypersensitivity	01JUN2009		Y
				01MAY2007		Y
			Seasonal allergy	01APR1990		Y
		Infections and infestations	Herpes simplex	01JAN1985		Y
		Nervous system disorders	Narcolepsy	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161074	Vascular disorders	Hypertension	01SEP2015		Y
	C4591001 1016 10161075	Endocrine disorders	Hypothyroidism	01AUG2014		Y
		Nervous system disorders	Seizure	01OCT1978		Y
	C4591001 1016 10161079	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2015		Y
		Immune system disorders	Seasonal allergy	01FEB2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2005		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01NOV2019		Y
	C4591001 1016 10161083	Immune system disorders	Allergy to chemicals	01MAY2010		Y
			Drug hypersensitivity	01MAY2010		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2018		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2010		Y
		Nervous system disorders	Neuropathy peripheral	01FEB2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2010		Y
	C4591001 1016 10161086	Congenital, familial and genetic disorders	Factor V Leiden mutation	01SEP2015		Y
		Immune system disorders	Seasonal allergy	01MAR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2005		Y
		Psychiatric disorders	Anxiety	01JUN2005		Y
			Depression	01JUN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01SEP2015	30SEP2015	N
			Sleep apnoea syndrome	01OCT2017		Y
		Surgical and medical procedures	Uvulectomy	01OCT2017	31OCT2017	N
			Vasectomy	01AUG2000	31AUG2000	N
		Vascular disorders	Hypertension	01MAR2005		Y
	C4591001 1016 10161088	Metabolism and nutrition disorders	Hypercholesterolaemia	29MAY2008		Y
			Type 2 diabetes mellitus	09JUL2008		Y
		Vascular disorders	Hypertension	23JAN2008		Y
	C4591001 1016 10161089	Cardiac disorders	Palpitations	01MAY2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG1992		Y
		Immune system disorders	Seasonal allergy	01FEB2020		Y
		Infections and infestations	Herpes simplex	01AUG2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2003		Y
	C4591001 1016 10161090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2017		Y
		Immune system disorders	Seasonal allergy	01APR2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2005		Y
		Surgical and medical procedures	Vasectomy	01FEB1995		Y
	C4591001 1016 10161096	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y
		Psychiatric disorders	Insomnia	01MAR2018		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1016 10161098	Eye disorders	Ocular rosacea	01APR2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01AUG2000		Y
		Psychiatric disorders	Anxiety	01AUG1995		Y
			Depression	01AUG1995		Y
		Reproductive system and breast disorders	Menopausal symptoms	01NOV2005		Y
		Skin and subcutaneous tissue disorders	Alopecia	01SEP2017		Y
	C4591001 1016 10161099	Immune system disorders	Seasonal allergy	01APR1960		Y
		Metabolism and nutrition disorders	Gout	01JUN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01NOV2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2000		Y
		Vascular disorders	Hypertension	01MAR1998		Y
	C4591001 1016 10161100	Infections and infestations	Onychomycosis	01MAY2020		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2002	31JAN2002	N
			Appendectomy	01JAN2004	31JAN2004	N
	C4591001 1016 10161108	Endocrine disorders	Hypothyroidism	01AUG2000		Y
		Gastrointestinal disorders	Gastric ulcer	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01APR1998		Y
	C4591001 1016 10161110	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01FEB2019		Y
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1016 10161111	Immune system disorders	Seasonal allergy	01APR1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
	C4591001 1016 10161112	Immune system disorders	Seasonal allergy	01MAY2000		Y
		Investigations	Hormone level abnormal	01JUN1991		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01APR2016		Y
		Psychiatric disorders	Anxiety	01APR2016		Y
			Insomnia	01MAR2017		Y
		Surgical and medical procedures	Hysterectomy	01OCT1981	31OCT1981	N
	C4591001 1016 10161113	Psychiatric disorders	Anxiety	01OCT2017		Y
			Depression	01JUL2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1016 10161115	Immune system disorders	Seasonal allergy	01MAR2000		Y
		Surgical and medical procedures	Vasectomy	01JUL2008	31JUL2008	N
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1016 10161116	Immune system disorders	Seasonal allergy	01AUG2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2008		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2019		Y
		Vascular disorders	Hypertension	01MAY2006		Y
	C4591001 1016 10161124	Immune system disorders	Drug hypersensitivity	01APR2018		Y
			Seasonal allergy	01MAR1990		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2018		Y
			Back pain	01APR1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01MAR2010		Y
		Surgical and medical procedures	Hysterectomy	01JUL2003	31JUL2003	N
			Meniscus operation	01APR2018	30APR2018	N
	C4591001 1016 10161127	Endocrine disorders	Hypothyroidism	01JUL2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2004		Y
		Infections and infestations	Herpes simplex	01DEC1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2016		Y
	C4591001 1016 10161129	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01NOV2016	30NOV2016	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2016	31JAN2016	N
			Inguinal hernia repair	01JAN2016	31JAN2016	N
			Knee arthroplasty	01NOV2016	30NOV2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1016 10161131	Eye disorders	Dry eye	01JUN2018		Y
		Immune system disorders	Seasonal allergy	01APR2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01APR2015		Y
			Bursitis	01FEB2019		Y
			Intervertebral disc degeneration	01APR2015		Y
			Osteoarthritis	01JUN2018		Y
			Spinal stenosis	01APR2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161132	Endocrine disorders	Hypothyroidism	01SEP2018		Y
		Immune system disorders	Seasonal allergy	01SEP2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2005		Y
		Psychiatric disorders	Insomnia	01SEP2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 1016 10161134	Endocrine disorders	Hyperthyroidism	01JUN1995		Y
		Immune system disorders	Seasonal allergy	01APR2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Back pain	01JAN2020		Y
			Osteoarthritis	01MAR2017		Y
			Pain in extremity	01APR2020		Y
		Reproductive system and breast disorders	Endometriosis	01MAY1985	31MAY1993	N
		Surgical and medical procedures	Hysterectomy	01MAY1993	31MAY1993	N
		Vascular disorders	Hypertension	01JUN1995		Y
	C4591001 1016 10161135	Immune system disorders	Seasonal allergy	01MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2014		Y
		Vascular disorders	Hypertension	01MAY2014		Y
	C4591001 1016 10161137	Cardiac disorders	Atrial fibrillation	01JUN1998		Y
		Endocrine disorders	Hyperthyroidism	01JUN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2013		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2010		Y
			Type 2 diabetes mellitus	01JUL2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUN1998		Y
	C4591001 1016 10161138	Eye disorders	Glaucoma	01FEB2016		Y
		Immune system disorders	Seasonal allergy	01JAN1952		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN1990		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01AUG2000	31AUG2019	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JUN1997		Y
	C4591001 1016 10161141	Endocrine disorders	Hypothyroidism	01JUN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2010		Y
		Immune system disorders	Seasonal allergy	01APR2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01SEP2011		Y
			Osteoarthritis	01AUG2015		Y
			Spinal stenosis	01SEP2011		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01OCT1979	31OCT1997	N
		Surgical and medical procedures	Hormone replacement therapy	01JUN1999		Y
			Hysterectomy	01OCT1997	31OCT1997	N
			Ligament operation	01JUN2014	30JUN2014	N
	C4591001 1016 10161142	Eye disorders	Chorioretinopathy	01JUN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2005		Y
			Vitamin D deficiency	01JUN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2012		Y
		Surgical and medical procedures	Appendectomy	01AUG2008	31AUG2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia repair	01AUG2008	31AUG2008	N
	C4591001 1016 10161146	Immune system disorders	Seasonal allergy	01APR1961		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006		Y
		Psychiatric disorders	Anxiety	01MAY2015		Y
			Depression	01MAY2015		Y
		Renal and urinary disorders	Hypertonic bladder	01MAY2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01APR2017		Y
	C4591001 1016 10161149	Gastrointestinal disorders	Gastrooesophageal reflux disease	01APR1991		Y
		Hepatobiliary disorders	Gallbladder disorder	01APR2007	31MAY2007	N
		Immune system disorders	Seasonal allergy	01APR1996		Y
		Metabolism and nutrition disorders	Hypokalaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2016		Y
			Intervertebral disc degeneration	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2015	30SEP2015	N
		Nervous system disorders	Neuropathy peripheral	01JUN2016		Y
		Psychiatric disorders	Anxiety	01JUN2016		Y
			Depression	01JUN2016		Y
			Insomnia	01JUN2000		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2007	31MAY2007	N
			Female sterilisation	01JUL1990	01JUL1990	N
			Mastectomy	20OCT2015	20OCT2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal fusion surgery	01AUG2016	31AUG2016	N
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1016 10161151	Immune system disorders	Seasonal allergy	01MAR2000		Y
		Investigations	Vitamin D decreased	01AUG2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1016 10161153	Immune system disorders	Seasonal allergy	01MAR1954		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JUN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	01JUN2016	30JUN2016	N
		Nervous system disorders	Intracranial aneurysm	01MAR1988	31MAR1988	N
		Psychiatric disorders	Depression	01AUG2005		Y
		Surgical and medical procedures	Intra-cerebral aneurysm operation	01MAR1988	31MAR1988	N
			Nephrectomy	01JUN2016	30JUN2016	N
			Rotator cuff repair	01JUN1995	30JUN1995	N
			Shoulder arthroplasty	01JUN1995	30JUN1995	N
		Vascular disorders	Hypertension	01JUN2000		Y
	C4591001 1016 10161157	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2002		Y
			Haemorrhoids	01JUN2011		Y
		Immune system disorders	Seasonal allergy	01MAR1952		Y
		Infections and infestations	Diverticulitis	01SEP1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2005		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JUN2010		Y
			Osteoarthritis	01JUN2010		Y
		Psychiatric disorders	Depression	01JUN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01MAY2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN1980		Y
		Surgical and medical procedures	Intestinal resection	01SEP2014	30SEP2014	N
		Vascular disorders	Hypertension	01JUN1980		Y
	C4591001 1016 10161158	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR1990		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01APR1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2012	31DEC2012	N
		Nervous system disorders	Migraine	01SEP2005		Y
		Psychiatric disorders	Anxiety	01NOV2001		Y
			Post-traumatic stress disorder	01NOV2001		Y
		Surgical and medical procedures	Foraminotomy	01JUL2012		Y
			Vasectomy	01OCT1973	31OCT1973	N
		Vascular disorders	Hypertension	01MAR1990		Y
	C4591001 1016 10161161	Immune system disorders	Seasonal allergy	01MAR2019		Y
		Surgical and medical procedures	Hormone replacement therapy	01JUN2003		Y
	C4591001 1016 10161162	Cardiac disorders	Cardiac septal hypertrophy	01OCT2010		Y
		Endocrine disorders	Hyperthyroidism	01JUN2004		Y
		Immune system disorders	Seasonal allergy	01APR2008		Y
	C4591001 1016 10161165	Immune system disorders	Contrast media allergy	01APR1981		Y
			Seasonal allergy	01MAR2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2018		Y
		Renal and urinary disorders	Nephrolithiasis	01APR1981		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01NOV1994	30NOV1994	N
	C4591001 1016 10161166	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2018		Y
		Immune system disorders	Drug hypersensitivity	01MAR1968		Y
			Seasonal allergy	(b) (6) 1962		Y
		Infections and infestations	Herpes simplex	01JUL2000		Y
		Surgical and medical procedures	Haemorrhoid operation	01APR2004	30APR2004	N
			Ligament operation	01AUG1995	31AUG1995	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1016 10161169	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	22SEP2006		Y
	C4591001 1016 10161173	Endocrine disorders	Hyperthyroidism	01AUG1998		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Pain in extremity	01JAN2019		Y
		Psychiatric disorders	Anxiety	01NOV2006		Y
		Surgical and medical procedures	Hysterectomy	01MAR2004	31MAR2004	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1016 10161174	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Nervous system disorders	Myasthenia gravis	01DEC2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01MAY2000		Y
		Surgical and medical procedures	Vasectomy	01MAY1998	31MAY1998	N
	C4591001 1016 10161175	Psychiatric disorders	Anxiety	01MAR2004		Y
			Depression	01MAR2004		Y
			Insomnia	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1016 10161179	Immune system disorders	Seasonal allergy	01JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
		Surgical and medical procedures	Female sterilisation	01AUG1979	31AUG1979	N
			Thyroidectomy	01MAR2015	31MAR2015	N
		Vascular disorders	Hypertension	01APR2018		Y
	C4591001 1016 10161180	Cardiac disorders	Cardiomegaly	01OCT1983		Y
			Myocardial infarction	01OCT1983	31OCT1983	N
		Immune system disorders	Seasonal allergy	01AUG2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT1983		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01DEC2011		Y
	C4591001 1016 10161187	Immune system disorders	Seasonal allergy	01MAR1978		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01APR1994		Y
		Psychiatric disorders	Depression	01DEC1990		Y
		Vascular disorders	Hypertension	01FEB2017		Y
	C4591001 1016 10161188	Vascular disorders	Hypertension	01DEC2017		Y
	C4591001 1016 10161191	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01APR2014	30JUN2015	N
			Neck pain	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAR2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Surgical and medical procedures	Spinal fusion surgery	01JUN2015	30JUN2015	N
			Vasectomy	01JAN1984	31JAN1984	N
		Vascular disorders	Hypertension	01OCT2008		Y
	C4591001 1016 10161194	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2010		Y
		Surgical and medical procedures	Vasectomy	01JUL1984	31JUL1984	N
	C4591001 1016 10161195	Cardiac disorders	Cardiovascular disorder	01AUG2005	31AUG2005	N
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2005	31AUG2005	N
	C4591001 1016 10161197	Immune system disorders	Food allergy	01SEP1959		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1016 10161198	General disorders and administration site conditions	Oedema	01AUG2019		Y
		Immune system disorders	Drug hypersensitivity	01MAY2000		Y
			Seasonal allergy	01MAR2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2009		Y
			Osteoporosis	01FEB2007		Y
		Psychiatric disorders	Anxiety	01MAY2008		Y
		Social circumstances	Postmenopause	01FEB2007		Y
	C4591001 1016 10161199	Surgical and medical procedures	Vasectomy	01OCT1981	31OCT1981	N
		Vascular disorders	Hypertension	01SEP1989		Y
	C4591001 1016 10161200	Cardiac disorders	Palpitations	01SEP1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast calcifications	01JUN2020		Y
	C4591001 1016 10161201	Immune system disorders	Seasonal allergy	01APR1960		Y
		Investigations	Blood calcium increased	01APR2000	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder transitional cell carcinoma	01DEC2007	31DEC2007	N
		Renal and urinary disorders	Nephrolithiasis	01DEC2007	02JAN2020	N
		Surgical and medical procedures	Knee arthroplasty	01DEC2014	31DEC2014	N
			Parathyroidectomy	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JUN2005		Y
	C4591001 1016 10161202	Immune system disorders	Seasonal allergy	01APR2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01APR2005		Y
	C4591001 1016 10161203	Immune system disorders	Seasonal allergy	01MAR2000		Y
		Infections and infestations	Sinusitis	01APR2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Nasal sinus irrigation	27JUL2020	27JUL2020	N
	C4591001 1016 10161207	Immune system disorders	Hypersensitivity	01JUN2020		Y
		Investigations	Heart rate irregular	01NOV2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994		Y
			Thyroidectomy	01JUL2004		Y
	C4591001 1016 10161211	Endocrine disorders	Autoimmune thyroiditis	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01MAR2000		Y
		Surgical and medical procedures	Thyroidectomy	01MAR2016	31MAR2016	N
	C4591001 1016 10161212	Endocrine disorders	Hypothyroidism	01MAR2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Nervous system disorders	Migraine	01MAR2010		Y
			Neuropathy peripheral	01JUL1990		Y
		Psychiatric disorders	Depression	01MAR2010		Y
		Reproductive system and breast disorders	Ovarian fibrosis	01OCT1985	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01MAR2010		Y
	C4591001 1016 10161214	Surgical and medical procedures	Hysterectomy	01APR2011	30APR2011	N
	C4591001 1016 10161220	Cardiac disorders	Coronary artery occlusion	01APR2020		Y
			Ventricular extrasystoles	01AUG1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	29MAY2020	29MAY2020	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	29MAY2020		Y
	C4591001 1016 10161221	Endocrine disorders	Hypothyroidism	01MAR2015		Y
		Immune system disorders	Seasonal allergy	01MAR2005		Y
		Musculoskeletal and connective tissue disorders	Vertebral osteophyte	01SEP2018		Y
		Surgical and medical procedures	Hysterectomy	01MAR1985	31MAR1985	N
			Spinal fusion surgery	01MAR1976	31MAR1976	N
	C4591001 1016 10161222	Immune system disorders	Seasonal allergy	01JUL2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2005		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2013	31DEC2013	N
			Vasectomy	01NOV1990	30NOV1990	N
	C4591001 1016 10161224	Immune system disorders	Seasonal allergy	01MAR2010		Y
		Surgical and medical procedures	Vasectomy	01OCT2007	31OCT2007	N
	C4591001 1016 10161236	Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2010		Y
		Surgical and medical procedures	Vasectomy	01APR2000	30APR2000	N
	C4591001 1016 10161238	Cardiac disorders	Coronary artery disease	01DEC2008		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Nerve compression	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JUL2012	31JUL2012	N
			Coronary arterial stent insertion	01DEC2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1016 10161239	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01MAR1985		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAR1980		Y
	C4591001 1016 10161240	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01MAR2019		Y
		Nervous system disorders	Restless legs syndrome	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161241	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2013		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JUL2002		Y
	C4591001 1016 10161247	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01NOV2008		Y
		Vascular disorders	Hypertension	01MAR2008		Y
	C4591001 1016 10161254	Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	01DEC2010	30APR2011	N
		Endocrine disorders	Hyperthyroidism	01OCT2017		Y
		Psychiatric disorders	Anxiety	01NOV2018		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01NOV2018		Y
		Social circumstances	Postmenopause	01OCT2016		Y
		Surgical and medical procedures	Intervertebral disc operation	01SEP2010	30SEP2010	N
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 1016 10161257	Immune system disorders	Seasonal allergy	01MAR1984		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN1998		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01MAR1992	31MAR1992	N
			Gastric bypass	01JUN2010	30JUN2010	N
			Oophorectomy	01JAN1988	31JAN1988	N
	C4591001 1016 10161260	Cardiac disorders	Ventricular extrasystoles	01FEB2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2016		Y
		Nervous system disorders	Cerebrovascular accident	07JUL2020	07JUL2020	N
		Reproductive system and breast disorders	Prostatomegaly	01SEP2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1016 10161262	Gastrointestinal disorders	Diarrhoea	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01APR1954		Y
	C4591001 1016 10161263	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01OCT2000		Y
		Surgical and medical procedures	Vasectomy	01JUN1977	30JUN1977	N
		Vascular disorders	Hypertension	01AUG2012		Y
	C4591001 1016 10161264	Immune system disorders	Seasonal allergy	01MAY2016		Y
	C4591001 1016 10161266	Vascular disorders	Hypertension	01SEP2015		Y
	C4591001 1016 10161267	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2010		Y
		Immune system disorders	Seasonal allergy	01MAR1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2005		Y
		Psychiatric disorders	Depression	01OCT1994		Y
		Surgical and medical procedures	Umbilical hernia repair	01OCT2005	31OCT2005	N
		Vascular disorders	Hypertension	01APR2000		Y
	C4591001 1016 10161270	Infections and infestations	Urethritis	01MAY2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01FEB2008		Y
			Obsessive-compulsive disorder	01JUN2006		Y
	C4591001 1016 10161271	Blood and lymphatic system disorders	Anaemia	01JAN1975		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2000		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2005		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Thyroidectomy	01MAR2016	31MAR2016	N
	C4591001 1016 10161274	Immune system disorders	Hypersensitivity	01MAY2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUL2013		Y
		Surgical and medical procedures	Hysterectomy	01JUN2008	30JUN2008	N
	C4591001 1016 10161278	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2009		Y
		Immune system disorders	Seasonal allergy	01MAR2010		Y
	C4591001 1016 10161282	Endocrine disorders	Hypothyroidism	01APR2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN1980		Y
		Metabolism and nutrition disorders	Gout	01MAY2015		Y
			Hypercholesterolaemia	01SEP1995		Y
		Psychiatric disorders	Depression	01APR1970		Y
		Renal and urinary disorders	Chronic kidney disease	06AUG2020		Y
		Surgical and medical procedures	Inguinal hernia repair	01JUN2013	30JUN2013	N
			Intervertebral disc operation	01SEP1996	30SEP1996	N
				01SEP2008	30SEP2008	N
			Prostatectomy	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01APR2010		Y
	C4591001 1016 10161283	Immune system disorders	Seasonal allergy	01SEP1979		Y
		Investigations	Blood testosterone decreased	01FEB2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181002	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1018 10181004	Blood and lymphatic system disorders	Anaemia	01JAN2007	31DEC2007	N
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Eye disorders	Myopia	01JAN1969		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
			Diverticulum	01JAN2002		Y
			Haemorrhoids	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
			Oral herpes	01JAN1959	29JUL2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Synovial cyst	01JAN2012	31DEC2012	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Liposuction	01JAN2000	31DEC2000	N
			Synovial cyst removal	01JAN2012	31DEC2012	N
		Vascular disorders	Varicose vein	01JAN2008		Y
	C4591001 1018 10181005	Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Osteopenia	25OCT2019		Y
			Osteoporosis	01JAN2015	25OCT2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Carpal tunnel decompression	01JAN2015	31DEC2015	N
	C4591001 1018 10181006	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
			Iodine allergy	01JAN2005		Y
		Investigations	Arthroscopy	01APR2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Hernia repair	01DEC2011	31DEC2011	N
			Shoulder operation	01DEC2001	31DEC2001	N
		Vascular disorders	Deep vein thrombosis	01JAN2012	31DEC2012	N
	C4591001 1018 10181023	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1018 10181035	Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Eye disorders	Glaucoma	01JAN1982		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Reproductive system and breast disorders	Varicocele	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1018 10181041	Surgical and medical procedures	Tonsillectomy	01JAN1984	31DEC1984	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1018 10181043	Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
		Eye disorders	Myopia	01JAN2015		Y
			Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1018 10181060	Blood and lymphatic system disorders	Anaemia	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
		Nervous system disorders	Migraine	01JAN1973		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Caesarean section	07JUN1991	07JUN1991	N
			Endometrial ablation	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1998	31DEC1998	N
			Open reduction of fracture	01JAN1995	31DEC1995	N
	C4591001 1018 10181061	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Breast cyst excision	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1018 10181063	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Alcohol abuse	01JAN1979	07JUN2004	N
			Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
	C4591001 1018 10181065	Eye disorders	Strabismus	01JAN1966		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2017	31AUG2017	N
		Surgical and medical procedures	Carpal tunnel decompression	01SEP2004	30SEP2004	N
			Micrographic skin surgery	01AUG2017	31AUG2017	N
			Rhinoplasty	01AUG2017	31AUG2017	N
			Strabismus correction	01JAN1966	31DEC1966	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1018 10181068	General disorders and administration site conditions	Oedema peripheral	01APR2020		Y
		Injury, poisoning and procedural complications	Radius fracture	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1996		Y
					31DEC1996	N
				01JAN2004	31DEC2004	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Open reduction of fracture	01JAN1988	31DEC1988	N
			Vasectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1018 10181069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JUL2020		Y
			Rosacea	01JUL2020		Y
		Surgical and medical procedures	Cataract operation	29MAY2020	29MAY2020	N
			Eye laser surgery	01JUL2001	31JUL2001	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1018 10181070	Infections and infestations	Cystitis	01JAN1970	31DEC2000	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1970	31DEC1973	N
		Surgical and medical procedures	Anorectal operation	01JAN2002	31DEC2002	N
	C4591001 1018 10181073	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1018 10181075	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2018	31DEC2018	N
			Hyperlipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965	31DEC1976	N
				01JAN1976		Y
		Surgical and medical procedures	Tenoplasty	01JAN2005	31DEC2005	N
	C4591001 1018 10181078	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1018 10181080	Ear and labyrinth disorders	Presbycusis	01JAN2014		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2007		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1991		Y
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Haemorrhoid operation	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1971	31DEC1971	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1018 10181087	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	03AUG1983	03AUG1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				06JUL1988	06JUL1988	N
	C4591001 1018 10181092	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Electrocardiogram abnormal	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01APR2019		Y
		Social circumstances	Tobacco user	01JAN1989	31DEC1997	N
	C4591001 1018 10181096	Gastrointestinal disorders	Gastric ulcer	01JAN2005	31DEC2005	N
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2012		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Malaria	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Ligament injury	01JAN1995	31DEC1995	N
		Investigations	Helicobacter test positive	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
			Umbilical hernia repair	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1018 10181097	Endocrine disorders	Hypogonadism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1991	31DEC1991	N
	C4591001 1018 10181099	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1018 10181101	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1982	31DEC1982	N
			Jaw fracture	01JAN1984	31DEC1984	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Finger repair operation	01JAN1982	31DEC1982	N
			Inguinal hernia repair	01JAN1967	31DEC1967	N
			Jaw operation	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1018 10181102	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018	30JUN2020	N
		Surgical and medical procedures	Vasectomy	10JUL2002	10JUL2002	N
	C4591001 1018 10181110	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
	C4591001 1018 10181112	Cardiac disorders	Mitral valve prolapse	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
	C4591001 1018 10181115	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181117	Vascular disorders	Hypertension	01JAN2010		Y
		Eye disorders	Myopia	01JAN1956		Y
			Presbyopia	01JAN1997		Y
		Investigations	Biopsy breast	01JAN1987	31DEC1987	N
				01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1987	31DEC1987	N
				01JAN1996	31DEC1996	N
			Psychiatric disorders	Depression	01JAN2007	31DEC2008
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1018 10181122	Vascular disorders	Hypertension	01JAN2014		Y
		Eye disorders	Myopia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Hepatic steatosis	16JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Impaired fasting glucose	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	31DEC2017	N
	C4591001 1018 10181123	Vascular disorders	Hypertension	01JAN2015		Y
		Ear and labyrinth disorders	Vertigo	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	01JAN2015		Y
			Myopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1949		Y
				01JAN1975		Y
		Infections and infestations	Urinary tract infection	01SEP2019	31OCT2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2017	31DEC2017	N
				01JAN2017	08JUN2017	N
		Renal and urinary disorders	Stress urinary incontinence	24OCT2017		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Skin neoplasm excision	01DEC2017	31DEC2017	N
				01JUL2017	31JUL2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1018 10181124	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2017	31DEC2017	N
			Intervertebral disc degeneration	01FEB2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01OCT2003	31OCT2003	N
			Physiotherapy	01MAY2020		Y
			Spinal decompression	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1018 10181132	Ear and labyrinth disorders	Vertigo	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2004		Y
			Gastrooesophageal reflux disease	01JAN1994	31DEC2004	N
			Large intestine polyp	28APR2017		Y
		General disorders and administration site conditions	Fatigue	01JAN2012		Y
			Oedema peripheral	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Iodine allergy	01JAN2018		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Bronchitis	01JAN1988		Y
				15DEC2016	31DEC2016	N
				19MAR2019	31MAR2019	N
			Rhinitis	11DEC2018	31DEC2018	N
			Urinary tract infection	14AUG2019	31DEC2019	N
		Injury, poisoning and procedural complications	Concussion	28MAY2019	31DEC2019	N
			Contusion	28MAY2019	31DEC2019	N
			Face injury	01JAN1988	31DEC1988	N
			Facial bones fracture	28MAY2019	31DEC2019	N
			Foot fracture	01JAN2017	31DEC2017	N
			Muscle strain	14JUN2017	31DEC2017	N
			Periorbital haematoma	28MAY2019	31DEC2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012	31DEC2014	N
			Hyperlipidaemia	01JAN2000		Y
			Vitamin B12 deficiency	01JAN2016		Y
			Vitamin D deficiency	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01MAR2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Foot deformity	01JAN2007		Y
			Osteoarthritis	01JAN1988		Y
			Osteoporosis	01JUN2008		Y
			Pain in jaw	14JUN2017	31DEC2017	N
			Tenosynovitis stenosans	09DEC2016	09DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2010		Y
			Presyncope	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Telangiectasia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Fracture treatment	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Jaw operation	01JAN1988	31DEC1988	N
			Knee arthroplasty	14MAY2007	14MAY2007	N
			Nasal operation	01JAN1988	31DEC1988	N
			Oesophagogastric fundoplasty	01JAN2004	31DEC2004	N
			Tendon sheath incision	09DEC2016	09DEC2016	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1018 10181134	Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Tonsillectomy	01JAN1958	31DEC1958	N
			Vasectomy	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181136	Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
	C4591001 1018 10181137	Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN1999		Y
		Investigations	Blood testosterone decreased	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Spinal fusion surgery	01DEC2017	31DEC2017	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1018 10181138	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1982	31DEC1982	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Chest tube insertion	01JAN2011	31DEC2011	N
			Inguinal hernia repair	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181140	Cardiac disorders	Atrial fibrillation	01JAN2013	31DEC2013	N
			Coronary artery disease	01JAN2009		Y
		Congenital, familial and genetic disorders	Hamartoma	01JAN2007	31DEC2007	N
		Endocrine disorders	Hyperparathyroidism	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2020	30JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
		Surgical and medical procedures	Breast tumour excision	01JAN2007	31DEC2007	N
			Cancer surgery	01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
			Coronary arterial stent insertion	01JAN2009	31DEC2009	N
			Parathyroidectomy	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1018 10181147	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1987	31DEC1987	N
				01JAN1988	31DEC1988	N
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
				01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1964	31DEC1964	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181153	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Contrast media allergy	01JAN2017		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
			Pulmonary mass	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2020	31JAN2020	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2018	31JAN2020	N
	C4591001 1018 10181155	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2012	31JAN2012	N
		Investigations	Colonoscopy	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
		Surgical and medical procedures	Internal fixation of fracture	01FEB2012	29FEB2012	N
			Open reduction of fracture	01FEB2012	29FEB2012	N
			Vasectomy	01JUL2011	31JUL2011	N
	C4591001 1018 10181168	Immune system disorders	Mycotic allergy	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Varicose vein	01JAN2017	31JAN2019	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181169	Eye disorders	Cataract	01MAR2017	30JUN2017	N
		Investigations	Blood testosterone decreased	01AUG2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2019		Y
		Surgical and medical procedures	Vasectomy	01DEC2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1018 10181175	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2019		Y
		Surgical and medical procedures	Cartilage graft	01JAN2017	31DEC2017	N
			Splenic artery embolisation	01MAY2018	31MAY2018	N
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2017		Y
	C4591001 1018 10181179	Eye disorders	Myopia	01JAN2012		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1992		Y
			Seasonal allergy	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
	C4591001 1018 10181190	Eye disorders	Amblyopia	01JAN1960		Y
			Presbyopia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Brain operation	01JAN1997	31DEC1997	N
			Myomectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1018 10181192	Eye disorders	Glaucoma	01MAY2019		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Oesophageal achalasia	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1018 10181212	Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Retinal detachment	01JAN2010	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2006		Y
			Seasonal allergy	01JAN1955		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Incisional drainage	01JAN2006	31DEC2006	N
			Intraocular lens implant	01JAN2012	31DEC2012	N
			Scleral buckling surgery	01JUL2011	31JUL2011	N
			Vitrectomy	01MAY2010	31MAY2010	N
	C4591001 1018 10181213	Eye disorders	Cataract	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Allergy to arthropod bite	01JAN1975		Y
			Seasonal allergy	01JAN1955		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1976	31DEC1976	N
			Upper limb fracture	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypercholesterolaemia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
			Chromophobe renal cell carcinoma	01JAN2019	12FEB2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Lip operation	01JAN2010	31DEC2010	N
			Nephrectomy	12FEB2019	12FEB2019	N
			Tenoplasty	01JAN1976	31DEC1976	N
	C4591001 1018 10181220	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cancer surgery	01JAN2005	31DEC2005	N
	C4591001 1018 10181231	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2005	31DEC2005	N
			Shoulder arthroplasty	01JAN2019	31DEC2019	N
			Tenoplasty	01JAN1990	31DEC1990	N
			Vasectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1018 10181239	Vascular disorders	Hypertension	01JAN2010		Y
		Cardiac disorders	Supraventricular extrasystoles	01FEB2017		Y
		Endocrine disorders	Hypothyroidism	01SEP1995		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN1995	01AUG1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1018 10181243		Hysterectomy	01JAN1995	31DEC1995	N
			Small intestinal resection	01JAN2010	31DEC2010	N
		Congenital, familial and genetic disorders	Factor V Leiden carrier	(b) (6) 1961		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015	31DEC2016	N
			Obesity	01JAN2015	31DEC2015	N
			Type 2 diabetes mellitus	01JAN2007	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
			Osteochondrosis	01JAN1976		Y
		Surgical and medical procedures	Chondroplasty	01JAN1996	31DEC1996	N
				01JAN2001	31DEC2001	N
		Hernia repair	24JUN2019	24JUN2019	N	
		Plastic surgery to the face	01JAN2004	31DEC2004	N	
		Uvulopalatopharyngoplasty	01JAN2007	31DEC2007	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2007	31DEC2015	N
	C4591001 1018 10181248	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Investigations	Colonoscopy	01DEC2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Exostosis	29MAY2019	29MAY2019	N
			Osteopenia	01JAN2000		Y
			Synovial cyst	29MAY2019	29MAY2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1985	31DEC1985	N
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
			Rosacea	01JAN2015		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN1985	31DEC1985	N
			Bone lesion excision	29MAY2020	29MAY2020	N
			Caesarean section	01JAN1983	31DEC1983	N
			Synovial cyst removal	29MAY2019	29MAY2019	N
	C4591001 1018 10181249	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Social circumstances	Blood donor	01JAN2004		Y
		Surgical and medical procedures	Bone operation	01JAN1989	31DEC1989	N
			Gastric stapling	01JAN1999	31DEC1999	N
			Ligament operation	01JAN1976	31DEC1976	N
			Mammoplasty	01JAN2018	31DEC2018	N
			Skin cosmetic procedure	01JAN2018		Y
	C4591001 1018 10181250	Immune system disorders	Seasonal allergy	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2004	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1018 10181265	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Surgical and medical procedures	Vasectomy	01JAN1995		Y
	C4591001 1018 10181270	Ear and labyrinth disorders	Otosclerosis	01JAN2015		Y
		Eye disorders	Strabismus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
			Malignant melanoma	01DEC2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Ligament operation	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2020	31JAN2020	N
			Strabismus correction	01JAN1991	31DEC1991	N
				01JAN2008	31DEC2008	N
			Urinary bladder suspension	01JAN2011	31DEC2011	N
		Vascular disorders	Hot flush	01JAN2009		Y
	C4591001 1018 10181274	Ear and labyrinth disorders	Presbycusis	01JAN2014		Y
		Eye disorders	Presbyopia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1970	31DEC1970	N
		Renal and urinary disorders	Micturition urgency	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Endometrial ablation	01JAN2005		Y
			Varicose vein operation	01JAN1999	31DEC1999	N
		Vascular disorders	Varicose vein	01JAN1990	31DEC1999	N
	C4591001 1018 10181278	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Gout	01AUG2018		Y
			Hyperlipidaemia	01JAN2010		Y
			Vitamin D deficiency	01AUG2020		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1978		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1018 10181281	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y
	C4591001 1018 10181285	Cardiac disorders	Arrhythmia	01JAN2016		Y
		Eye disorders	Cataract	01JAN1995	31DEC1997	N
			Eye irritation	01JAN2013		Y
			Glaucoma	01JAN1995		Y
			Presbyopia	01JAN1997		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
			Sciatica	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1988		Y
			Insomnia	01JAN1988		Y
		Renal and urinary disorders	Acute kidney injury	01OCT2019	31OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1992		Y
		Surgical and medical procedures	Gastric banding	01JAN2004	31DEC2004	N
			Glaucoma drainage device placement	01JAN2016	31DEC2016	N
			Intraocular lens implant	01JAN1997	31DEC1997	N
		Vascular disorders	Arteriosclerosis	01JAN2019		Y
	C4591001 1018 10181291	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
				01JAN2019	31JAN2019	N
				01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Oophorectomy	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1018 10181296	Eye disorders	Myopia	01JAN1972		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
			Parathyroid tumour benign	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Parathyroidectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1018 10181300	Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Eye disorders	Myopia	01JAN1963	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Bile duct stone	27JUL2020	27JUL2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Joint stiffness	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006	31DEC2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1978	31DEC1978	N
				01JAN1979	31DEC1979	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Cataract operation	01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
			Cholecystectomy	27JUL2020	27JUL2020	N
			Haemorrhoid operation	01JAN1988	31DEC1988	N
			Keratomileusis	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1018 10181303	Musculoskeletal and connective tissue disorders	Spinal synovial cyst	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01OCT2018	31DEC2018	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2010		Y
			Skin neoplasm excision	01DEC2008	31DEC2008	N
			Spinal laminectomy	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1018 10181308	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2008	31DEC2008	N
				01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1018 10181312	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2010		Y
				01JUN2020	30JUN2020	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Investigations	Cardiac murmur	01JAN2011		Y
			Colonoscopy	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
				01JUL2020	31JUL2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01DEC2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lipoma excision	01JAN1980	31DEC1980	N
		Vascular disorders	Deep vein thrombosis	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
	C4591001 1018 10181328	Gastrointestinal disorders	Large intestine polyp	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2019		Y
			Obesity	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1018 10181332	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC2005	N
	C4591001 1018 10181339	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Vitamin B12 deficiency	01FEB2020		Y
			Vitamin D deficiency	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1018 10181348	Cardiac disorders	Arrhythmia	01JAN2017		Y
		Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Eye disorders	Myopia	01JAN1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Hepatitis A	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	30SEP2018	N
			Intervertebral disc protrusion	01JAN1987	31DEC1987	N
			Plantar fasciitis	01JAN2012	30SEP2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1992	31DEC1992	N
		Nervous system disorders	Sciatica	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Bunion operation	01SEP2018	30SEP2018	N
			Caesarean section	01JAN1989	31DEC1989	N
			Fasciotomy	01SEP2018	30SEP2018	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Intervertebral disc operation	01JAN1987	31DEC1987	N
	C4591001 1019 10191001	Ear and labyrinth disorders	Deafness	01JAN1996		Y
		Eye disorders	Cataract	01JAN2017	31DEC2019	N
			Presbyopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN1996	31DEC1996	N
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Muscle contractions involuntary	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Spinal decompression	01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN1996	31DEC1996	N
			Tenoplasty	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191003	Eye disorders	Myopia	01JAN1997		Y
			Presbyopia	01JAN1997		Y
		Gastrointestinal disorders	Diverticulum	01JAN2011		Y
		Injury, poisoning and procedural complications	Femur fracture	01NOV2019	30NOV2019	N
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
			Sinus headache	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	15SEP2017		Y
			Nasal septum deviation	01JAN2010		Y
			Rhinitis allergic	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Intramedullary rod insertion	01NOV2019	30NOV2019	N
	C4591001 1019 10191004	Ear and labyrinth disorders	Deafness	01JAN1994		Y
		Eye disorders	Presbyopia	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN1987		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Infections and infestations	Bronchitis	01JAN2017	31DEC2017	N
			Malaria	01JAN1984	31DEC1993	N
			Pneumonia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	18JUL2020		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017		Y
			Rhinitis allergic	01JAN1985		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1019 10191008	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2019		Y
		Eye disorders	Myopia	01JAN1950		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Rectal prolapse	01JAN2003	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1995		Y
			Sinusitis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Seizure	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1989		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2003	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Colporrhaphy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1019 10191009	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Diverticulum	10AUG2010		Y
		Infections and infestations	Herpes zoster	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Muscle spasms	01JAN2018		Y
			Myalgia	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
				01JAN1982	31DEC1982	N
			Female sterilisation	01JAN1982	31DEC1982	N
	C4591001 1019 10191010	Blood and lymphatic system disorders	Iron deficiency anaemia	01SEP2010	31JUL2020	N
		Cardiac disorders	Atrial fibrillation	01NOV2017		Y
			Mitral valve incompetence	01JAN2005		Y
		Congenital, familial and genetic disorders	Familial tremor	01JAN1974		Y
		Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Myopia	01JAN1984		Y
			Presbyopia	01JAN1984		Y
		Gastrointestinal disorders	Anal fistula	01JAN1981	31DEC1981	N
			Constipation	01APR2010		Y
			Dry mouth	01JAN2012		Y
			Duodenal ulcer	01JAN1990	31DEC2000	N
			Dyspepsia	01JAN1990		Y
			Haemorrhoids	01JAN2010		Y
			Oesophageal ulcer	01JAN1990	31DEC2000	N
		General disorders and administration site conditions	Chest pain	01JAN2018		Y
			Oedema peripheral	25APR2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Infections and infestations	Bronchitis	12NOV2010	24NOV2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Device related infection	01JAN2014	31DEC2014	N
			Pneumonia	01MAR2009	31MAR2009	N
			Tonsillitis	01JAN1961	31DEC1961	N
		Injury, poisoning and procedural complications	Epicondylitis	01JAN1998	31DEC1999	N
			Foot fracture	01JAN2003	31DEC2003	N
				01JAN2010	31DEC2010	N
			Stress fracture	01AUG2010	05OCT2010	N
			Upper limb fracture	01JUL2010	31JUL2010	N
		Investigations	Arthroscopy	01JAN1980	31DEC1980	N
			Cardiac murmur	01JAN2004		Y
		Metabolism and nutrition disorders	Gout	01JAN1998		Y
			Hypercholesterolaemia	01JAN1994		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1980		Y
			Arthropathy	01JAN2009	31JUL2010	N
			Back pain	01JAN2004		Y
			Fibromyalgia	01APR2014		Y
			Muscle spasms	01APR2018		Y
			Osteoarthritis	01JAN1997		Y
			Osteopenia	01JAN2012		Y
			Osteoporosis	01JAN2016		Y
			Rotator cuff syndrome	01JAN2018	01MAR2018	N
			Tendonitis	01JAN2006	31JAN2006	N
			Trigger finger	01JAN1999	31DEC1999	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1996	31DEC1996	N
			Diabetic neuropathy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tension headache	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001		Y
			Insomnia	01JAN2014		Y
		Renal and urinary disorders	Chronic kidney disease	25APR2018		Y
			Urinary incontinence	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1960	31DEC1980	N
			Uterine disorder	01JAN2005	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1984		Y
			Nasal polyps	01MAY2018		Y
			Rhinitis allergic	01JAN1972		Y
			Sleep apnoea syndrome	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2002		Y
			Rosacea	26NOV2001		Y
		Surgical and medical procedures	Anal fistula repair	01JAN1981	31DEC1981	N
			Ankle operation	01JUL2010	31JUL2010	N
			Carpal tunnel decompression	01JAN1996	31DEC1996	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Continuous positive airway pressure	01JAN1989		Y
			Implantable cardiac monitor insertion	01NOV2017		Y
			Knee arthroplasty	01JAN2007	31DEC2007	N
			Rotator cuff repair	01MAR2018	01MAR2018	N
			Shoulder arthroplasty	01APR2014	30APR2014	N
				01JAN2013	31DEC2013	N
			Tendon sheath incision	01JAN1999	31DEC1999	N
			Tenoplasty	01JAN2006	31JAN2006	N
			Tonsillectomy	01JAN1961	31DEC1961	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2004		Y
			Peripheral vascular disorder	01MAY2018		Y
	C4591001 1019 10191011	Eye disorders	Myopia	01JAN1958		Y
			Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Abdominal wall mass	01JAN1978	31DEC1978	N
			Constipation	01JAN2000	31DEC2000	N
			Diverticulum	01JAN2003		Y
			Gastroesophageal reflux disease	01JAN2002		Y
			Haemorrhoids	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Herpes zoster	01JUN2019	01JUL2019	N
			Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
			Osteopenia	01JAN1988		Y
		Nervous system disorders	Sinus headache	01JAN1988		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1966	31DEC1978	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Abdominal wall operation	01JAN1978	31DEC1978	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191012	Cardiac disorders	Atrial fibrillation	01NOV2005		Y
			Coronary artery disease	01NOV2005	30NOV2005	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Cataract	01JAN2008	31DEC2008	N
			Myopia	01JAN1948		Y
			Presbyopia	01JAN1948		Y
			Strabismus	01JAN1943	31DEC1948	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Gout	01JAN1988		Y
			Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01APR2020	30APR2020	N
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
			Coronary artery bypass	01NOV2005	30NOV2005	N
			Lithotripsy	01JAN2012	31DEC2012	N
			Skin lesion removal	01APR2020	30APR2020	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1019 10191013	Cardiac disorders	Aortic valve incompetence	01JAN2010		Y
			Coronary artery disease	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mitral valve incompetence	01JAN2010		Y
			Mitral valve prolapse	01OCT2019	31OCT2019	N
			Supraventricular extrasystoles	01JAN2010		Y
		Eye disorders	Cataract	01JAN2009		Y
					28FEB2011	N
			Macular degeneration	01SEP2016		Y
			Myopia	01JAN1970		Y
			Presbyopia	01JAN1970		Y
			Retinal detachment	01SEP2016	04AUG2020	N
		Gastrointestinal disorders	Diverticulum	01JAN2009		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN1975		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
			Sinusitis	01JAN2003	31OCT2007	N
			Urinary tract infection	01JAN2006		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Gout	12SEP2018		Y
			Hypercholesterolaemia	01JAN2007		Y
			Impaired fasting glucose	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Osteoarthritis	01JAN2007		Y
			Osteopenia	01JAN2007		Y
			Osteoporosis	01MAR2006		Y
			Pain in extremity	01JAN2007		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinus headache	01JAN1970		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2001		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1975	31DEC1975	N
			Ovarian cyst	01JAN1980	31DEC1980	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1940		Y
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Caesarean section	01JAN1969	31DEC1975	N
			Cataract operation	01FEB2011	28FEB2011	N
			Cholecystectomy	01JAN1975	31DEC1975	N
			Coronary arterial stent insertion	01JAN2007	31DEC2007	N
			Coronary artery bypass	01JUN2014	30JUN2014	N
			Hernia hiatus repair	01JAN1975	31DEC1975	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Mitral valve repair	01OCT2019	31OCT2019	N
			Oophorectomy bilateral	01JAN1980	31DEC1980	N
			Urinary bladder suspension	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2004		Y
			Peripheral arterial occlusive disease	01JAN2008		Y
	C4591001 1019 10191014	Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010	31DEC2019	N
			Dyspepsia	01JAN2012	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
			Herpes zoster	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2005		Y
			Hypercholesterolaemia	01JAN2013		Y
			Lactose intolerance	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
				01JAN2016		Y
			Back pain	01JAN2010	31DEC2017	N
			Muscle spasms	01JAN2012	31DEC2019	N
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
			Migraine	01JAN2005	31DEC2016	N
			Tension headache	01JAN1967		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2013		Y
			Rales	11AUG2020		Y
			Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191016	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191017	Eye disorders	Myopia	01JAN2010		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Diarrhoea	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
			Vitamin D deficiency	25NOV2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	31JUL2018	N
			Foot deformity	01JAN2003	26NOV2013 30JUN2014	N N
				01JAN2006		Y
			Osteoarthritis	01JAN1990		Y
			Rotator cuff syndrome	01JUL2018	31JUL2018	N
		Nervous system disorders	Neuropathy peripheral	08DEC2016		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN1991		Y
		Reproductive system and breast disorders	Pruritus genital	04JAN2016		Y
			Uterine prolapse	01JAN1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
		Surgical and medical procedures	Bunion operation	01JUN2014	30JUN2014	N
				26NOV2013	26NOV2013	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
			Rotator cuff repair	01JUL2018	31JUL2018	N
			Urinary bladder suspension	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191019	Eye disorders	Myopia	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Lipoma excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1019 10191020	Eye disorders	Presbyopia	01JAN1979		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Irritable bowel syndrome	01JAN1984		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
				01JAN1996		Y
		Infections and infestations	Hepatitis A	01JAN1982	31DEC1982	N
		Investigations	Cardiac murmur	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
			Uterine leiomyoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Restless legs syndrome	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N
			Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Face lift	01JAN2006	31DEC2006	N
				01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1019 10191021	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2011	31DEC2013	N
		Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Cataract	01JAN2014	31DEC2015 31DEC2017	N N
			Myopia	01JAN2017		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	10MAY2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Injury, poisoning and procedural complications	Hand fracture	09JUL2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	10FEB1999		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01MAR2016	30JUN2016	N
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Carotid endarterectomy	01JAN2009	31DEC2009	N
			Cataract operation	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Coronary angioplasty	01JAN2007	31DEC2007	N
			Peripheral artery bypass	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Peripheral arterial occlusive disease	01MAR2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191022	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Myopia	01JAN1990	31DEC2018	N
			Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Infections and infestations	Herpes zoster	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191024	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
			Tinnitus	01JAN2015		Y
		Eye disorders	Cataract	01JAN2009		Y
			Myopia	01JAN1967		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2020		Y
			Muscle spasms	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Drug abuse	01JAN2008	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2013		Y
			Rhinitis allergic	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191025	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Endocrine disorders	Thyroid mass	28AUG2017	31DEC2019	N
		Eye disorders	Dry age-related macular degeneration	01JAN2010		Y
			Myopia	01JAN1963		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		General disorders and administration site conditions	Precancerous condition	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Infections and infestations	Hepatitis C	01JAN2000	31DEC2005	N
		Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tonsil cancer	28AUG2017	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2011		Y
		Social circumstances	Substance use	01JAN1971	31DEC2019	N
		Surgical and medical procedures	Brachytherapy to prostate	01JAN2011	31DEC2011	N
	C4591001 1019 10191026	Eye disorders	Myopia	01JAN1980		Y
			Presbyopia	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Chlamydial cervicitis	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1990	31DEC1990	N
			Ligament rupture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Psychiatric disorders	Drug abuse	01JAN1971	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Ligament operation	01JAN1990	31DEC1990	N
	C4591001 1019 10191029	Endocrine disorders	Thyroid mass	01JAN2001	31DEC2001	N
				27JUN2017		Y
		Eye disorders	Presbyopia	01JAN2011		Y
		Gastrointestinal disorders	Diverticulum	20SEP2016		Y
			Gastroesophageal reflux disease	01JAN2003		Y
			Haemorrhoids	01JAN1988	31DEC1992	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2003	N
		Immune system disorders	Food allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Gout	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
			Fibromyalgia	01JAN2006		Y
			Foot deformity	01JAN1985	31DEC1985	N
			Osteoarthritis	01JAN2000		Y
			Osteopenia	22AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Temporomandibular joint syndrome	01APR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC2002	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2003		Y
			Cervical radiculopathy	01JAN2015		Y
			Tension headache	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN1964	31DEC1964	N
		Surgical and medical procedures	Bone debridement	01JAN2000	31DEC2000	N
			Bunion operation	01JAN1985	31DEC1985	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Meniscus operation	01JAN2000	31DEC2000	N
			Skin graft	01JAN1966	31DEC1966	N
			Thyroid nodule removal	01JAN2001	31DEC2001	N
			Venous ligation	01JAN1966	31DEC1966	N
		Vascular disorders	Varicose vein	08JUN2017		Y
	C4591001 1019 10191030	Ear and labyrinth disorders	Vertigo	01FEB2011	28FEB2011	N
		Eye disorders	Myopia	01JAN1980		Y
			Presbyopia	01MAR2013		Y
		Gastrointestinal disorders	Abdominal pain	01JAN1994	01JUN2019	N
			Constipation	01JAN1994		Y
			Haemorrhoids	01JAN1994	31DEC2000	N
		Infections and infestations	Bronchitis	22APR2014	28APR2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2008		Y
			Obesity	01JAN2008	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
				01OCT2012		Y
				15OCT2014	15NOV2014	N
			Exostosis	01JAN2008	31DEC2010	N
			Intervertebral disc protrusion	01JAN2001	31DEC2001	N
			Osteoarthritis	01DEC2012		Y
			Pain in extremity	15OCT2014	15NOV2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JUN2017		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1019 10191031	Eye disorders	Presbyopia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2017	30JUN2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
	C4591001 1019 10191035	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Infections and infestations	Herpes zoster	01JAN2005	31DEC2005	N
			Meningitis	01JAN1971	31DEC1971	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1997	31DEC1997	N
				01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Fascial rupture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012	31DEC2012	N
			Intervertebral disc protrusion	01JAN2012	31DEC2012	N
			Osteopenia	01JAN2015	31DEC2017	N
			Pain in extremity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31JUL2010	N
		Nervous system disorders	Migraine	01JAN1998		Y
		Renal and urinary disorders	Bladder disorder	01JUN2010		Y
			Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01APR2010	31JUL2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1974	31DEC1974	N
				01JAN1976	31DEC1976	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Hysterectomy	01JUL2010	31JUL2010	N
			Intervertebral disc operation	01JAN2012	31DEC2012	N
	C4591001 1019 10191037	Cardiac disorders	Cardiac arrest	01JAN2015	31DEC2015	N
			Coronary artery disease	01JAN2008		Y
			Coronary artery occlusion	01JAN2015	31DEC2015	N
		Eye disorders	Presbyopia	01JAN1997		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1975		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Investigations	Cystoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2019	31DEC2019	N
			Prostate cancer	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Coronary arterial stent insertion	01JAN2008	31DEC2008	N
			Implantable defibrillator insertion	01JAN2015	31DEC2015	N
			Radical prostatectomy	01JAN2004	31DEC2004	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1019 10191039	Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Injury, poisoning and procedural complications	Splenic rupture	01JAN1990	31DEC1990	N
			Wrist fracture	01JAN1986	31DEC1986	N
		Nervous system disorders	Tremor	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1959		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Splenectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1019 10191040	Cardiac disorders	Cardiac failure congestive	01MAR2017		Y
			Coronary artery disease	01JUL2019		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vertigo	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	24FEB2016		Y
		Eye disorders	Blindness unilateral	01SEP2019		Y
			Myopia	01JAN2011		Y
			Presbyopia	01JAN2011		Y
		Gastrointestinal disorders	Constipation	01FEB2019		Y
			Gastroesophageal reflux disease	01JAN2008		Y
			Pancreatitis	01JAN2001	31DEC2001	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1991	31JAN1991	N
		Investigations	Arthroscopy	01MAY2007	31MAY2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1970		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2012		Y
			Osteoarthritis	01JAN2007		Y
			Pain in extremity	01JAN1991		Y
			Spinal osteoarthritis	01JAN2013		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAR2011	31DEC2012 31DEC2013	N N
			Sciatica	01JAN2013		Y
			Trigeminal neuralgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2001		Y
			Sleep disorder	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01FEB2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2009		Y
			Cough	01JAN2009		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Coronary arterial stent insertion	01JUL2019	31JUL2019	N
			Open reduction of fracture	01JAN1991	31JAN1991	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1019 10191042	Eye disorders	Myopia	01JAN2005		Y
			Presbyopia	01JAN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	14APR2011	31JAN2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2008		Y
		Infections and infestations	Bronchitis	01JAN2010	20MAY2010	N
			Pneumonia	01JAN2019	30APR2019	N
			Tonsillitis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y
			Foot deformity	01JAN2008	31DEC2008	N
			Intervertebral disc protrusion	01JAN1977	31DEC1993	N
				25JAN2020		Y
			Osteoarthritis	01JAN2009		Y
			Tenosynovitis stenosans	01JAN1973	31DEC1973	N
				01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Cough	01JAN2010		Y
			Nasal septum deviation	23JUL2010		Y
			Rhinitis allergic	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Blepharoplasty	01JAN2004	31DEC2004	N
			Bunion operation	01JAN2008	31DEC2008	N
				29OCT2011	29OCT2011	N
			Intervertebral disc operation	01JAN1993	31DEC1993	N
			Liposuction	01JAN1987	31DEC1987	N
			Mammoplasty	01JAN1973	31DEC1973	N
				01MAR2017	01MAY2017	N
			Neurectomy	01JAN2009	31DEC2009	N
			Tenoplasty	01JAN1973	31DEC1973	N
				01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1987	31DEC1987	N
	C4591001 1019 10191043	Cardiac disorders	Aortic valve incompetence	10APR2010		Y
			Atrial fibrillation	01JAN2006		Y
			Atrioventricular block complete	01AUG2014		Y
			Coronary artery disease	10FEB2010		Y
			Pericardial effusion	01SEP2013	30SEP2013	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Myopia	01JAN1988		Y
			Presbyopia	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JUL2015	31JUL2015	N
		Infections and infestations	Ear infection	01JAN2006	31DEC2008	N
			Sinusitis	21SEP2017	01OCT2017	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Obesity	01JAN1960		Y
			Type 2 diabetes mellitus	01JAN2014		Y
			Vitamin K deficiency	01JAN2007		Y
		Nervous system disorders	Tension headache	01JAN1960		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2002		Y
			Prostatomegaly	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Surgical and medical procedures	Cardiac ablation	01AUG2014	31AUG2014	N
				01DEC2014	31DEC2014	N
				01SEP2013	30SEP2013	N
			Cardiac pacemaker insertion	01AUG2014	31DEC2014	N
			Pericardial excision	01SEP2013	30SEP2013	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Transurethral prostatectomy	01FEB2017	28FEB2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1019 10191045	Ear and labyrinth disorders	Deafness unilateral	01JAN1997		Y
			Meniere's disease	01JAN1997		Y
			Tinnitus	01JAN1997		Y
		Eye disorders	Glaucoma	01JAN2019		Y
			Myopia	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN1979	31DEC1979	N
			Hand fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Gout	01DEC2009		Y
			Hypercholesterolaemia	01JAN1990		Y
			Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Rotator cuff syndrome	01NOV2007	30NOV2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2019		Y
			Bronchitis chronic	01FEB2019		Y
			Rhinitis allergic	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1960		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1995	31DEC1995	N
			Prostatectomy	01DEC2011	31DEC2011	N
			Rotator cuff repair	01NOV2007	30NOV2007	N
	C4591001 1019 10191046	Ear and labyrinth disorders	Deafness unilateral	01JAN2019		Y
		Eye disorders	Cataract	01JAN2015		Y
					30SEP2019	N
			Eye irritation	01OCT2018	31OCT2018	N
			Macular fibrosis	01OCT2018	31OCT2018	N
			Myopia	01JAN1958		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2008	31DEC2008	N
		Investigations	Plasminogen activator inhibitor increased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAY2019		Y
			Synovial cyst	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01NOV2008	30NOV2008	N
			Squamous cell carcinoma	01JAN2009	31JAN2009	N
				01SEP1996	30SEP1996	N
				01SEP2016	30SEP2016	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1964	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018	31DEC2018	N
			Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01MAY2011		Y
		Surgical and medical procedures	Cancer surgery	01JAN2009	31JAN2009	N
				01SEP1996	30SEP1996	N
				01SEP2016	30SEP2016	N
			Cataract operation	01SEP2019	30SEP2019	N
			Endometrial ablation	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Plastic surgery to the face	01JAN2008	31DEC2008	N
			Retinal operation	01OCT2018	31OCT2018	N
			Skin neoplasm excision	01NOV2008	30NOV2008	N
	C4591001 1019 10191048	Endocrine disorders	Hypothyroidism	01JUL2005		Y
		Eye disorders	Cataract	01JAN2016	31DEC2019	N
			Myopia	01JAN1966	31MAR2005	N
			Presbyopia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Abdominal hernia	01JAN1957	31DEC1969	N
			Diverticulum	01JUN2006		Y
			Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Hepatitis A	01JAN1990	31DEC1990	N
			Pneumonia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1997	31DEC1997	N
				01JAN2003	31DEC2003	N
				01MAR2008	30JUN2008	N
			Epicondylitis	01JAN1984	31DEC1986	N
			Foot fracture	01AUG2004	31OCT2004	N
				01JUL2016	31JUL2016	N
				01MAR2010	31MAY2010	N
				01OCT2006	31DEC2006	N
				11SEP2010	31OCT2010	N
			Ligament rupture	01JAN1998	31DEC1998	N
			Limb injury	01MAR2017	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2016	N
			Rotator cuff syndrome	25MAR2018	02AUG2018	N
			Temporomandibular joint syndrome	01JAN1991	31AUG1993	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1997	31DEC1997	N
				01JAN2009	31DEC2009	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
			Transient ischaemic attack	01MAR2016	31MAR2016	N
		Psychiatric disorders	Anxiety	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01APR2020		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2002	31DEC2011	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1977	31DEC2000	N
				01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Nasal septum deviation	01JAN2012		Y
			Rhinitis allergic	01JAN1987		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01AUG2003		Y
		Surgical and medical procedures	Abdominal hernia repair	01JUL1969	31JUL1969	N
			Cataract operation	01DEC2019	31DEC2019	N
			Keratomileusis	31MAR2005	31MAR2005	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Ligament operation	01JAN1998	31DEC1998	N
			Orthognathic surgery	01AUG1993	31AUG1993	N
			Rotator cuff repair	02AUG2018	02AUG2018	N
			Tenoplasty	01DEC1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1990	31MAY2020	N
	C4591001 1019 10191049	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2019		Y
			Myopia	01JAN1966		Y
			Presbyopia	01JAN1966		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955	31DEC1973	N
			Chronic obstructive pulmonary disease	01OCT2018		Y
			Rhinitis allergic	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2006		Y
			Substance use	01JAN1973	31DEC1974	N
		Surgical and medical procedures	Mammoplasty	01JAN1986	31DEC1986	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1019 10191051	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
			Tinnitus	01JAN2000		Y
		Eye disorders	Astigmatism	01JAN1961		Y
			Myopia	01JAN1961		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Genital herpes	01JAN1995		Y
			Herpes zoster	01JAN1990	31DEC1990	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Sinusitis	01JAN2016		Y
			Tonsillitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1979	31DEC1979	N
				01JAN1980		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Foot fracture	01JAN1975	31DEC1975	N
			Rib fracture	01JAN1997	31DEC1997	N
			Upper limb fracture	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
			Muscle spasms	01JAN2000		Y
			Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
			Trigger finger	02JUL2020	10AUG2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
				01JAN2012	31DEC2012	N
		Nervous system disorders	Sinus headache	01JAN1970		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Ankle operation	01JAN1979	31DEC1979	N
				01JAN1980	31DEC1980	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2001	31DEC2001	N
			Spinal laminectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1019 10191052	Eye disorders	Myopia	01JAN1978		Y
			Presbyopia	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	15JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1019 10191053	Eye disorders	Astigmatism	01JAN1970		Y
			Myopia	01JAN1970		Y
			Presbyopia	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991		Y
		Nervous system disorders	Migraine	01JAN1984		Y
			Tension headache	01JAN1984		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1991	31DEC1991	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
			Uterine dilation and curettage	01JAN1991	31DEC1991	N
	C4591001 1019 10191054	Eye disorders	Presbyopia	01JAN1975		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinusitis	01JAN2000	31DEC2015	N
			Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1993	31DEC1993	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1973	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
			Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Granuloma annulare	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1984	31DEC1984	N
			Caesarean section	01JAN1981	31DEC1981	N
				01JAN1988	31DEC1988	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191055	Eye disorders	Presbyopia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Infections and infestations	Otitis media	01JAN2015	31DEC2018	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1976	31DEC1981	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2010	31DEC2012	N
	C4591001 1019 10191057	Eye disorders	Presbyopia	01JAN2005		Y
		Infections and infestations	Hepatitis C	01JAN2015	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1019 10191060	Eye disorders	Cataract	01JAN2008		Y
			Dry eye	01JAN2008		Y
			Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Abdominal adhesions	01JAN2008	31DEC2008	N
			Diverticulum	01JAN2013		Y
			Gastroesophageal reflux disease	01JAN2013		Y
			Haemorrhoids	01JAN2013	31DEC2013	N
			Hiatus hernia	01JAN2013		Y
			Irritable bowel syndrome	01JAN2013		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
			Onychomycosis	01JAN1980		Y
			Pneumonia	01JAN1961	31DEC1961	N
			Sinusitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	18AUG2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1988		Y
			Morton's neuralgia	01JAN2013		Y
			Sinus headache	01JAN1988		Y
			Tension headache	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN1998		Y
			Insomnia	01JAN2008		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Endometriosis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
			Vitiligo	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Adhesiolysis	01JAN2008		Y
			Scar excision	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1019 10191061	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
				01JAN2016		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191062	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
				01JAN2012		Y
		Infections and infestations	Rhinitis	01JAN1990		Y
			Sinusitis	01JAN1975	30APR2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Cervicogenic headache	01JAN2010		Y
			Sinus headache	01JAN1990		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1983		Y
		Social circumstances	Postmenopause	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191064	Congenital, familial and genetic disorders	Hydrocele	(b) (6) 1958	(b) (6) 1958	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
			Tinnitus	01JAN2010		Y
		Eye disorders	Cataract	18DEC2019		Y
			Presbyopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN2016	31DEC2016	N
			Large intestine polyp	01JAN2013	31DEC2013	N
		Infections and infestations	Cytomegalovirus infection	01JAN2000	31DEC2000	N
			Herpes zoster	01JAN1987	31DEC1987	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
			Osteoarthritis	01JAN2013		Y
		Surgical and medical procedures	Hydrocele operation	(b) (6) 1958	(b) (6) 1958	N
			Inguinal hernia repair	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1019 10191065	Cardiac disorders	Atrial flutter	01JAN2015	31DEC2015	N
		Eye disorders	Presbyopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1994	31DEC1994	N
			Muscle injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017	31DEC2017	N
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Intervertebral disc operation	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN1994	31DEC1994	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
			Tenoplasty	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Transurethral prostatectomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1019 10191066	Eye disorders	Myopia	01JAN2003		Y
			Presbyopia	01JAN2003		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1994		Y
		General disorders and administration site conditions	Cyst	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Herpes zoster	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc protrusion	01JAN2005		Y
			Muscle spasms	01JAN2000		Y
			Myalgia	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
			Migraine	01JAN2001	31DEC2003	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
		Vascular disorders	Hypotension	01JAN2005		Y
	C4591001 1019 10191067	Eye disorders	Presbyopia	01JAN2002	31DEC2018	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Pneumonia	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dehydration	01JAN2001		Y
			Hypocalcaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2019		Y
		Nervous system disorders	Headache	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2006		Y
		Surgical and medical procedures	Keratomileusis	01JAN2018	31DEC2018	N
			Rhinoplasty	01JAN1980	31DEC1980	N
			Venous operation	01JAN2017	31DEC2017	N
		Vascular disorders	Peripheral venous disease	01JAN2017	31DEC2017	N
	C4591001 1019 10191069	Eye disorders	Presbyopia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2020	30MAR2020	N
		Surgical and medical procedures	Prostatectomy	30MAR2020	30MAR2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1019 10191070	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Presbyopia	01JAN1964		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1992	31DEC1992	N
		Social circumstances	Postmenopause	01APR1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1019 10191071	Cardiac disorders	Cardiomegaly	04OCT2016		Y
			Coronary artery disease	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
			Inguinal hernia	01JAN2013	31DEC2013	N
		Infections and infestations	Pneumonia	01JAN1993	31DEC1993	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Gout	01APR2018		Y
			Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Back pain	01JAN2008		Y
			Osteoarthritis	01JAN2008		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1952		Y
			Chronic obstructive pulmonary disease	01JAN2013		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN2013	31DEC2013	N
			Internal fixation of fracture	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1019 10191072	Ear and labyrinth disorders	Deafness unilateral	01JAN2016		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Food allergy	01JAN1955		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Milk allergy	01JAN1955		Y
		Infections and infestations	Sinusitis	01JAN1957		Y
			Syphilis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1967	31DEC1967	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01JAN1991		Y
			Intervertebral disc protrusion	01JAN1991		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
			Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Hand amputation	01JAN1972	31DEC1972	N
			Hernia repair	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191075	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Eye disorders	Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Abdominal pain	01JAN1993		Y
			Impaired gastric emptying	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1976	31DEC1976	N
				01JAN1977	31DEC1977	N
				01JAN1978	31DEC1978	N
				01JAN1979	31DEC1979	N
				01JAN1980	31DEC1980	N
			Ligament rupture	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020		Y
			Osteoarthritis	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
			Ligament operation	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1019 10191078	Eye disorders	Cataract	01JAN2017		Y
			Myopia	01JAN1978	31DEC1998	N
			Presbyopia	01JAN1968		Y
		Nervous system disorders	Migraine	01JAN1970		Y
			Sinus headache	01JAN1970		Y
			Tension headache	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1019 10191079	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
			Tinnitus	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1996	31DEC1996	N
			Transurethral prostatectomy	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1019 10191080	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Endocrine disorders	Hypogonadism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2019		Y
			Glaucoma	01JAN2015		Y
			Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Diverticulum	01JAN2005		Y
			Haemorrhoids	01JAN2005	31DEC2005	N
			Inguinal hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Sinusitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN1978	31DEC1978	N
				01JAN1988	31DEC1988	N
				01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
		Nervous system disorders	Peroneal nerve palsy	01JAN1988		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
			Sleep disorder	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Substance use	01JAN1960	31DEC1970	N
		Surgical and medical procedures	Bone graft	01JAN1984	31DEC1984	N
			Hip arthroplasty	01JAN1978	31DEC1978	N
				01JAN1988	31DEC1988	N
				01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
				16DEC2019	16DEC2019	N
			Keratomileusis	01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
			Sinuplasty	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1019 10191082	Cardiac disorders	Ventricular extrasystoles	01JAN2016		Y
		Ear and labyrinth disorders	Deafness	01JAN2017		Y
		Eye disorders	Dry eye	01JAN2010		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Constipation	01JAN1970		Y
			Gastrooesophageal reflux disease	01JAN1970		Y
			Haemorrhoids	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Infections and infestations	Pneumonia	01JAN2020	31JAN2020	N
			Sinusitis	01JAN1980		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
		Investigations	Cardiac murmur	01JAN2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1984		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2004	31DEC2004	N
				01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014		Y
					31DEC2015	N
			Tremor	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1982	31DEC1982	N
				01JAN1986	31DEC1986	N
			Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Toe operation	01JAN2004	31DEC2004	N
				01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
	C4591001 1019 10191084	Cardiac disorders	Coronary artery disease	01MAY2020		Y
		Ear and labyrinth disorders	Deafness unilateral	01MAY2020		Y
		Eye disorders	Astigmatism	01JAN1980		Y
			Cataract	01JAN2002		Y
			Myopia	01JAN1952	31DEC1997	N
		Gastrointestinal disorders	Hiatus hernia	01JAN1990		Y
			Inguinal hernia	01MAY2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1969	31DEC1969	N
		Investigations	Cardiac murmur	01JAN1985	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Bursitis	01JUN2020		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Urinary incontinence	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1969	31DEC1969	N
			Keratomileusis	01JAN1997		Y
			Knee arthroplasty	01NOV2019	30NOV2019	N
			Prostatectomy	01JAN2014	31DEC2014	N
			Scar excision	27JAN2020	27JAN2020	N
	C4591001 1019 10191086	Congenital, familial and genetic disorders	Familial tremor	01JAN1956		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Diverticulum	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
			Pneumonia	01JAN2010	31DEC2010	N
			Tonsillitis	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2009		Y
			Trigger finger	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
			Neuroendocrine carcinoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN1971		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1982	31DEC1983	N
			Ovarian cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Caesarean section	01JAN1979	31DEC1979	N
			Cancer surgery	01JAN2012	31DEC2012	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Mastectomy	01JAN2016	31DEC2016	N
			Spinal rod insertion	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
				01OCT2019	31OCT2019	N
			Tonsillectomy	01JAN1986	31DEC1986	N
	C4591001 1019 10191087	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2018		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1019 10191088	Surgical and medical procedures	Tonsillectomy	01JAN1966	31DEC1966	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2019		Y
			Tinnitus	01JAN2019		Y
		Eye disorders	Astigmatism	01JAN2002		Y
		Gastrointestinal disorders	Pancreatic cyst	01DEC2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	01FEB2019	31DEC2019	N
			Throat cancer	01FEB2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Urge incontinence	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Lymphadenectomy	01FEB2019	28FEB2019	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1019 10191089	Eye disorders	Myopia	01JAN1967		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Colitis microscopic	01JAN2015		Y
			Inguinal hernia	01JAN1968	31DEC1968	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
			Spinal stenosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC1999	N
		Psychiatric disorders	Depression	01JUN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1964		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
			Inguinal hernia repair	01JAN1968	31DEC1968	N
			Spinal decompression	01JAN2018	31DEC2018	N
	C4591001 1019 10191091	Endocrine disorders	Goitre	01JAN1980	31DEC1980	N
			Hypothyroidism	01JAN1980		Y
		Eye disorders	Cataract	01JAN1998	31DEC1998	N
			Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Constipation	01JAN1963		Y
			Gastroesophageal reflux disease	10OCT2010		Y
			Hiatus hernia	01OCT2018		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1984		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1969	31DEC1969	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Sinusitis	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
			Foot deformity	01NOV2009	30NOV2009	N
			Intervertebral disc protrusion	01JAN2009		Y
			Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2017		Y
			Breast cancer	01NOV2010	31JAN2011	N
		Nervous system disorders	Olfactory nerve disorder	01JAN1984	31DEC1984	N
		Reproductive system and breast disorders	Rectocele	01FEB2011	28FEB2011	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010		Y
		Surgical and medical procedures	Benign tumour excision	01JAN1984	31DEC1984	N
			Bunion operation	01NOV2009	30NOV2009	N
			Cataract operation	01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN1969	31DEC1969	N
			Hysterectomy	01FEB2011	28FEB2011	N
				01NOV2010	01NOV2010	N
			Rectocele repair	01FEB2011	28FEB2011	N
			Sinuplasty	01JAN1998	31DEC1998	N
		Eye disorders	Presbyopia	01JAN2007		Y
	C4591001 1019 10191092					
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2014		Y
			Irritable bowel syndrome	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2006	31DEC2006	N
				01JAN2013	31DEC2013	N
		Nervous system disorders	Tension headache	01JAN1977		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rotator cuff repair	01JAN2006	31DEC2006	N
				01JAN2013	31DEC2013	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191093	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
		Investigations	Prostatic specific antigen increased	01AUG2019	30SEP2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1967		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2008	31DEC2008	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
			Meniscus operation	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
			Radiotherapy	01AUG2019	30SEP2019	N
			Vasectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1019 10191094	Eye disorders	Presbyopia	01JAN1990		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1974	31DEC1975	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1955		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Endometrial ablation	01JAN1975	31DEC1975	N
	C4591001 1019 10191095	Eye disorders	Cataract	01JAN2019		Y
			Presbyopia	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
			Chronic sinusitis	01JAN1990	31DEC1995	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1964	31DEC1964	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2000	N
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1960		Y
			Depression	01JAN1960		Y
		Renal and urinary disorders	Renal cyst	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN1995	31DEC1995	N
		Social circumstances	Substance use	01JAN1965	31DEC2005	N
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Joint dislocation reduction	01JAN1964	31DEC1964	N
			Renal surgery	01JAN2000	31DEC2000	N
			Sinuplasty	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1019 10191096	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Eye disorders	Dry eye	01JAN2000		Y
			Eyelid ptosis	01JAN2000	31DEC2010	N
			Myopia	01JAN1997	31DEC1999	N
			Presbyopia	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Infections and infestations	Rhinitis	01JAN1970		Y
		Investigations	Intraocular pressure increased	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1967		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016	31DEC2016	N
			Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Blepharoplasty	01JAN2010	31DEC2010	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Nasal septal operation	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prostatic operation	01JAN2016	31DEC2016	N
			Turbinectomy	01JAN1990	31DEC1990	N
	C4591001 1019 10191097	Ear and labyrinth disorders	Deafness unilateral	01FEB2015		Y
			Tinnitus	01FEB2020		Y
		Eye disorders	Myopia	01JAN2011		Y
			Presbyopia	01JAN2011		Y
		Gastrointestinal disorders	Constipation	01JAN1981		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1019 10191099	Cardiac disorders	Ventricular extrasystoles	01JAN2017		Y
		Eye disorders	Cataract	01JAN2019		Y
			Presbyopia	01JAN2005		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2003	31DEC2003	N
			Tibia fracture	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Muscle spasms	01JAN2010		Y
			Osteoarthritis	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2013	N
			Squamous cell carcinoma	01JAN2005	31DEC2013	N
		Nervous system disorders	Tension headache	01JAN1975		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cancer surgery	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2013	31DEC2013	N
		Eye disorders	Myopia	01JAN1963		Y
	C4591001 1019 10191103	General disorders and administration site conditions	Drug intolerance	01JAN1985		Y
				01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01SEP2018	30SEP2018	N
		Surgical and medical procedures	Appendectomy	01SEP2018	30SEP2018	N
	C4591001 1019 10191104	Eye disorders	Myopia	01JAN1972		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Muscle strain	03AUG2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Fibromyalgia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
			Face lift	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN2010	31DEC2010	N
	C4591001 1019 10191105	Ear and labyrinth disorders	Tinnitus	01JUN2020		Y
		Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1985	31DEC1985	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1984	31DEC1984	N
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1019 10191107	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Eye disorders	Cataract	01JAN2014		Y
			Macular fibrosis	01JAN2015	31DEC2015	N
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Barrett's oesophagus	12MAY2014		Y
			Gastrooesophageal reflux disease	01JAN2012		Y
			Haemorrhoids	03JUL2017		Y
			Oesophageal ulcer	03JUL2017	03AUG2017	N
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2020		Y
			Lumbar spinal stenosis	08MAR2017		Y
			Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01OCT2017	19OCT2017	N
				20APR2016	20APR2016	N
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2007	31DEC2007	N
			Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Fracture treatment	01JAN1997	31DEC1997	N
			Nasal septal operation	01JAN2007	31DEC2007	N
			Retinal operation	01JAN2015	31DEC2015	N
			Rotator cuff repair	19OCT2017	19OCT2017	N
			Shoulder operation	20APR2016	20APR2016	N
			Tonsillectomy	01JAN1954	31DEC1954	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191109	Eye disorders	Myopia	01JAN2017		Y
			Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Penetrating abdominal trauma	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2011	31DEC2011	N
			Polyneuropathy alcoholic	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tremor	01JAN2017		Y
		Psychiatric disorders	Alcohol abuse	01JAN1966	31DEC1986	N
			Depression	01JAN1980	31DEC1990	N
			Drug abuse	01JAN1966	31DEC1986	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2017	31DEC2017	N
			Abdominal operation	01JAN1980	31DEC1980	N
			Carpal tunnel decompression	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1019 10191111	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Obesity	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Throat cancer	04JUN2014	04NOV2014	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2014		Y
			Rhinitis allergic	01JAN2002		Y
		Surgical and medical procedures	Cancer surgery	04JUN2014	04JUN2014	N
			Inguinal hernia repair	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1019 10191112	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Myopia	01JAN1990		Y
			Presbyopia	01JAN1990		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1984	31DEC1984	N
			Muscle spasms	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01DEC1999		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1984	31DEC1984	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1019 10191117	Eye disorders	Myopia	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN1960		Y
		Infections and infestations	Herpes zoster	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000		Y
			Rhinitis allergic	01JAN1953		Y
			Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1019 10191118	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1970	31DEC1970	N
			Jaw fracture	01JAN1974	31DEC1974	N
			Meniscus injury	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
			Muscle spasms	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Sinus headache	01JAN1962		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1962		Y
		Surgical and medical procedures	Meniscus operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1019 10191119	Cardiac disorders	Cardiac failure congestive	01JAN2015		Y
			Coronary artery disease	01JAN2019		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2013		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2018	31DEC2018	N
		Infections and infestations	Herpes zoster	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Forearm fracture	01JAN1963	31DEC1963	N
			Radius fracture	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Arthrodesis	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Cardiac pacemaker insertion	01JAN2009	31DEC2009	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
					31DEC2017	N
			Coronary artery bypass	01JAN2009	31DEC2009	N
			Hernia repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1019 10191120	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
			Tinnitus	01JAN2000		Y
		Endocrine disorders	Thyroid mass	01JAN1972	31DEC1977	N
		Eye disorders	Macular degeneration	01JAN2018		Y
			Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Haemorrhoids	01JAN1978		Y
		Injury, poisoning and procedural complications	Ureteric injury	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1988		Y
			Osteopenia	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Nervous system disorders	Migraine	01JAN1978	31DEC1998	N
		Reproductive system and breast disorders	Breast cyst	01JAN1972	31DEC1972	N
			Endometriosis	01JAN1995	31DEC1995	N
			Ovarian cyst	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995		Y
			Rhinitis allergic	01JAN1998		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1972	31DEC1972	N
			Hysterectomy	01JAN1995	31DEC1995	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thyroidectomy	01JAN1977	31DEC1977	N
			Ureteric repair	01JAN1996	31DEC1996	N
	C4591001 1019 10191121	Cardiac disorders	Coronary artery disease	14SEP2014		Y
			Myocardial infarction	01NOV2019	30NOV2019	N
				14SEP2014	14SEP2014	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2011		Y
			Meniere's disease	01JAN2011		Y
		Endocrine disorders	Adrenal insufficiency	01JAN2016		Y
			Hypothyroidism	01JAN2016		Y
		Eye disorders	Cataract	01JAN2004	31DEC2010	N
			Macular hole	01JAN2002	31DEC2002	N
			Myopia	01JAN1942		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
			Inguinal hernia	01JAN1987	31DEC1987	N
				01JAN2016	31DEC2016	N
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
			Hepatitis A	01JAN1949	31DEC1949	N
			Hepatitis B	01MAY1968	31MAY1968	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31DEC2016	N
				15JUN2020	25JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1998	31DEC1998	N
			Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1953		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2016		Y
			Psoriasis	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN2002	31DEC2002	N
			Cancer surgery	01JAN2016	31DEC2016	N
			Cataract operation	01JAN2010	31DEC2010	N
			Coronary arterial stent insertion	14SEP2014	14SEP2014	N
			Inguinal hernia repair	01JAN1987	31DEC1987	N
				01JAN2016	31DEC2016	N
			Neck dissection	01JAN2016	31DEC2016	N
			Parotidectomy	01JAN2016	31DEC2016	N
			Skin neoplasm excision	25JUN2020	25JUN2020	N
			Tooth extraction	14SEP2014	14SEP2014	N
			Transurethral prostatectomy	01JAN1998	31DEC1998	N
			Varicose vein operation	01JAN1992	31DEC1992	N
			Vasectomy	01JAN1973	31DEC1973	N
			Vitrectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Varicose vein	01JAN1957		Y
	C4591001 1019 10191122	Blood and lymphatic system disorders	Iron deficiency anaemia	01AUG2007		Y
		Endocrine disorders	Hypothyroidism	01JAN1973		Y
		Eye disorders	Cataract	01AUG2019		Y
			Myopia	01JAN1963		Y
			Presbyopia	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Haemorrhoids	01JAN2000		Y
			Inguinal hernia	01JAN2001	31DEC2001	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Infections and infestations	Herpes zoster	01SEP2007	30SEP2007	N
			Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Meniscus injury	01JUL2013	31JUL2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Muscle spasms	01JAN2018		Y
			Osteoarthritis	01JAN2009		Y
				01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1975		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1996		Y
			Urinary incontinence	01MAY2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2019		Y
			Erectile dysfunction	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Hernia repair	01JAN2001	31DEC2001	N
			Meniscus operation	01JUL2013	31JUL2013	N
			Tonsillectomy	01JAN1972	31DEC1972	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Varicose vein operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2019		Y
			Varicose vein	01JAN2001	31DEC2001	N
	C4591001 1019 10191126	Ear and labyrinth disorders	Deafness bilateral	01JAN1988		Y
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Appendicitis	01AUG2019	31AUG2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019		Y
				01MAY2020		Y
			Muscle spasms	01JAN2018		Y
			Osteoporosis	01JAN2020		Y
		Nervous system disorders	Tremor	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Breast cyst	01JAN1992	31DEC1992	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Cough	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Appendicectomy	01AUG2019	31AUG2019	N
			Cyst removal	01JAN1992	31DEC1992	N
	C4591001 1019 10191130	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon injury	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Neck pain	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1980	31DEC1980	N
			Tenoplasty	01JAN2003	31DEC2003	N
	C4591001 1019 10191131	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
			Presbyopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Infections and infestations	Pneumonia	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2018	31DEC2018	N
			Wrist fracture	01JAN2016	31DEC2016	N
		Investigations	Human papilloma virus test positive	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1976	31DEC1976	N
		Nervous system disorders	Migraine	01JAN1967	31DEC1997	N
			Petit mal epilepsy	01JAN1960	31DEC1961	N
			Tension headache	01JAN1997		Y
		Psychiatric disorders	Insomnia	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
		Surgical and medical procedures	Female sterilisation	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN1976	31DEC1976	N
	C4591001 1019 10191132	Eye disorders	Myopia	01JAN1969	31DEC1995	N
			Presbyopia	01JAN1995		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Infections and infestations	Herpes zoster	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N
			Keratomileusis	01JAN1995	31DEC1995	N
	C4591001 1019 10191134	Cardiac disorders	Mitral valve prolapse	01JAN1989		Y
		Eye disorders	Myopia	01JAN2003		Y
			Presbyopia	01JAN2015		Y
		Infections and infestations	Chlamydial infection	01JAN2016	31DEC2016	N
			Diverticulitis	01JAN2009	31DEC2009	N
			Pneumonia	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2002		Y
			Back pain	01JAN2015	31DEC2015	N
			Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01SEP2001	30SEP2002	N
		Nervous system disorders	Cerebrovascular accident	01JAN1989	31DEC1989	N
			Migraine	01JAN1989		Y
			Restless legs syndrome	01JAN2015		Y
			Tension headache	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Product issues	Device leakage	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Bipolar disorder	01JAN2007		Y
			Insomnia	01JAN2009		Y
		Renal and urinary disorders	Stress urinary incontinence	01SEP2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2010		Y
			Cough	01JAN2001		Y
			Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2003		Y
			Substance use	01JAN1986	31DEC1990	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2002	31DEC2002	N
			Colectomy	01JAN2009	31DEC2009	N
	C4591001 1019 10191135	Eye disorders	Myopia	01JAN2002		Y
			Presbyopia	01JAN1998		Y
		Infections and infestations	Pneumonia	01JAN2019	31JAN2019	N
			Sinusitis	01JAN2010	31DEC2013	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1972	31DEC1972	N
			Ligament rupture	01JAN2004	31DEC2004	N
			Meniscus injury	01JAN2004	31DEC2004	N
			Wrist fracture	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01JAN2006	31DEC2006	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Seizure	01JAN2006	31DEC2006	N
			Sinus headache	01JAN2000		Y
			Tension headache	01JAN2000		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
			Rhinitis allergic	01JAN1969		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1969	31DEC1969	N
			Craniotomy	01JAN2006	31DEC2006	N
			Ligament operation	01JAN2004	31DEC2004	N
			Meniscus operation	01JAN2004	31DEC2004	N
			Sinuplasty	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1019 10191136	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Cataract	01JAN2000	31DEC2000	N
			Myopia	01JAN1949		Y
		Injury, poisoning and procedural complications	Hip fracture	01JAN1987	31DEC1987	N
			Spinal fracture	01JAN1975	31DEC1975	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1984		Y
			Back pain	01JAN1975		Y
			Osteoporosis	01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN1995	31DEC1995	N
		Nervous system disorders	Epilepsy	01JAN1975		Y
			Migraine	01JAN1954		Y
			Tension headache	01JAN1954		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1995	31DEC1995	N
			Cataract operation	01JAN2000	31DEC2000	N
				01JAN2002	31DEC2002	N
			Nasal septal operation	01JAN1980	31DEC1980	N
		Cardiac disorders	Atrial fibrillation	01JAN2018	31DEC2018	N
		Eye disorders	Myopia	01JAN1961		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1978		Y
		Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2013		Y
		Infections and infestations	Herpes zoster	01MAY2020	30JUN2020	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1981		Y
		Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1019 10191143	Eye disorders	Cataract	01JAN2014	31JUL2015	N
					31OCT2015	N
			Myopia	01JAN1978		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
			Psoriasis	01JAN2011		Y
		Surgical and medical procedures	Cataract operation	01OCT2015	31OCT2015	N
				07JUL2015	07JUL2015	N
	C4591001 1019 10191144	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Eye disorders	Cataract	01JAN2017		Y
			Myopia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1968	31DEC2015	N
			Spondylolisthesis	01JAN1968	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1989	31DEC1989	N
			Sinus headache	01JAN2010		Y
			Tension headache	01JAN1983		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1989	31DEC1989	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Laparotomy	01JAN1986	31DEC1986	N
			Spinal cord operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1019 10191146	Cardiac disorders	Atrial fibrillation	30OCT2019		Y
		Eye disorders	Myopia	01JAN1960		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Muscle spasms	01JAN1972		Y
			Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN1986		Y
			Sleep apnoea syndrome	01NOV2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1019 10191148	Eye disorders	Astigmatism	01JAN2005	31DEC2005	N
			Cataract	20AUG2020		Y
			Dry eye	01JAN2005		Y
			Myopia	01JAN1954		Y
			Presbyopia	01JAN1974		Y
		Gastrointestinal disorders	Constipation	01JAN1969		Y
			Gastrooesophageal reflux disease	01JAN2005		Y
			Haemorrhoids	01JAN1969		Y
			Oesophageal achalasia	01JAN2018		Y
		General disorders and administration site conditions	Cyst	01JAN2016	31DEC2016	N
		Infections and infestations	Herpes zoster	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ligament rupture	01AUG2020		Y
			Meniscus injury	01AUG2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31JUL2020	N
			Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Migraine	01JAN1955		Y
			Restless legs syndrome	01JAN2010		Y
			Tremor	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
			Stress urinary incontinence	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Face lift	01JAN2010	31DEC2010	N
			Keratomileusis	01JAN2005	31DEC2005	N
			Rhinoplasty	01JAN1969	31DEC1969	N
			Spinal operation	01JAN2016	31DEC2016	N
			Urinary bladder suspension	01JAN2005	31DEC2005	N
	C4591001 1019 10191150	Eye disorders	Cataract	01JAN2014	31DEC2015	N
			Glaucoma	01JAN1996		Y
			Myopia	01JAN1961		Y
			Presbyopia	01JAN1994		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
			Spigelian hernia	01JAN2015	31DEC2016	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1982	31DEC1982	N
		Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
			Sinusitis	01JAN1954	31JAN2020	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	11AUG2020		Y
			Uterine leiomyoma	01JAN1987	31DEC1987	N
		Nervous system disorders	Migraine	01JAN1960	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1987	31DEC1987	N
			Menorrhagia	01JAN1986	31DEC1987	N
			Ovarian cyst	01JAN1984	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1954		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	10AUG2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN1987	31DEC1987	N
			Oophorectomy	01JAN1985	31DEC1985	N
	C4591001 1019 10191151	Blood and lymphatic system disorders	Anaemia	01JAN2014		Y
		Cardiac disorders	Coronary artery disease	01JAN2006		Y
			Myocardial infarction	01JAN2006	31DEC2006	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1971		Y
			Haemorrhoids	01JAN2010		Y
			Inguinal hernia	01JAN2015	31DEC2015	N
		Infections and infestations	Osteomyelitis	01JAN1952		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1952	31DEC1952	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1980	31DEC1980	N
		Psychiatric disorders	Depression	01JAN1983	31DEC1983	N
			Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Bone debridement	01JAN2014	31DEC2014	N
			Cataract operation	01JAN2010	31DEC2010	N
			Coronary artery bypass	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN1980	31DEC1980	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1019 10191152	Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Animal bite	01MAR2020	31MAR2020	N
			Upper limb fracture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1995	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Wound closure	01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191153	Ear and labyrinth disorders	Deafness bilateral	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Eye disorders	Cataract	01JAN2004		Y
					03FEB2020	N
			Myopia	01JAN1959		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1981		Y
		Infections and infestations	Genital herpes	01JAN1978		Y
			Sinusitis	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1981		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Psychiatric disorders	Depression	01JAN1991		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1960	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
				01JAN1988	31DEC1988	N
				01JAN1991	31DEC1991	N
			Cataract operation	03FEB2020	03FEB2020	N
			Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1019 10191155	Eye disorders	Cataract	01JAN2004	31DEC2004	N
			Glaucoma	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Salivary gland cyst	01JAN2008	31DEC2008	N
				01JAN2013	31DEC2013	N
			Umbilical hernia	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN2001		Y
				01JAN2010		Y
				01JAN2016		Y
			Iodine allergy	01JAN2012		Y
		Infections and infestations	Sinusitis	01JAN2014		Y
			Urinary tract infection	10AUG2017	31DEC2019	N
		Injury, poisoning and procedural complications	Patella fracture	01JAN1988	31DEC1988	N
			Ulna fracture	16MAY2018	31JUL2018	N
		Investigations	Arthroscopy	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1947		Y
			Type 2 diabetes mellitus	01AUG2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1988		Y
				01JAN2015		Y
			Back pain	01JAN1988		Y
			Fibromyalgia	09JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1988	31DEC1988	N
				01JAN1999	31DEC1999	N
			Sinus headache	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01FEB2017	31MAY2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Stress urinary incontinence	01JAN2008		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1957	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Bronchitis chronic	01JAN2013		Y
			Rhinitis allergic	01JAN2008		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1988	31DEC1988	N
			Cataract operation	01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Intraocular lens implant	01JAN2004	31DEC2004	N
			Parotidectomy	01JAN2008	31DEC2008	N
				01JAN2013	31DEC2013	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
	C4591001 1019 10191158	Eye disorders	Myopia	01JAN1984		Y
		Infections and infestations	Pneumonia	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Impaired fasting glucose	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1019 10191160	Cardiac disorders	Atrial fibrillation	01JAN2005	31DEC2015	N
		Eye disorders	Presbyopia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Food allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01AUG2016	08AUG2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1998		Y
		Surgical and medical procedures	Knee arthroplasty	08AUG2016	08AUG2016	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191162	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1957		Y
		Cardiac disorders	Coronary artery disease	01JAN2015		Y
			Myocardial infarction	01JAN2015	31DEC2015	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2019		Y
		Eye disorders	Cataract	01JAN2018	30JUN2020	N
					31JAN2020	N
			Myopia	01JAN1957	31DEC2005	N
			Presbyopia	01JAN2020		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1961		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Infections and infestations	Hepatitis B	01JAN1997	27AUG2020	N
			Herpes simplex	01JAN1992		Y
			Onychomycosis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2020		Y	
			Osteoporosis	01JAN2018		Y	
		Renal and urinary disorders	Nephrolithiasis	21AUG2020		Y	
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y	
		Surgical and medical procedures	Burn operation	01JAN1964	31DEC1964	N	
			Caesarean section	01JAN1977	31DEC1977	N	
			Cataract operation	01JAN2020	31JAN2020	N	
				01JUN2020	30JUN2020	N	
			Cholecystectomy	01JAN1998	31DEC1998	N	
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N	
			Female sterilisation	01JAN1977	31DEC1977	N	
			Hysterectomy	01JAN1986	31DEC1986	N	
			Toe amputation	01JAN1964	31DEC1964	N	
			Urinary bladder suspension	01JAN1986	31DEC1986	N	
			Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1019 10191163		Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1999	31DEC1999	N
			Eye disorders	Myopia	01JAN1982		Y
			Gastrointestinal disorders	Gastric ulcer	01JAN2003	31DEC2003	N
		Gastrointestinal perforation		01JAN2003	31DEC2003	N	
		Gastroesophageal reflux disease		01JAN1996	31DEC1999	N	
		Immune system disorders		Food allergy	01JAN1973		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC1999	N	
		Nervous system disorders	Sinus headache	01JAN2011		Y	
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
	C4591001 1019 10191167	Eye disorders	Presbyopia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Muscle spasms	01JAN2017		Y
		Nervous system disorders	Sinus headache	01JAN1965		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1976	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1019 10191169	Ear and labyrinth disorders	Deafness bilateral	01JAN1970		Y
			Tinnitus	01JAN1999		Y
		Eye disorders	Myopia	01JAN1961		Y
			Presbyopia	01JAN1961		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1957	31DEC1957	N
				01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1957	31DEC1957	N
				01JAN1986	31DEC1986	N
			Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191170	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN1990		Y
			Presbyopia	01JAN1990		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1985		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2005	31DEC2005	N
				01JAN2016	31DEC2016	N
		Investigations	Cardiac murmur	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Osteoarthritis	01JAN2005		Y
			Osteoporosis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bone cancer	01JAN2015	31DEC2015	N
			Breast cancer	01JAN2005	31DEC2005	N
		Psychiatric disorders	Alcohol abuse	01JAN1970	31MAY2010	N
			Bipolar disorder	01JAN2010		Y
			Drug abuse	01JAN2005	31MAY2010	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Surgical and medical procedures	Gastric bypass	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Jaw lesion excision	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mastectomy	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
	C4591001 1019 10191176	Cardiac disorders	Ventricular extrasystoles	01APR2011	31DEC2012	N
		Ear and labyrinth disorders	Deafness unilateral	01DEC2012		Y
		Endocrine disorders	Hypogonadism	01JAN2016		Y
		Eye disorders	Cataract	01JAN2015	31DEC2016	N
			Myopia	01JAN1954	31DEC2016	N
			Presbyopia	01JAN1990	31DEC2016	N
		Gastrointestinal disorders	Barrett's oesophagus	27JUL2010	31DEC2018	N
			Gastrooesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	27JUL2010		Y
		General disorders and administration site conditions	Oedema peripheral	01AUG2019		Y
		Infections and infestations	Pneumonia	01JAN2010	31DEC2010	N
			Poliomyelitis	01JAN1956	31DEC1956	N
			Sinusitis	24SEP2018	01OCT2018	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1988	31DEC1988	N
			Clavicle fracture	01JAN1997	31DEC1997	N
			Patella fracture	01JAN1969	31DEC1969	N
			Spinal compression fracture	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Exostosis	01APR2011	30APR2011	N
				15FEB2013		Y
			Osteopenia	01JAN2006		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Plantar fascial fibromatosis	01JAN2003		Y
			Plantar fasciitis	24SEP2018		Y
			Rotator cuff syndrome	01JAN2011	31DEC2011	N
			Spinal osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	24MAR2018		Y
			Osteochondroma	01JAN1954	31DEC1954	N
				01JAN1957	31DEC1957	N
				01JAN1962	31DEC1962	N
			Seborrhoeic keratosis	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN1970	31DEC2010	N
			Sinus headache	01JAN1966	31DEC1970	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01DEC2005		Y
			Rhinitis allergic	01JAN1966		Y
		Surgical and medical procedures	Ankle operation	01JAN1988	31DEC1988	N
			Intraocular lens implant	01JAN2016	31DEC2016	N
			Oesophagectomy	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Aortic aneurysm	01JAN2010		Y
			Hypertension	01JAN2006		Y
			Peripheral vascular disorder	01SEP2018		Y
		Eye disorders	Presbyopia	01JAN2015		Y
	C4591001 1019 10191177	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
			Chondropathy	01JAN2011	29FEB2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN1991	31DEC1991	N
			Knee arthroplasty	01FEB2020	29FEB2020	N
			Skin neoplasm excision	01MAR2020	31MAR2020	N
	C4591001 1019 10191178	Blood and lymphatic system disorders	Anaemia	01JUL2020		Y
		Cardiac disorders	Angina pectoris	01JUN2015		Y
		Eye disorders	Myopia	01JAN1956		Y
		Gastrointestinal disorders	Diverticulum	01JAN2011		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN2003	31DEC2003	N
		Infections and infestations	Cholecystitis infective	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN1979	31DEC1979	N
			Foot fracture	01JAN1976	31DEC1976	N
				01JAN2000	31DEC2000	N
			Fracture	01JAN1997	31DEC1997	N
			Meniscus injury	01JAN1987	31DEC1987	N
				01JAN1991	31DEC1991	N
				01JAN1998	31DEC1998	N
				01JAN2006	31DEC2006	N
			Spinal compression fracture	01AUG2018	31AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC1997		Y
			Hyperlipidaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01DEC1997		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2012	N
			Transient ischaemic attack	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anger	01JAN2010		Y
			Insomnia	01JAN1988	31DEC1992	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN1987	31DEC1987	N
			Hernia hiatus repair	01JAN2003	31DEC2003	N
			Meniscus operation	01JAN1987	31DEC1987	N
				01JAN1991	31DEC1991	N
				01JAN1998	31DEC1998	N
				01JAN2006	31DEC2006	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Spinal decompression	01JAN2013	31DEC2013	N
			Spinal laminectomy	01AUG2018	31AUG2018	N
			Vasectomy	01JAN1977	31DEC1977	N
				01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy reversal	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01DEC1997		Y
	C4591001 1019 10191179	Eye disorders	Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Diarrhoea	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
			Neck pain	01JAN1986		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1985	31DEC1985	N
			Cerebrovascular accident	01JUN2016	30JUN2016	N
			Cluster headache	01JUN2016	31DEC2016	N
			Intracranial aneurysm	01DEC2016	31DEC2016	N
				01JUN2016	30JUN2016	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1985	31DEC1985	N
			Hysterectomy	01JAN1970	31DEC1970	N
			Intra-cerebral aneurysm operation	01DEC2016	31DEC2016	N
				01JUN2016	30JUN2016	N
			Rib excision	01JAN1986	31DEC1986	N
			Spinal fracture treatment	01JAN1985	31DEC1985	N
	C4591001 1019 10191180	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Glaucoma	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Macular degeneration	01JAN2018		Y
			Presbyopia	01JAN2003		Y
		Infections and infestations	Rhinitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
			Lip squamous cell carcinoma	01JAN2017	31DEC2017	N
			Uterine leiomyoma	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2000		Y
		Surgical and medical procedures	Cancer surgery	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2017	31DEC2017	N
			Myomectomy	01JAN2004	31DEC2004	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1019 10191182	Eye disorders	Astigmatism	01JAN1993		Y
			Myopia	01JAN1993	31DEC1993	N
			Presbyopia	01JAN1993		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1993	31DEC1993	N
			Rib fracture	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1980		Y
		Surgical and medical procedures	Keratotomy	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191190	Cardiac disorders	Mitral valve prolapse	01JAN1971		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Eye disorders	Myopia	01JAN2000		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2013		Y
		Infections and infestations	Groin abscess	01JAN2011	31DEC2011	N
			Pilonidal cyst	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Neck pain	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2002	N
		Nervous system disorders	Diabetic neuropathy	01APR2020		Y
			Essential tremor	01JAN1975		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1983		Y
		Surgical and medical procedures	Abscess drainage	01JAN2011	31DEC2011	N
			Pilonidal sinus repair	01JAN1989	31DEC1989	N
	C4591001 1019 10191191	Cardiac disorders	Supraventricular tachycardia	01JAN2009	31DEC2009	N
		Eye disorders	Cataract	01JAN2018		Y
			Glaucoma	01JAN2010		Y
			Myopia	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
			Herpes zoster	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Neck pain	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN1975		Y
		Reproductive system and breast disorders	Breast mass	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Appendectomy	01JAN1988	31DEC1988	N
			Cardiac ablation	01JAN2009	31DEC2009	N
	C4591001 1019 10191199	Eye disorders	Dry eye	01JAN2005		Y
			Glaucoma	01MAR2020		Y
			Presbyopia	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
			Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Alcohol abuse	01JAN1969	31DEC2016	N
			Anxiety	01JAN2016		Y
			Depression	01JAN2018	31DEC2018	N
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Cough	01JAN2018		Y
			Rhinitis allergic	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191200	Eye disorders	Myopia	01JAN1963		Y
			Strabismus	(b) (6) 1953	31DEC1984	N
		Infections and infestations	Onychomycosis	01JAN2017		Y
			Tonsillitis	01JAN1963	31DEC1963	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Oral neoplasm benign	01JAN1960	31DEC1963	N
		Psychiatric disorders	Depression	01JAN1990		Y
		Surgical and medical procedures	Oral cavity neoplasm surgery	01JAN1963	31DEC1963	N
			Strabismus correction	01JAN1984	31DEC1984	N
	C4591001 1019 10191201	Eye disorders	Cataract	01JAN2000	02JUL2012	N
					21NOV2011	N
			Glaucoma	01JAN2000		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Inguinal hernia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	02JUL2012	02JUL2012	N
				21NOV2011	21NOV2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1019 10191202	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Presbyopia	01JAN2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Sinusitis	01JAN1996	31DEC2008	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1987		Y
			Osteoarthritis	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2004	31DEC2004	N
			Caesarean section	01JAN1989	31DEC1989	N
				01JAN1992	31DEC1992	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
			Chondroplasty	01JAN1987	31DEC1987	N
			Female sterilisation	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Mammoplasty	01JAN2004	31DEC2004	N
			Meniscus operation	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Sinuplasty	01JAN2008	31DEC2008	N
			Myopia	01JAN1976		Y
	C4591001 1019 10191204	Eye disorders				
		Injury, poisoning and procedural complications	Foot fracture	01JAN1977	31DEC1977	N
			Joint injury	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Prostatitis	01JAN2009		Y
		Surgical and medical procedures	Peripheral nerve operation	01JAN2008	31DEC2008	N
			Transurethral prostatectomy	01JAN2009	31DEC2009	N
	C4591001 1019 10191207	Eye disorders	Myopia	01JAN1965		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1019 10191210	Cardiac disorders	Supraventricular tachycardia	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1968		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Haemorrhoids	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2016	31DEC2016	N
			Meniscus injury	01JAN2011	31DEC2011	N
			Tendon rupture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Foot operation	01JAN2016	31DEC2016	N
			Tenoplasty	01JAN2019	31DEC2019	N
	C4591001 1019 10191219	Eye disorders	Myopia	14FEB2009		Y
			Presbyopia	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Infections and infestations	Sinusitis	01JAN1960		Y
		Investigations	Arthroscopy	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006	31DEC2012	N
				01JAN2015		Y
			Obesity	01AUG2008	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2010		Y
			Muscle spasms	01JAN1990	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2008	31DEC2008	N
		Nervous system disorders	Sinus headache	01JAN2006		Y
			Tension headache	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01APR2008	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2008	31DEC2008	N
			Caesarean section	21JUL1995	21JUL1995	N
			Cholecystectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2004	31DEC2012	N
				01JAN2015		Y
	C4591001 1019 10191221	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2013		Y
		Eye disorders	Myopia	01JAN1979		Y
			Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
			Haemorrhoids	01JAN1984	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Infections and infestations	Chlamydial infection	01JAN1985	31DEC1985	N
			Sinusitis	01JAN1974		Y
		Metabolism and nutrition disorders	Obesity	21SEP2020		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2007	N
			Muscle spasms	01JAN1981	31DEC1981	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Sinus headache	01JAN1984		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1990	31DEC2017	N
			Ovarian cyst	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Bunion operation	01JAN2007	31DEC2007	N
			Caesarean section	01JAN1987	31DEC1987	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Myomectomy	01JAN2012	31DEC2012	N
			Ovarian cystectomy	01JAN2012	31DEC2012	N
	C4591001 1019 10191223	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
			Pneumonia	01JAN2009	31DEC2009	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
			Upper limb fracture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
			Osteopenia	01JAN2017		Y
		Nervous system disorders	Sinus headache	01JAN1998		Y
		Renal and urinary disorders	Bladder perforation	01JAN2009	31DEC2009	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1975	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Rhinitis allergic	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Caesarean section	01JAN1983	31DEC1983	N
				01JAN1985	31DEC1985	N
			Elbow operation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Explorative laparotomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy bilateral	01JAN2009	31DEC2009	N
	C4591001 1019 10191224	Cardiac disorders	Atrial flutter	01JAN2015	31DEC2015	N
		Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Eye disorders	Presbyopia	01JAN1971		Y
		Infections and infestations	Herpes zoster	01JAN2011	31DEC2011	N
			Pneumonia	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191228	Eye disorders	Myopia	01JAN1981		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Myomectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191229	Eye disorders	Myopia	01JAN1988		Y
		Gastrointestinal disorders	Abdominal pain	01JAN2012		Y
			Constipation	01JAN2012	31DEC2015	N
			Haemorrhoids	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN1995		Y
			Osteoporosis	01JAN2013		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Nasal septum deviation	01AUG2018		Y
			Rhinitis allergic	01JAN1995		Y
	C4591001 1019 10191231	Surgical and medical procedures	Breast cyst excision	01JAN2001	31DEC2001	N
		Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2015		Y
			Costochondritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN2017		Y
			Tension headache	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1964	31DEC1980	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1019 10191233	Ear and labyrinth disorders	Deafness unilateral	01JAN2016		Y
			Meniere's disease	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Infections and infestations	Genital herpes	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01MAY2009		Y
			Substance use	01JAN1990		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2007	31DEC2007	N
			Caesarean section	01DEC1994	31DEC1994	N
				01JUL1993	31JUL1993	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01MAY1998	31MAY1998	N
			Female sterilisation	01JAN1998	31DEC1998	N
			Mastectomy	01JAN2007	31DEC2007	N
			Skin cyst excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000	30JUN2020	N
	C4591001 1019 10191237	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Ear and labyrinth disorders	Meniere's disease	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2018		Y
			Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Impaired fasting glucose	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1998	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1019 10191239	Ear and labyrinth disorders	Deafness unilateral	01JAN1970		Y
		Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01FEB2020		Y
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
			Nasal septum deviation	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Nasal septal operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191240	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2019		Y
			Haemorrhoids	01JAN2015	31DEC2018	N
			Hiatus hernia	01JAN2016		Y
		Hepatobiliary disorders	Biliary cyst	01JAN2012	31DEC2012	N
		Infections and infestations	Diverticulitis	01JAN2016		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1956	31DEC1956	N
				01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
			Osteoarthritis	01JAN1998		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
			Erectile dysfunction	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Gallbladder operation	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN2005	31DEC2005	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191241	Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Myopia	01JAN2015	31DEC2015	N
		Immune system disorders	Food allergy	01JAN1968		Y
		Infections and infestations	Herpes zoster	01JAN2013	31DEC2013	N
			Sinusitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Osteoarthritis	01JAN2017		Y
			Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1958		Y
			Rhinitis allergic	01JAN1968		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2005		Y
		Social circumstances	Postmenopause	01NOV2005		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2015	31DEC2015	N
			Cataract operation	01JAN2015	31DEC2015	N
			Keratomileusis	01JAN2015	31DEC2015	N
			Sinuplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191243	Eye disorders	Myopia	01JAN1971		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1979		Y
			Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1019 10191244	Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Haemorrhoids	01JAN2005	31DEC2010	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1990	31DEC1990	N
			Hip fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Back pain	01JAN2014		Y
			Osteoarthritis	01JAN2017		Y
			Periarthritis	01MAR2020	31MAR2020	N
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
			Nerve compression	01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Peripheral nerve decompression	01JAN2005	31DEC2005	N
			Shoulder arthroplasty	01MAR2020	31MAR2020	N
			Spinal operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1019 10191248	Eye disorders	Presbyopia	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1993	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JUL1980	31JUL1980	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1019 10191250	Eye disorders	Presbyopia	01JAN2004		Y
		Infections and infestations	Sinusitis	01JAN1990	30NOV2019	N
		Injury, poisoning and procedural complications	Scrotal injury	01JAN1978	31DEC1978	N
		Investigations	Arthroscopy	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
		Social circumstances	Substance use	01JAN1985	31DEC1989	N
		Surgical and medical procedures	Chondroplasty	01JAN1978	31DEC1978	N
			Scrotal operation	01JAN1978	31DEC1978	N
			Sinuplasty	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2002		Y
		Gastrointestinal disorders	Haemorrhoids	01JUL2020		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1977	31DEC1977	N
			Rib fracture	01JAN2008	31DEC2008	N
		Nervous system disorders	Syncope	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Bunion operation	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JUL2020		Y
		Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
				01JAN2017	05DEC2018	N
			Presbyopia	03JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	07FEB2011	N
		Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	10JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN1970		Y
			Upper respiratory tract infection	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Muscle spasms	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2018	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980		Y
			Nerve compression	01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	19JAN2017		Y
			Chronic obstructive pulmonary disease	19JAN2017		Y
			Cough	01JAN1980		Y
			Pulmonary embolism	19JAN2017	19JAN2017	N
			Sleep apnoea syndrome	19NOV2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
				05DEC2018	05DEC2018	N
			Cholecystectomy	07FEB2011	07FEB2011	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Spinal operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191259	Eye disorders	Presbyopia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Constipation	01JAN1980		Y
			Haemorrhoids	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Urinary tract infection	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Nervous system disorders	Facial paralysis	01JAN2008	31DEC2008	N
			Migraine	01JAN1974		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2007		Y
			Insomnia	01JAN2003		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1991	31DEC1999	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2004		Y
		Surgical and medical procedures	Adhesiolysis	01JAN2005	31DEC2005	N
			Appendicectomy	01JAN1991	31DEC1991	N
			Face lift	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Hysterectomy	01DEC1999	31DEC1999	N
			Liposuction	01SEP2000	30SEP2020	N
			Mammoplasty	01JAN2012	31DEC2012	N
			Plastic surgery to the face	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2010	31DEC2010	N
	C4591001 1019 10191261	Eye disorders	Myopia	01JAN1977		Y
			Presbyopia	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Renal and urinary disorders	Pelvi-ureteric obstruction	01JAN1999	31DEC1999	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Renal surgery	01JAN1999	31DEC1999	N
	C4591001 1019 10191263	Congenital, familial and genetic disorders	Atrial septal defect	01JUN2020		Y
		Eye disorders	Cataract	01JAN2014	31DEC2014	N
			Myopia	01JAN1966		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1990	31DEC2010	N
			Hiatus hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Pneumonia	01JAN1997	31DEC1997	N
			Sinusitis	01JAN1983		Y
			Tonsillitis	01JAN1958	31DEC1958	N
		Injury, poisoning and procedural complications	Stress fracture	01JAN2010	31DEC2010	N
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Exostosis	01JAN1993	31DEC1993	N
			Foot deformity	01JAN1993	31DEC1993	N
			Muscle spasms	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31DEC2018	N
				01JAN2000	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2001	31DEC2001	N
					31DEC2002	N
			Cerebrovascular accident	01MAY2020	31MAY2020	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1962	31DEC2008	N
			Pulmonary granuloma	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN1993	31DEC1993	N
			Carpal tunnel decompression	01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
			Cataract operation	01JAN2015	31DEC2015	N
			Coccygectomy	01JAN2001	31DEC2001	N
			Fascial operation	01JAN1993	31DEC1993	N
			Gastric banding	01JAN2010		Y
			Hysterectomy	01MAR2000	31MAR2000	N
			Nasal septal operation	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191266	Eye disorders	Myopia	01JAN2003		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Presbyopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Gout	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1019 10191271	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN2015		Y
			Hiatus hernia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1941		Y
			Food allergy	01JAN1981		Y
		Infections and infestations	Sinusitis	01JAN2009	31DEC2012	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Dehydration	01JAN1990		Y
			Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign salivary gland neoplasm	01JAN1990	31DEC1990	N
		Nervous system disorders	Headache	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Coronary artery bypass	01JAN2008	31DEC2008	N
			Salivary gland resection	01JAN1990	31DEC1990	N
			Sinuplasty	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1019 10191272	Cardiac disorders	Bundle branch block left	01JAN2000		Y
		Eye disorders	Cataract	01JAN2010	31DEC2018	N
			Macular fibrosis	01JAN1995		Y
			Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Diverticulum	01JAN2000		Y
			Haemorrhoids	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2020	31AUG2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191274	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
			Umbilical hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1019 10191275	Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Eye disorders	Cataract	01JAN2017	28FEB2019 30APR2019	N N
			Myopia	01JAN1970	30APR2019	N
			Presbyopia	01JAN1988		Y
		Gastrointestinal disorders	Diverticulum	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Chronic sinusitis	01JAN2005	31DEC2015	N
			Diverticulitis	05JUL2013	05JUL2013	N
			Hepatitis A	01JAN1974	31DEC1974	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009		Y
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Osteoarthritis	01JAN2005		Y
				01JAN2017		Y
				01JUL2019		Y
			Osteopenia	01JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1984	31DEC1984	N
				01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1969		Y
		Surgical and medical procedures	Colectomy	05JUL2013	05JUL2013	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Sinuplasty	01JAN2005	31DEC2015	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1019 10191277	Eye disorders	Myopia	01JAN1986	31DEC2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Haemorrhoids	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Infections and infestations	Herpes zoster	01JAN2013		Y
		Investigations	Cardiac murmur	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Nervous system disorders	Tension headache	01JAN1990		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Photorefractive keratectomy	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1019 10191278	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Glaucoma	01SEP2020		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1964	31DEC1964	N
			Radius fracture	01JAN1965	31DEC1965	N
			Ulna fracture	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Muscle spasms	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Varicocele repair	01JAN1978	31DEC1978	N
		Vascular disorders	Varicose vein ruptured	01JAN1978	31DEC1978	N
	C4591001 1019 10191282	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
			Tinnitus	01JAN2015		Y
		Eye disorders	Myopia	01JAN1964		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Haemorrhoids	01JAN1981		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Bronchitis	01JAN1966	31DEC1966	N
			Pneumonia	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1972	31DEC1972	N
			Ulna fracture	01JAN2017	31DEC2017	N
			Wrist fracture	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Epilepsy	01JAN1977	31DEC1988	N
			Generalised tonic-clonic seizure	01JAN1977	31DEC1988	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1978	31DEC1978	N
			Pulmonary embolism	01JAN1978	31DEC1978	N
			Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN1972	31DEC1972	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1019 10191284	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2013		Y
		Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN1953		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Chest pain	01JAN2017	31DEC2017	N
		Infections and infestations	Pneumonia	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1956	31DEC1956	N
			Ulna fracture	01JAN1956	31DEC1956	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
			Limb mass	01JAN2019		Y
			Muscle spasms	01JAN2018		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1996		Y
			Rhinitis allergic	01JAN2010		Y
		Social circumstances	Substance use	01JAN1965	31DEC1975	N
		Surgical and medical procedures	Angioplasty	01JAN2012	31DEC2012	N
			Stent placement	01JAN2012	31DEC2012	N
			Vascular stent insertion	01JAN2012	31DEC2012	N
		Vascular disorders	Arteriosclerosis	01JAN2012	31DEC2012	N
			Hypertension	01JAN2010		Y
			Peripheral vascular disorder	01JAN2012	31DEC2012	N
	C4591001 1019 10191285	Eye disorders	Myopia	01JAN2000		Y
			Presbyopia	01JAN2018		Y
		Infections and infestations	Herpes zoster	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1991	31DEC1991	N
			Wrist fracture	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Scleroderma	01JAN1994	31DEC1994	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989	31DEC1989	N
	C4591001 1019 10191286	Eye disorders	Myopia	01JAN1964	31DEC1985	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2003		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1975		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1979	31DEC1979	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1963	31DEC1963	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Back pain	01JAN1980	31DEC2000	N
			Trigger finger	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC2019	N
				01JAN2015	31DEC2015	N
			Malignant melanoma	01JAN2010	31DEC2010	N
			Squamous cell carcinoma	01JAN1985	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1980		Y
		Surgical and medical procedures	Appendectomy	01JAN1979	31DEC1979	N
			Cholecystectomy	01JAN1979	31DEC1979	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Keratomileusis	01JAN1985	31DEC1985	N
			Tenotomy	01JAN2019	31DEC2019	N
	C4591001 1019 10191287	Eye disorders	Myopia	01JAN1977	31DEC2000	N
			Presbyopia	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Lithotripsy	01JAN2010	31DEC2010	N
	C4591001 1019 10191291	Ear and labyrinth disorders	Deafness unilateral	01JAN2017		Y
			Endolymphatic hydrops	01JAN2016		Y
			Tinnitus	01JAN2005		Y
		Eye disorders	Myopia	01JAN1970	31DEC1991	N
			Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2014	31DEC2014	N
			Joint dislocation	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1991		Y
			Back pain	01JAN1991		Y
			Fibromyalgia	01JAN1996		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1991		Y
			Spinal osteoarthritis	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1996	31DEC1996	N
				01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1988		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2018		Y
		Reproductive system and breast disorders	Breast dysplasia	01JUN2020	30JUN2020	N
			Menorrhagia	01JAN1985	31DEC2007	N
			Ovarian cyst	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
			Rhinitis allergic	01JAN1986		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Substance use	01JAN2016	31DEC2019	N
		Surgical and medical procedures	Breast conserving surgery	01JUN2020	30JUN2020	N
			Caesarean section	01SEP1992	30SEP1992	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Joint surgery	01JAN1998	31DEC1998	N
			Keratotomy	01JAN1991	31DEC1991	N
				01JAN1993	31DEC1993	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1019 10191297	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Presbyopia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diverticulum	01JAN1975		Y
			Haemorrhoids	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1983	31DEC1983	N
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Rotator cuff syndrome	01JAN2015	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC1985	N
			Squamous cell carcinoma	01JAN1988	31DEC1988	N
				01JAN1991	31DEC1991	N
			Squamous cell carcinoma of skin	01JAN1995	31DEC1995	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1976	31DEC1976	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1970		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN1983	31DEC1983	N
			Lithotripsy	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1019 10191298	Endocrine disorders	Addison's disease	01JAN1985		Y
			Hypothyroidism	01JAN1985		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Constipation	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoids	01JAN1970		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Immune system disorders	Allergy to arthropod sting	01JAN1952		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
			Pneumonia	01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
			Sinusitis	01JAN1950		Y
		Injury, poisoning and procedural complications	Hip fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC2017	N
			Squamous cell carcinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN1960	31DEC1975	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Nasal septum deviation	01JAN1950		Y
			Rhinitis allergic	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
			Cataract operation	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Fracture treatment	01JAN2008	31DEC2008	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
			Micrographic skin surgery	01JAN2008	31DEC2008	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1019 10191299	Eye disorders	Cataract	12OCT2020		Y
			Myopia	01JAN1972		Y
		Infections and infestations	Cholera	01JAN1970	31DEC1970	N
			Dengue fever	01JAN1996	31DEC1996	N
			Epidemic typhus	01JAN1980	31DEC1980	N
			Herpes zoster	01JAN2016	31DEC2016	N
			Malaria	01JAN1991	31DEC1991	N
		Investigations	Cardiac murmur	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Social circumstances	Substance use	01JAN1970		Y
		Surgical and medical procedures	Transurethral bladder resection	01JAN2010	31DEC2010	N
	C4591001 1019 10191302	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Infections and infestations	Sinusitis	01JAN1980		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2010	N
		Nervous system disorders	Sinus headache	01JAN2006		Y
		Psychiatric disorders	Drug abuse	01JAN1967	31DEC1967	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
			Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
			Meniscus operation	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
			Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1019 10191303	Eye disorders	Chalazion	01JAN2018	31DEC2018	N
			Myopia	01JAN1960		Y
			Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1975	31DEC1975	N
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
				01JAN2013		Y
			Food allergy	01JAN1987		Y
				01JAN1995		Y
		Infections and infestations	Diverticulitis	01JAN2005	31DEC2013	N
			Epstein-Barr virus infection	01JAN1995	31DEC1995	N
			Varicella	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Nervous system disorders	Sinus headache	01JAN1995		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
				01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1958		Y
			Cough	01JAN2018		Y
			Rhinitis allergic	01JAN1957		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Eyelid cyst removal	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN1975	31DEC1975	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
			Urinary calculus removal	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1019 10191307	Cardiac disorders	Coronary artery disease	01JAN2004		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
				01SEP2020		Y
			Meniere's disease	01JAN1988		Y
			Vertigo	01APR2020		Y
		Eye disorders	Myopia	01JAN2015		Y
			Presbyopia	01JAN2015		Y
		General disorders and administration site conditions	Chest pain	01JAN2004	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Obesity	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2004	31DEC2004	N
				01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1019 10191308	Eye disorders	Presbyopia	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Sinuplasty	01JAN1983	31DEC1983	N
	C4591001 1019 10191309	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Pneumonia	01JAN2010	31DEC2010	N
			Sinusitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2019	31DEC2019	N
		Investigations	Cardiac murmur	01APR2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2003	31DEC2003	N
			Sinus headache	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Joint dislocation reduction	01JAN2019	31DEC2019	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191310	Congenital, familial and genetic disorders	Patent ductus arteriosus	(b) (6) 1947	31DEC1953	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2005	31DEC2018	N
			Myopia	01JAN1958	31DEC2018	N
			Presbyopia	01JAN1990	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Infections and infestations	Appendicitis	01JAN1963	31DEC1963	N
		Investigations	Cardiac murmur	(b) (6) 1947		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
			Spinal osteoarthritis	01JAN2017		Y
			Tenosynovitis stenosans	01JAN2014	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2003	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
			Ovarian cancer	01JAN2000	31DEC2000	N
		Nervous system disorders	Migraine	01JAN1967	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01MAR2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1963	31DEC1963	N
			Caesarean section	01JAN1978	31DEC1978	N
				01JAN1981	31DEC1981	N
			Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Patent ductus arteriosus repair	01JAN1953	31DEC1953	N
			Skin neoplasm excision	01JAN2003	31DEC2003	N
				01JAN2018	31DEC2018	N
			Tendon sheath incision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000	31DEC2010	N
	C4591001 1019 10191311	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Myopia	01JAN1990		Y
			Presbyopia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01NOV2019	30NOV2019	N
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Micrographic skin surgery	01NOV2019	30NOV2019	N
	C4591001 1019 10191313	Eye disorders	Presbyopia	01JAN1956		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Haemorrhoids	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Psychiatric disorders	Initial insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1019 10191314	Eye disorders	Myopia	01JAN1972		Y
			Presbyopia	01JAN2004		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1980		Y
			Nervous system injury	01JAN1980		Y
		Nervous system disorders	Coordination abnormal	01JAN1980		Y
			Motor dysfunction	01JAN1980		Y
	C4591001 1019 10191316	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2008	31DEC2008	N
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
			Sinusitis	01JAN1950		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01FEB2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2008	31DEC2008	N
			Appendicectomy	01JAN2012	31DEC2012	N
			Cardiac pacemaker insertion	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	01JAN2014	31DEC2014	N
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1019 10191317	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN1961		Y
			Presbyopia	01JAN1988		Y
		Gastrointestinal disorders	Diverticulum	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	13JUN2002		Y
		Infections and infestations	Sinusitis	01JAN2007	31DEC2009	N
			Tonsillitis	05DEC1972	05DEC1972	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	03DEC2019	N
		Investigations	Intraocular pressure increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2006	31MAR2006	N
			Muscle spasms	01JAN2018		Y
			Osteoarthritis	01JAN2015		Y
			Pain in extremity	01JAN2018		Y
			Plantar fasciitis	15OCT1996	31DEC1999	N
			Temporomandibular joint syndrome	01JAN1998	14FEB2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	14FEB1997	09MAR1997	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	25APR2005	N
			Facial paralysis	21MAR1997	30SEP1997	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Stress urinary incontinence	01JAN2002		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1997	09MAR1997	N
			Ovarian cyst	14FEB1997	14FEB1997	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2019		Y
			Nasal septum deviation	01JAN2007	31JUL2009	N
			Rhinitis allergic	01JAN1986		Y
		Social circumstances	Substance use	01JAN1976	31DEC1978	N
		Surgical and medical procedures	Appendicectomy	09MAR1997	09MAR1997	N
			Bone lesion excision	31MAR2006	31MAR2006	N
			Carpal tunnel decompression	25APR2005	25APR2005	N
			Hysterectomy	09MAR1997	09MAR1997	N
			Joint arthroplasty	14FEB2003	14FEB2003	N
			Meniscus operation	03DEC2019	03DEC2019	N
			Nasal septal operation	31JUL2009	31JUL2009	N
			Oophorectomy	14FEB1997	14FEB1997	N
			Tonsillectomy	05DEC1972	05DEC1972	N
			Urinary bladder suspension	20MAY2005	20MAY2005	N
		Vascular disorders	Hypotension	01MAR2020		Y
	C4591001 1019 10191319	Cardiac disorders	Atrial fibrillation	01JAN1987	31DEC1987	N
		Ear and labyrinth disorders	Deafness bilateral	19OCT2020		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1986		Y
				01JAN1989		Y
			Drug hypersensitivity	01JAN1981		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diverticulitis	01JAN2010		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1999		Y
			Osteoarthritis	01JAN1999		Y
		Nervous system disorders	Vestibular migraine	01JAN1994		Y
		Reproductive system and breast disorders	Breast mass	01JAN2003	31DEC2003	N
			Endometriosis	01JAN1980	31DEC1980	N
			Menorrhagia	01JAN1965	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Appendectomy	01JAN1989	31DEC1989	N
			Blepharoplasty	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1019 10191320	Endocrine disorders	Hypothyroidism	01JAN1972		Y
		Eye disorders	Cataract	01JAN2017	31DEC2018	N
			Myopia	01JAN1968	31DEC2018	N
			Ocular hypertension	01JAN2017		Y
			Presbyopia	01JAN1995	31DEC2018	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2008	31DEC2008	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Chronic sinusitis	01JAN1990	31DEC2015	N
			Urinary tract infection	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN1982		Y
			Type 2 diabetes mellitus	01JAN1997		Y
			Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
			Tendonitis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1985	31DEC1990	N
			Headache	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2013		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
			Chronic obstructive pulmonary disease	01JAN2005		Y
			Rhinitis allergic	01JAN1986		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1990	31DEC1990	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Gastric bypass	01JAN2006	31DEC2006	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1019 10191322	Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Myopia	01JAN1960	31DEC1960	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2012	31DEC2012	N
		Infections and infestations	Herpes simplex	01JAN1995		Y
			Herpes zoster	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005		Y
			Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Gastric banding	01JAN2012	31DEC2012	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Immune tolerance induction	01JAN2005	31DEC2008	N
			Joint dislocation reduction	01JAN1976	31DEC1976	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1019 10191323	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Eye disorders	Myopia	01JAN1987		Y
			Presbyopia	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Inguinal hernia	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986	31DEC2014	N
			Snapping hip syndrome	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Tremor	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1978		Y
		Surgical and medical procedures	Cardioversion	01JAN2017	31DEC2017	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Meniscus operation	01JAN1976	31DEC1976	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1021 10211001	Gastrointestinal disorders	Gastric ulcer	01JAN1998	30NOV2019	N
			Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	01JAN2019	31DEC2019	N
			Pneumonia	01JAN2016		Y
					31DEC2016	N
		Injury, poisoning and procedural complications	Neurological procedural complication	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1998	31DEC1998	N
		Nervous system disorders	Facial paralysis	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN1978	31DEC1992	N
			Ovarian cyst	01JAN1995	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Oophorectomy bilateral	01JAN1998	31DEC1998	N
	C4591001 1021 10211002	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1997		Y
			Intervertebral disc protrusion	01JAN1978	31DEC1978	N
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN1978	31DEC1978	N
	C4591001 1021 10211003	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Surgical and medical procedures	Prostatectomy	01JAN2009	31DEC2009	N
			Stent placement	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211004	Endocrine disorders	Hyperthyroidism	01JAN1987	31DEC1988	N
			Hypothyroidism	01JAN1988		Y
		General disorders and administration site conditions	Cyst	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Perennial allergy	01JAN1973		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Psychiatric disorders	Depression	01MAR2020		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Limb operation	01JAN2013	31DEC2013	N
			Thyroidectomy	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1021 10211005	Blood and lymphatic system disorders	Anaemia	01JUN2018		Y
		Eye disorders	Cataract	01JAN2011	31DEC2011	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1975	31DEC1975	N
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
				01JAN2008		Y
				01JAN2016		Y
		Infections and infestations	Sinusitis	01JAN1999		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
			Tendonitis	01MAR2020		Y
		Nervous system disorders	Sciatica	01NOV2018		Y
			Sinus headache	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
			Cholecystectomy	01JAN1975	31DEC1975	N
			Metabolic surgery	01JAN2010	31DEC2010	N
	C4591001 1021 10211006	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Depression	01MAY2020		Y
	C4591001 1021 10211007	Surgical and medical procedures	Stent placement	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2007	N
				01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1021 10211008	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989	31DEC1999	N
				01JAN2010	31DEC2013	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN1999	31DEC1999	N
			Shoulder arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1021 10211009	Cardiac disorders	Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2005	31DEC2005	N
			Hernia repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211010	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31JAN2020	N
				01NOV2016	30NOV2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2015	N
			Foot deformity	01JAN1986	31DEC1988	N
			Osteoarthritis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Transient ischaemic attack	01FEB2018	28FEB2018	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1972	31DEC1972	N
			Bone lesion excision	01JAN2015	31DEC2015	N
			Bunion operation	01JAN1988	31DEC1988	N
			Knee operation	01JAN2020	31JAN2020	N
				01NOV2016	30NOV2016	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1021 10211013	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Eye disorders	Glaucoma	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Reproductive system and breast disorders	Nipple exudate bloody	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Mammary ductectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1021 10211014	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004	31DEC2005	N
			Intervertebral disc protrusion	01JAN1983	31DEC1983	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intervertebral disc operation	01JAN1975	31DEC1975	N
				01JAN1983	31DEC1983	N
			Prostatectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1021 10211015	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
				01JAN2010		Y
				01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
			Wrist surgery	01JAN1989	31DEC1989	N
	C4591001 1021 10211017	Gastrointestinal disorders	Hiatus hernia	01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01OCT1996	31OCT1996	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1992		Y
			Foot deformity	01JAN2013	31DEC2013	N
		Nervous system disorders	Cerebrovascular accident	01MAY2018	31MAY2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Bunion operation	01JAN2013	31DEC2013	N
			Cholecystectomy	01OCT1996	31OCT1996	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211018	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Diplopia	01JAN2012	31DEC2018	N
		Gastrointestinal disorders	Pancreatitis	01JAN2013	31DEC2013	N
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
			Herpes simplex	01JAN2008		Y
			Peritonitis	01JAN1992	31DEC1995	N
			Tonsillitis	01JAN1957	31DEC1957	N
		Injury, poisoning and procedural complications	Meniscus injury	01AUG2017	31AUG2017	N
			Rib fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Exostosis	01JAN2016		Y
			Intervertebral disc protrusion	01JAN2001	31DEC2014	N
			Osteoarthritis	01JAN2009		Y
			Synovial cyst	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN1999		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1988	31DEC1988	N
				01JAN1992	31DEC1992	N
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Cataract operation	01JAN2016	31DEC2016	N
			Eye operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy bilateral	01JAN1995	31DEC1995	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
				01JAN2016	31DEC2016	N
			Spinal laminectomy	01JAN2014	31DEC2014	N
			Spinal operation	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1021 10211019	Gastrointestinal disorders	Abdominal hernia	01JAN2012	31DEC2012	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
			Obesity	01JAN1960		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31DEC2013	N
				01JAN2016		Y
			Spinal osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1988		Y
		Surgical and medical procedures	Gastric bypass	01JAN2004	31DEC2004	N
			Hernia repair	01JAN2012	31DEC2012	N
			Hip arthroplasty	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1021 10211020	Gastrointestinal disorders	Abdominal hernia	01JAN2013	31DEC2013	N
			Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007		Y
			Fibromyalgia	01JAN2017		Y
		Renal and urinary disorders	Polyuria	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211021	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2013		Y
		Cardiac disorders	Acute myocardial infarction	03AUG2018	03AUG2018	N
			Coronary artery disease	01JUL2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				03AUG2012		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
			Tonsillitis	01JAN2000	31DEC2000	N
		Investigations	Arthroscopy	01JAN2011	31DEC2011	N
				20MAY2020	20MAY2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000	31DEC2006	N
			Osteoarthritis	01JAN2003	31DEC2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015		Y
			Periarthritis	01JAN2018	20MAY2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1979	31DEC1995	N
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Intervertebral disc operation	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Knee arthroplasty	01MAY2016	31MAY2016	N
			Sinus operation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211022	Endocrine disorders	Goitre	01JAN2016	31DEC2016	N
			Hypothyroidism	01JAN2016	31DEC2016	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Sinusitis	01JAN1993	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Iron deficiency	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
			Vitamin D deficiency	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2000	31DEC2016	N
			Uterine leiomyoma	01JAN1985	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephropathy	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2016		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN2000	31DEC2000	N
			Ear tube insertion	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Nephrectomy	01JAN2016	31DEC2016	N
			Oophorectomy bilateral	01JAN1985	31DEC1985	N
			Urethral operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1021 10211023	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Constipation	01JAN2011		Y
			Gastroesophageal reflux disease	01JAN1984		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JUN2020		Y
			Vitamin B12 deficiency	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
				01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1021 10211024	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
			Pulmonary embolism	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Aortic aneurysm	01JAN2007	31DEC2007	N
			Hypertension	01JAN2012		Y
	C4591001 1021 10211025	Immune system disorders	Contrast media allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007	31DEC2009	N
				01JAN2009		Y
				01JAN2012	31DEC2014	N
			Osteopenia	01JAN2007		Y
			Rotator cuff syndrome	01JAN1985		Y
		Nervous system disorders	Restless legs syndrome	01JAN2012		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1964		Y
		Surgical and medical procedures	Hip surgery	01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
			Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1021 10211026	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Cardiac murmur	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1021 10211027	Congenital, familial and genetic disorders	Thyroglossal cyst	01JAN1980	31DEC1980	N
		Eye disorders	Fuchs' syndrome	01JAN1975	31DEC2012	N
			Macular degeneration	01JAN2015		Y
		Gastrointestinal disorders	Gastric ulcer	01MAR2020	31MAR2020	N
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
			Rubber sensitivity	01JAN1995		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2016	31DEC2016	N
			Spinal stenosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN1998	31DEC2000	N
			Osteoma	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN1972		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Corneal transplant	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Gastric bypass	01JAN1978	31DEC1978	N
			Jaw operation	01JAN2003	31DEC2003	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Mammoplasty	01JAN1980	31DEC1980	N
			Thyroglossal cyst excision	01JAN1980	31DEC1980	N
			Wrist surgery	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1968		Y
	C4591001 1021 10211028	Ear and labyrinth disorders	Vertigo	01JAN2018	31DEC2019	N
		Eye disorders	Glaucoma	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis perforated	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01SEP2019		Y
			Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N
			Micrographic skin surgery	01JAN2018	31DEC2018	N
	C4591001 1021 10211029	Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
			Genital herpes	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Osteoporosis	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1021 10211030	Ear and labyrinth disorders	Deafness unilateral	01JAN1968	31DEC1968	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2016		Y
			Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis perennial	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Mastoidectomy	01JAN1968	31DEC1968	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1021 10211031	Cardiac disorders	Atrial fibrillation	01JUN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Cataract	01JAN2000	31DEC2017	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN1966		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1966		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin D deficiency	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2013	31DEC2013	N
			Uterine leiomyoma	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1974	31DEC1974	N
			Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2013	31DEC2013	N
			Meniscus operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1021 10211033	Gastrointestinal disorders	Inguinal hernia	01FEB2014	28FEB2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2018	28FEB2018	N
			Prostate cancer	01JUN2014	30JUN2014	N
		Renal and urinary disorders	Nephrolithiasis	01DEC2014	31DEC2014	N
		Surgical and medical procedures	Inguinal hernia repair	01FEB2014	28FEB2014	N
			Micrographic skin surgery	01FEB2018	28FEB2018	N
			Prostatectomy	01JUN2014	30JUN2014	N
	C4591001 1021 10211034	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1987	31DEC1987	N
				01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1987	31DEC1987	N
				01JAN1991	31DEC1991	N
	C4591001 1021 10211035	Cardiac disorders	Cardiac arrest	01MAR2018	31MAR2018	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1962		Y
		Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Eye disorders	Cataract	01JAN2007	31DEC2007	N
			Macular degeneration	01JAN2016		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2002		Y
			Gastroesophageal reflux disease	01JAN1987		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Immune system disorders	Anaphylactic reaction	01JAN2018	31DEC2018	N
			Contrast media allergy	01MAR2018		Y
			Seasonal allergy	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
			Chronic sinusitis	01JAN1972		Y
			Herpes zoster	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1974	31DEC1974	N
		Investigations	Heart rate irregular	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970	31DEC1970	N
			Spinal osteoarthritis	01JAN1999	31DEC1999	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN1997		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2013		Y
			Hypertonic bladder	01JAN2017		Y
			Nocturia	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Cataract operation	01JAN2007	31DEC2007	N
			Foot operation	01JAN1974	31DEC1974	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
			Spinal laminectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN1961		Y
	C4591001 1021 10211036	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1973	31DEC1973	N
				01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Rotator cuff syndrome	01JAN1992	31DEC1992	N
		Psychiatric disorders	Insomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1998		Y
		Surgical and medical procedures	Meniscus operation	01JAN1973	31DEC1973	N
			Shoulder operation	01JAN1987	31DEC1987	N
			Shoulder operation	01JAN1992	31DEC1992	N
			Vasectomy	01JAN1997	31DEC1997	N
		Ear and labyrinth disorders	Vertigo	01JAN1966		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Dry eye	01JAN2017		Y
			Glaucoma	01JAN2017		Y
			Retinal tear	01JAN1990	31DEC1990	N
		Gastrointestinal disorders	Gastric ulcer	01JAN1958	31DEC1972	N
			Nausea	01JAN1966		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Infections and infestations	Fungal infection	01JAN1996		Y
			Sinusitis	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN1990		Y
			Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN1966		Y
			Restless legs syndrome	01JAN1990		Y
			Sciatica	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1982	31DEC1982	N
				01JAN1983	31DEC1983	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Rhinitis perennial	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Retinal operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1021 10211038	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Eye disorders	Cataract	01JAN2009	31DEC2011	N
			Retinal tear	01JAN2009	31DEC2009	N
		Gastrointestinal disorders	Duodenal ulcer	01JAN1968	31DEC1968	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1976		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN1999		Y
				01JAN2015		Y
			Food allergy	01JAN1984		Y
			Seasonal allergy	01JAN1955		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Intervertebral disc protrusion	01JAN1989	31DEC1989	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
			Retinal operation	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN1989	31DEC1989	N
			Spinal laminectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1021 10211039	Gastrointestinal disorders	Abdominal distension	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2015	31DEC2018	N
			Nausea	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Immune system disorders	Allergy to arthropod sting	01JAN1985		Y
			Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN1973		Y
		Infections and infestations	Chronic sinusitis	01JAN1973		Y
		Injury, poisoning and procedural complications	Incisional hernia	01JAN1999	31DEC1999	N
			Meniscus injury	01JAN1995	31DEC1995	N
				01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN1995	31OCT2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2011	N
		Renal and urinary disorders	Hypertonic bladder	01JAN1985	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2017	30APR2018	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2011	31DEC2011	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1985	31DEC1985	N
			Gastric bypass	01JAN2017	31DEC2017	N
			Incisional hernia repair	01JAN1999	31DEC1999	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN1995	31DEC1995	N
				01JAN2001	31DEC2001	N
			Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1021 10211041	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN1946	31DEC1946	N
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1946	31DEC1946	N
	C4591001 1021 10211043	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211044	Endocrine disorders	Goitre	01JAN2014	31DEC2014	N
			Hyperthyroidism	01JAN2014	31DEC2014	N
			Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2015	N
				01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2014	31DEC2014	N
			Atrial fibrillation	01JAN2015		Y
	C4591001 1021 10211045	Cardiac disorders				
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN1979		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1021 10211046	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Diarrhoea	01JAN2017		Y
			Inguinal hernia	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1990	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
			Squamous cell carcinoma of skin	01JAN2019	31DEC2019	N
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
			Panic disorder	01JAN2012	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cancer surgery	01JAN2019	31DEC2019	N
			Cataract operation	01JAN2017	31DEC2017	N
			Coronary artery bypass	01JAN2012	31DEC2012	N
			Gastric banding	01JAN2009	31DEC2009	N
			Inguinal hernia repair	01JAN1990	31DEC1990	N
			Joint surgery	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1021 10211047	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					27JAN2020	N
			Synovial cyst	01JAN1967	31DEC1967	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
		Surgical and medical procedures	Knee arthroplasty	27JAN2020	27JAN2020	N
			Lipoma excision	01JAN2011	31DEC2011	N
			Synovial cyst removal	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1021 10211048	Cardiac disorders	Mitral valve disease	01JAN2008		Y
		Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Inguinal hernia	01JAN1998	31DEC1998	N
			Umbilical hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
				01JAN2008		Y
		Infections and infestations	Chronic sinusitis	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1948		Y
			Rhinitis perennial	01JAN1948		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mitral valve replacement	01JAN2008	31DEC2008	N
			Umbilical hernia repair	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211049	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
			Inguinal hernia	01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1949		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2013	N
			Migraine	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1949		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1949		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Coronary arterial stent insertion	01JAN2005	31DEC2005	N
			Hip surgery	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2006	31DEC2006	N
			Wrist surgery	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1021 10211050	Cardiac disorders	Angina pectoris	01JAN2001	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1021 10211051	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
		Surgical and medical procedures	Prostatectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211052	Cardiac disorders	Atrial tachycardia	01JAN2006		Y
		Eye disorders	Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1993	31DEC1993	N
			Inguinal hernia	01JAN2015	31DEC2015	N
			Irritable bowel syndrome	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
				01JAN2014		Y
				01JAN2015		Y
					31DEC2017	N
				01JAN2019	22JUN2020	N
			Osteopenia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1990		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1975	31DEC1975	N
		Psychiatric disorders	Depression	01JAN1985		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1993	31DEC1993	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
				22JUN2020	22JUN2020	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Uterine dilation and curettage	01JAN1975	31DEC1975	N
				01JAN1994	31DEC1994	N
	C4591001 1021 10211053	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2013	31DEC2014	N
			Macular degeneration	01SEP2019		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2014		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2004	31DEC2004	N
			Osteoarthritis	01JAN2010		Y
				01JAN2014		Y
			Spinal osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1978	31DEC1978	N
		Nervous system disorders	Migraine	01JAN1987		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Blepharoplasty	01JAN2009	31DEC2009	N
			Cataract operation	01JAN2014	31DEC2014	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Lipoma excision	01JAN1978	31DEC1978	N
			Shoulder operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211054	Ear and labyrinth disorders	Deafness unilateral	01JAN1950		Y
		Eye disorders	Cataract	01JAN2020	31JAN2020	N
			Diabetic retinopathy	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211055	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Glaucoma	01JAN2013		Y
		Gastrointestinal disorders	Coeliac disease	01JAN1997		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Immune system disorders	Rubber sensitivity	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
			Oral herpes	01JAN2010		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JUN2020	08JUL2020	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
			Prostate cancer	01JAN2015	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
			Psoriasis	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N
			Prostatectomy	01JAN2018	31DEC2018	N
			Tendon operation	08JUL2000	08JUL2000	N
	C4591001 1021 10211056	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN1995		Y
		Investigations	Biopsy breast	01JAN1979	31DEC1979	N
				01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1979	31DEC1979	N
				01JAN1991	31DEC1991	N
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1021 10211057	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Hepatitis C	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2003		Y
			Vitamin D deficiency	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2009	31MAR2020	N
			Depression	01JAN2009	31MAR2020	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1021 10211058	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Investigations	Arthroscopy	30SEP2008	30SEP2008	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Neck pain	01JAN2010		Y
			Rotator cuff syndrome	01JAN2005	30SEP2008	N
	C4591001 1021 10211059	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1992	31DEC1992	N
		Nervous system disorders	Cervical radiculopathy	01JAN2004	31DEC2004	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1021 10211060	Ear and labyrinth disorders	Deafness	01JAN1980		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Macular degeneration	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Injury, poisoning and procedural complications	Joint injury	01JAN1961	31AUG2019	N
			Meniscus injury	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Muscle injury	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
			Tendon rupture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013	31DEC2013	N
			Rotator cuff syndrome	01JAN2012	31DEC2012	N
				01JAN2019	31DEC2019	N
			Trigger finger	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1978	31DEC1978	N
			Cataract operation	01JAN2010	31DEC2010	N
			Cochlea implant	01JUN2019		Y
			Knee arthroplasty	01AUG2019	31AUG2019	N
			Meniscus operation	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Muscle operation	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN2012	31DEC2012	N
				01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
			Tendon sheath incision	01JAN2007	31DEC2007	N
			Tenoplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1021 10211062	Ear and labyrinth disorders	Deafness unilateral	01JAN1980		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2015		Y
			Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
				01JAN2000		Y
		Surgical and medical procedures	Ear tube insertion	01JAN1980	31DEC1980	N
				01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1021 10211063	Cardiac disorders	Coronary artery disease	01NOV2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2013	31DEC2014	N
		Investigations	Catheterisation cardiac	01NOV2019	30NOV2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990	31DEC1997	N
			Diastasis recti abdominis	01JAN2004	31DEC2004	N
			Osteoarthritis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	31DEC1997	N
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2004	31DEC2004	N
			Blepharoplasty	01JAN1996	31DEC1996	N
			Breast conserving surgery	01JAN1997	31DEC1997	N
			Spinal fusion surgery	01JAN1997	31DEC1997	N
			Spinal laminectomy	01JAN1990	31DEC1990	N
				01JAN1994	31DEC1994	N
			Wrist surgery	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
	C4591001 1021 10211064	Immune system disorders	Seasonal allergy	01JAN1957		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2006	31DEC2006	N
			Rib fracture	01JAN2006	31DEC2006	N
		Investigations	Biopsy prostate	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1978	31DEC1978	N
			Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Neurosurgery	01JAN2006	31DEC2006	N
			Radiotherapy to prostate	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN1978	31DEC1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thoracotomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1021 10211065	Cardiac disorders	Coronary artery disease	01JAN2015		Y
			Pericarditis	01JAN1985	31DEC1990	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1985	31DEC1990	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
		Psychiatric disorders	Alcoholism	01JAN1980	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2005		Y
		Surgical and medical procedures	Cardiac operation	01JAN2015	31DEC2015	N
			Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN1995	31DEC1995	N
			Spinal laminectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Aortic aneurysm	01JAN2015	31DEC2015	N
			Hypertension	01JAN2015		Y
	C4591001 1021 10211067	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2000	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN1965	31DEC1965	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2000	31DEC2000	N
			Wrist surgery	01JAN2015	31DEC2015	N
	C4591001 1021 10211068	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Investigations	Biopsy breast	01JAN1983	31DEC1983	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
			Osteoarthritis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1983	31DEC1983	N
			Lipoma	01JAN1983	31DEC1983	N
				01JAN1990	31DEC1990	N
		Nervous system disorders	Trigeminal neuralgia	01JAN2011		Y
		Psychiatric disorders	Bipolar disorder	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Lipoma excision	01JAN1983	31DEC1983	N
				01JAN1990	31DEC1990	N
	C4591001 1021 10211070	Cardiac disorders	Congestive cardiomyopathy	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1021 10211071	Immune system disorders	Reaction to colouring	01JAN2017		Y
			Rubber sensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1992	31DEC1992	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Ligament operation	01JAN1992	31DEC1992	N
			Prostatectomy	01JAN2017	31DEC2017	N
			Cataract	01JAN2017	31DEC2017	N
		Eye disorders	Glaucoma	01JAN1985	31DEC2017	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2000	31DEC2008	N
			Inguinal hernia	01JAN1993	31DEC1993	N
				01JAN2005	31DEC2005	N
		Immune system disorders	Food allergy	01JAN1964		Y
			Seasonal allergy	01JAN1964		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
			Herpes simplex	01JAN2005		Y
		Investigations	Biopsy prostate	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2016		Y
			Prostatic mass	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2002	N
			Breast conserving surgery	01JAN2012	31DEC2012	N
			Cataract operation	01JAN2017	31DEC2017	N
			Hernia repair	01JAN1993	31DEC1993	N
				01JAN2005	31DEC2005	N
			Prostatic urethral lift procedure	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1021 10211073	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2020		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
			Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Spinal osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1997	31DEC1997	N
			Sleep apnoea syndrome	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Rash	01MAY2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
	C4591001 1021 10211074	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
			Tonsillitis	01JAN1965	31DEC1965	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1021 10211075	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
		Surgical and medical procedures	Prostatectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1021 10211076	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
	C4591001 1021 10211077	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Appendix cancer	01JAN2019	31MAR2019	N
			Breast cancer	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2018	31DEC2019	N
			Insomnia	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN2019	31DEC2019	N
			Breast conserving surgery	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1021 10211078	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Prostatectomy	01MAR2012	31MAR2012	N
	C4591001 1021 10211079	Endocrine disorders	Basedow's disease	01JAN1985		Y
			Testicular failure	01JAN2012		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Renal and urinary disorders	Nocturia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211080	Endocrine disorders	Thyroid mass	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1961	31DEC1961	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Investigations	Biopsy breast	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2014		Y
			Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1980	31DEC1980	N
			Fibroma	01JAN2016	31DEC2016	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1983	31DEC1983	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1961	31DEC1961	N
			Meniscus operation	01JAN2015	31DEC2015	N
			Tumour excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1021 10211081	Immune system disorders	Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1961		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1985	31DEC1985	N
			Tendon rupture	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	31DEC2016	N
				01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
			Ligament operation	01JAN1985	31DEC1985	N
			Prostatectomy	01JAN2017	31DEC2017	N
			Tenoplasty	01JAN1980	31DEC1980	N
	C4591001 1021 10211082	Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Nervous system disorders	Migraine	01JAN2001		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hot flush	01JAN2006		Y
	C4591001 1021 10211084	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
			Oesophageal achalasia	01JAN2000	31DEC2016	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1968	31DEC1968	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2000		Y
				01JAN2005		Y
				01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1968	31DEC1968	N
			Chronic sinusitis	01JAN1990		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2019	25JUN2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1988	31DEC1988	N
				01JAN2000	31DEC2000	N
			Osteoarthritis	01JAN2020		Y
			Osteopenia	01JAN2018		Y
			Spinal osteoarthritis	01JAN1980		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN1975	31DEC1975	N
			Vulvovaginal dryness	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Skin atrophy	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1968	31DEC1968	N
			Cholecystectomy	01JAN1968	31DEC1968	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Intervertebral disc operation	01JAN1988	31DEC1988	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000	31DEC2000	N
			Oesophageal operation	01JAN2016	31DEC2016	N
			Shoulder operation	25JUN2020	25JUN2020	N
			Sinus operation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211085	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Infections and infestations	Staphylococcal infection	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN2009		Y
		Nervous system disorders	Parkinson's disease	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1975	31DEC2018	N
		Surgical and medical procedures	Knee operation	01JAN1990	31DEC1990	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Spinal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211086	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN2000		Y
		Nervous system disorders	Seizure	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Bipolar disorder	01JAN2000		Y
			Suicide attempt	14JUL2019	14JUL2019	N
		Vascular disorders	Deep vein thrombosis	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211087	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01FEB2018		Y
				01JAN1998		Y
				01JAN2012		Y
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2015		Y
			Breast cyst	01JAN1995	31DEC1995	N
			Ovarian cyst	01JAN1988	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
			Rhinitis perennial	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Rash	01JUN2019		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1995	31DEC1995	N
			Ovarian cystectomy	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1021 10211088	Ear and labyrinth disorders	Deafness bilateral	01JAN2014		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Eye laser surgery	01FEB2019	28FEB2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1021 10211089	Gastrointestinal disorders	Inguinal hernia	01JAN1997	31DEC1997	N
		Infections and infestations	Oral herpes	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1997	31DEC1997	N
			Micrographic skin surgery	01JAN2018	31DEC2018	N
	C4591001 1021 10211090	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
				01JAN1991	31DEC1991	N
	C4591001 1021 10211091	Eye disorders	Cataract	01JAN2015	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994	31DEC2014	N
				01JAN1999		Y
			Osteoporosis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010		Y
				01JAN2015	31DEC2015	N
			Carpal tunnel decompression	01JAN2016	31DEC2016	N
			Cataract operation	01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN2014	31DEC2014	N
			Appendicitis perforated	01JUN2020	01JUN2020	N
	C4591001 1021 10211093	Infections and infestations				
		Injury, poisoning and procedural complications	Kidney rupture	01JAN1961	31DEC1961	N
			Rib fracture	01JUN2020	01JUN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2020	13AUG2020	N
			Malignant melanoma	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Appendicectomy	01JUN2020	01JUN2020	N
			Fracture treatment	01JUN2020	01JUN2020	N
			Renal surgery	01JAN1961	31DEC1961	N
			Skin neoplasm excision	01JAN2002	31DEC2002	N
				13AUG2020	13AUG2020	N
	C4591001 1021 10211094	Cardiac disorders	Myocardial infarction	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Psychiatric disorders	Insomnia	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2017		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2003	31DEC2003	N
			Implantable defibrillator insertion	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211095	Cardiac disorders	Coronary artery disease	01MAY2019		Y
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2019	31MAY2019	N
	C4591001 1021 10211096	Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1021 10211098	Cardiac disorders	Atrial fibrillation	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2012		Y
		Infections and infestations	Chronic sinusitis	01JAN1975		Y
			Tinea versicolour	01JAN2010		Y
			Tonsillitis	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Exostosis	01FEB2020	31MAR2020	N
			Intervertebral disc protrusion	01JAN2002	31DEC2002	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC1990	N
				01JAN1997	31DEC1997	N
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	01JAN2000		Y
		Surgical and medical procedures	Bone lesion excision	01MAR2020	31MAR2020	N
			Cardiac ablation	01JAN2017	31DEC2017	N
			Cardioversion	01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N
				01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Intervertebral disc operation	01JAN2002	31DEC2002	N
			Nasal septal operation	01JAN1990	31DEC1990	N
				01JAN1997	31DEC1997	N
			Sinus operation	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1021 10211100	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Panic disorder	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Sterilisation reversal	01JAN2001	31DEC2001	N
	C4591001 1021 10211102	Eye disorders	Glaucoma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Macular hole	01JAN2007	31DEC2007	N
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Investigations	Cardiac murmur	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
			Osteopenia	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1996	31DEC1998	N
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1998	31DEC1998	N
			Cataract operation	01JAN2009	31DEC2009	N
			Retinal operation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1021 10211103	Cardiac disorders	Myocardial infarction	01NOV2019	30NOV2019	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Rotator cuff syndrome	01OCT2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2020		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary arterial stent insertion	01NOV2019	30NOV2019	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2004	31DEC2004	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211105	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Gastric bypass	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211106	Cardiac disorders	Bundle branch block right	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Injury, poisoning and procedural complications	Limb injury	01JAN1976	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2006	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2006	31DEC2006	N
			Shoulder arthroplasty	01JAN1976	31DEC1976	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1952	31DEC1952	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Aortic stenosis	01JAN2019		Y
			Hypertension	01JAN2005		Y
	C4591001 1021 10211107	Gastrointestinal disorders	Inguinal hernia	01JAN1951	31DEC1951	N
				01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970	31DEC2010	N
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
			Inguinal hernia repair	01JAN1951	31DEC1951	N
				01JAN2005	31DEC2005	N
			Renal stone removal	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1021 10211108	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Abscess neck	01JAN2012	31DEC2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2011	31DEC2011	N
			Malignant melanoma	01JAN2006	31DEC2006	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Abscess drainage	01JAN2012	31DEC2012	N
			Micrographic skin surgery	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211109	Nervous system disorders	Carpal tunnel syndrome	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2019	N
		Vascular disorders	Hypertension	01DEC2019	31DEC2019	N
	C4591001 1021 10211110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211111	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2000	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Dry eye	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1955		Y
			Type 1 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1960		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2012		Y
		Social circumstances	Postmenopause	01JUN2020		Y
		Surgical and medical procedures	Corneal transplant	01JAN1994		Y
				01AUG2018	31AUG2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1021 10211113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Infections and infestations	Herpes simplex	01JAN2015		Y
			Tonsillitis	01JAN1955	31DEC1955	N
		Investigations	Biopsy breast	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN1978	31DEC1978	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
			Rhinitis perennial	01JAN1975		Y
		Surgical and medical procedures	Breast prosthesis removal	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1978	31DEC1978	N
			Mammoplasty	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1021 10211114	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
			Tinea versicolour	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1978	31DEC1978	N
	C4591001 1021 10211115	Blood and lymphatic system disorders	Monoclonal B-cell lymphocytosis	01JAN2016		Y
			Splenomegaly	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2011	31DEC2011	N
			Tibia fracture	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1972		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Knee operation	01JAN2011	31DEC2011	N
			Lipoma excision	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Vasectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Peripheral venous disease	01JAN2016		Y
	C4591001 1021 10211116	Cardiac disorders	Coronary artery disease	01APR2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
			Mouth cyst	01JAN1964	31DEC1964	N
		General disorders and administration site conditions	Chest pain	01APR2020		Y
			Oedema peripheral	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
			Obesity	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Bipolar disorder	01JAN1988		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Coronary artery bypass	01APR2017	30APR2017	N
			Cyst removal	01JAN1964	31DEC1964	N
			Renal stone removal	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1021 10211118	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Obstruction gastric	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Periarthritis	01NOV2019		Y
			Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Epilepsy	01JAN1973		Y
			Migraine	01JAN2000		Y
			Seizure	01JAN1973		Y
		Psychiatric disorders	Depression	01JAN1988		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
			Cataract operation	01JAN2018	31DEC2018	N
			Gastrectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Intervertebral disc operation	01JAN1998	31DEC1998	N
	C4591001 1021 10211120	Gastrointestinal disorders	Dysphagia	01JAN2005	31DEC2005	N
			Gastroesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Food allergy	01JAN1965		Y
			Seasonal allergy	01JAN1955		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Erectile dysfunction	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
			Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N
			Oesophageal dilation procedure	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211121	Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Food allergy	01JAN1953		Y
		Infections and infestations	Tonsillitis	01JAN1948	31DEC1948	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1982	31DEC1982	N
				01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1975	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1982	31DEC1982	N
				01JAN2000	31DEC2000	N
			Nasal septal operation	01JAN1980	31DEC1980	N
			Rhinoplasty	01JAN1975	31DEC1975	N
			Tonsillectomy	01JAN1948	31DEC1948	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1021 10211122	Gastrointestinal disorders	Hiatus hernia	01JAN2005	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1991		Y
			Insomnia	01JAN2006		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
				01JAN2003	31DEC2003	N
			Endometrial ablation	01JAN2008	31DEC2008	N
			Oesophagogastric fundoplasty	01JAN2010	31DEC2010	N
	C4591001 1021 10211124	Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1021 10211125	Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2018		Y
			Osteoarthritis	01JAN2019		Y
			Trigger finger	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1996	31DEC2006	N
		Surgical and medical procedures	Knee arthroplasty	01NOV2019	01NOV2019	N
			Radiotherapy	01JAN1996	31DEC1996	N
			Tendon sheath incision	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211126	Infections and infestations	Oral herpes	01JAN2017		Y
		Injury, poisoning and procedural complications	Skin laceration	01JAN1961	31DEC1961	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Wound closure	01JAN1961	31DEC1961	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1021 10211128	Ear and labyrinth disorders	Deafness bilateral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1021 10211129	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1992		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1021 10211131	Immune system disorders	Allergy to metals	01JAN1960		Y
			Drug hypersensitivity	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1963	31DEC1963	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
			Trigger finger	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
			Meniscus operation	01JAN2012	31DEC2012	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1021 10211132	Infections and infestations	Onychomycosis	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN1992	31DEC1992	N
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1021 10211133	Injury, poisoning and procedural complications	Meniscus injury	01JAN1992	31DEC1992	N
		Investigations	Arthroscopy	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
			Osteoarthritis	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
			Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1021 10211134	Metabolism and nutrition disorders	Gout	01JAN1999		Y
			Hypercholesterolaemia	01JAN2013		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1976	31DEC1996	N
			Osteoarthritis	01JAN2009		Y
			Spinal stenosis	01JAN1991	31DEC2001	N
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN1976	31DEC1976	N
				01JAN1984	31DEC1984	N
				01JAN1996	31DEC1996	N
				01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2013		Y
			Intermittent claudication	01JAN2019		Y
	C4591001 1021 10211135	Cardiac disorders	Atrial fibrillation	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1021 10211136	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1969		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
				01JAN2019		Y
		Nervous system disorders	Spondylitic myelopathy	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Insomnia	01JAN1999		Y
		Renal and urinary disorders	Bladder irritation	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Rhinitis perennial	01JAN1955		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Spinal laminectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Deep vein thrombosis	01JAN2002	31DEC2002	N
			Hypertension	01JAN2015		Y
	C4591001 1021 10211138	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1993	31DEC1993	N
			Ligament rupture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign salivary gland neoplasm	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Elbow operation	01JAN1993	31DEC1993	N
			Ligament operation	01JAN1995	31DEC1995	N
			Salivary gland operation	01JAN1990	31DEC1990	N
			Tendon sheath incision	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211139	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1960	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1021 10211140	Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
		Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2005		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1959	31DEC1959	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteitis deformans	01JAN2008	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1959	31DEC1959	N
			Cardiac ablation	01JAN2016	31DEC2016	N
			Cardioversion	01JAN2016	31DEC2016	N
			Cataract operation	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN2011	31DEC2011	N
			Meniscus operation	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211141	Gastrointestinal disorders	Diarrhoea	01JAN2009		Y
		Immune system disorders	Allergy to animal	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
			Osteoporosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01FEB2000	31MAR2000	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01MAR2000	31MAR2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211143	Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211144	Congenital, familial and genetic disorders	Congenital joint malformation	01MAR2018	31DEC2018	N
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Phlebectomy	01JAN2020	31JAN2020	N
			Shoulder arthroplasty	01MAR2018	31MAR2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2002		Y
			Phlebitis	01AUG2019	31JAN2020	N
	C4591001 1021 10211145	Eye disorders	Photophobia	01JAN2018		Y
			Retinal detachment	01MAR2018	31MAR2018	N
				01MAR2019	31MAR2019	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1980	31DEC1980	N
		Investigations	Arthroscopy	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Retinal operation	01MAR2018	31MAR2018	N
				01MAR2019	31MAR2019	N
	C4591001 1021 10211148	Cardiac disorders	Palpitations	01JAN2016		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
		Nervous system disorders	Migraine	01JAN1989	31DEC2004	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2011	31DEC2011	N
			Penile prosthesis insertion	01OCT2017	31OCT2017	N
	C4591001 1021 10211150	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Laparoscopic surgery	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211151	Cardiac disorders	Atrial fibrillation	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1021 10211153	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1986	31DEC1986	N
		Hepatobiliary disorders	Biliary obstruction	01JAN1983		Y
			Cholelithiasis	01JAN1983	31DEC1983	N
		Investigations	Biopsy breast	01JAN1992	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1970	31DEC2005	N
					31DEC2007	N
				01JAN2015		Y
					31DEC2017	N
				01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1992	31DEC1992	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Subarachnoid haemorrhage	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Cholecystectomy	01JAN1983	31DEC1983	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Haemorrhoid operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1021 10211155	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
			Cardiac failure congestive	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypogonadism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Investigations	Catheterisation cardiac	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2019	30NOV2019	N
		Surgical and medical procedures	Cardiac ablation	01JAN2014	31DEC2014	N
			Cardiac pacemaker insertion	01JUL2019		Y
					31JUL2019	N
			Skin neoplasm excision	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1021 10211159	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
	C4591001 1021 10211160	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2005	31DEC2009	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1970	31DEC1970	N
				01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
			Squamous cell carcinoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31JAN2019	N
		Surgical and medical procedures	Bunion operation	01JAN1990	31DEC1990	N
			Inguinal hernia repair	01JAN1970	31DEC1970	N
				01JAN1999	31DEC1999	N
			Micrographic skin surgery	01JAN2005	31DEC2005	N
			Penile prosthesis insertion	01JAN2014	31DEC2014	N
			Radical prostatectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Deep vein thrombosis	01MAY2017	31MAY2017	N
			Hypertension	01JAN2000		Y
	C4591001 1021 10211161	Eye disorders	Glaucoma	01JAN2000		Y
			Myopia	01JAN1980	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2010	31DEC2010	N
		Investigations	Biopsy prostate	01JAN2005	31DEC2005	N
			Prostatic specific antigen increased	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Gout	01JAN2000	31DEC2000	N
			Hypercholesterolaemia	01JAN2014		Y
		Reproductive system and breast disorders	Calculus prostatic	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N
			Keratomileusis	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1021 10211162	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
			Coronary artery disease	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Chest pain	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Catheterisation cardiac	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1021 10211163	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
				01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
			Biopsy breast	01JAN1983	31DEC1983	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1983	31DEC1983	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1021 10211164	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN1997	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Lithotripsy	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
	C4591001 1021 10211165	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
			Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Meniscus operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211166	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2017		Y
		Investigations	Arthroscopy	01SEP2016	30SEP2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
					30SEP2016	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1021 10211167	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
			Rocky mountain spotted fever	01SEP2018	30NOV2018	N
		Investigations	Transaminases increased	01SEP2018	30NOV2018	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01SEP2018	31MAR2019	N
			Squamous cell carcinoma of skin	01MAR2019	31MAR2019	N
		Nervous system disorders	Sciatica	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JUN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1973	31DEC1973	N
			Colectomy	01JAN2010	31DEC2010	N
			Lipoma excision	01MAR2019	31MAR2019	N
			Micrographic skin surgery	01MAR2019	31MAR2019	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1021 10211169	Immune system disorders	Drug hypersensitivity	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1980		Y
			Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Limb injury	01JAN1992	31DEC1992	N
			Tibia fracture	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y
			Osteoporosis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2008	31DEC2008	N
				01JAN2016	31DEC2016	N
			Spondylolysis	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Acoustic neuroma removal	01JAN1992	31DEC1992	N
			Bone operation	01JAN1968	31DEC1968	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
				01JAN2016	31DEC2016	N
			Shoulder operation	01JAN1992	31DEC1992	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
			Uterine prolapse repair	01JAN2013	31DEC2013	N
			Wrist surgery	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211170	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 1 diabetes mellitus	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Shoulder operation	01JAN2015	31DEC2015	N
			Wrist surgery	01JAN2016	31DEC2016	N
	C4591001 1021 10211171	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2014		Y
			Drug hypersensitivity	01JAN1991		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1954	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 1 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1994	31DEC1995	N
			Articular calcification	01NOV2008	31DEC2008	N
			Back pain	01JAN2015	31DEC2016	N
			Rotator cuff syndrome	01JAN2005	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1960	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seborrhoeic keratosis	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN1990		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1991	31DEC1999	N
			Rhinitis perennial	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2006	31DEC2007	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	31DEC2015	N
			Knee operation	01JAN1995	31DEC1995	N
			Nasal polypectomy	01JAN1991	31DEC1991	N
				01JAN1992	31DEC1992	N
				01JAN1996	31DEC1996	N
				01JAN1999	31DEC1999	N
			Shoulder operation	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Thyroidectomy	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1954	31DEC1954	N
			Vasectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Raynaud's phenomenon	01JAN2004		Y
	C4591001 1021 10211172	Cardiac disorders	Bradycardia	01JAN1980		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1994	31DEC1994	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2018		Y
	C4591001 1021 10211173	Eye disorders	Glaucoma	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1994	31DEC2016	N
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC2010	N
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Knee operation	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Myomectomy	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2004		Y
	C4591001 1021 10211174	Eye disorders	Cataract	01JAN2011	31DEC2013	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoids	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Infections and infestations	Sinusitis	01JAN1990		Y
			Tonsillitis	01JAN1951	31DEC1951	N
			Urinary tract infection	01JAN1968		Y
		Investigations	Cystoscopy	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2002	31MAY2020	N
			Osteoarthritis	01JAN2008		Y
			Rotator cuff syndrome	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
			Rhinitis perennial	01JAN1994		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
			Haemorrhoid operation	01JAN1990	31DEC1990	N
			Shoulder arthroplasty	01MAY2020	31MAY2020	N
			Shoulder operation	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1951	31DEC1951	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1021 10211175	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2010	N
			Lower limb fracture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N
			Limb operation	01JAN2006	31DEC2006	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1021 10211176	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Seasonal allergy	01JAN1970		Y
			Fibromyalgia	01JAN1990		Y
			Foot deformity	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN1970		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1983	31DEC1996	N
		Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1021 10211177	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
			Osteoporosis	01JAN2019		Y
		Nervous system disorders	Cubital tunnel syndrome	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Peripheral nerve decompression	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1021 10211178	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2004	31DEC2004	N
			Ligament injury	01JAN1970	31DEC1970	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus injury	01JAN2011	31DEC2011	N
		Investigations	Arthroscopy	01JAN2004	31DEC2004	N
			Precancerous cells present	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dermatofibrosarcoma protuberans	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cardiac ablation	01JAN2010		Y
			Hysterectomy	01JAN2018	31DEC2018	N
			Knee operation	01JAN2005	31DEC2005	N
			Oophorectomy bilateral	01JAN1970	31DEC1970	N
			Sarcoma excision	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1021 10211179	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1975		Y
			Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1985		Y
		Surgical and medical procedures	Shoulder operation	01JAN2008	31DEC2008	N
	C4591001 1021 10211180	Endocrine disorders	Hyperparathyroidism	01JAN2018	31DEC2018	N
			Hypothyroidism	01JAN2016		Y
			Parathyroid disorder	01JAN2016	31DEC2016	N
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2017		Y
			Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1021 10211181	Endocrine disorders	Hypothyroidism	01JAN2004		Y
			Toxic nodular goitre	01JAN2003	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
				01JAN1959		Y
				01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1021 10211183	Injury, poisoning and procedural complications	Joint injury	01JAN1985	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1021 10211184	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Jaw operation	01JAN1990	31DEC1990	N
			Limb operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1021 10211186	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
				20JUL2020	28JUL2020	N
	C4591001 1021 10211187	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1967		Y
	C4591001 1021 10211188	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAR2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211189	Gastrointestinal disorders	Haemorrhoids	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
			Intervertebral disc protrusion	01JAN2000	31DEC2000	N
			Osteoarthritis	01JAN1993	31DEC2013	N
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Appendectomy	01JAN1979	31DEC1979	N
			Haemorrhoid operation	01JAN1982	31DEC1982	N
			Hip arthroplasty	01JAN2013	31DEC2013	N
	C4591001 1021 10211190	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1021 10211191	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
	C4591001 1021 10211192	General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Infections and infestations	Conjunctivitis	10AUG2020	17AUG2020	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2017	31DEC2017	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN2015	31DEC2015	N
			Tendon sheath incision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1021 10211193	Gastrointestinal disorders	Constipation	01MAY2020		Y
			Gastroesophageal reflux disease	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31MAY2019	N
					31MAY2020	N
				01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2007		Y
		Surgical and medical procedures	Arthrodesis	01MAY2020	31MAY2020	N
			Finger amputation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211194	Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2005		Y
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01AUG2019	31MAR2020	N
		Nervous system disorders	Morton's neuralgia	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Intestinal resection	21AUG2019	21AUG2019	N
			Neurectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211195	Cardiac disorders	Myocardial infarction	01JUN2018	30JUN2018	N
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2011	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUN2018	30JUN2018	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
			Thyroidectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211196	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
			Coronary artery disease	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989		Y
			Hiatus hernia	01JAN2014	31DEC2014	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2009		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
			Obesity	01JAN1980	31DEC2010	N
			Type 2 diabetes mellitus	01JAN1994		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
			Vocal cord polyp	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Coronary arterial stent insertion	01JAN2004	31DEC2004	N
				01JAN2011	31DEC2011	N
			Gastric bypass	01JAN2010	31DEC2010	N
			Hernia repair	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Vocal cord polypectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1021 10211197	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1021 10211198	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1021 10211199	Endocrine disorders	Hyperthyroidism	01JAN1998	31DEC2000	N
			Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign gastric neoplasm	01DEC2019	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Nasal polyps	01JAN2000		Y
		Surgical and medical procedures	Stomach lesion excision	01JAN2020	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1021 10211200	Gastrointestinal disorders	Thyroidectomy	01JAN2000	31DEC2000	N	
			Constipation	01JAN2017		Y	
			Diverticulum	01JAN2012		Y	
			Gastroesophageal reflux disease	01JAN2015		Y	
		Immune system disorders	Seasonal allergy	01JAN1989		Y	
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2009	31DEC2010	N	
		Metabolism and nutrition disorders	Fluid retention	01JAN2019		Y	
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y	
			Osteopenia	01JAN2013		Y	
		Nervous system disorders	Migraine	01JAN1989		Y	
		Psychiatric disorders	Insomnia	01JAN2015		Y	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y	
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1989		Y	
		Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N	
			Caesarean section	01JAN1996	31DEC1996	N	
				01JAN1999	31DEC1999	N	
			Hysterectomy	01JAN2005	31DEC2005	N	
			Oophorectomy bilateral	01JAN2008	31DEC2008	N	
		Vascular disorders	Hot flush	01JAN2011		Y	
		C4591001 1021 10211201	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
					01JAN1965		Y
					01JAN2004		Y
	Infections and infestations			Tonsillitis	01JAN1950	31DEC1950	N
	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y		



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN1997		Y
			Insomnia	01JAN1985		Y
		Reproductive system and breast disorders	Endometrial disorder	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Hip arthroplasty	01JAN2013	31DEC2013	N
			Oophorectomy bilateral	01JAN2016	31DEC2016	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Appendicitis	01JAN1960	31DEC1960	N
	C4591001 1021 10211203	Infections and infestations				
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
				01JUL2020	07JUL2020	N
		Nervous system disorders	Migraine	01JAN1990		Y
			Sciatica	01FEB2020		Y
		Renal and urinary disorders	Urinary retention	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211204	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Tooth impacted	01JAN1971	31DEC1971	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N
		Immune system disorders	Food allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1965	31DEC1965	N
			Cholecystectomy	01JAN1988	31DEC1988	N
			Wisdom teeth removal	01JAN1971	31DEC1971	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1021 10211205	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
			Joint arthroplasty	01JAN2010	31DEC2010	N
			Shoulder operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1021 10211206	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Surgical and medical procedures	Tongue tie operation	01JAN1974	31DEC1974	N
	C4591001 1021 10211207	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005		Y
			Malignant melanoma	17AUG2020	31AUG2020	N
		Nervous system disorders	Sciatica	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Laryngeal operation	01JAN2018	31DEC2018	N
			Limb operation	01JAN2005	31DEC2005	N
			Skin neoplasm excision	31AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1021 10211208	Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN1996		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Dental implantation	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2013	31DEC2013	N
			Renal stone removal	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1021 10211209	Gastrointestinal disorders	Inguinal hernia	01JAN1985	31DEC1985	N
			Irritable bowel syndrome	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Dust allergy	01JAN1990		Y
			Mycotic allergy	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
				01JAN2008		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Investigations	Aspiration bursa	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
			Bursitis	01JAN1999	31DEC1999	N
			Spondylitis	01JAN1995		Y
			Trigger finger	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1985	31DEC1985	N
			Lymphadenectomy	01JAN1996	31DEC1996	N
			Tendon sheath incision	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1021 10211214	Gastrointestinal disorders	Diarrhoea	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2015		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1021 10211215	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Bipolar disorder	01JAN1990		Y
			Depression	01JAN1990		Y
			Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1021 10211217	Eye disorders	Macular degeneration	01JAN2019		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1021 10211218	Gastrointestinal disorders	Gingival disorder	01MAR2020		Y
		Infections and infestations	Osteomyelitis	01JAN1961	31DEC1961	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2017	04JAN2018	N
		Psychiatric disorders	Depression	01JAN1997		Y
		Renal and urinary disorders	Nocturia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Ankle operation	01JAN1961	31DEC1961	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip arthroplasty	04JAN2018	04JAN2018	N
	C4591001 1021 10211221	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1021 10211222	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2005	N
				01JAN2015	31DEC2017	N
			Spinal osteoarthritis	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2009		Y
			Ovarian cyst	01JAN1974	31DEC1974	N
			Uterine polyp	01JAN2009	31DEC2013	N
		Surgical and medical procedures	Ankle arthroplasty	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN1987	31DEC1987	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
			Salpingectomy	01JAN1974	31DEC1974	N
			Uterine dilation and curettage	01JAN2009	31DEC2009	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1021 10211225	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1021 10211226	Eye disorders	Glaucoma	01JAN2012	31JAN2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1993	31DEC1993	N
		Infections and infestations	Diverticulitis	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1984	31DEC1985	N
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Eye operation	01JAN2019	31JAN2019	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Intestinal resection	01JAN2019	31JAN2019	N
	C4591001 1021 10211227	Cardiac disorders	Arrhythmia	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Sinusitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2004	31DEC2004	N
				01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1990		Y
			Osteoarthritis	01JAN2015	31DEC2018	N
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
			Spinal osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2003	31DEC2003	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Surgical and medical procedures	Limb operation	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2004	31DEC2004	N
				01JAN2009	31DEC2009	N
			Nasal septal operation	01JAN2010	31DEC2010	N
			Prostatectomy	01JAN2003	31DEC2003	N
			Shoulder operation	01JAN2013	31DEC2013	N
			Sinus operation	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN1998	31DEC1998	N
				01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Spinal laminectomy	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1021 10211228	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Prostatectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1021 10211229	Endocrine disorders	Hyperparathyroidism	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hot flush	01JAN2017		Y
			Raynaud's phenomenon	01JAN2010		Y
	C4591001 1021 10211231	Eye disorders	Cataract	01JAN2014	31JAN2015	N
			Eyelid ptosis	01JAN1978	31DEC1982	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Immune system disorders	Allergy to arthropod sting	01JAN1959		Y
			Drug hypersensitivity	01JAN1963		Y
				01JAN1982		Y
				01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2012	31JAN2015	N
			Osteoporosis	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1980	31DEC1980	N
			Benign lung neoplasm	01JAN2019	31DEC2019	N
			Parathyroid tumour benign	01JAN1998	31DEC1998	N
			Uterine leiomyoma	01JAN1981	31DEC1981	N
		Nervous system disorders	Migraine	01JAN1959		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2016		Y
		Surgical and medical procedures	Blepharoplasty	01JAN1982	31DEC1982	N
			Breast conserving surgery	01JAN1980	31DEC1980	N
			Cataract operation	01DEC2015	31DEC2015	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN1981	31DEC1981	N
			Knee arthroplasty	01JAN2015	31JAN2015	N
			Oophorectomy	01JAN1981	31DEC1981	N
			Osteotomy	01JAN1976	31DEC1976	N
			Parathyroid gland operation	01JAN1998	31DEC1998	N
			Pulmonary resection	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1021 10211232	Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Dry eye	01JAN2018		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Inguinal hernia	01JAN1974	31DEC1974	N
				01JAN1976	31DEC1976	N
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
			Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Lacrimal structure injury	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	18JUN2020	18JUN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1955	31DEC1955	N
		Surgical and medical procedures	Adenoidectomy	01JAN1955	31DEC1955	N
			Cataract operation	01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN1974	31DEC1974	N
				01JAN1976	31DEC1976	N
			Lacrimal duct procedure	01JAN1954	31DEC1954	N
			Micrographic skin surgery	01JAN2014	31DEC2014	N
			Rotator cuff repair	18JUN2020	18JUN2020	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1021 10211233	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1021 10211234	Gastrointestinal disorders	Colitis microscopic	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Infections and infestations	Genital herpes	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN1972	31DEC1972	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1954		Y
		Surgical and medical procedures	Hysterectomy	01JAN1972	31DEC1972	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1021 10211236	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Gastric bypass	01JAN2008	31DEC2008	N
	C4591001 1021 10211237	Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
			Oesophageal fistula	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
				01JAN1983		Y
			Food allergy	01JAN1954		Y
			Sarcoidosis	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1955	N
				01JAN1955	31DEC1955	N
		Injury, poisoning and procedural complications	Ligament injury	01JAN1978	31DEC1978	N
			Limb injury	01JAN2017	31DEC2017	N
			Tendon injury	01JAN1990	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	02MAR2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine leiomyoma	01JAN2007	31DEC2008	N
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
			Tremor	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1972	31DEC1972	N
			Pulmonary embolism	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Abdominoplasty	01JAN1989	31DEC1989	N
			Cataract operation	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Finger repair operation	01JAN1978	31DEC1978	N
			Foot operation	01JAN2017	31DEC2017	N
			Hand repair operation	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Knee arthroplasty	02MAR2020	02MAR2020	N
			Nasal operation	01JAN1972	31DEC1972	N
			Tonsillectomy	01JAN1952	31DEC1952	N
			Vena cava filter insertion	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1021 10211238	Infections and infestations	Genital herpes	01JAN2016		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01DEC1981	31DEC1981	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Oophorectomy	01DEC1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1021 10211241	Cardiac disorders	Coronary artery disease	01JAN2013	31DEC2013	N
		Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Vertebral osteophyte	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01JAN1957	31DEC1957	N
			Coronary artery bypass	01JAN2013	31DEC2013	N
			Transurethral prostatectomy	01JAN2006	31DEC2006	N
	C4591001 1021 10211243	Vascular disorders	Hypertension	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Infections and infestations	Oral herpes	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Amnesia	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1021 10211249	Eye disorders	Cataract	01JAN1984	31DEC1985	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2007	31DEC2007	N
			Wrist fracture	01JAN2014	31DEC2014	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Cataract operation	01JAN1985	31DEC1985	N
			Limb operation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Wrist surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Deep vein thrombosis	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
				Hypertension	01JAN1962	
	C4591001 1021 10211250	Immune system disorders	Seasonal allergy	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Nasal septal operation	01JAN1990	31DEC1990	N
			Tenotomy	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1021 10211251	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
			Sinusitis	01JAN1995	31DEC2001	N
			Tonsillitis	01JAN1970	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2015	31DEC2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000	31DEC2004	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1996	31DEC1999	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
			Breast conserving surgery	01FEB2015	28FEB2015	N
			Endometrial ablation	01JAN1999	31DEC1999	N
			Nasal septal operation	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1973	31DEC1973	N
			Urinary bladder suspension	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1022 10221001	Gastrointestinal disorders	Gastroesophageal reflux disease	09APR2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	29AUG2013		Y
			Vitamin B12 deficiency	12NOV2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	26FEB2014		Y
		Psychiatric disorders	Depression	29AUG2013		Y
			Generalised anxiety disorder	04MAY2018		Y
			Social anxiety disorder	04MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29AUG2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	29AUG2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1022 10221002	Gastrointestinal disorders	Gastroesophageal reflux disease	27JUN2012		Y
			Large intestine polyp	03DEC2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1022 10221003	Congenital, familial and genetic disorders	Type V hyperlipidaemia	25JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	08DEC2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	31JAN2015		Y
			Obesity	31JAN2015		Y
		Nervous system disorders	Migraine	21JAN2010		Y
		Psychiatric disorders	Depression	31JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	10MAY2017		Y
		Social circumstances	Postmenopause	31JAN2015		Y
	C4591001 1022 10221005	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	04JAN2019		Y
		Gastrointestinal disorders	Diverticulum	30SEP2011		Y
			Gastroesophageal reflux disease	18MAY2012		Y
		Investigations	Blood bilirubin increased	01JAN2015		Y
			Blood glucose increased	10JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2012	11OCT2012	N
		Nervous system disorders	Migraine	01JAN2005		Y
			Resting tremor	01JAN2015		Y
		Reproductive system and breast disorders	Uterine enlargement	01JUN2012	11OCT2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	18MAY2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	18MAY2012		Y
		Surgical and medical procedures	Hysterectomy	11OCT2012	11OCT2012	N
	C4591001 1022 10221006	Gastrointestinal disorders	Gastroesophageal reflux disease	10APR2018		Y
		Infections and infestations	Rhinitis	03AUG2010		Y
		Metabolism and nutrition disorders	Hypercalcaemia	28JUN2006		Y
			Vitamin D deficiency	30MAY2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	30MAY2013		Y
			Osteoporosis	10JUN2013		Y
			Scoliosis	19APR2017		Y
		Nervous system disorders	Migraine	18FEB2014		Y
		Psychiatric disorders	Insomnia	30MAY2013		Y
		Vascular disorders	Hypertension	30MAY2013		Y
	C4591001 1022 10221007	Cardiac disorders	Palpitations	11MAY2009		Y
		Endocrine disorders	Goitre	17DEC2008		Y
			Hypothyroidism	16MAY2018		Y
	C4591001 1022 10221008	Cardiac disorders	Palpitations	08JUL2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16APR2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29MAR2013		Y
		Surgical and medical procedures	Hysterectomy	01DEC1992	31DEC1992	N
		Vascular disorders	Hypertension	08JUL2005		Y
	C4591001 1022 10221009	Gastrointestinal disorders	Gastroesophageal reflux disease	09JUN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	02NOV2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	03FEB2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221011	Vascular disorders	Hypertension	02NOV2005		Y
		Endocrine disorders	Hypothyroidism	28NOV2010		Y
			Thyroid mass	27DEC2006	01FEB2007	N
		General disorders and administration site conditions	Drug intolerance	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	28NOV2010		Y
			Iron deficiency	20JAN2018		Y
			Obesity	29MAY2015		Y
		Psychiatric disorders	Adjustment disorder	30SEP2016		Y
			Anxiety	30SEP2016		Y
			Major depression	02OCT2015		Y
			Obsessive-compulsive disorder	28NOV2010		Y
			Panic disorder	28NOV2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13JAN2012		Y
		Surgical and medical procedures	Female sterilisation	08JAN2012	08JAN2012	N
	C4591001 1022 10221012		Thyroidectomy	01FEB2007	28FEB2007	N
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	29SEP2017		Y
		Endocrine disorders	Hypothyroidism	04APR2008		Y
		Hepatobiliary disorders	Hepatic cyst	14JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	29JUL2019		Y
		Psychiatric disorders	Insomnia	07APR2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03APR2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	20SEP2016		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1022 10221014	Endocrine disorders	Hypothyroidism	20MAY2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05JUL2013		Y
		Musculoskeletal and connective tissue disorders	Arthritis	15MAY2018		Y
			Osteoarthritis	20MAY2012		Y
			Osteoporosis postmenopausal	08MAR2018		Y
			Scoliosis	30NOV2018		Y
		Nervous system disorders	Headache	20MAY2012		Y
			Lumbar radiculopathy	02AUG2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	19APR2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1022 10221015	Blood and lymphatic system disorders	Antiphospholipid syndrome	25SEP2015		Y
		Cardiac disorders	Supraventricular tachycardia	09MAY2003		Y
		Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	05MAY2008		Y
		Immune system disorders	Rubber sensitivity	09MAY2003		Y
		Nervous system disorders	Cervical radiculopathy	10APR2013		Y
			Migraine	27JUN2013		Y
	C4591001 1022 10221021	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	14DEC2005		Y
		Endocrine disorders	Hypothyroidism	24NOV2009		Y
		General disorders and administration site conditions	Oedema peripheral	18NOV2011		Y
		Metabolism and nutrition disorders	Obesity	24NOV2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Menopause	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Essential hypertension	14DEC2005		Y
	C4591001 1022 10221022	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	15JUL2008		Y
		Nervous system disorders	Migraine	02AUG2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	04SEP2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	02AUG2007		Y
	C4591001 1022 10221026	Congenital, familial and genetic disorders	Congenital cystic kidney disease	26MAY2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	26JUL2007		Y
	C4591001 1022 10221029	Musculoskeletal and connective tissue disorders	Senile osteoporosis	11NOV2019		Y
		Social circumstances	Postmenopause	14APR2014		Y
	C4591001 1022 10221032	Cardiac disorders	Tachycardia	13NOV2002		Y
		Gastrointestinal disorders	Diverticulum	31JUL2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13NOV2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1022 10221034	Gastrointestinal disorders	Diverticulum	29DEC2015		Y
			Gastroesophageal reflux disease	19MAR2004		Y
		Immune system disorders	Seasonal allergy	19MAR2004		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	26JAN2010		Y
		Nervous system disorders	Headache	22JAN2010		Y
			Radiculitis brachial	26JAN2010		Y
		Psychiatric disorders	Insomnia	29DEC2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Prostatomegaly	13DEC2017		Y
	C4591001 1022	Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
	10221036	Cardiac disorders	Palpitations	05MAY2016		Y
		Psychiatric disorders	Insomnia	01AUG2019		Y
		Reproductive system and breast disorders	Menopausal symptoms	02JUL2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1022	Vascular disorders	Hypertension	27APR2018		Y
	10221037	Musculoskeletal and connective tissue disorders	Arthritis	16DEC2019		Y
			Osteoarthritis	09MAY2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	26SEP2016	26SEP2016	N
		Nervous system disorders	Migraine	01MAR2006		Y
	C4591001 1022	Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	10221038	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	28JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	21NOV2014	21NOV2014	N
		Nervous system disorders	Carpal tunnel syndrome	04JUN2020		Y
			Migraine	07DEC2009		Y
		Psychiatric disorders	Anxiety	20NOV2017		Y
			Depression	20NOV2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	17APR2018		Y
		Vascular disorders	Hypertension	17APR2018		Y
	C4591001 1022	Endocrine disorders	Thyroid mass	29MAR2016		Y
	10221039					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	29JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Lymphoedema	28JUL2011		Y
	C4591001 1022 10221041	Immune system disorders	Seasonal allergy	15APR2013		Y
		Infections and infestations	Herpes zoster	01MAR2012		Y
		Musculoskeletal and connective tissue disorders	Enthesopathy	15APR2013		Y
			Osteopenia	17SEP2018		Y
			Osteoporosis	20OCT2018		Y
		Vascular disorders	Phlebitis	15APR2013		Y
			Thrombophlebitis	15APR2013		Y
	C4591001 1022 10221042	Cardiac disorders	Supraventricular tachycardia	29FEB2008		Y
		Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	24AUG2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	18APR2019		Y
		Infections and infestations	Herpes simplex	06FEB2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Choroid melanoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	15JUL2013		Y
			Insomnia	29FEB2008		Y
		Renal and urinary disorders	Stress urinary incontinence	29FEB2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29FEB2008		Y
		Vascular disorders	Hypertension	18APR2011		Y
	C4591001 1022 10221044	Infections and infestations	Herpes simplex	14JUN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	14JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	14JUN2019		Y
	C4591001 1022 10221045	Nervous system disorders	Cerebrovascular accident	17DEC2018	17DEC2018	N
			Seizure	10JUL2010		Y
		Vascular disorders	Hypertension	10SEP2010		Y
	C4591001 1022 10221046	Gastrointestinal disorders	Gastric ulcer	18FEB2011		Y
			Gastrooesophageal reflux disease	23FEB2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	18JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985		Y
			Hip arthroplasty	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	18JAN2010		Y
	C4591001 1022 10221047	Immune system disorders	Seasonal allergy	18JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	18JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07MAY2011		Y
			Sleep apnoea syndrome	16FEB2010		Y
		Vascular disorders	Hypertension	19OCT2015		Y
			Thrombophlebitis	03DEC2013		Y
	C4591001 1022 10221050	Metabolism and nutrition disorders	Hypercholesterolaemia	06JAN2010		Y
		Vascular disorders	Hypertension	06JAN2010		Y
	C4591001 1022 10221053	Immune system disorders	Seasonal allergy	17JUL2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	16NOV2007		Y
		Social circumstances	Menopause	04DEC2018		Y
	C4591001 1022 10221056	Psychiatric disorders	Depression	12SEP2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	06JUN2011		Y
			Sleep apnoea syndrome	16APR2015		Y
		Social circumstances	Menopause	29SEP2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1022 10221060	Congenital, familial and genetic disorders	Type V hyperlipidaemia	18APR2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	18APR2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	30MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	14AUG2007		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1022 10221061	Gastrointestinal disorders	Gastrooesophageal reflux disease	20JUN2013		Y
		Vascular disorders	Hypertension	20JUN2013		Y
	C4591001 1022 10221063	Gastrointestinal disorders	Constipation	01FEB2017		Y
			Dysphagia	10FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10OCT2012		Y
		Social circumstances	Postmenopause	20JAN2016		Y
	C4591001 1022 10221065	Blood and lymphatic system disorders	Leukopenia	28FEB2017		Y
		Cardiac disorders	Supraventricular tachycardia	01JAN1999	31DEC2001	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990	31DEC2010	N
		Nervous system disorders	Cervical radiculopathy	30JUL2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	03DEC2012		Y
	C4591001 1022 10221067	Endocrine disorders	Hypothyroidism	25SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract nuclear	13DEC2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02MAR2020		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	16SEP2015		Y
	C4591001 1022 10221068	Gastrointestinal disorders	Gastroesophageal reflux disease	29FEB2012		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	08JUL2014		Y
		Nervous system disorders	Periodic limb movement disorder	02MAR2016		Y
	C4591001 1022 10221071	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01MAY2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	30JUL2012		Y
			Osteoarthritis	07JAN2019		Y
			Scoliosis	24AUG2012		Y
		Psychiatric disorders	Major depression	29MAR2019		Y
		Renal and urinary disorders	Stress urinary incontinence	07SEP2007		Y
		Vascular disorders	Hypertension	10MAR2014		Y
	C4591001 1022 10221073	Endocrine disorders	Hypothyroidism	27OCT2015		Y
		Hepatobiliary disorders	Biliary colic	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	19MAR2015		Y
		Social circumstances	Menopause	16JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Knee arthroplasty	01APR2015	01APR2015	N
	C4591001 1022 10221075	Ear and labyrinth disorders	Deafness	10FEB2010		Y
		Immune system disorders	Seasonal allergy	12JUL2016		Y
		Psychiatric disorders	Sleep disorder	10FEB2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221077	Blood and lymphatic system disorders	Polycythaemia	17JAN2014		Y
		Immune system disorders	Seasonal allergy	01MAY2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2011		Y
			Hyperlipidaemia	07OCT2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	28JUL2005		Y
		Nervous system disorders	Facial paralysis	05OCT2006	31OCT2006	N
		Vascular disorders	Hypertension	24DEC2012		Y
	C4591001 1022 10221079	Congenital, familial and genetic disorders	Type V hyperlipidaemia	09APR2013		Y
		Ear and labyrinth disorders	Vertigo	18SEP2015		Y
		Metabolism and nutrition disorders	Obesity	09APR2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	09APR2013		Y
		Nervous system disorders	Migraine	09APR2013		Y
			Radicular pain	04NOV2019		Y
		Psychiatric disorders	Depression	09APR2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17APR2006		Y
			Sleep apnoea syndrome	16APR2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
	C4591001 1022 10221082	Cardiac disorders	Atrioventricular block first degree	25MAR2019		Y
			Supraventricular tachycardia	01FEB2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	17DEC2019		Y
		Nervous system disorders	Radiculitis brachial	24JUL2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	27AUG2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1022 10221085	Gastrointestinal disorders	Irritable bowel syndrome	04JUN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2010	30SEP2011	N
		Nervous system disorders	Migraine	27AUG2007		Y
		Psychiatric disorders	Restless legs syndrome	09MAY2007		Y
		Psychiatric disorders	Persistent depressive disorder	05APR2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18MAR2017		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	17JUL2010		Y
	C4591001 1022 10221086	Psychiatric disorders	Insomnia	01JAN2011		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1022 10221089	Endocrine disorders	Hypothyroidism	25AUG2014		Y
		Psychiatric disorders	Insomnia	04AUG2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10JUN2005		Y
		Social circumstances	Menopause	01AUG2016		Y
	C4591001 1022 10221090	Metabolism and nutrition disorders	Hyperlipidaemia	14DEC2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	04MAR2019		Y
			Myofascial pain syndrome	06JUN2012		Y
			Osteoarthritis	28MAY2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	10DEC2013		Y
			Rhinitis allergic	10JUL2005		Y
		Social circumstances	Menopause	20OCT2008		Y
	C4591001 1022 10221091	Cardiac disorders	Coronary artery disease	31MAR2014		Y
		Metabolism and nutrition disorders	Iron metabolism disorder	02APR2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	02AUG2019		Y
		Psychiatric disorders	Anxiety disorder	29MAR2012		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	20DEC2012		Y
	C4591001 1022 10221092	Cardiac disorders	Cardiomyopathy	20DEC2017		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	15OCT2012		Y
		Ear and labyrinth disorders	Tinnitus	29OCT2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	12OCT2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007		Y
		Nervous system disorders	Sensory disturbance	12OCT2012		Y
		Psychiatric disorders	Anxiety	09MAR2000		Y
			Insomnia	09MAR2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	15OCT2012		Y
		Respiratory, thoracic and mediastinal disorders	Hypersensitivity pneumonitis	24NOV2017		Y
	C4591001 1022 10221095	Musculoskeletal and connective tissue disorders	Osteoarthritis	31OCT2016		Y
		Nervous system disorders	Migraine	15OCT2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221096	Cardiac disorders	Atrial fibrillation	23JUL2008		Y
		Immune system disorders	Seasonal allergy	19MAR2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	04JUL2020		Y
			Osteoarthritis	09FEB2015		Y
			Sacroiliitis	06SEP2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Aortic arteriosclerosis	14MAR2008		Y
			Hypertension	09JAN2006		Y
	C4591001 1022 10221097	Metabolism and nutrition disorders	Hyperlipidaemia	21MAY2013		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	17MAY2013		Y
		Nervous system disorders	Cerebral infarction	03MAR2013	29APR2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	17MAY2013		Y
	C4591001 1022 10221099	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	17MAY2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	28APR2006		Y
	C4591001 1022 10221102	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	18SEP2008		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	23JUN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	22APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	29DEC2009		Y
		Vascular disorders	Hypertension	08DEC2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221103	Metabolism and nutrition disorders	Hypercholesterolaemia	18JUN2018		Y
		Musculoskeletal and connective tissue disorders	Bursitis	06DEC2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2004	31AUG2004	N
		Nervous system disorders	Migraine	12AUG2004		Y
			Restless legs syndrome	05APR2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	15JAN2019		Y
		Vascular disorders	Hypertension	20FEB2011		Y
	C4591001 1022 10221104	Cardiac disorders	Arrhythmia	12JUN2006		Y
			Mitral valve disease	12JUN2006		Y
		Investigations	Blood cholesterol increased	20AUG2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	17MAR2016		Y
			Osteoarthritis	06JUL2011		Y
		Psychiatric disorders	Insomnia	30NOV2011		Y
		Reproductive system and breast disorders	Cervical dysplasia	06DEC2012		Y
		Social circumstances	Menopause	30NOV2011		Y
	C4591001 1022 10221107	Ear and labyrinth disorders	Deafness neurosensory	30MAY2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15FEB2019		Y
		Psychiatric disorders	Insomnia	20MAR2020		Y
		Renal and urinary disorders	Bladder outlet obstruction	13MAY2019		Y
	C4591001 1022 10221109	Gastrointestinal disorders	Gastroesophageal reflux disease	07DEC2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	18JUL2018	04AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	06MAR2007		Y
			Lipoprotein deficiency	23NOV2011		Y
			Vitamin D deficiency	06AUG2012		Y
		Nervous system disorders	Migraine	10MAY2019		Y
			Neuropathy peripheral	06MAY2003		Y
		Psychiatric disorders	Depression	17JUN2015		Y
			Insomnia	17JUN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13JUN2012		Y
		Surgical and medical procedures	Cholecystectomy	04AUG2020	04AUG2020	N
	C4591001 1022 10221114	Metabolism and nutrition disorders	Hypertriglyceridaemia	27JUL2016		Y
			Obesity	03APR2019		Y
		Nervous system disorders	Meralgia paraesthetica	03JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	09MAY2014		Y
		Vascular disorders	Hypertension	28AUG2017		Y
	C4591001 1022 10221116	Metabolism and nutrition disorders	Hypercholesterolaemia	06OCT2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	26SEP2013		Y
		Psychiatric disorders	Insomnia	17MAY2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	08AUG2014		Y
		Social circumstances	Menopause	17MAY2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
			Hip arthroplasty	25MAR2011	25MAR2011	N
	C4591001 1022 10221118	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Lactose intolerance	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1022 10221121	Endocrine disorders	Hypothyroidism	14NOV2015		Y
		Gastrointestinal disorders	Large intestinal stenosis	07JAN2020		Y
		Metabolism and nutrition disorders	Decreased appetite	13JAN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	27MAY2020		Y
		Vascular disorders	Hypertension	14NOV2015		Y
	C4591001 1022 10221124	Cardiac disorders	Ventricular tachycardia	05DEC2016		Y
		Ear and labyrinth disorders	Tinnitus	09MAR2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	20OCT2009		Y
			Type 2 diabetes mellitus	12MAY2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	20OCT2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	20OCT2009		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01APR2010	30APR2010	N
		Vascular disorders	Hypertension	20OCT2009		Y
	C4591001 1022 10221132	Gastrointestinal disorders	Gastroesophageal reflux disease	26OCT2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis	04FEB2013		Y
			Back pain	06MAY2014		Y
			Osteoarthritis	26OCT2009		Y
			Spinal stenosis	12JUN2006		Y
		Nervous system disorders	Carpal tunnel syndrome	12JUN2006		Y
		Psychiatric disorders	Depression	03JUN2016		Y
		Social circumstances	Menopause	19OCT2009		Y
		Vascular disorders	Hypertension	26OCT2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1022 10221140	Cardiac disorders	Atrial fibrillation	13DEC2012		Y
		General disorders and administration site conditions	Chest pain	06MAR2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	06MAR2008		Y
			Impaired fasting glucose	18APR2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	16SEP2010		Y
		Psychiatric disorders	Insomnia	12JAN2006		Y
		Renal and urinary disorders	Stress urinary incontinence	06MAR2008		Y
		Vascular disorders	Hypertension	08SEP2009		Y
	C4591001 1022 10221141	Cardiac disorders	Atrial fibrillation	15DEC2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	12NOV2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12DEC2006		Y
		Nervous system disorders	Migraine	28JUN2013		Y
	C4591001 1022 10221145	Endocrine disorders	Hypothyroidism	23NOV2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16NOV2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	23NOV2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30DEC2019		Y
		Vascular disorders	Hypertension	19AUG2009		Y
	C4591001 1022 10221146	Cardiac disorders	Coronary artery disease	07FEB2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29NOV2004		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	24JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	29JUL2011		Y
	C4591001 1022 10221148	Metabolism and nutrition disorders	Hyperlipidaemia	26OCT2013		Y
		Nervous system disorders	Neuropathy peripheral	30MAR2018		Y
		Reproductive system and breast disorders	Peyronie's disease	30MAR2018		Y
	C4591001 1022 10221149	Gastrointestinal disorders	Gastrooesophageal reflux disease	13MAR2013		Y
		Metabolism and nutrition disorders	Gout	13MAR2013		Y
			Obesity	13MAR2013		Y
		Nervous system disorders	Migraine	13MAR2013		Y
		Psychiatric disorders	Anxiety	13MAR2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	07MAY2010		Y
			Sleep apnoea syndrome	07MAY2010		Y
		Vascular disorders	Hypertension	13MAR2013		Y
	C4591001 1022 10221151	General disorders and administration site conditions	Fatigue	01JAN2019		Y
			Oedema peripheral	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal pain	01JAN2018		Y
			Spondylitis	19JUN2017		Y
		Psychiatric disorders	Anxiety	29AUG2013		Y
			Libido decreased	01JAN2019		Y
		Renal and urinary disorders	Nocturia	01JAN2016		Y
			Single functional kidney	20OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	17APR2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221152	Immune system disorders	Seasonal allergy	10DEC2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Psoriasis	17NOV2011		Y
	C4591001 1022 10221153	Cardiac disorders	Mitral valve prolapse	03JUN2003	03JUN2003	N
		Endocrine disorders	Hypothyroidism	03JUN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10MAR2020		Y
	C4591001 1022 10221154	Cardiac disorders	Aortic valve stenosis	26NOV2014		Y
			Coronary artery disease	22AUG2017		Y
		Gastrointestinal disorders	Diverticulum	27MAR2008		Y
		Investigations	Catheterisation cardiac	29JUN2017	29JUN2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	04JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JUL2020	27OCT2020	N
		Surgical and medical procedures	Aortic valve replacement	18JUL2017	18JUL2017	N
		Vascular disorders	Hypertension	04JAN2006		Y
	C4591001 1022 10221155	Cardiac disorders	Atrial fibrillation	03FEB2012		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Nervous system disorders	Essential tremor	26MAY2006		Y
			Headache	09APR2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01APR2003		Y
	C4591001 1022 10221157	Infections and infestations	Bronchitis	03NOV2007	30NOV2007	N
		Investigations	Blood cholesterol increased	16JUN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	21MAY2007		Y
		Nervous system disorders	Diabetic neuropathy	16JUN2014		Y
		Vascular disorders	Hypertension	21MAY2007		Y
	C4591001 1022 10221158	Cardiac disorders	Atrial fibrillation	18JUN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05SEP2014		Y
			Hyperlipidaemia	30APR2019		Y
			Obesity	15JAN2020		Y
			Type 2 diabetes mellitus	30APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	14SEP2016		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	03JUL2014		Y
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1022 10221160	Endocrine disorders	Hypothyroidism	20MAY2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19MAR2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Large intestine benign neoplasm	23JUN2008		Y
		Psychiatric disorders	Anxiety disorder	14SEP2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1022 10221161	Metabolism and nutrition disorders	Hypercholesterolaemia	10MAR2005		Y
			Type 2 diabetes mellitus	10MAR2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	09JUN2020	09JUN2020	N
				22MAY2018	22MAY2018	N
		Nervous system disorders	Diabetic neuropathy	10MAR2005		Y
			Migraine	10JUL2014		Y
		Surgical and medical procedures	Vasectomy	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221162	Cardiac disorders	Aortic valve incompetence	17DEC2014		Y
			Chronic left ventricular failure	17DEC2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	17DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	02NOV2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	06FEB2006		Y
	C4591001 1022 10221163	Cardiac disorders	Tachycardia	07FEB2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	02JUL2015		Y
		Immune system disorders	Seasonal allergy	02JUL2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	30JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	15FEB2017	29JAN2021	N
		Nervous system disorders	Restless legs syndrome	07FEB2013		Y
		Psychiatric disorders	Insomnia	20JUL2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07FEB2013		Y
			Pulmonary mass	28JAN2020		Y
		Social circumstances	Menopause	01JAN2007		Y
		Vascular disorders	Hypertension	20JUL2005		Y
	C4591001 1022 10221165	Eye disorders	Cataract	24MAY2018	11NOV2020	N
					21OCT2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	02FEB2012		Y
		Investigations	Blood cholesterol increased	02FEB2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	22OCT2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1022 10221166	Metabolism and nutrition disorders	Hypercholesterolaemia	10DEC2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1022 10221167	Metabolism and nutrition disorders	Hypercholesterolaemia	18OCT2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2013	N
			Malignant melanoma	01JAN2013	31DEC2013	N
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1022 10221168	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Reproductive system and breast disorders	Erectile dysfunction	21JUN2018		Y
	C4591001 1022 10221169	Social circumstances	Menopause	18JUL2012		Y
	C4591001 1022 10221170	Cardiac disorders	Bradycardia	30OCT2012		Y
		Hepatobiliary disorders	Hepatic steatosis	07MAY2015		Y
		Metabolism and nutrition disorders	Hyperglycaemia	07MAY2015		Y
			Hyperlipidaemia	07MAY2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	07JUL2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1999	31DEC1999	N
		Psychiatric disorders	Generalised anxiety disorder	02MAY2012		Y
			Insomnia	03MAY2012		Y
		Surgical and medical procedures	Prostatectomy	01JAN1999	31DEC1999	N
	C4591001 1022 10221171	Gastrointestinal disorders	Irritable bowel syndrome	27JUN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	14JUL2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	27JUN2008		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1022 10221173	Psychiatric disorders	Depression	10SEP2010		Y
		Social circumstances	Menopause	01JAN2002		Y
	C4591001 1022 10221174	Congenital, familial and genetic disorders	Von Willebrand's disease	17NOV2009		Y
		Ear and labyrinth disorders	Deafness	19FEB2019		Y
		Endocrine disorders	Hypothyroidism	17NOV2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	24OCT2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	15OCT2019		Y
			Sleep apnoea syndrome	08OCT2007		Y
	C4591001 1022 10221175	Metabolism and nutrition disorders	Hypercholesterolaemia	15FEB2013		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	23OCT2020	N
			Spinal osteoarthritis	24OCT2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	15FEB2013		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1022 10221176	Musculoskeletal and connective tissue disorders	Back pain	13JUN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13APR2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	13APR2011		Y
	C4591001 1022 10221177	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2007	31DEC2007	N
		Nervous system disorders	Cervical radiculopathy	01DEC2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31JAN2012	N
	C4591001 1022 10221178	Congenital, familial and genetic disorders	Type V hyperlipidaemia	20APR2012		Y
		General disorders and administration site conditions	Fatigue	14OCT2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	13DEC2016		Y
			Neck pain	10SEP2008		Y
			Osteoarthritis	25JAN2010		Y
		Psychiatric disorders	Insomnia	07DEC2012		Y
		Vascular disorders	Hypertension	24JUN2014		Y
	C4591001 1024 10241003	Infections and infestations	Diverticulitis	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2013	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1024 10241008	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241010	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1024 10241017	Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1024 10241018	Nervous system disorders	Migraine	01JAN1990		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2012		Y
		Social circumstances	Postmenopause	01AUG2006		Y
	C4591001 1024 10241019	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1024 10241024	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1024 10241028	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1024 10241031	Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1024 10241034	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1024 10241041	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1024 10241048	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1024 10241049	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1024 10241050	Nervous system disorders	Seizure	01JAN2000		Y
	C4591001 1024 10241053	Cardiac disorders	Coronary artery disease	01JAN1993		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1024 10241057	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1024 10241059	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1024 10241060	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1024 10241062	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1024 10241065	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1024 10241068	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01DEC2005	01DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1024 10241069	Surgical and medical procedures	Aortic valve replacement	01JAN2014		Y
	C4591001 1024 10241076	Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1024 10241077	Eye disorders	Retinal detachment	28JUL2020	28JUL2020	N
	C4591001 1024 10241079	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1024 10241087	Psychiatric disorders	Depression	01JAN1990		Y
	C4591001 1024 10241089	Cardiac disorders	Sinus arrhythmia	01DEC2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1024 10241093	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1024 10241096	Investigations	Blood cholesterol increased	01JAN1991		Y
	C4591001 1024 10241097	Social circumstances	Postmenopause	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1024 10241105	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1024 10241110	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241111	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
	C4591001 1024 10241113	Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1024 10241115	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01OCT2019	31MAY2020	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1024 10241116	Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
	C4591001 1024 10241119†	Investigations	HIV test positive	11JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01MAY2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Hip arthroplasty	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1024 10241120†	Investigations	Blood cholesterol increased	01JAN2017		Y
			HIV test positive	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1024 10241122†	Investigations	HIV test positive	22OCT2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	11FEB2011		Y
	C4591001 1024 10241125	Cardiac disorders	Coronary artery disease	01JAN1989		Y
	C4591001 1024 10241126	Injury, poisoning and procedural complications	Ligament rupture	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1024 10241127	Investigations	Blood cholesterol increased	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1024 10241128†	Investigations	Blood cholesterol increased	01JAN2010		Y
			HIV test positive	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1024 10241130†	Investigations	HIV test positive	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1024 10241133†	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Investigations	HIV test positive	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1024 10241134†	Investigations	HIV test positive	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271001	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013		Y
			Osteopenia	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1974		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1992	31DEC1994	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1027 10271002	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
	C4591001 1027 10271003	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Appendicitis	01JUL2020	15JUL2020	N
		Investigations	Intraocular pressure increased	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	15JUL2020	15JUL2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1027 10271004	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Renal and urinary disorders	Single functional kidney	(b) (6) 1964		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271006	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1997	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1027 10271007	Cardiac disorders	Cardiac failure congestive	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
			Rubber sensitivity	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
			Emphysema	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271008	Ear and labyrinth disorders	Deafness unilateral	01AUG2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Nervous system disorders	Carotid artery stenosis	01JUN2018	24AUG2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Carotid endarterectomy	24AUG2018	24AUG2018	N
			Radiotherapy	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1027 10271009	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1978		Y
				01JAN1984		Y
		Nervous system disorders	Cerebrovascular accident	01MAY2020	31MAY2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	01DEC2019		Y
		Vascular disorders	Aortic aneurysm	01DEC2019		Y
			Hypertension	01JAN2010		Y
	C4591001 1027 10271010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1027 10271011	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1027 10271013	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1027 10271014	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1027 10271015	Eye disorders	Macular degeneration	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
			Spinal stenosis	01JAN2016		Y
		Nervous system disorders	Sciatica	01JAN2012		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1027 10271016	Congenital, familial and genetic disorders	Factor II mutation	(b) (6) 1952		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2003		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1972		Y
			Onychomycosis	01JAN2012	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2017	N
			Osteopenia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN1999		Y
		Psychiatric disorders	Insomnia	01SEP2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2009		Y
		Reproductive system and breast disorders	Metrorrhagia	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1027 10271018	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2012	N
		Renal and urinary disorders	Hydronephrosis	01JAN2017		Y
		Surgical and medical procedures	Prostatectomy	06JAN2012	06JAN2012	N
			Vascular stent insertion	08NOV2017	08NOV2017	N
		Vascular disorders	Deep vein thrombosis	01JAN2017	31DEC2017	N
	C4591001 1027 10271020	Metabolism and nutrition disorders	Gout	01JAN1980		Y
			Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1027 10271022	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2008	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1027 10271023	Investigations	Prostatic specific antigen increased	01JAN2019	31MAY2020	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Radiculopathy	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2020	30APR2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1027 10271024	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Surgical and medical procedures	Vasectomy	01JUN1984	30JUN1984	N
	C4591001 1027 10271025	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2010		Y
			Osteoarthritis	01JAN2006		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Surgical and medical procedures	Spinal fusion surgery	07MAY2019	07MAY2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271027	Ear and labyrinth disorders	Vertigo positional	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
			Spinal osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1027 10271030	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1027 10271031	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
				01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2013	31DEC2013	N
		Nervous system disorders	Paraesthesia	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271034	Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN1994		Y
	C4591001 1027 10271035	Reproductive system and breast disorders	Menorrhagia	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
				01JAN1995		Y
			Sarcoidosis	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	31DEC2008	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Psychiatric disorders	Depression	01JAN2005	
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1027 10271036	Surgical and medical procedures	Hip arthroplasty	01JAN2008	31DEC2008	N
			Shoulder operation	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
		Endocrine disorders	Hypogonadism	01JAN2010		Y
			Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01MAY2019	31MAY2019	N
	C4591001 1027 10271038	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1027 10271039	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010	31DEC2019	N
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1027 10271042	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Eye disorders	Retinal detachment	28AUG2019	20NOV2019	N
		Gastrointestinal disorders	Constipation	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Retinopexy	28AUG2019	28AUG2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Aneurysm	01JAN2010	31DEC2010	N
			Hypertension	01JAN1990		Y
	C4591001 1027 10271043	Cardiac disorders	Arrhythmia	01JAN2005	31DEC2005	N
			Wolff-Parkinson-White syndrome	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Nervous system disorders	Epilepsy	01JAN2002	31DEC2008	N
			Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Exeresis	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271044	Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1027 10271045	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2005		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1027 10271047	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016		Y
			Rubber sensitivity	01JAN2007		Y
			Seasonal allergy	01JAN1959		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1027 10271048	Cardiac disorders	Bundle branch block right	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1027 10271050	Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2000		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271051	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Seasonal allergy	01JAN1958		Y
			Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2005		Y
			Uterine leiomyoma	01JAN2003	31DEC2003	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1027 10271052	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2010	N
				01JAN2010	31DEC2017	N
			Spinal osteoarthritis	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
	C4591001 1027 10271053	Gastrointestinal disorders	Inguinal hernia	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2018		Y
			Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2006	31DEC2006	N
	C4591001 1027 10271054	Cardiac disorders	Bundle branch block left	01JAN2010		Y
			Palpitations	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN1996		Y
				01JAN1998		Y
				01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2008		Y
		Psychiatric disorders	Nicotine dependence	01JAN1980	31JAN2017	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1027 10271055	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271056	Cardiac disorders	Angina pectoris	01NOV2001		Y
			Coronary artery disease	01NOV2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Intervertebral disc compression	01JAN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	21MAY2019		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2002		Y
		Vascular disorders	Essential hypertension	01JAN2001		Y
	C4591001 1027 10271057	Cardiac disorders	Atrial fibrillation	01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2002		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1027 10271060	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Herpes virus infection	01JAN1974		Y
			Sepsis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1995		Y
			Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1027 10271062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1027 10271063	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1971		Y
		Social circumstances	Postmenopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271064	Cardiac disorders	Supraventricular tachycardia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2005		Y
			Macular hole	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2003		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1027 10271065	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1027 10271066	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2015	N
					31DEC2016	N
					31DEC2018	N
			Vertebral osteophyte	01JAN2013	31DEC2014	N
		Nervous system disorders	Peroneal nerve palsy	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Rachiotomy	01JAN2014	31DEC2014	N
			Shoulder arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1027 10271067	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1027 10271068	Cardiac disorders	Bradycardia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31DEC2012	N
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
			Spinal osteoarthritis	01JAN2009	31DEC2009	N
		Nervous system disorders	Migraine	01JAN1961		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2012	31DEC2012	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
			Spinal operation	01JAN2009	31DEC2009	N
			Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1027 10271070	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1985		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1027 10271071	Vascular disorders	Thrombosis	01MAR2020	30APR2020	N
	C4591001 1027 10271072	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
			Spinal stenosis	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1027 10271073	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1027 10271074	Cardiac disorders	Mitral valve prolapse	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1027 10271075	Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN1985		Y
			Type 2 diabetes mellitus	21MAY2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271076	Endocrine disorders	Hyperthyroidism	01JAN2005		Y
			Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Hiatus hernia	01JAN1990		Y
			Irritable bowel syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1027 10271077	Immune system disorders	Drug hypersensitivity	01JUN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUN2017		Y
		Nervous system disorders	Facial paralysis	25DEC2012		Y
			Facial paresis	25DEC2012		Y
		Psychiatric disorders	Nicotine dependence	01JAN1977		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1027 10271078	Psychiatric disorders	Insomnia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1027	Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	10271080	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
			Keratomileusis	01JAN2001	31DEC2001	N
	C4591001 1027	Eye disorders	Dry age-related macular degeneration	01JAN2014		Y
	10271081					
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1027	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
	10271082					
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN1962		Y
	C4591001 1027	Endocrine disorders	Hypothyroidism	01JAN1988		Y
	10271084					
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2018	18FEB2019	N
		Social circumstances	Organ donor	01OCT2010	31OCT2010	N
			Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Breast conserving surgery	07DEC2018	07DEC2018	N
	C4591001 1027	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
	10271085					
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271087	Blood and lymphatic system disorders	Anaemia	01MAY2020		Y
		Eye disorders	Macular degeneration	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2016		Y
		Infections and infestations	Cellulitis	01APR2019	30JUN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
			Intervertebral disc protrusion	01JAN2014	31MAY2020	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Finger amputation	24MAY2019	24MAY2019	N
			Intervertebral disc operation	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1027 10271088	Endocrine disorders	Hypogonadism	01JAN1995		Y
			Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1949		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
			Hyperlipidaemia	01JAN1990		Y
			Obesity	01JAN1967		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
			Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1027 10271089	Eye disorders	Angle closure glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Herpes simplex	01JAN1970		Y
		Investigations	Cytology abnormal	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2002		Y
			Back pain	01JAN2000		Y
			Intervertebral disc degeneration	01JAN2005		Y
			Osteopenia	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Endometriosis	01JAN1975	31DEC1983	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
			Oophorectomy bilateral	01JAN1983	31DEC1983	N
	C4591001 1027 10271090	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Nervous system disorders	Trigeminal neuralgia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2001		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1027 10271092	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hyperlipidaemia	01JAN1975		Y
			Iron deficiency	01JUN2020		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Diabetic foot	01JAN2018		Y
		Vascular disorders	Aortic aneurysm	01JAN2019		Y
			Hypertension	01JAN2000		Y
	C4591001 1027 10271093	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2013		Y
				01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016		Y
			Osteoarthritis	01JAN2008		Y
			Tendonitis	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1027 10271095	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1027 10271096	Eye disorders	Blindness unilateral	01JAN2013		Y
			Dacryostenosis acquired	01JUL2020	05AUG2020	N
			Glaucoma	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Intervertebral disc degeneration	01JAN2010		Y
			Osteoarthritis	01JAN2007		Y
		Psychiatric disorders	Nicotine dependence	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Dacryocystorhinostomy	05AUG2020	05AUG2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1027 10271097	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1027 10271098	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Knee operation	01JAN2012	31DEC2012	N
	C4591001 1027 10271099	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1986	31DEC1986	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Mastectomy	01JAN1986	31DEC1986	N
	C4591001 1027 10271100	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Prostatectomy	01JAN2004	31DEC2004	N
	C4591001 1027 10271101	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2001		Y
	C4591001 1027 10271102	Gastrointestinal disorders	Peptic ulcer haemorrhage	01JAN1999	31DEC1999	N
		Infections and infestations	Urinary tract infection	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Vitamin B12 deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
			Testis cancer	01JAN1971	31DEC1971	N
		Nervous system disorders	Peroneal nerve palsy	01JAN2012		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
			Renal artery stenosis	01SEP2015		Y
			Single functional kidney	01JAN1937		Y
		Surgical and medical procedures	Orchidectomy	01JAN1971	31DEC1971	N
			Radical prostatectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2013		Y
			Peripheral arterial occlusive disease	01JAN2005		Y
	C4591001 1027 10271103	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1027 10271106	Injury, poisoning and procedural complications	Gun shot wound	01JAN1971	31DEC1971	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000	31DEC2015	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
	C4591001 1027 10271109	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Irritable bowel syndrome	01JAN1980		Y
		Hepatobiliary disorders	Cholecystitis chronic	01JAN2012	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986		Y
				01JAN2017		Y
			Spinal osteoarthritis	01JAN1986	31DEC1986	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Ovarian disorder	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Spinal operation	01JAN1986	31DEC1986	N
	C4591001 1027 10271110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1027 10271111	Infections and infestations	Herpes simplex	01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01MAY2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
			Spondylolisthesis	01JAN2017	17MAY2019	N
		Psychiatric disorders	Depression	01JAN1966		Y
			Insomnia	01JAN1966		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Spinal fusion surgery	17MAY2019	17MAY2019	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1027 10271112	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Dry eye	01JAN2000		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1027 10271113	Metabolism and nutrition disorders	Gout	01JAN1995		Y
			Hyperlipidaemia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1027 10271114	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma	01JAN2008	31DEC2008	N
			Mantle cell lymphoma	01AUG2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2017		Y
	C4591001 1027 10271115	Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	21MAR2015		Y
				01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01APR1991	30APR1991	N
		Nervous system disorders	Migraine	01JAN1995		Y
	C4591001 1027 10271116	Surgical and medical procedures	Hysterectomy	01APR1991	30APR1991	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1969		Y
			Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1027 10271117	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1992	31DEC1994	N
			Road traffic accident	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1027 10271118	Endocrine disorders	Hypothyroidism	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1027 10271120	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y
				01JAN2017		Y
		Infections and infestations	Hepatitis A	01JAN1980	31DEC1980	N
			Urinary tract infection	01JAN1998		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2007		Y
			Nocturia	01JAN2007		Y
			Urinary incontinence	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Spinal operation	01JAN2000	31DEC2000	N
	C4591001 1027 10271121	Cardiac disorders	Coronary artery disease	01JAN2002		Y
		Infections and infestations	Hepatitis C	01JAN2002	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Colectomy	01JAN2002	31DEC2002	N
			Coronary arterial stent insertion	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1027 10271122	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Brachytherapy to prostate	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271123	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUL2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
	C4591001 1027 10271124	Cardiac disorders	Mitral valve prolapse	01JAN1986		Y
		Eye disorders	Pterygium	01JAN2017		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1977	31DEC1977	N
		Infections and infestations	Urinary tract infection	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018		Y
			Osteopenia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1999	31DEC1999	N
			Breast cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN1981		Y
			Sciatica	01JAN2018		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2013		Y
			Hypertonic bladder	01JAN2009		Y
			Nephrolithiasis	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1971		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN1977	31DEC1977	N
			Micrographic skin surgery	01JAN1999	31DEC1999	N
			Renal stone removal	01JAN2014	31DEC2014	N
	C4591001 1027 10271125	Endocrine disorders	Hyperthyroidism	01JAN1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1027 10271128	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Abdominal pain	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1027 10271130	Gastrointestinal disorders	Barrett's oesophagus	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1980		Y
		Social circumstances	Menopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271131	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
	C4591001 1027 10271132	Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN1996		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2007		Y
			Gout	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2006		Y
			Intervertebral disc protrusion	01JAN1999		Y
			Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Sleep apnoea syndrome	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1027 10271133	Injury, poisoning and procedural complications	Tendon rupture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017	31DEC2018	N
			Spinal osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2018	31DEC2018	N
			Carpal tunnel decompression	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1027 10271134	Gastrointestinal disorders	Crohn's disease	01JAN1984		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1027 10271135	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
	C4591001 1027 10271136	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271137	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271138	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
			Seasonal allergy	01JAN1972		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JUN2020	30JUN2020	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
			Knee operation	01JUL2020	31JUL2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271139	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1027 10271140	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2015	31DEC2015	N
			Uterine leiomyoma	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271141	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
			Benign breast neoplasm	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1027 10271142	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
	C4591001 1027 10271143	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2012		Y
				01JAN2013		Y
		Infections and infestations	Pneumonia	01JUN2019	31JUL2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1987	31DEC2004	N
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1987	31DEC1987	N
			Mastectomy	01JAN2004	31DEC2004	N
	C4591001 1027 10271144	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Periodontitis	10AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2010		Y
			Type 2 diabetes mellitus	01APR2010		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2013		Y
			Osteopenia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Renal and urinary disorders	Dysuria	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271146	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1027 10271147	Eye disorders	Dry eye	01JAN2013		Y
			Eyelid ptosis	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Rhinitis allergic	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Eyelid operation	01NOV2018	30NOV2018	N
		Vascular disorders	Hypotension	01JAN2015		Y
	C4591001 1027 10271148	Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1987		Y
				01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Rhinitis allergic	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1027 10271149	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1027 10271150	Cardiac disorders	Coronary artery disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myocardial infarction	01JAN2005	31DEC2005	N
		Eye disorders	Glaucoma	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1027 10271151	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Mastectomy	01JAN2002	31DEC2002	N
	C4591001 1027 10271153	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN1984		Y
			Type 2 diabetes mellitus	01JAN1986		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Nervous system disorders	Cerebrovascular accident	11APR1995	11APR1995	N
		Surgical and medical procedures	Gastric bypass	10DEC2012	10DEC2012	N
			Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1969		Y
	C4591001 1027 10271154	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1027 10271156	Cardiac disorders	Atrial flutter	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1027 10271159	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	23JUL2019		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1027 10271160	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Obesity	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1027 10271161	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1984		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Fibromuscular dysplasia	01JAN2015		Y
	C4591001 1027 10271164	Eye disorders	Dry eye	01JAN2000		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1988		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1990		Y
			Seasonal allergy	01JAN1967		Y
		Investigations	Blood cholesterol increased	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1027 10271165	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1027 10271166	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
			Depression	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Knee arthroplasty	10AUG2020	10AUG2020	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1027 10271167	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1027 10271168	Endocrine disorders	Hypothyroidism	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2009		Y
			Vitamin D deficiency	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1027 10271169	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1027 10271170	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1027 10271171	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1975		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1027 10271174	Eye disorders	Cataract	01FEB2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1027 10271175	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1027 10271176	Endocrine disorders	Hypogonadism	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Radical prostatectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1027 10271177	Cardiac disorders	Mitral valve prolapse	01JAN1991		Y
			Ventricular extrasystoles	01JAN1991		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Fatigue	01JAN1976		Y
		Infections and infestations	Sepsis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2005	31DEC2005	N
		Investigations	Prostatic specific antigen increased	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Osteoporosis	01JAN2016		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN2011	31DEC2011	N
			Basal cell carcinoma	01JAN1994	31DEC1994	N
		Psychiatric disorders	Depression	01JAN1994		Y
			Obsessive-compulsive disorder	01JAN1994		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Tenoplasty	01JAN2005	31DEC2005	N
	C4591001 1027 10271178	Cardiac disorders	Coronary artery disease	01MAR2018	31MAR2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2019	N
	C4591001 1027 10271179	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
	C4591001 1027 10271180	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hyperlipidaemia	01JAN2000		Y
	C4591001 1027 10271181	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1027 10271184	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV2018	30APR2020	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Breast conserving surgery	01DEC2018	31DEC2018	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1027 10271185	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1027 10271186	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN1976		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1994	31DEC1994	N
			Spinal laminectomy	01JAN1976	31DEC1976	N
			Vasectomy	01JAN1983	31DEC1983	N
	C4591001 1027 10271187	Infections and infestations	Localised infection	01JUL2020	31AUG2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Toe amputation	01AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1027 10271188	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2010	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1981	N
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271189	Cardiac disorders	Bradycardia	01JAN2005		Y
		Eye disorders	Ocular vascular disorder	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Haemochromatosis	01JAN1990		Y
			Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1027 10271190	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2009		Y
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1027 10271191	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2017	31JAN2018	N
			Thyroid cancer	01JAN1982	31DEC1982	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thyroidectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1027 10271194	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN1950		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1027 10271195	Gastrointestinal disorders	Colitis ulcerative	01JAN1986		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1027 10271196	Endocrine disorders	Hypogonadism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1027 10271198	Eye disorders	Dry eye	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1969		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1027 10271200	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1027 10271201	Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1027 10271202	Cardiac disorders	Supraventricular tachycardia	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
				01JAN2003		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2016		Y
			Neck pain	10SEP2020		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Restless legs syndrome	01JAN2005		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2007	31DEC2007	N
			Fibrocystic breast disease	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1027 10271204	Eye disorders	Cataract	01JAN2019	30JUN2020	N
					31JUL2020	N
		Hepatobiliary disorders	Hepatic cyst	01MAY2019	30JUN2019	N
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Liver operation	01JUN2019	30JUN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1027 10271205	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Gastrointestinal ulcer	01JAN2018	31DEC2018	N
			Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1027 10271206†	Vascular disorders	Hypertension	01JAN2018		Y
		Endocrine disorders	Hypogonadism	01JAN2005		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2008	31DEC2008	N
			Radius fracture	01JAN2008	31DEC2008	N
		Investigations	HIV test positive	01JAN1987		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1027 10271209†	Eye disorders	Visual impairment	01JAN2017		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Investigations	HIV test positive	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
			Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Intracranial aneurysm	01JAN1999	31DEC1999	N
			Neuropathy peripheral	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
			Single functional kidney	01JAN1955		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1969		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1027 10271211	Eye disorders	Retinal detachment	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2014		Y
			Osteoarthritis	01JAN2016		Y
			Scoliosis	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Insomnia	01JAN2012		Y
		Surgical and medical procedures	Retinal operation	01FEB2020	29FEB2020	N
	C4591001 1027 10271213	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2013	31DEC2013	N
		Vascular disorders	Aortic aneurysm	01MAR2020		Y
	C4591001 1028 10281004	Investigations	Colonoscopy	05JUL2013	05JUL2013	N
				14JUN2018	14JUN2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2015		Y
		Nervous system disorders	Carotid artery occlusion	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281006	Blood and lymphatic system disorders	Anaemia	01JAN1995		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2015		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01FEB2017	12FEB2020	N
		Reproductive system and breast disorders	Menorrhagia	01FEB2017	12FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	12FEB2020	12FEB2020	N
			Salpingectomy	12FEB2020	12FEB2020	N
	C4591001 1028 10281008	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2015		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2013		Y
			Vertigo	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2013		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Investigations	Colonoscopy	01JAN2000	31DEC2000	N
				13OCT2014	13OCT2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	25JAN2019	30JAN2019	N
			Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2007		Y
			Spinal osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1956		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hot flush	01JAN1990		Y
	C4591001 1028 10281011	Injury, poisoning and procedural complications	Foot fracture	01JAN1975	31DEC1975	N
		Investigations	Colonoscopy	19JUN2015	19JUN2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1028 10281012	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
			Tinnitus	01JAN2010		Y
		Eye disorders	Cataract	01DEC2013	01DEC2013	N
				20FEB2014	20FEB2014	N
		Gastrointestinal disorders	Abdominal distension	01JAN2008	31DEC2009	N
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
		Investigations	Colonoscopy	15NOV2018	15NOV2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Impaired fasting glucose	01JAN1976		Y
			Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
			Osteoarthritis	01JAN1965		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Appendicectomy	01JAN1955	31DEC1955	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Urinary bladder suspension	01APR1986	30APR1986	N
				01AUG1984	31DEC1984	N
		Vascular disorders	Hot flush	01JAN1985	31DEC2014	N
	C4591001 1028 10281014	Investigations	Colonoscopy	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2015	18AUG2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Libido decreased	01JAN2015		Y
		Reproductive system and breast disorders	Dyspareunia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
	C4591001 1028 10281015	Blood and lymphatic system disorders	Anaemia	01JUN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Infections and infestations	Acute sinusitis	09MAR2020	01APR2020	N
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Osteopenia	01JUN2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN2014		Y
	C4591001 1028 10281016	Gastrointestinal disorders	Inguinal hernia	01JAN2016	04MAY2016	N
		Investigations	Arthroscopy	01JUN2015	01JUN2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Large intestinal polypectomy	28OCT2015	28OCT2015	N
	C4591001 1028 10281020	Investigations	Colonoscopy	11MAR2019	11MAR2019	N
				19MAR2019	19MAR2019	N
				25FEB2014	25FEB2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2010	19AUG2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Large intestinal polypectomy	11MAR2019	11MAR2019	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1028 10281021	Eye disorders	Cataract	01JAN2016	31DEC2018	N
			Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Peptic ulcer	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1945	31DEC1945	N
			Urinary tract infection	01JAN2008		Y
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	26MAR2018		Y
		Investigations	Colonoscopy	04JUN2018	04JUN2018	N
				05MAY2015	05MAY2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endoscopy upper gastrointestinal tract	01JAN2015	31DEC2015	N
			Prostatic specific antigen increased	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	31MAR2016	31MAR2016	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Micturition urgency	01JAN2008		Y
			Nocturia	01JAN2008		Y
			Urinary incontinence	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
			Erectile dysfunction	26MAR2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Thyroidectomy	31MAR2016	31MAR2016	N
			Tonsillectomy	01JAN1945	31DEC1945	N
			Transurethral prostatectomy	03MAR2018		Y
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1028 10281032	Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Endocrine disorders	Basedow's disease	01JAN1977	31DEC1977	N
			Hypothyroidism	01JAN1977		Y
		Eye disorders	Dry eye	01JAN2019		Y
			Glaucoma	01JAN2005		Y
		Infections and infestations	Malaria	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000	31DEC2008	N
			Neck pain	01JAN2000	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2008	31DEC2008	N
		Psychiatric disorders	Nicotine dependence	01JAN1965	31DEC2008	N
		Reproductive system and breast disorders	Erectile dysfunction	04SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
			Chronic obstructive pulmonary disease	01JUN2020		Y
			Rhinitis allergic	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
			Large intestinal polypectomy	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2008	31DEC2008	N
			Vasectomy	01JAN1984	31DEC1984	N
	C4591001 1028 10281034	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2012		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1985	31DEC1985	N
		Investigations	Arthroscopy	01JAN1985	31DEC1985	N
			Colonoscopy	01JAN2004	31DEC2004	N
				22AUG2013	22AUG2013	N
			Endoscopy upper gastrointestinal tract	05FEB2015	05FEB2015	N
				22AUG2013	22AUG2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990	31DEC1990	N
		Psychiatric disorders	Alcoholism	01JAN2000	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Adenoidectomy	01JAN1961	31DEC1961	N
			Large intestinal polypectomy	01JAN2004	31DEC2004	N
			Spinal operation	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1961	31DEC1961	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1028 10281037	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Investigations	Colonoscopy	28JUN2019	28JUN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JAN2014		Y
		Psychiatric disorders	Libido decreased	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1994		Y
		Social circumstances	Postmenopause	01APR2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Caesarean section	25JUN1985	25JUN1985	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1028 10281039	Ear and labyrinth disorders	Deafness unilateral	01JAN1995		Y
		Eye disorders	Cataract	01JAN2018	18APR2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				11APR2018		Y
			Hypersensitivity	01JAN1965		Y
		Infections and infestations	Oral herpes	01JAN1990		Y
		Injury, poisoning and procedural complications	Contusion	01APR2009	30JUN2009	N
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				27OCT2015	27OCT2015	N
		Musculoskeletal and connective tissue disorders	Chondromalacia	01JAN2015		Y
			Osteoarthritis	01JAN2009		Y
			Plantar fasciitis	06JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	12FEB2009	28FEB2009	N
			Lipoma	09JUN2007	09JUN2007	N
			Seborrhoeic keratosis	12FEB2009	28FEB2009	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2003	31DEC2013	N
				16DEC2013	16DEC2013	N
			Hypoaesthesia	01JUN2013	16DEC2016	N
		Reproductive system and breast disorders	Endometriosis	01JAN1982	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01APR2018	31DEC2018	N
			Skin discolouration	01JAN2009		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1960	31DEC1960	N
			Carpal tunnel decompression	01JAN2003	31DEC2003	N
			Cataract operation	11APR2018	11APR2018	N
				18APR2018	18APR2018	N
			Endometriosis ablation	01JAN1997	31DEC1997	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Large intestinal polypectomy	17MAR2017	17MAR2017	N
			Ovarian neoplasm surgery	01JAN1982	31DEC1982	N
				01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Tooth extraction	01JAN1980	31DEC1980	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine operation	01JAN1982	31DEC1982	N
				01JAN1987	31DEC1987	N
		Vascular disorders	Hot flush	01JAN2005		Y
			Varicose vein	01MAR2018		Y
	C4591001 1028 10281040	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
	C4591001 1028 10281041	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31DEC2016	N
			Pain in extremity	20JUL2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1028 10281042	Endocrine disorders	Hypothyroidism	20JAN2010		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Foot deformity	11OCT2019		Y
			Plantar fasciitis	30AUG2019		Y
		Renal and urinary disorders	Hypertonic bladder	20AUG2014	29DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000		Y
		Social circumstances	Postmenopause	01AUG2019		Y
		Vascular disorders	Hot flush	01JUN2019		Y
	C4591001 1028 10281045	Gastrointestinal disorders	Haemorrhoids	01JAN2016	31DEC2016	N
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01SEP2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	10FEB2020	27FEB2020	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1995	31DEC1995	N
			Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1028 10281046	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Eye disorders	Cataract	05MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Rubber sensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Impaired fasting glucose	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
			Synovial cyst	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2014	31DEC2018	N
			Insomnia	01JAN2014	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Cervical dysplasia	01JAN2009	31DEC2009	N
			Cystocele	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1028 10281051	Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN2009	31DEC2009	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1975		Y
			Peptic ulcer	01JAN1974	31DEC1974	N
			Umbilical hernia	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2014	31DEC2014	N
		Investigations	Arthroscopy	13OCT2016	13OCT2016	N
			Colonoscopy	01JUN2016	01JUN2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	13OCT2016	N
		Surgical and medical procedures	Appendicectomy	01JAN1964	31DEC1964	N
			Fracture treatment	01JAN2014	31DEC2014	N
			Large intestinal polypectomy	01JUN2016	01JUN2016	N
			Rotator cuff repair	13OCT2016	13OCT2016	N
			Umbilical hernia repair	01JAN2014	31DEC2014	N
	C4591001 1028 10281056	Gastrointestinal disorders	Inguinal hernia	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Colonoscopy	10JAN2019	10JAN2019	N
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
		Surgical and medical procedures	Large intestinal polypectomy	10JAN2019	10JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281057	Eye disorders	Cataract	01JAN2012	29MAY2012	N
			Dry eye	01JAN2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Dyslipidaemia	16DEC2009		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1960	31DEC1960	N
			Cataract operation	29MAY2012	29MAY2012	N
			Foot operation	01JAN1960	31DEC1960	N
			Knee arthroplasty	20JAN2020	20JAN2020	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	16DEC2009		Y
			Varicose vein	22FEB2014		Y
	C4591001 1028 10281058	Ear and labyrinth disorders	Vertigo	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		General disorders and administration site conditions	Fatigue	01JAN2015		Y
		Infections and infestations	Pneumonia	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteopenia	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN2004	31DEC2004	N
		Vascular disorders	Hot flush	01JAN2008		Y
	C4591001 1028 10281063	Eye disorders	Cataract nuclear	01JAN2017		Y
			Hypermetropia	01JAN2011		Y
		General disorders and administration site conditions	Pain	01JAN1973		Y
		Infections and infestations	Herpes zoster	19MAR2020		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2013	26AUG2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma of skin	01MAR2020	29MAR2020	N
			Seborrhoeic keratosis	01JAN1963		Y
		Social circumstances	Postmenopause	01JUL2015		Y
		Surgical and medical procedures	Caesarean section	18JUN1990	18JUN1990	N
			Wisdom teeth removal	01JAN1982	31DEC1982	N
	C4591001 1028 10281064	Investigations	Colonoscopy	18JUL2012	18JUL2012	N
				23APR2004	23APR2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				28JUL2017	28JUL2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	14JUL2019	14JUL2019	N
		Psychiatric disorders	Anxiety	01JAN1984		Y
			Depression	01JAN1984		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Cystocele	17DEC2007	17DEC2007	N
			Menorrhagia	01JAN2007	17DEC2007	N
		Surgical and medical procedures	Hysterectomy	17DEC2007	17DEC2007	N
			Large intestinal polypectomy	28NOV2017	28NOV2017	N
			Rectocele repair	17DEC2007	17DEC2007	N
			Varicose vein operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2015		Y
			Varicose vein	01JAN2015		Y
	C4591001 1028 10281067	Eye disorders	Cataract	01JAN2008	31DEC2010	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1970	31DEC1970	N
		Investigations	Colonoscopy	14SEP2018	14SEP2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2015	31DEC2017	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1028 10281068	Cardiac disorders	Arteriosclerosis coronary artery	08OCT2018		Y
			Palpitations	01JAN2015		Y
		Eye disorders	Cataract	01JAN2019		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Investigations	Colonoscopy	27AUG2018	27AUG2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Impaired fasting glucose	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma of skin	01JAN2019		Y
			Melanocytic naevus	01JAN2019		Y
			Seborrhoeic keratosis	01JAN2019		Y
			Squamous cell carcinoma	05JAN2011	05JAN2011	N
		Nervous system disorders	Carotid artery stenosis	08OCT2018		Y
			Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Lentigo	01JAN2019		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1962	31DEC1962	N
			Large intestinal polypectomy	27AUG2018	27AUG2018	N
			Tonsillectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1028 10281073	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Eye disorders	Cataract	01JAN2018	31MAR2020	N
			Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb injury	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Gout	01JAN2001		Y
			Hyperglycaemia	01JAN2017		Y
			Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008	31DEC2008	N
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
				01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2004	31DEC2004	N
		Nervous system disorders	Embolic stroke	01MAY2017	31MAY2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2012		Y
			Dermatitis	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01FEB2020	29FEB2020	N
				01MAR2020	31MAR2020	N
			Finger amputation	01JAN1982	31DEC1982	N
			Large intestinal polypectomy	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1028 10281074	Congenital, familial and genetic disorders	Porokeratosis	01JAN1999		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2016		Y
			Thyroid mass	01OCT2018	31OCT2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	28AUG2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN1997	31JAN2020	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
				01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Liposuction	01JAN2005	31DEC2005	N
			Parathyroidectomy	10OCT2018	10OCT2018	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1028 10281076	Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Eye disorders	Cataract	01JAN2004	31DEC2004	N
			Macular degeneration	01JAN2016		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2010	31DEC2010	N
			Rib fracture	01JAN2010	31DEC2010	N
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				28JAN2014	28JAN2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
			Spinal stenosis	01JAN2007		Y
			Tendonitis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01FEB2020		Y
			Prostate cancer	16JUN2011	23AUG2011	N
			Squamous cell carcinoma	01MAY1994	31MAY1994	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1952		Y
		Surgical and medical procedures	Cataract operation	01JAN2004	31DEC2004	N
			Intervertebral disc operation	01JUL2008	31JUL2008	N
			Radical prostatectomy	23AUG2011	23AUG2011	N
			Retinal operation	01JAN1997	31DEC1997	N
			Spinal laminectomy	01JUL2008	31JUL2008	N
			Tonsillectomy	01JAN1945	31DEC1945	N
			Vasectomy	01JAN1967	31DEC1967	N
	C4591001 1028 10281081	Cardiac disorders	Ventricular extrasystoles	01JAN2003		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
			Tinnitus	01JAN2015		Y
		Eye disorders	Cataract	01JAN2018		Y
			Presbyopia	01JAN2008		Y
			Vitreous detachment	01JAN2011	31DEC2011	N
			Vitreous haemorrhage	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	07MAY2013	07MAY2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	19APR2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Keratomileusis	01JAN2003	31DEC2003	N
			Oophorectomy bilateral	01JAN2005	31DEC2005	N
			Uterine dilation and curettage	01JAN2003	31DEC2003	N
	C4591001 1028 10281082	Congenital, familial and genetic disorders	Ichthyosis	01JAN1951		Y
		Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1971		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2000	31DEC2000	N
				01JAN2018	31DEC2018	N
		Investigations	Colonoscopy	01JUN2010	30JUN2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1981		Y
			Back pain	01JAN2005		Y
			Osteoarthritis	01JAN1981		Y
				01JAN1989		Y
			Osteopenia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1981		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urinary incontinence	01JAN1981		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1964	31DEC1981	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1981	31DEC1981	N
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1028 10281083	Gastrointestinal disorders	Inguinal hernia	01JAN1996	31DEC2002	N
		Investigations	Colonoscopy	06DEC2007	06DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Bursitis	21JUN2017	13MAR2018	N
			Intervertebral disc protrusion	01JAN1999	31DEC1999	N
			Osteoarthritis	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01SEP2019		Y
		Surgical and medical procedures	Hip arthroplasty	14JUN2007	14JUN2007	N
			Inguinal hernia repair	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
				01JAN2002	31DEC2002	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	11NOV2011		Y
	C4591001 1028 10281084	Gastrointestinal disorders	Diverticulum intestinal	07DEC2011		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Infections and infestations	Hordeolum	01JAN2015		Y
			Tonsillitis	01JAN1958	31DEC1958	N
		Investigations	Colonoscopy	09JUL2020	09JUL2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	12JUN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JUN2020	30JUN2020	N
			Melanocytic hyperplasia	09JUN2020		Y
		Surgical and medical procedures	Large intestinal polypectomy	09JUL2020	09JUL2020	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1028 10281091	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Acanthosis nigricans	01JAN2010		Y
			Skin atrophy	01JAN2010		Y
			Skin hypertrophy	01JAN2010		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1028 10281092	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
			Umbilical hernia	01JAN1960	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Patella fracture	24OCT2019	01DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	07FEB2018	07FEB2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Umbilical hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Peripheral arterial occlusive disease	01JAN2010		Y
	C4591001 1028 10281093	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
			Otosclerosis	01JAN2000		Y
		Eye disorders	Cataract	01JAN2017		Y
		Infections and infestations	Herpes zoster	29MAR2010	31DEC2010	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2002	31DEC2002	N
		Investigations	Colonoscopy	11MAY2010	11MAY2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ankle operation	01JAN2002	31JAN2002	N
			Female sterilisation	01JAN1976	31DEC1976	N
			Stapedectomy	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
	C4591001 1028 10281099	Eye disorders	Vitreous degeneration	01JAN2005		Y
		Investigations	Colonoscopy	25MAR2016	25MAR2016	N
			Oestrogen receptor assay negative	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2010	01SEP2020	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
			Caesarean section	04APR1981	04APR1981	N
			Chemotherapy	01JAN2012	31DEC2012	N
			Female sterilisation	01SEP1999	01SEP1999	N
		Vascular disorders	Hypertension	01JAN2013		Y
			Peripheral venous disease	01JAN1992		Y
	C4591001 1028 10281102	Blood and lymphatic system disorders	Increased tendency to bruise	01MAY2020	31JUL2020	N
			Iron deficiency anaemia	01JAN2014		Y
		Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Toxic nodular goitre	01JAN2013		Y
		Eye disorders	Cataract nuclear	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Fatigue	01JAN2015		Y
			Malaise	01JAN2015		Y
		Investigations	Biopsy small intestine normal	16AUG2016	16AUG2016	N
			Colonoscopy	14FEB2014	14FEB2014	N
			Endoscopy upper gastrointestinal tract	01JAN2014	31DEC2014	N
				04JAN2016	04JAN2016	N
				17AUG2016	17AUG2016	N
			Oesophageal manometry	12FEB2018	12FEB2018	N
			Oesophageal pH	16AUG2016	16AUG2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01FEB2020		Y
			Osteoarthritis	01JAN2007		Y
			Osteoporosis	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1965	31DEC1965	N
		Skin and subcutaneous tissue disorders	Dermatitis	05AUG2020	08AUG2020	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
			Female sterilisation	01JAN1976	31DEC1976	N
			Knee operation	01JAN1983	31DEC1983	N
			Large intestinal polypectomy	14FEB2014	14FEB2014	N
			Oophorectomy	01JAN1965	31DEC1965	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281107	Eye disorders	Cataract	01JAN2014	31DEC2014	N
			Glaucoma	01JAN2015		Y
		Infections and infestations	Appendicitis perforated	01JAN1945	31DEC1945	N
			Tonsillitis	01JAN1942	31DEC1942	N
		Investigations	Biopsy breast normal	01JAN1999	31DEC1999	N
			Colonoscopy	08FEB2019	08FEB2019	N
				09JAN2014	09JAN2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
				01JAN2016	31DEC2016	N
			Seborrhoeic keratosis	26MAY2020		Y
			Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1940		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Appendectomy	01JAN1945	31DEC1945	N
			Cataract operation	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1942	31DEC1942	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1028 10281108	Eye disorders	Amaurosis fugax	15JUL2020	15JUL2020	N
		Gastrointestinal disorders	Angular cheilitis	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	19SEP2017		Y
			Hypersensitivity	17APR2013		Y
		Investigations	Colonoscopy	01APR2013	30APR2013	N
			Prostatic specific antigen increased	27JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2003		Y
		Nervous system disorders	Transient ischaemic attack	01JUN2020	30JUN2020	N
		Reproductive system and breast disorders	Erectile dysfunction	30MAY2018		Y
			Prostatic disorder	27JUN2019		Y
			Prostatitis	01JAN2018		Y
		Surgical and medical procedures	Bunion operation	01JAN2008	31DEC2008	N
			Keratomileusis	01JAN2002	31JAN2002	N
			Nasal septal operation	01JAN1982	31DEC1982	N
		Cardiac disorders	Palpitations	01JAN2015		Y
	C4591001 1028 10281109	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Colonoscopy normal	29AUG2019	29AUG2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1986		Y
			Obesity	01JAN1965		Y
		Psychiatric disorders	Insomnia	01JAN1986	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1975		Y
			Dermal cyst	01JAN2012	31DEC2012	N
			Dermatitis allergic	01JAN1980		Y
		Surgical and medical procedures	Sebaceous cyst excision	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1963	31DEC1963	N
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1028 10281111	Cardiac disorders	Coronary artery disease	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01SEP2017	07NOV2017	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN2015	31DEC2015	N
		Investigations	Colonoscopy	17JUL2018	17JUL2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2016	N
			Lipoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	07NOV2017	07NOV2017	N
				31OCT2017	31OCT2017	N
			Inguinal hernia repair	01JAN1980	31DEC1980	N
			Intraocular lens implant	07NOV2017	07NOV2017	N
				31OCT2017	31OCT2017	N
			Lipoma excision	01JAN1990	31DEC1990	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1028 10281113	Blood and lymphatic system disorders	Anaemia	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Oral herpes	01JAN1996		Y
			Urinary tract infection	01JAN1992		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1964	31DEC1964	N
			Wrist fracture	01JAN2015	31DEC2015	N
		Investigations	Biopsy breast normal	01JAN1995	31DEC1995	N
			Colonoscopy	23OCT2012	23OCT2012	N
			Mammogram	26FEB2016	26FEB2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Fracture treatment	01JAN2015	31DEC2015	N
			Intervertebral disc operation	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2000	31DEC2000	N
			Wrist surgery	27FEB2018	27FEB2018	N
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1028 10281115	Eye disorders	Cataract	10AUG2020		Y
		Hepatobiliary disorders	Bile duct stone	01JAN2014		Y
			Cholelithiasis	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1982		Y
				01JAN1995		Y
				01JAN2006		Y
			Rubber sensitivity	01JAN2006		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Radius fracture	01DEC2018	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN1990		Y
			Vitamin D deficiency	22JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN2000		Y
			Osteoporosis	01DEC2018		Y
			Scoliosis	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Rash	01JUN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
			Open reduction of fracture	01JAN2019	31JAN2019	N
	C4591001 1028 10281117	Eye disorders	Cataract	01JAN2014	31DEC2017	N
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1948	31DEC1948	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1956	31DEC1956	N
				01JAN1977	31DEC1977	N
		Investigations	Angiocardiogram	01JAN1998	31DEC1998	N
			Colonoscopy	01JAN2015	31DEC2015	N
				12MAY2017	12MAY2017	N
				22MAY2020	22MAY2020	N
				28APR2016	28APR2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	12MAY2020	12MAY2020	N
			Prostate cancer	01DEC1999	30JUN2000	N
			Squamous cell carcinoma	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1948	31DEC1948	N
			Cataract operation	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
			Large intestinal polypectomy	01JAN2015	31DEC2015	N
				22MAY2020	22MAY2020	N
		Vascular disorders	Aortic aneurysm	01JAN2019		Y
			Hypertension	01JAN2008		Y
	C4591001 1028 10281123	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Colonoscopy	01NOV2017	31DEC2017	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1990	31DEC1990	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
				01JAN2018	31DEC2018	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Dyspareunia	01JAN2018		Y
			Ovarian cyst	01JAN2000	31DEC2000	N
			Vulvovaginal dryness	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JUN2019		Y
		Surgical and medical procedures	Large intestinal polypectomy	01NOV2017	30NOV2017	N
		Vascular disorders	Hot flush	01JAN2017		Y
			Hypertension	01JAN2013		Y
	C4591001 1028 10281127	Eye disorders	Cataract	01JAN2010	31MAR2012	N
				01JAN2018	31DEC2018	N
			Dry eye	01MAR2012		Y
			Keratoconus	01JAN2012	10JAN2017	N
					30MAR2012	N
			Myopia	01JAN1966		Y
			Presbyopia	01JAN1966		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	29SEP2012	31DEC2017	N
		Investigations	Colonoscopy	28FEB2014	28FEB2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	09MAY2015	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Muscle spasms	01JAN2015	31DEC2017	N
			Osteoarthritis	23FEB2014		Y
			Osteopenia	01JAN2014		Y
			Rotator cuff syndrome	01APR2019	30APR2019	N
			Spinal osteoarthritis	23FEB2014		Y
		Psychiatric disorders	Anxiety	14JAN2014		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	14JAN2014		Y
		Renal and urinary disorders	Pollakiuria	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
				01JUL2013	31JUL2013	N
			Corneal transplant	01MAR2012	31MAR2012	N
				10JAN2017	10JAN2017	N
			Intervertebral disc operation	01JAN2005	31DEC2005	N
			Spinal laminectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1028 10281128	Eye disorders	Cataract	01JAN2016		Y
			Chalazion	01DEC2017	23FEB2018	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2003	31DEC2003	N
		Investigations	Colonoscopy	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Scoliosis	01JAN2017		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
			Eye operation	23FEB2018	23FEB2018	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1028 10281129	Cardiac disorders	Arrhythmia	01JAN1983		Y
		Eye disorders	Cataract	01JAN2020		Y
		Gastrointestinal disorders	Haemorrhoids	10JUL2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
			Diverticulitis	10JUL2018		Y
		Injury, poisoning and procedural complications	Ankle fracture	03JUL2010	03JUL2010	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
			Colonoscopy	01JAN2013	31DEC2013	N
				10JUL2018	10JUL2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Hypertriglyceridaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
			Spinal osteoarthritis	01JAN2000		Y
			Trigger finger	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				12AUG2020	12AUG2020	N
		Psychiatric disorders	Alcoholism	01JAN1971	31DEC1983	N
			Depression	01JAN2008		Y
			Nicotine dependence	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Social circumstances	Tobacco user	01JAN2011		Y
				01JAN2015	31DEC2020	N
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
			Appendectomy	01JAN1973	31DEC1973	N
			Keratomileusis	01JAN2006	31DEC2006	N
			Large intestinal polypectomy	01JAN2013	31DEC2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				10JUL2018	10JUL2018	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
			Tendon sheath incision	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
				12AUG2020	12AUG2020	N
			Toe operation	01JAN2005	31DEC2005	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
			Hypertension	01JAN2015		Y
	C4591001 1028 10281132	Gastrointestinal disorders	Inguinal hernia	01JAN2018	22JUN2018	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1972	31DEC1972	N
				01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
			Squamous cell carcinoma	01JAN1985	31DEC1985	N
				01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	22JUN2018	22JUN2018	N
	C4591001 1028 10281137	Endocrine disorders	Hypothyroidism	01JAN1979		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	17SEP2019	N
			Cholelithiasis	01JAN2014	17SEP2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN1987		Y
				01JAN2004		Y
			Reaction to food additive	01JAN2009		Y
			Rubber sensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1979	31DEC1979	N
		Investigations	Arthroscopy	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Obesity	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1980		Y
				01JAN1999		Y
			Back pain	01JAN1979		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2002	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
			Rhinitis ulcerative	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	17SEP2019	17SEP2019	N
			Elbow operation	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
			Gastric banding	12FEB2008	12FEB2008	N
			Gastric banding reversal	17SEP2019	17SEP2019	N
			Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee operation	01JAN2004	31DEC2004	N
			Spinal operation	01JAN1984	31DEC1984	N
			Wrist surgery	01JAN1979	31DEC1979	N
	C4591001 1028 10281139	Gastrointestinal disorders	Anal haemorrhage	01JAN2016	31DEC2016	N
			Anal incontinence	01JAN2016	31DEC2016	N
			Haemorrhoids	01JAN1990		Y
			Rectal haemorrhage	01JAN2016	31DEC2016	N
		Immune system disorders	Allergy to plants	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN1965		Y
			Herpes zoster	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1981	31DEC1981	N
		Investigations	Colonoscopy	15JUN2016	15JUN2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N
			Squamous cell carcinoma	01JAN2018	31DEC2018	N
	C4591001 1028 10281140	Gastrointestinal disorders	Rectal haemorrhage	01JAN1975	31DEC1975	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1971	31DEC1971	N
			Facial bones fracture	01JAN1970	31DEC1970	N
			Rib fracture	01JAN1970	31DEC1970	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2018		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2015		Y
			Intervertebral disc degeneration	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Neuralgia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01APR2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1962	31DEC1962	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1028 10281142	Eye disorders	Cataract	01AUG2016	31AUG2016	N
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Haemorrhoids	01JUL2020	31JUL2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
				01JAN1990		Y
				01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2016		Y
			Tonsillitis	01JAN1981	31DEC1981	N
		Investigations	Colonoscopy	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
				01JAN2013		Y
			Back pain	01JAN2000		Y
			Neck pain	01JAN2000		Y
			Osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendonitis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN1994		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN2020		Y
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
			Caesarean section	01JAN1990	31DEC1990	N
			Cataract operation	01AUG2016	31AUG2016	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Large intestinal polypectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1028 10281145	Immune system disorders	Rubber sensitivity	01JAN2016		Y
			Seasonal allergy	01JAN1998		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Fracture	01JAN1964	31DEC1964	N
			Tendon injury	01JAN2005	31DEC2005	N
		Investigations	Colonoscopy	19SEP2014	19SEP2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1976		Y
			Syncope	24OCT2018	24OCT2018	N
		Social circumstances	Postmenopause	20APR2014		Y
		Surgical and medical procedures	Tenoplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281147	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Reaction to food additive	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Investigations	Colonoscopy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Vitamin D deficiency	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
			Exostosis	01JAN2005	31DEC2019	N
			Fibromyalgia	01JAN2007		Y
			Myalgia	01JAN2010		Y
			Myositis	01JAN2010		Y
			Tendonitis	01JAN2004		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Cystitis haemorrhagic	13JUL2020	31DEC2020	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Appendicectomy	01JAN1975	31DEC1975	N
			Bone lesion excision	09OCT2019	09OCT2019	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Tenoplasty	09OCT2019	09OCT2019	N
	C4591001 1028 10281148	Eye disorders	Cataract	01JAN2002	31JAN2002	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2005		Y
			Pancreatitis	23JUN2015	31JUL2015	N
		Hepatobiliary disorders	Cholelithiasis	23JUN2015	23JUN2015	N
		Infections and infestations	Ludwig angina	01JAN1977	31DEC1977	N
				01JAN1984	31DEC1984	N
			Tonsillitis	01JAN1951	31DEC1951	N
		Investigations	Cardiac murmur	01JAN2015		Y
			Endoscopy upper gastrointestinal tract	04FEB2013	04FEB2013	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
			Pain in extremity	01OCT2018		Y
			Spinal stenosis	01JAN2018		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2018		Y
			Sciatica	06NOV2018		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Vulval disorder	14JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1951	31DEC1951	N
			Caesarean section	07JAN1980	07JAN1980	N
			Cataract operation	01JAN2002	31JAN2002	N
			Cholecystectomy	23JUN2015	23JUN2015	N
			Intraocular lens implant	01JAN2002	31JAN2002	N
			Lens capsulotomy	01MAY2020	01MAY2020	N
				21MAY2002	21MAY2002	N
			Tonsillectomy	01JAN1951	31DEC1951	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281149	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Diarrhoea	01DEC2019	29FEB2020	N
			Dyspepsia	01DEC2019	29FEB2020	N
		General disorders and administration site conditions	Fatigue	01JAN1979		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Drug hypersensitivity	01JAN1982		Y
				01JAN1992		Y
				01JAN1995		Y
				01JAN2001		Y
				01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2013	31DEC2013	N
		Investigations	Arthroscopy	01JAN1996	31DEC1996	N
				03MAR2014	03MAR2014	N
				25MAR2015	25MAR2015	N
			Colonoscopy	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Impaired fasting glucose	01JAN2015		Y
			Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Osteoarthritis	01JAN1996		Y
		Nervous system disorders	Migraine	01JAN1992	31DEC2012	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1975		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN1975		Y
			Snoring	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Bunion operation	11OCT2013	11OCT2013	N
			Foot operation	12DEC2014	12DEC2014	N
			Joint arthroplasty	11OCT2013	11OCT2013	N
			Keratomileusis	01JAN2001	31DEC2001	N
			Ligament operation	01JAN2004	31DEC2004	N
			Rotator cuff repair	27FEB2014	27FEB2014	N
			Tenotomy	11OCT2013	11OCT2013	N
			Toe operation	11OCT2013	11OCT2013	N
	C4591001 1028 10281151	Endocrine disorders	Thyroid cyst	29AUG2008	29AUG2008	N
		Investigations	Human papilloma virus test positive	13AUG2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	29AUG2008	29AUG2008	N
		Renal and urinary disorders	Hydronephrosis	01JUL2008	31JUL2008	N
			Nephrolithiasis	01JUL2008	31JUL2008	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Parathyroidectomy	29AUG2008	29AUG2008	N
			Renal stone removal	01JUL2008	31JUL2008	N
			Thyroidectomy	29AUG2008	29AUG2008	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1028 10281157	Eye disorders	Cataract	01JAN2014	31DEC2016	N
			Retinal detachment	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Constipation	01JAN2004		Y
			Gastroesophageal reflux disease	01JAN2001		Y
			Irritable bowel syndrome	01JAN2004		Y
			Umbilical hernia	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Infections and infestations	Chronic sinusitis	15OCT2019		Y
			Conjunctivitis	15OCT2019	20OCT2019	N
			Influenza	01OCT2019	31OCT2019	N
		Investigations	Colonoscopy	01JAN2009	31DEC2009	N
				11DEC2019	11DEC2019	N
			Endoscopy upper gastrointestinal tract	16JUL2018	16JUL2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2001	31DEC2013	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
			Depression	01MAR2020		Y
			Persistent depressive disorder	01MAR2020		Y
			Psychosexual disorder	01JAN2005		Y
			Sexual inhibition	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
			Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1977		Y
			Rosacea	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Retinopexy	01JAN2001	31DEC2001	N
			Umbilical hernia repair	01JAN2014	31DEC2014	N
			Varicose vein operation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
			Varicose vein	01JAN2016	31DEC2016	N
	C4591001 1028 10281160	Congenital, familial and genetic disorders	Cerebrovascular arteriovenous malformation	01JAN1990		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1983	31DEC1983	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1993		Y
		Investigations	Colonoscopy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01OCT2019		Y
			Dupuytren's contracture	01JAN2017		Y
			Foot deformity	01JAN2019		Y
			Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN1993		Y
			Temporomandibular joint syndrome	01JAN1982		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1993	31DEC1993	N
				01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
		Nervous system disorders	Headache	01JAN1967		Y
			Migraine	01JAN1967		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Lichenification	01JAN2014		Y
			Neurodermatitis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1983	31DEC1983	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Jaw operation	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281163	Immune system disorders	Large intestinal polypectomy	01JAN2017	31DEC2017	N
			Hypersensitivity	01JAN1975		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2008	31DEC2008	N
			Tibia fracture	01MAR2019	31MAR2019	N
			Investigations	Arthroscopy	01JAN2008	31DEC2008
		Colonoscopy		01JAN2006	31DEC2006	N
				19MAY2016	19MAY2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Nervous system disorders	Carpal tunnel syndrome	01JAN1981	31DEC1982
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Dysuria	17OCT2019	31OCT2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1982	31DEC1982	N
			Fracture treatment	01MAR2019	31MAR2019	N
	Knee arthroplasty		01JAN2016	31JAN2016	N	
	C4591001 1028 10281164	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Ear and labyrinth disorders	Deafness bilateral	01JAN2010	
		Gastrointestinal disorders	Diverticulum	01JAN2008		Y
			Gastroesophageal reflux disease	01JAN1980		Y
			Haemorrhoids	01JAN1975		Y
			Inguinal hernia	01JAN1947	31DEC1947	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1998		Y
			Hepatobiliary disorders	Hepatitis	01JAN1975	31DEC1975

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Injury, poisoning and procedural complications	Fibula fracture	01FEB2019	28FEB2019	N
			Hand fracture	01FEB1992	29FEB1992	N
		Investigations	Mycobacterium tuberculosis complex test positive	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2016		Y
			Impaired fasting glucose	01JAN2010		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2002	30JUN2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01DEC2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
			Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	03AUG2020	08AUG2020	N
		Surgical and medical procedures	Appendicectomy	01JAN1959	31DEC1959	N
			Bone cyst excision	01JAN1984	31DEC1984	N
			Inguinal hernia repair	01JAN1947	31DEC1947	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1028 10281166	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Infections and infestations	Herpes simplex	01JAN1993		Y
		Investigations	Colonoscopy	17DEC2015	17DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endoscopy upper gastrointestinal tract	26SEP2016	26SEP2016	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1956		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1028 10281168	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Astigmatism	01JAN1960		Y
			Cataract	01JAN2017		Y
					30APR2019	N
			Dry eye	01JAN2010		Y
			Keratitis	01JAN2010		Y
			Macular fibrosis	01JAN2018		Y
			Myopia	01JAN1955		Y
			Vitreous detachment	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
			Gastroesophageal reflux disease	01JAN1983		Y
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1962	31DEC1962	N
		Investigations	Colonoscopy	01JAN2000	31DEC2000	N
			Human papilloma virus test positive	01JAN1980		Y
			Smear cervix abnormal	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Obesity	01JAN2000	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Psychiatric disorders	Libido decreased	01JAN2005		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Rectocele	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1962	31DEC1962	N
			Rhinitis allergic	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1957		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01APR2019	30APR2019	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hot flush	01JAN2005		Y
	C4591001 1028 10281169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
		General disorders and administration site conditions	Pain	01JAN1978		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1974	31DEC1974	N
			Lower limb fracture	01JAN1964	31DEC1964	N
			Upper limb fracture	01JAN1965	31DEC1965	N
				01JAN1966	31DEC1966	N
				01JAN1968	31DEC1968	N
				01JAN1969	31DEC1969	N
				01JAN1970	31DEC1970	N
				01JAN1971	31DEC1971	N
				01JAN1972	31DEC1972	N
		Investigations	Laparoscopy	01JAN1990	31DEC1990	N
				01JAN1997	31DEC1997	N
				01JAN2016	31DEC2016	N
			Weight increased	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Insulin resistance	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JUN2020		Y
			Foot deformity	01JAN2003	31DEC2003	N
			Neck pain	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Endometriosis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Cholecystectomy	13DEC2012	13DEC2012	N
			Elbow operation	01JAN2000	31DEC2000	N
			Large intestinal polypectomy	01JAN2000	31DEC2000	N
			Peripheral nerve operation	01JAN1995	31DEC1995	N
			Synovial cyst removal	20DEC2016	20DEC2016	N
			Toe operation	01JAN2003	31DEC2003	N
		Vascular disorders	Hot flush	01JAN2007		Y
	C4591001 1028 10281171	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
		Hepatobiliary disorders	Cholecystitis	01APR2019	30APR2019	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1995	31DEC1995	N
		Investigations	Angiocardiogram	01JAN2018	31DEC2018	N
			Arthroscopy	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
			Colonoscopy	06SEP2018	06SEP2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Renal and urinary disorders	Hydronephrosis	01AUG2015	31AUG2015	N
			Ureterolithiasis	01AUG2015	31AUG2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN1960	31DEC1960	N
			Cholecystectomy	01APR2019	30APR2019	N
			Inguinal hernia repair	01JAN2009	31DEC2009	N
			Large intestinal polypectomy	06SEP2018	06SEP2018	N
			Prostatectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1028 10281173	Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Inguinal hernia	10OCT2018	10OCT2018	N
			Umbilical hernia	10OCT2018	10OCT2018	N
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Infections and infestations	Lyme disease	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Rib fracture	01MAR2018	31MAR2018	N
		Investigations	Arthroscopy	01NOV2018	30NOV2018	N
			Colonoscopy	10MAR2020	10MAR2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01NOV2018	30NOV2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Renal and urinary disorders	Nephrolithiasis	01JUL2020	31JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01MAR2018		Y
		Surgical and medical procedures	Inguinal hernia repair	10OCT2018	10OCT2018	N
			Large intestinal polypectomy	10MAR2020	10MAR2020	N
			Umbilical hernia repair	10OCT2018	10OCT2018	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1028 10281175	Ear and labyrinth disorders	Vertigo	01AUG2020		Y
		Endocrine disorders	Thyroid mass	01JAN2016		Y
		Gastrointestinal disorders	Diverticulum intestinal	04DEC2018	04DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1953	31DEC1953	N
			Tonsillitis	01JAN1960	31DEC1960	N
		Investigations	Biopsy breast	01JAN2013	31DEC2013	N
			Biopsy thyroid gland	04MAR2020	04MAR2020	N
			Colonoscopy	05DEC2018	05DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1963		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1963		Y
			Back pain	01JAN2007		Y
			Osteoarthritis	01JAN1992		Y
			Osteoporosis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01DEC2012	31DEC2013	N
				01JUL2013	31JUL2013	N
			Colon adenoma	05DEC2018	05DEC2018	N
		Psychiatric disorders	Nicotine dependence	01JAN1968	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
			Emphysema	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN1997		Y
			Tobacco user	01JAN1968	31DEC2011	N
		Surgical and medical procedures	Appendectomy	01JAN1953	31DEC1953	N
			Female sterilisation	01JAN1989	31DEC1989	N
			Large intestinal polypectomy	05DEC2018	05DEC2018	N
			Mammoplasty	01JAN2001	31DEC2001	N
			Meniscus removal	01JAN1983	31DEC1983	N
			Sinus operation	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1028 10281178	Eye disorders	Cataract	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyponatraemia	11JUN2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
				01JAN2005		Y
			Back pain	01JAN2000		Y
			Foot deformity	01JAN1980		Y
			Osteoarthritis	01JAN2000		Y
			Pain in extremity	01JAN2000		Y
			Rotator cuff syndrome	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1995		Y
			Peripheral venous disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1028 10281179	Investigations	Arthroscopy	01JAN2017	31DEC2017	N
			Colonoscopy	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Osteoarthritis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Polypectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1028 10281180	Eye disorders	Dry eye	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1987	31DEC1987	N
			Hand fracture	01JAN1980	31DEC1980	N
			Wrist fracture	01JAN1987	31DEC1987	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Impaired fasting glucose	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Patellofemoral pain syndrome	01JAN2010		Y
			Somatic dysfunction	01JAN2010		Y
		Psychiatric disorders	Adjustment disorder	01JAN2010		Y
			Alcoholism	01JAN1996	31DEC2003	N
			Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nicotine dependence	01JAN1980	31DEC2018	N
			Post-traumatic stress disorder	01AUG2019		Y
		Surgical and medical procedures	Intervertebral disc operation	01NOV2018	30NOV2018	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1028 10281181	Gastrointestinal disorders	Diverticulum	17JUN2020		Y
		Investigations	Colonoscopy	17JUN2020	17JUN2020	N
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal neoplasm	01JAN1997	31DEC1997	N
		Psychiatric disorders	Nicotine dependence	01JAN1970	01JAN1990	N
		Surgical and medical procedures	Large intestinal polypectomy	17JUN2020	17JUN2020	N
			Rectal lesion excision	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1028 10281182	Cardiac disorders	Palpitations	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1970	31DEC1970	N
			Meniscus injury	01JAN2008	31DEC2008	N
		Investigations	Arthroscopy	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2017		Y
			Overweight	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1987	31DEC1997	N
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Bunion operation	01JAN1987	31DEC1987	N
				01JAN1997	31DEC1997	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Meniscus removal	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2007		Y
			Hypertension	01JAN2003		Y
			Varicose vein	01JAN2015		Y
		Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2016	N
	C4591001 1028 10281185	Gastrointestinal disorders	Diverticulum	14MAY2014		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN2016	31DEC2016	N
			Inguinal hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Stress fracture	01JAN1991	31DEC1991	N
			Wrist fracture	01JAN1968	31DEC1968	N
		Investigations	Arthroscopy	19MAY2020	19MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Colonoscopy	14MAY2014	14MAY2014	N
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1983		Y
			Rotator cuff syndrome	01JAN2018		Y
		Reproductive system and breast disorders	Scrotal cyst	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961	31DEC1962	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Large intestinal polypectomy	14MAY2014	14MAY2014	N
			Ligament operation	01JAN1983	31DEC1983	N
			Meniscus removal	01JAN1983	31DEC1983	N
			Tonsillectomy	01JAN1972	31DEC1972	N
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1028 10281187	Cardiac disorders	Coronary artery disease	01FEB2017		Y
		Eye disorders	Cataract	01JAN2002	31JAN2006	N
			Vitreous detachment	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Infections and infestations	Pilonidal cyst	01JAN1958	31DEC1958	N
		Investigations	Angiocardiogram	01FEB2017	28FEB2017	N
				16JAN2018	16JAN2018	N
			Colonoscopy	01JAN2018	31DEC2018	N
				07APR2015	07APR2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1952	31DEC1952	N
			Cataract operation	01JAN2006	31JAN2006	N
			Coronary artery bypass	01FEB2017	28FEB2017	N
				16JAN2018	16JAN2018	N
			Large intestinal polypectomy	07APR2015	07APR2015	N
			Tonsillectomy	01JAN1946	31DEC1946	N
			Vasectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1028 10281189	Gastrointestinal disorders	Anal fissure	01JAN2015	31DEC2015	N
			Gastric ulcer	01JAN1986	31DEC1988	N
			Haemorrhoids	01JAN2015		Y
			Proctalgia	01JAN2015		Y
			Stomatitis	01JAN1981		Y
		Hepatobiliary disorders	Liver disorder	01JAN1982	31DEC1982	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2007	31DEC2007	N
			Wrist fracture	01JAN1964	31DEC1964	N
		Investigations	Biopsy liver normal	01JAN1982	31DEC1982	N
			Colonoscopy	27NOV2018	27NOV2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1973		Y
				27JUL2020		Y
			Back pain	01JAN2010		Y
			Osteoarthritis	08DEC2015		Y
			Plantar fasciitis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN1994		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Anorectal operation	01JAN2015	31DEC2015	N
			Appendectomy	01JAN1964	31DEC1964	N
			Meniscus operation	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1968	31DEC1968	N
			Wisdom teeth removal	01JAN1986	31DEC1986	N
			Wrist surgery	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1028 10281193	Endocrine disorders	Hypothyroidism	03NOV2017		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
			Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	03OCT2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1028 10281194	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Cardiac disorders	Left ventricular hypertrophy	01JAN1974		Y
		Endocrine disorders	Androgen deficiency	11SEP2013		Y
		Eye disorders	Cataract	12SEP2019		Y
		Gastrointestinal disorders	Haemorrhoids	16DEC2013		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Rubber sensitivity	01JAN1990		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2010	31DEC2010	N
		Investigations	Colonoscopy	23JAN2019	23JAN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	10SEP2010		Y
			Vitamin D deficiency	27AUG2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	16DEC2013	16DEC2013	N
		Renal and urinary disorders	Haematuria	01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Large intestinal polypectomy	16DEC2013	16DEC2013	N
			Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1028 10281195	Gastrointestinal disorders	Haemorrhoids	01JAN2016		Y
			Umbilical hernia	01MAR2018	31MAR2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	01FEB2016	29FEB2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Large intestinal polypectomy	01FEB2016	31DEC2016	N
			Tonsillectomy	01JAN1969	31DEC1969	N
			Umbilical hernia repair	01MAR2018	31MAR2018	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1028 10281196	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1977		Y
		Investigations	Arthroscopy	24OCT2019	24OCT2019	N
			Colonoscopy	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperglycaemia	04DEC2018		Y
			Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Bursitis	13JAN2016		Y
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
			Sleep apnoea syndrome	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2013	31DEC2013	N
			Large intestinal polypectomy	01JAN2013	31DEC2013	N
			Limb operation	01JAN2008	31DEC2008	N
			Meniscus removal	24OCT2019	24OCT2019	N
			Tenoplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2014		Y
			Hypertension	15MAR2018		Y
			Varicose vein	24FEB2016		Y
	C4591001 1028 10281199	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Investigations	Colonoscopy	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	03SEP2010		Y
			Vitamin B12 deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2008		Y
			Osteoporosis	13SEP2010		Y
		Nervous system disorders	Migraine	01JAN1970	31DEC1994	N
		Psychiatric disorders	Anxiety	27JAN2009		Y
			Insomnia	13SEP2020		Y
		Reproductive system and breast disorders	Cystocele	01JAN1995	31DEC1995	N
			Endometriosis	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01DEC1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cystocele repair	01JAN1995	31DEC1995	N
			Hysterectomy	01DEC1994	31DEC1994	N
			Large intestinal polypectomy	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2006	31DEC2006	N
			Rectocele repair	01JAN1995	31DEC1995	N
			Toe operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	24SEP2012		Y
	C4591001 1028 10281201	Ear and labyrinth disorders	Deafness	21DEC2009		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2016	08NOV2018	N
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2012		Y
			Neck mass	01JAN1980	31DEC1980	N
			Spinal stenosis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Umbilical hernia repair	08NOV2018	08NOV2018	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1028 10281204	Ear and labyrinth disorders	Deafness bilateral	01AUG2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2020		Y
			Macular fibrosis	01JAN2014		Y
			Retinal degeneration	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitreous detachment	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN1970		Y
			Onychomycosis	01JAN2009	31DEC2009	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
			Hand fracture	01JAN1975	31DEC1975	N
		Investigations	Colonoscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Pain in extremity	01JAN2015		Y
		Nervous system disorders	Hypersomnia	01JAN1995		Y
			Neuropathy peripheral	01JAN2000		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2017		Y
			Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	01JAN2016		Y
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1028 10281206	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1959	31DEC1959	N
		Infections and infestations	Onychomycosis	01JAN2019		Y
			Oral herpes	01JAN1960		Y
			Rhinitis	01JAN1960		Y
		Investigations	Colonoscopy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
			Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Transient ischaemic attack	01JAN2016	31DEC2016	N
		Psychiatric disorders	Nicotine dependence	01JAN1978	31DEC1986	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2016	31DEC2016	N
			Upper-airway cough syndrome	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1959	31DEC1959	N
			Keratoplasty	01JAN1989	31DEC1989	N
			Large intestinal polypectomy	01JAN2005	31DEC2005	N
			Nasal septal operation	01DEC2016	31DEC2016	N
			Rhinoplasty	01DEC2016	31DEC2016	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1028 10281210	Blood and lymphatic system disorders	Anaemia	01JAN1980	31DEC1985	N
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Vitamin D deficiency	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Hypersomnia	01JAN2014		Y
			Restless legs syndrome	01JAN2014		Y
		Psychiatric disorders	Agoraphobia	01JAN1998		Y
			Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
			Panic disorder	01JAN1998		Y
			Sleep disorder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1970	31DEC1970	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1028 10281212	Ear and labyrinth disorders	Deafness bilateral	01JAN1959		Y
		Endocrine disorders	Hypothyroidism	06NOV2015		Y
		Eye disorders	Cataract	01JUN2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Encephalitis	01JAN1959	31DEC1959	N
		Investigations	Arthroscopy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Psychiatric disorders	Nicotine dependence	01JAN1972		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1956	31DEC1956	N
	C4591001 1028 10281214	Gastrointestinal disorders	Umbilical hernia	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	04OCT2013	31DEC2013	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1970	31DEC1970	N
			Hand fracture	01JAN1969	31DEC1969	N
		Investigations	Biopsy prostate normal	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
				01MAR2019	31MAR2019	N
			Colonoscopy	04SEP2012	04SEP2012	N
				26FEB2016	26FEB2016	N
			Prostatic specific antigen increased	01JAN2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	03DEC2019		Y
			Squamous cell carcinoma	09JAN2020	09JAN2020	N
				12FEB2020	12FEB2020	N
		Reproductive system and breast disorders	Erectile dysfunction	18MAR2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	03DEC2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Large intestinal polypectomy	04SEP2012	04SEP2012	N
				26FEB2016	26FEB2016	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
		Vascular disorders	Prehypertension	31MAY2017		Y
	C4591001 1028 10281215	Eye disorders	Cataract	01JAN2019		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1980		Y
			Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1963	31DEC1963	N
			Female sterilisation	01JAN1986	31DEC1986	N
			Finger amputation	01JAN2014	31DEC2014	N
			Urinary bladder suspension	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1028 10281217	Eye disorders	Cataract	05JUN2019		Y
		Gastrointestinal disorders	Acquired oesophageal web	01DEC2019		Y
			Gastric ulcer	01JAN2015	31DEC2015	N
			Gastrooesophageal reflux disease	01JAN2012		Y
			Hiatus hernia	01DEC2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	05OCT2015	05OCT2015	N
		Immune system disorders	Drug hypersensitivity	01DEC2019		Y
				01JAN2018		Y
				01JAN2019		Y
				01JUN2020		Y
		Investigations	Colonoscopy	01DEC2019	31DEC2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	12APR2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertriglyceridaemia	12APR2013		Y
			Impaired fasting glucose	01JAN2015		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019	31DEC2019	N
		Nervous system disorders	Head titubation	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	05OCT2015	05OCT2015	N
			Female sterilisation	01JAN1980	31DEC1980	N
				05OCT2015	05OCT2015	N
			Large intestinal polypectomy	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1028 10281218	Infections and infestations	Hepatitis C	01JUN2019	08JAN2020	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Antiviral treatment	08AUG2019	08JAN2020	N
			Ligament operation	01JAN1985	31DEC1985	N
	C4591001 1028 10281220	Eye disorders	Cataract	01JUL2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2017		Y
			Hyponatraemia	29JUL2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Impaired fasting glucose	01APR2017		Y
		Nervous system disorders	Syncope	01APR2017	30APR2017	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01APR2017		Y
	C4591001 1028 10281230	Eye disorders	Cataract	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Investigations	Colonoscopy	01FEB2016	29FEB2016	N
				14DEC2009	14DEC2009	N
		Metabolism and nutrition disorders	Obesity	01JAN1975		Y
			Type 2 diabetes mellitus	01JAN2005	31MAY2009	N
		Nervous system disorders	Headache	01NOV2019		Y
		Psychiatric disorders	Anxiety	01JUL2015	31OCT2015	N
			Depression	01JUL2015	31OCT2015	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982	30NOV2012	N
		Social circumstances	Postmenopause	13DEC2010		Y
		Surgical and medical procedures	Abdominoplasty	01NOV2012	30NOV2012	N
			Appendectomy	01JAN2016	31DEC2016	N
			Endometrial ablation	13DEC2010	13DEC2010	N
			Gastric bypass	21APR2009	21APR2009	N
			Rhinoplasty	01NOV2012	30NOV2012	N
		Vascular disorders	Hot flush	01JAN2011		Y
	C4591001 1028 10281232	Endocrine disorders	Hypothyroidism	04OCT2013		Y
		Infections and infestations	Oral herpes	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	06JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2019	31JUL2019	N
			Neuroendocrine tumour	11FEB2020	24FEB2020	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2018		Y
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2019	31DEC2019	N
			Meniscus operation	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JUL2013		Y
	C4591001 1028 10281233	Gastrointestinal disorders	Inguinal hernia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	19DEC2014		Y
				27FEB2012		Y
		Infections and infestations	Acute sinusitis	01JAN2014	31DEC2014	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1994	31DEC1994	N
			Meniscus injury	01APR2017	30APR2017	N
		Investigations	Arthroscopy	01APR2017	30APR2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998	31DEC2018	N
			Exostosis	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Uterine leiomyoma	08JUN2012	31DEC2012	N
		Psychiatric disorders	Libido decreased	01JUN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2006	31DEC2010	N
			Ovarian cyst	08JUN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2013		Y
			Rhinitis allergic	01JAN2014		Y
		Social circumstances	Postmenopause	01SEP2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Endometrial ablation	01FEB2010	28FEB2010	N
			Female sterilisation	01SEP2001	30SEP2001	N
			Hysterectomy	01DEC2012	31DEC2012	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN1998		Y
	C4591001 1028 10281234	Gastrointestinal disorders	Diverticulum	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN1995		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
			Chronic sinusitis	01JAN1995		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Patella fracture	01JAN1975	31DEC1975	N
		Investigations	Arthroscopy	01JAN1998	31DEC1998	N
			Biopsy breast normal	01JAN1995	31DEC1995	N
			Colonoscopy	07JAN2008	07JAN2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2019		Y
				01JAN1975		Y
			Back pain	01JAN2003		Y
			Dupuytren's contracture	01JAN2009	31DEC2009	N
			Intervertebral disc protrusion	01JAN2003	31DEC2004	N
			Joint swelling	01APR2019		Y
			Periarthritis	01JAN1998	31DEC1998	N
		Nervous system disorders	Headache	01JAN1980		Y
			Seizure	01JAN1977		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Insomnia	01JAN1995		Y
			Nicotine dependence	01JAN1971	06JAN2011	N
		Reproductive system and breast disorders	Breast cyst	01JAN1995	31DEC1995	N
			Uterine haemorrhage	01JUN1996	08DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN1987		Y
		Social circumstances	Postmenopause	08DEC1997		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
			Dupuytren's contracture operation	01JAN2009	31DEC2009	N
			Hysterectomy	08DEC1997	08DEC1997	N
			Spinal fusion surgery	01JAN2004	31DEC2004	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01DEC1997		Y
	C4591001 1028 10281235	Injury, poisoning and procedural complications	Ankle fracture	26JUL2018	26JUL2018	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Open reduction of fracture	26JUL2018	26JUL2018	N
	C4591001 1028 10281239	Vascular disorders	Hot flush	01JAN2013		Y
		Eye disorders	Cataract	01JAN2014	31DEC2015	N
			Glaucoma	01JAN2007		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2015		Y
			Duodenal ulcer	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1971	31DEC1971	N
		Investigations	Angiocardiogram	01JAN2018	31DEC2018	N
			Colonoscopy	16JAN2013	16JAN2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Nervous system disorders	Amnesia	01JAN2009		Y
			Migraine	01JAN1976		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Depression	01JAN1993		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	18NOV2019		Y
			Dyspareunia	18NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Cataract operation	01JAN2015	31DEC2015	N
			Hysterectomy	01MAY2014	31MAY2014	N
			Oophorectomy bilateral	01MAY2014	31MAY2014	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1028 10281245	Gastrointestinal disorders	Constipation	01JUN2020		Y
			Diverticulum	01JAN2017		Y
			Dyspepsia	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis acute	01JAN2012	31DEC2012	N
		Infections and infestations	Tube-ovarian abscess	04MAR2020	23JUN2020	N
		Injury, poisoning and procedural complications	Iliotibial band syndrome	01JAN2015	31DEC2016	N
			Radius fracture	01JAN2018	31DEC2018	N
		Investigations	Cardiac murmur	01JAN2007		Y
			Carotid bruit	01JAN2017		Y
			Colonoscopy	01JAN2017	31DEC2017	N
			Cystoscopy	23JUN2020	23JUN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Impaired fasting glucose	01JAN2014		Y
			Obesity	01JAN1998		Y
			Type 2 diabetes mellitus	01MAR2016		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc degeneration	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2016		Y
			Tendonitis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
			Lumbosacral radiculopathy	01JAN2005		Y
		Renal and urinary disorders	Micturition urgency	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Colectomy	23JUN2020	23JUN2020	N
			Oophorectomy	23JUN2020	23JUN2020	N
			Pain management	10FEB2014	10FEB2014	N
			Ureteral stent insertion	23JUN2020	23JUN2020	N
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1028 10281252	Endocrine disorders	Autoimmune thyroiditis	01JAN2016		Y
			Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Chronic sinusitis	01JAN2018		Y
		Investigations	Colonoscopy	13MAR2015	13MAR2015	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Rheumatoid arthritis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	14SEP2004	14SEP2004	N
			Large intestinal polypectomy	13MAR2015	13MAR2015	N
	C4591001 1028 10281264	Congenital, familial and genetic disorders	Hydrocele	02JAN2020		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
		Infections and infestations	Herpes zoster	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	04AUG2020	01SEP2020	N
		Psychiatric disorders	Affective disorder	01JAN2014		Y
			Premature ejaculation	18JUN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1028 10281266	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Ear and labyrinth disorders	Vertigo positional	13SEP2019	31DEC2019	N
		Eye disorders	Glaucoma	01SEP2019		Y
			Vitreous haemorrhage	13SEP2019	30SEP2019	N
		Infections and infestations	Tonsillitis	01JAN1989	31DEC1989	N
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1970	31DEC1970	N
		Investigations	Biopsy breast normal	01JAN1990	31DEC1990	N
			Colonoscopy	11APR2011	11APR2011	N
			Haemoglobin decreased	01JAN2019	24DEC2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2015		Y
			Osteoarthritis	01JAN2010		Y
			Synovial cyst	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Libido decreased	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1989	31DEC1989	N
			Wisdom teeth removal	01JAN1989	31DEC1989	N
	C4591001 1028 10281268	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Wrist fracture	23JAN2018	24JAN2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	04OCT2017	04OCT2017	N
				17APR2018	02MAY2018	N
			Laryngeal cancer	01JAN2006	31DEC2007	N
			Squamous cell carcinoma	04DEC2018	15JAN2019	N
				31JAN2019	31JAN2019	N
		Psychiatric disorders	Nicotine dependence	01JAN1969	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
			Dyspnoea	01MAY2008	28FEB2009	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	18OCT2017		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Laryngectomy	01JAN2011	31DEC2011	N
			Open reduction of fracture	24JAN2018	24JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pharyngeal operation	01JAN2012	31DEC2012	N
			Tracheostomy	01MAY2008	31MAY2008	N
			Tracheostomy tube removal	01FEB2009	28FEB2009	N
	C4591001 1028 10281270	Ear and labyrinth disorders	Deafness bilateral	01JAN1990		Y
		Endocrine disorders	Goitre	18JUN2020		Y
			Thyroid mass	18JUN2020		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Biopsy thyroid gland normal	01JUL2020	01JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Muscle spasms	01JAN2010		Y
			Neck pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	27JAN2017		Y
		Nervous system disorders	Essential tremor	01JAN2015		Y
			Headache	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Major depression	01JAN2006		Y
		Renal and urinary disorders	Urge incontinence	01SEP2019		Y
		Reproductive system and breast disorders	Ovarian cyst	27JAN2017		Y
			Pelvic pain	01MAY2020	31JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	07AUG1996	07AUG1996	N
				20OCT1991	20OCT1991	N
			Facial lesion excision	01JAN2005	31DEC2005	N
			Uterine dilation and curettage	01JAN2002	31DEC2002	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
		Vascular disorders	Hot flush	01JAN2007		Y
			Hypertension	01JAN2017		Y
	C4591001 1028 10281272	Cardiac disorders	Left ventricular dysfunction	09AUG2019		Y
			Mitral valve incompetence	09AUG2019		Y
		Eye disorders	Astigmatism	01JAN1998		Y
			Cataract cortical	01JAN2015		Y
			Meibomian gland dysfunction	01JAN2015	31DEC2017	N
			Myopia	01JAN1998		Y
			Presbyopia	01JAN1998		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
			Gastritis	08NOV2017		Y
		General disorders and administration site conditions	Drug intolerance	01JUN2015		Y
			Fatigue	04JUN2019		Y
			Oedema peripheral	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2008	31DEC2008	N
		Investigations	Cardiac murmur	18JUL2019		Y
			Colonoscopy	01JAN2007	31DEC2007	N
				01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	25OCT2002		Y
			Type 2 diabetes mellitus	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
			Neck pain	01JAN2010		Y
			Osteoarthritis	01JAN2016		Y
				10JAN2008		Y
				22JUN2007		Y
			Spinal osteoarthritis	22JUN2007		Y
			Synovial cyst	12SEP2017		Y
		Nervous system disorders	Head titubation	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2011		Y
			Nocturia	01JAN2011		Y
			Urge incontinence	01JAN2017		Y
			Urinary incontinence	10JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
			Large intestinal polypectomy	01JAN2007	31DEC2007	N
			Peripheral nerve neurostimulation	01JUN2016	30JUN2016	N
		Vascular disorders	Hypertension	01APR2015		Y
	C4591001 1028 10281273	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Contrast media allergy	01JAN2000		Y
			Drug hypersensitivity	01JAN1970		Y
				01JAN2000		Y
		Injury, poisoning and procedural complications	Dermatitis artefacta	04AUG2005	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	07FEB2014	07FEB2014	N
				16JUN2020	16JUN2020	N
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2015		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Neck mass	27DEC2017	27DEC2017	N
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1983		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2008	N
			Dyskinesia	01JAN1990		Y
		Psychiatric disorders	Affective disorder	01JAN1983		Y
			Anxiety	01JAN1983		Y
			Schizoaffective disorder	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
			Large intestinal polypectomy	07FEB2014	07FEB2014	N
				16JUN2020	16JUN2020	N
			Neck dissection	27DEC2017	27DEC2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1028 10281277	Ear and labyrinth disorders	Deafness unilateral	20MAY2002		Y
			Tinnitus	20MAY2002		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Haemorrhoids	18MAR2005	31DEC2008	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1957	31DEC1957	N
		Investigations	Biopsy breast normal	01JAN2007	31DEC2007	N
			Biopsy site unspecified normal	03JUL2003	03JUL2003	N
		Musculoskeletal and connective tissue disorders	Axillary mass	03JUL2003	03JUL2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1985	31DEC1985	N
				01JAN1987	31DEC1987	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1994	31DEC1994	N
			Neuropathy peripheral	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	23APR1983	23APR1983	N
			Carpal tunnel decompression	01JAN1994	31DEC1994	N
			Cataract operation	01JAN2017	31DEC2017	N
			Large intestinal polypectomy	18MAR2008	18MAR2008	N
				24AUG2018	24AUG2018	N
	C4591001 1028 10281278	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Infections and infestations	Tonsillitis	01JAN1983	31DEC1983	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2003	31DEC2003	N
			Lower limb fracture	01JAN2013	31DEC2013	N
			Upper limb fracture	01JAN1956	31DEC1956	N
				01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast cyst	01APR2011	06MAY2011	N
		Surgical and medical procedures	Breast cyst excision	06MAY2011	06MAY2011	N
			Cataract operation	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1028 10281283	Cardiac disorders	Supraventricular tachycardia	01JAN2020		Y
		Eye disorders	Cataract	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Infections and infestations	Oral herpes	01JAN2013		Y
		Injury, poisoning and procedural complications	Muscle injury	01JAN2005	31DEC2005	N
			Skin laceration	01JAN2013	31DEC2013	N
		Investigations	Colonoscopy	08MAR2013	08MAR2013	N
				28JUL2018	28JUL2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Impaired fasting glucose	01JAN2015		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1977		Y
			Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2019		Y
			Paraesthesia	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2014		Y
			Renal cyst	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Large intestinal polypectomy	08MAR2013	08MAR2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				28JUL2018	28JUL2018	N
			Tenoplasty	01JAN2005	31DEC2005	N
				01JAN2013	31DEC2013	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1028 10281288	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Pancreatitis	01JAN2013	31DEC2013	N
			Peptic ulcer	01JAN1995	31DEC1995	N
		Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Investigations	Colonoscopy	05MAY2015	05MAY2015	N
				19OCT2020	19OCT2020	N
			Prostatic specific antigen abnormal	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01OCT2019		Y
			Plantar fasciitis	01OCT2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
			Vocal cord paralysis	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Post-traumatic stress disorder	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1980		Y
			Nasal polyps	27FEB2018		Y
			Nasal septum deviation	27FEB2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pulmonary mass	01JAN2017		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2020	29FEB2020	N
			Vitiligo	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Large intestinal polypectomy	05MAY2015	05MAY2015	N
				19OCT2020	19OCT2020	N
			Tonsillectomy	01JAN1980	31DEC1980	N
			Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1028 10281289	Cardiac disorders	Cardiac failure congestive	01JAN1996		Y
		Eye disorders	Cataract	01JAN2020		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1996		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
		Investigations	Biopsy breast normal	01JAN2001	31DEC2001	N
				01JAN2008	31DEC2008	N
				28JAN2013	28JAN2013	N
			Colonoscopy	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC1993	N
		Psychiatric disorders	Seasonal affective disorder	01JAN1974		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2001		Y
			Ovarian cyst	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	07JUN2009		Y
		Surgical and medical procedures	Blepharoplasty	05FEB2014	05FEB2014	N
			Breast conserving surgery	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Carpal tunnel decompression	01JAN1993	31DEC1993	N
		Vascular disorders	Peripheral venous disease	01JAN1996		Y
	C4591001 1028 10281292	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Cataract	01JAN2016	30JUN2020	N
		Gastrointestinal disorders	Dyspepsia	01OCT2019		Y
		Hepatobiliary disorders	Cholelithiasis	01MAR2019	31MAR2019	N
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Investigations	Colonoscopy	01JAN2011	31DEC2011	N
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2012	02OCT2012	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Cataract operation	01JUN2020	30JUN2020	N
			Cholecystectomy	01MAR2019	31MAR2019	N
			Hysterectomy	02OCT2012	02OCT2012	N
			Large intestinal polypectomy	01JAN2011	31DEC2011	N
			Salpingo-oophorectomy bilateral	02OCT2012	02OCT2012	N
	C4591001 1028 10281293	Gastrointestinal disorders	Constipation	01JAN2020		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Arthroscopy	08DEC2017	08DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Colonoscopy	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017	08DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	20APR2018	N
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Prostatectomy	20APR2018	20APR2018	N
			Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1028 10281295	Ear and labyrinth disorders	Deafness neurosensory	01JAN2010		Y
		Eye disorders	Cataract	01JAN2015	31DEC2018	N
			Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Haemorrhoids	15FEB2018	31DEC2018	N
			Hiatus hernia	18NOV2019	18NOV2019	N
		Hepatobiliary disorders	Biliary dyskinesia	01JAN1992	31DEC1992	N
		Immune system disorders	Allergy to arthropod sting	07AUG2018		Y
			Contrast media allergy	01JAN1972		Y
			Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y
			Food allergy	01JAN2000		Y
			Reaction to colouring	01JAN2015		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Helicobacter gastritis	01JAN2019	31JAN2019	N
			Tonsillitis	01JAN1953	31DEC1953	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2001	31DEC2001	N
			Pelvic fracture	01JAN1953	31DEC1953	N
		Investigations	Arthroscopy	01JAN2001	31DEC2001	N
			Colonoscopy	01JAN1990	31DEC1990	N
				01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
				01JAN2015	31DEC2015	N
				18NOV2019	18NOV2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1992	31DEC1992	N
			Large intestinal polypectomy	01JAN2015	31DEC2015	N
				18NOV2019	18NOV2019	N
			Meniscus removal	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Vasectomy	01JAN1980	31DEC1980	N
			Vasectomy reversal	01JAN1984	31DEC1984	N
			Anaemia	01JAN2010		Y
	C4591001 1028 10281296	Blood and lymphatic system disorders				
		Cardiac disorders	Coronary artery disease	01JAN2004		Y
			Myocardial infarction	01NOV2004	30NOV2004	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Infections and infestations	Oral herpes	01JAN2017		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	12DEC2016	31DEC2017	N
			Pelvic fracture	01JAN1996	31DEC1996	N
			Peripheral nerve injury	01JAN1998	31DEC1998	N
		Investigations	Arthroscopy	01AUG2009	31AUG2009	N
			Colonoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2007	31DEC2010	N
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Plantar fasciitis	01JUN2019		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Psychiatric disorders	Anxiety	12DEC2016	31DEC2017	N
			Insomnia	01JAN2000		Y
			Nicotine dependence	01JAN1968	31DEC2014	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1997		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Coronary arterial stent insertion	01JAN2005	31JAN2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2010	31DEC2010	N
			Inguinal hernia repair	01JAN2016	31DEC2016	N
			Peripheral nerve operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1030 10301007	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
	C4591001 1030 10301009	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1030 10301017	Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1030 10301020	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1030 10301024	Cardiac disorders	Cardiomyopathy	01SEP2005		Y
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
	C4591001 1030 10301025	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Duodenogastric reflux	01MAR2020		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1030 10301031	Cardiac disorders	Coronary artery disease	06JAN2020		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Nervous system disorders	Hypersomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Coronary arterial stent insertion	06JAN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1030 10301033	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
	C4591001 1030 10301034	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1030 10301035	Surgical and medical procedures	Female sterilisation	01JAN2010	01JAN2010	N
	C4591001 1030 10301036	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2019	31MAY2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1030 10301037	Surgical and medical procedures	Hysterectomy	01JAN2015	01JAN2015	N
	C4591001 1030 10301046	Investigations	Blood cholesterol increased	01JAN2019		Y
	C4591001 1030 10301047	Gastrointestinal disorders	Stomatitis	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JUL2020		Y
	C4591001 1030 10301051	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1030 10301058	Investigations	Blood cholesterol increased	01JUL2019		Y
	C4591001 1030 10301059	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1030 10301062	Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	01MAY2020		Y
	C4591001 1030 10301064	Gastrointestinal disorders	Gastrointestinal fistula	18AUG2016	18AUG2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Renal and urinary disorders	Urine flow decreased	01JAN2018		Y
	C4591001 1030 10301066	Cardiac disorders	Atrioventricular block	01JAN2017	01JAN2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JUN2019		Y
	C4591001 1030 10301067	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1030 10301068	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
	C4591001 1030 10301073	Congenital, familial and genetic disorders	Hereditary motor and sensory neuropathy	(b) (6) 1948		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1030 10301074	Cardiac disorders	Atrial fibrillation	01DEC2007		Y
	C4591001 1030 10301076	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1030 10301078	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1030 10301079	Cardiac disorders	Atrial fibrillation	01JAN2019	01MAR2019	N
			Atrioventricular block	01JAN2015	01JAN2017	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
			Thrombophlebitis	01JAN2017	01MAR2017	N
	C4591001 1030 10301084	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Infections and infestations	Herpes zoster	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	01JAN1999	N
	C4591001 1030 10301085	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	01JAN2010	N
	C4591001 1030 10301086	Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2012	01JAN2014	N
	C4591001 1030 10301089	Immune system disorders	Seasonal allergy	01JAN2015		Y
	C4591001 1030 10301091	Surgical and medical procedures	Hysterectomy	01JAN2015	01JAN2015	N
	C4591001 1030 10301092	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2018		Y
		Renal and urinary disorders	Bladder spasm	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1030 10301094	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1030 10301096	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
	C4591001 1030 10301098	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1030 10301105	Eye disorders	Glaucoma	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	01JAN2019	N
		Psychiatric disorders	Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
			Urinary retention	01JAN2018		Y
	C4591001 1030 10301108	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	01JAN2012	N
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1030 10301109	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1030 10301111	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Social circumstances	Menopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1030 10301112	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
			Irritable bowel syndrome	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
	C4591001 1030 10301114	Eye disorders	Glaucoma	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1030 10301116	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1030 10301118	Surgical and medical procedures	Hysterectomy	01JAN2010	01JAN2010	N
	C4591001 1030 10301119	Endocrine disorders	Hypothyroidism	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Social circumstances	Menopause	01JAN2000	01JAN2000	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1030 10301121	Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2009	01JAN2009	N
	C4591001 1030 10301125	Eye disorders	Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1030 10301126	Investigations	Blood cholesterol increased	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1030 10301131	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1030 10301132	Endocrine disorders	Hypothyroidism	01JUL2020		Y
		General disorders and administration site conditions	Pain	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1030 10301133	Cardiac disorders	Coronary artery disease	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1030 10301135	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
	C4591001 1030 10301138	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Salpingectomy	01JAN2000	01JAN2000	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1030 10301140	General disorders and administration site conditions	Inflammatory pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Menopause	01SEP1990		Y
	C4591001 1030 10301141	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1030 10301144	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Vascular disorders	Hypertension	01FEB2005		Y
	C4591001 1030 10301147	Nervous system disorders	Migraine	01JAN1995		Y
	C4591001 1030 10301149	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1030 10301150	Cardiac disorders	Atrial fibrillation	05NOV2019		Y
		Eye disorders	Dry eye	01SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01SEP2020		Y
		Vascular disorders	Hot flush	01MAR2020		Y
	C4591001 1030 10301151	Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Social circumstances	Menopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1030 10301156	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Facial paralysis	01JAN2019	01MAR2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Social circumstances	Menopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1030 10301157	Renal and urinary disorders	Urinary retention	01JAN2015		Y
	C4591001 1030 10301158	Investigations	Blood cholesterol increased	01JAN2012		Y
	C4591001 1036 10361001	Surgical and medical procedures	Angioplasty	01JAN2016	31DEC2016	N
	C4591001 1036 10361002	Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	T-cell lymphoma	01JAN2011	31DEC2012	N
		Nervous system disorders	Seizure	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Neck pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN1998		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
			Prostatomegaly	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2001	31DEC2001	N
				01JAN2010	31DEC2010	N
			Coronary arterial stent insertion	01DEC2018	31DEC2018	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1036 10361005	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Infections and infestations	Hepatitis C	15MAY2020	10JUL2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008	31DEC2008	N
		Psychiatric disorders	Major depression	01JAN1968		Y
			Post-traumatic stress disorder	01JAN1968		Y
		Renal and urinary disorders	Urge incontinence	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Antiviral treatment	10JUL2020	10JUL2020	N
			Cataract operation	01OCT2019	31OCT2019	N
			Parathyroidectomy	01JAN2005	31DEC2005	N
			Rectal polypectomy	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1036 10361007	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1036 10361008	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Diverticulitis	01JAN2006		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
	C4591001 1036 10361010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
		Investigations	Low density lipoprotein increased	01NOV2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
	C4591001 1036 10361013	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1036 10361015	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361016	Gastrointestinal disorders	Dyspepsia	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1036 10361019	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1036 10361025	Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2017	31DEC2017	N
	C4591001 1036 10361028	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1965		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1036 10361031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
			Influenza immunisation	10AUG2020	10AUG2020	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1036 10361034	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Infections and infestations	Papilloma viral infection	01AUG2017	31OCT2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2017	31DEC2017	N
			Throat cancer	01JAN2017	31DEC2017	N
	C4591001 1036 10361035	Immune system disorders	Allergy to animal	01JAN1970		Y
			Seasonal allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Nervous system disorders	Migraine with aura	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
	C4591001 1036 10361036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN1975		Y
			Seasonal allergy	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Migraine	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bone operation	18FEB2016	18FEB2016	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Hip arthroplasty	27APR2016	27APR2016	N
			Hip surgery	03AUG2015	03AUG2015	N
			Knee arthroplasty	03JUL2019		Y
			Wrist surgery	01JUL2020	01JUL2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1036 10361041	Cardiac disorders	Coronary artery occlusion	01JAN2009	31DEC2009	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
			Peptic ulcer	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
			Coronary artery bypass	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361044	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1036 10361045	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
	C4591001 1036 10361046	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1036 10361049	Cardiac disorders	Coronary artery occlusion	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
			Pain in extremity	01JAN1970		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Gastrectomy	14MAY2018	14MAY2018	N
			Hernia repair	24JAN2020	24JAN2020	N
			Pancreaticoduodenectomy	14MAY2018	14MAY2018	N
		Vascular disorders	Hypertension	01JAN1973		Y
	C4591001 1036 10361051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
		Surgical and medical procedures	Cataract operation	02JUL2020	02JUL2020	N
				04MAR2020	31AUG2020	N
	C4591001 1036 10361052	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1036 10361054	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2012	31JAN2012	N
				01OCT2016	31OCT2016	N
	C4591001 1036 10361057	Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
				01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1036 10361058	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN1995		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361059	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Hypertriglyceridaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1036 10361063	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Infections and infestations	Poliomyelitis	01JAN1954	31DEC1954	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1036 10361066	Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Cardiac murmur	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1036 10361067	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Infections and infestations	Oral herpes	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1036 10361071	Surgical and medical procedures	Spinal fusion surgery	15SEP2019	15SEP2019	N
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Abdominal distension	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
	C4591001 1036 10361077	Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN2012		Y
		Infections and infestations	Lyme disease	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN1998	31DEC1998	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
	C4591001 1036 10361079	Immune system disorders	Drug hypersensitivity	01JAN1945		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
	C4591001 1036 10361080	Immune system disorders	Allergy to arthropod sting	01JAN1941		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN1941		Y
				01JAN2004		Y
			Food allergy	01JAN1941		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1036 10361081	Cardiac disorders	Tachycardia	01JAN1963		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
	C4591001 1036 10361082	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1036 10361083	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1036 10361087	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361089	Cardiac disorders	Palpitations	01JAN2010		Y
		Endocrine disorders	Thyroiditis	01JAN1990		Y
		Hepatobiliary disorders	Hepatic steatosis	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Social circumstances	Postmenopause	01AUG2005		Y
	C4591001 1036 10361090	Ear and labyrinth disorders	Deafness bilateral	11SEP2012		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Investigations	Blood testosterone decreased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
	C4591001 1036 10361091	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1036 10361092	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
	C4591001 1036 10361101	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
			Panic attack	01JAN2002		Y
		Renal and urinary disorders	Urine flow decreased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1983		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Gastric bypass	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1036 10361106	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1036 10361108	Gastrointestinal disorders	Abdominal hernia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1036 10361109	Immune system disorders	Allergy to animal	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1036 10361113	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361114	Blood and lymphatic system disorders	Coagulopathy	01MAR2020		Y
		Endocrine disorders	Thyroid mass	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1036 10361115	Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2003	31DEC2003	N
			Ovarian cancer	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
				01JAN2020	31DEC2020	N
	C4591001 1036 10361116	Gastrointestinal disorders	Colitis ulcerative	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
	C4591001 1036 10361120	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Cardiac failure	01JAN2013		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2008	31DEC2010	N
		Surgical and medical procedures	Prostatectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Aneurysm	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN1964		Y
	C4591001 1036 10361121	Cardiac disorders	Coronary artery disease	01JAN1995		Y
			Myocardial infarction	01JAN1995	31DEC1995	N
				01JAN2018	31DEC2018	N
	C4591001 1036 10361122	Surgical and medical procedures	Coronary artery bypass	01JAN1995	31DEC1995	N
		General disorders and administration site conditions	Face oedema	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2003	31DEC2003	N
	C4591001 1036 10361123	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood calcium increased	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Prostatectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1036 10361124	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Haemorrhoid operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1036 10361130	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01DEC2019	31DEC2019	N
	C4591001 1036 10361132	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1036 10361133	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
			Chronic obstructive pulmonary disease	01JAN2009		Y
	C4591001 1036 10361138	Infections and infestations	Hepatitis C	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
	C4591001 1036 10361139	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1036 10361140	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
			Osteoarthritis	01JAN2015		Y
			Scoliosis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1989		Y
		Renal and urinary disorders	Pollakiuria	01JAN2005		Y
		Surgical and medical procedures	Spinal operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1036 10361142	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1978	31DEC1978	N
			Mammoplasty	01JAN2019	31DEC2019	N
			Meniscus operation	01JAN2017	31DEC2017	N
	C4591001 1036 10361143	Cardiac disorders	Aortic valve stenosis	01JAN1990		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371001	Endocrine disorders	Hypothyroidism	01AUG2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2008		Y
		Social circumstances	Postmenopause	01JUL2005		Y
		Surgical and medical procedures	Spinal operation	01AUG2008	31AUG2008	N
	C4591001 1037 10371002	Injury, poisoning and procedural complications	Meniscus injury	01FEB2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371003	Infections and infestations	Herpes simplex	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1964	31DEC2013	N
			Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371004	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Infections and infestations	Toxic shock syndrome	01AUG1982	31AUG1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2018		Y
			Type 2 diabetes mellitus	01AUG2018		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1037 10371005	Metabolism and nutrition disorders	Gout	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371006	Endocrine disorders	Hyperthyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1037 10371009	Immune system disorders	Seasonal allergy	01APR1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	31JAN1980		Y
		Nervous system disorders	Headache	01JUL1990		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1037 10371011	Psychiatric disorders	Depression	01FEB2008	31JUL2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371012	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN1998		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2008	31DEC2008	N
			Spinal fusion surgery	01JAN2018	31DEC2018	N
	C4591001 1037 10371013	Gastrointestinal disorders	Diarrhoea	01JAN2009		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Fibromyalgia	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371014	Infections and infestations	Onychomycosis	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1037 10371015	Metabolism and nutrition disorders	Obesity	01SEP2014		Y
		Nervous system disorders	Diabetic neuropathy	01AUG2015		Y
		Surgical and medical procedures	Hip arthroplasty	01DEC2019	31DEC2019	N
			Vasectomy	01JAN2014	31JAN2014	N
		Vascular disorders	Hypertension	01JUL2015		Y
	C4591001 1037 10371016	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1037 10371019	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371020	Injury, poisoning and procedural complications	Wrist fracture	01JUL2020	31JUL2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01AUG2015	31AUG2015	N
		Social circumstances	Postmenopause	01JUL2008		Y
		Surgical and medical procedures	Hysterectomy	01AUG2015	31AUG2015	N
				01JAN2008	31DEC2008	N
			Wrist surgery	01JUL2020	31JUL2020	N
	C4591001 1037 10371022	Hepatobiliary disorders	Cholecystitis	01JUN2017	30JUN2017	N
		Metabolism and nutrition disorders	Obesity	01JUN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	31JUL2010		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2017	30JUN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371023	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Cellulitis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01DEC2004		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2011		Y
			Systemic lupus erythematosus	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1037 10371027	Blood and lymphatic system disorders	Anaemia	01JAN1965		Y
		Congenital, familial and genetic disorders	Sickle cell trait	(b) (6) 1955		Y
		Eye disorders	Glaucoma	01FEB1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2015		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG1992		Y
			Osteoarthritis	01APR2018		Y
		Psychiatric disorders	Major depression	01JAN2013	31JAN2018	N
		Reproductive system and breast disorders	Uterine prolapse	01MAR2017	30APR2017	N
		Surgical and medical procedures	Hysterectomy	01APR2017	30APR2017	N
	C4591001 1037 10371030	Blood and lymphatic system disorders	Anaemia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1037 10371031	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
			Irritable bowel syndrome	01FEB2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Rubber sensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1957		Y
		Infections and infestations	Renal tuberculosis	01JAN1988		Y
			Urinary tract infection	19AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Vitamin D deficiency	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2008	31DEC2008	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
			Nephrolithiasis	01DEC2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Urinary control neurostimulator implantation	01NOV2017	30NOV2017	N
	C4591001 1037 10371032	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Endocrine disorders	Hyperthyroidism	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Thyroidectomy	01JAN2019	31DEC2019	N
			Toe amputation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371033	Infections and infestations	Herpes simplex	01AUG1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01AUG2017		Y
			Vitamin D deficiency	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2014		Y
		Nervous system disorders	Diabetic neuropathy	01AUG2019		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Major depression	01JAN2012		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2011	31JAN2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31JAN2012	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1037 10371034	Congenital, familial and genetic disorders	Congenital eye disorder	(b) (6) 1953		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
		Immune system disorders	Food allergy	01APR2010		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypokalaemia	01AUG2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2018		Y
		Nervous system disorders	Sciatica	01JUL2018		Y
		Surgical and medical procedures	Hernia repair	01JAN2004	31JAN2004	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1037 10371036	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2015		Y
			Type 2 diabetes mellitus	31OCT1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007		Y
			Back pain	03DEC2010		Y
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1037 10371039	Cardiac disorders	Coronary artery disease	01JAN2004		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
			Peripheral vascular disorder	01JAN2004		Y
	C4591001 1037 10371040	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
				01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371048	Ear and labyrinth disorders	Deafness	(b) (6) 1953		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Overweight	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2008		Y
			Transient ischaemic attack	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01DEC2017		Y
	C4591001 1037 10371049	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1037 10371053	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1037 10371055	Congenital, familial and genetic disorders	Cerebral palsy	(b) (6) 1952		Y
		Immune system disorders	Drug hypersensitivity	01DEC2013		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypokalaemia	01JAN2005		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Arthritis	01DEC2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	30APR2019	N
		Nervous system disorders	Neuropathy peripheral	01JUN2020		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01JAN2017	30APR2019	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Hysterosalpingo-oophorectomy	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1037 10371059	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Psychiatric disorders	Major depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1037 10371062	Hepatobiliary disorders	Cholestasis	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1982	31DEC1982	N
			Female sterilisation	01JAN1987	31DEC1987	N
	C4591001 1037 10371063	Eye disorders	Glaucoma	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371064	Injury, poisoning and procedural complications	Gun shot wound	01OCT1987	31OCT1987	N
		Psychiatric disorders	Depression	01DEC2019		Y
		Surgical and medical procedures	Removal of foreign body	01OCT1987	31OCT1987	N
	C4591001 1037 10371066	Gastrointestinal disorders	Diverticulum	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Infections and infestations	Hepatitis C	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
			Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Back pain	01JAN2005		Y
			Intervertebral disc disorder	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
			Intervertebral disc operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371069	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371070	Eye disorders	Dry age-related macular degeneration	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y
					31DEC2013	N
			Arthritis	01JAN2009		Y
			Intervertebral disc degeneration	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	28FEB2014	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2013		Y
			Meniscus operation	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
	C4591001 1037 10371071	Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1037 10371075	General disorders and administration site conditions	Hyperplasia	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1037 10371079	Endocrine disorders	Hypothyroidism	01SEP2012		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
			Arthritis	01JAN2012		Y
		Surgical and medical procedures	Ankle operation	01JAN2019	31JAN2019	N
				01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371080	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
			Umbilical hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y
		Surgical and medical procedures	Meniscus operation	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
			Sinus operation	01JAN1995	31DEC1995	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371084	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Knee operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1037 10371085	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal adenoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Facial paralysis	01JAN2007		Y
		Psychiatric disorders	Major depression	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
		Surgical and medical procedures	Adrenalectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1037 10371086	Cardiac disorders	Bradycardia	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Diverticulum	01JAN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2010	31DEC2010	N
			Diverticulectomy	01JAN2012	31DEC2012	N
			Large intestinal polypectomy	01JAN2012	31DEC2012	N
	C4591001 1037 10371089	Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
		Investigations	Arthroscopy	01JAN1987	31DEC1987	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1986		Y
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Vasectomy	01JAN1984	31DEC1984	N
	C4591001 1037 10371090	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2007	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bladder operation	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371091	Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
			Knee operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1037 10371093	Endocrine disorders	Basedow's disease	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
	C4591001 1037 10371094	Congenital, familial and genetic disorders	Congenital spinal cord anomaly	01JAN2009	31DEC2009	N
		Endocrine disorders	Goitre	01JAN2012	31DEC2012	N
			Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
			Hiatus hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01NOV2010	30NOV2010	N
			Uterine cancer	01NOV2009	30NOV2009	N
		Surgical and medical procedures	Cancer surgery	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia hiatus repair	01JAN2009	31DEC2009	N
			Hysterectomy	01NOV2009	30NOV2009	N
			Spinal nerve stimulator implantation	01JAN2017	31DEC2017	N
	C4591001 1037 10371095	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Dry eye	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
			Bronchiectasis	01JUL2015		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1037 10371098	Cardiac disorders	Myocardial infarction	01JAN2019	31DEC2019	N
			Stress cardiomyopathy	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Umbilical hernia	01JAN1960	31DEC1960	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1960	31DEC1960	N
	C4591001 1037 10371099	Cardiac disorders	Supraventricular tachycardia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2007	31DEC2007	N
				01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1994		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2007	31DEC2007	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1037 10371100	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1037 10371101	Gastrointestinal disorders	Abdominal hernia	01JUN2020	09JUN2020	N
		General disorders and administration site conditions	Hyperplasia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Abdominal hernia repair	09JUN2020	09JUN2020	N
			Orchidectomy	01JAN1998	31DEC1998	N
	C4591001 1037 10371102	Endocrine disorders	Hypogonadism	01MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01FEB2005		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1037 10371103	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Hiatus hernia	01JAN2014	28SEP2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2002	31DEC2002	N
			Breast reconstruction	01NOV2003	30NOV2003	N
			Mastectomy	01JAN2003	31DEC2003	N
			Oophorectomy	01JAN2001	31JAN2001	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1037 10371105	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Hip surgery	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371106	Social circumstances	Menopause	01JAN2017		Y
	C4591001 1037 10371107	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1989	31DEC1989	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Colon cancer	01JAN2009	31DEC2009	N
		Social circumstances	Menopause	01JAN1994		Y
		Surgical and medical procedures	Colectomy	01JAN2009	31DEC2009	N
			Mastectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1037 10371108	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Major depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Nasal septal operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1037 10371111	Infections and infestations	Poliomyelitis	01JAN1952	31DEC1952	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2009	28FEB2009	N
		Psychiatric disorders	Insomnia	01JAN1955		Y
		Surgical and medical procedures	Prostatectomy	01FEB2009	28FEB2009	N
		Vascular disorders	Hypertension	01MAR2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371112	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Caesarean section	01DEC1979	31DEC1979	N
			Hysterectomy	01JAN1987	31JAN1987	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1037 10371113	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Intervertebral disc degeneration	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1037 10371114	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371117	General disorders and administration site conditions	Chest pain	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2005	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371119	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371120	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371121	Cardiac disorders	Atrial fibrillation	01AUG2016	31AUG2016	N
		Gastrointestinal disorders	Constipation	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Cardiac ablation	01AUG2016	31AUG2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1037 10371122	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
				01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
			Mastectomy	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
	C4591001 1037 10371123	Endocrine disorders	Autoimmune thyroiditis	01JAN1995	31DEC2010	N
		General disorders and administration site conditions	Cyst	01JAN2000	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC2001	N
		Surgical and medical procedures	Caesarean section	01MAR1990	31MAR1990	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1037 10371127	Endocrine disorders	Hyperparathyroidism	01MAY2019	30JUN2019	N
		Immune system disorders	Drug hypersensitivity	01JUL1959		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2010		Y
			Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31MAR2012	N
		Surgical and medical procedures	Parathyroidectomy	01JUN2019	30JUN2019	N
			Prostatectomy	01MAR2012	31MAR2012	N
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1037 10371128	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1037 10371129	Eye disorders	Glaucoma	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1957	31DEC1957	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2002		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
			Appendectomy	01JAN1957	31DEC1957	N
	C4591001 1037 10371132	Eye disorders	Dry eye	01AUG2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01AUG2020		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013	31DEC2013	N
		Psychiatric disorders	Major depression	01JAN2015		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN2005	31DEC2005	N
	C4591001 1037 10371133	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2018		Y
			Obesity	01JUL2019		Y
		Nervous system disorders	Migraine	01SEP2001		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01DEC2001		Y
		Surgical and medical procedures	Female sterilisation	01JUL1980	31JUL1980	N
		Vascular disorders	Hypertension	01JUL2018		Y
	C4591001 1037 10371134	Cardiac disorders	Coronary artery disease	01JAN1993		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1959		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hyperlipidaemia	01JAN1990		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1989		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN1993	31DEC1993	N
			Coronary arterial stent insertion	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371135	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01MAR1992	31MAR1992	N
			Meniscus operation	01JAN2018	31DEC2018	N
	C4591001 1037 10371136	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371137	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN2000	30APR2017	N
		General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1991		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Surgical and medical procedures	Hernia hiatus repair	01APR2017	30APR2017	N
			Hip arthroplasty	05DEC2016	05DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371139	Gastrointestinal disorders	Intestinal obstruction	01MAY2007	31MAY2007	N
				01MAY2009	31MAY2009	N
		Immune system disorders	Seasonal allergy	01FEB1980		Y
		Metabolism and nutrition disorders	Overweight	01OCT2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01OCT2001	31OCT2001	N
		Surgical and medical procedures	Intestinal operation	01JAN2009	31JAN2009	N
				01MAY2007	31MAY2007	N
			Prostatectomy	01JAN2001	31DEC2001	N
	C4591001 1037 10371141	Cardiac disorders	Cardiac failure congestive	01FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Hypokalaemia	01FEB2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31JAN2019	N
			Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Arterial thrombosis	01FEB2020	29FEB2020	N
			Hypertension	01JAN2010		Y
	C4591001 1037 10371143	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1037 10371144	Cardiac disorders	Tachycardia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2010		Y
		Social circumstances	Menopause	01JAN2011		Y
		Surgical and medical procedures	Shoulder operation	01JAN2019	31DEC2019	N
	C4591001 1037 10371146	Cardiac disorders	Atrial fibrillation	01JAN2011	31DEC2011	N
			Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2013	31DEC2013	N
			Prostate cancer	01JAN2011	31DEC2018	N
			Throat cancer	01MAR2019	31JUL2019	N
		Surgical and medical procedures	Atrial appendage closure	01JAN2012	31DEC2012	N
			Cardiac pacemaker insertion	01JAN2011	31DEC2011	N
			Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2013	31DEC2013	N
	C4591001 1037 10371147	Eye disorders	Blindness unilateral	01MAY1999		Y
			Retinal detachment	01MAY1999	31MAY1999	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01AUG2019	31AUG2020	N
		Nervous system disorders	Cerebrovascular accident	01SEP2018	30SEP2018	N
		Renal and urinary disorders	Urinary incontinence	01SEP2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Retinopexy	01MAY1999	31MAY1999	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1037 10371149	Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371151	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Major depression	01JAN2018		Y
		Surgical and medical procedures	Acoustic neuroma removal	01JAN2016	31DEC2016	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1037 10371153	Cardiac disorders	Arrhythmia	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1988		Y
	C4591001 1037 10371156	Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371158	Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2002		Y
			Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Tobacco user	01AUG2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31MAR2010	N
				01MAR2010	31MAR2010	N
			Hysterectomy	01JAN1994	31JAN1994	N
		Vascular disorders	Hypertension	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN1996		Y
	C4591001 1037 10371159	Injury, poisoning and procedural complications	Joint injury	01AUG2019	31AUG2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2007	31DEC2007	N
			Prostate cancer	01MAR2017	31MAR2017	N
		Psychiatric disorders	Major depression	01JAN2010		Y
		Surgical and medical procedures	Colectomy	01JAN2007	31DEC2007	N
			Knee arthroplasty	01AUG2019	31AUG2019	N
			Prostatectomy	01MAR2017	31MAR2017	N
			Thyroidectomy	01JAN1996	31DEC1996	N
	C4591001 1037 10371160	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2010		Y
			Irritable bowel syndrome	01SEP2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN1994		Y
			Large intestine infection	01MAR2020	30APR2020	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
			Osteoporosis	01JAN1999		Y
		Nervous system disorders	Autonomic nervous system imbalance	01JUL2016		Y
			Complex regional pain syndrome	01JUL1998		Y
		Psychiatric disorders	Anxiety	01SEP2016		Y
			Depression	01JUL2010		Y
			Insomnia	01SEP2019		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1995	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Rhinoplasty	01JAN1973	31DEC1973	N
	C4591001 1037 10371161	Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
	C4591001 1037 10371162	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1037 10371163	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01MAR1995		Y
	C4591001 1037 10371164	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1037 10371165	Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
		Eye disorders	Glaucoma	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hypercholesterolaemia	01JAN1980		Y
			Obesity	01JAN1990		Y
		Nervous system disorders	Normal pressure hydrocephalus	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
			Ventriculo-peritoneal shunt	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1037 10371166	Immune system disorders	Seasonal allergy	01FEB1965		Y
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1037 10371167	Immune system disorders	Drug hypersensitivity	01FEB2018		Y
	C4591001 1037 10371171	Endocrine disorders	Hypothyroidism	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	31DEC2018	N
			Thyroid cancer	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Mastectomy	01JAN2018	31DEC2018	N
			Thyroidectomy	01JAN2017	31DEC2017	N
	C4591001 1037 10371173	Infections and infestations	Onychomycosis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371174	Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31JAN1995	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2012	30JUN2012	N
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Ligament operation	01JAN1995	31JAN1995	N
			Mastectomy	01JUN2012	30JUN2012	N
	C4591001 1037 10371175	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Overweight	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Sleep apnoea syndrome	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371177	Surgical and medical procedures	Prostatectomy	01JAN2008	31DEC2008	N
		Eye disorders	Cataract	01JAN2008	31DEC2009	N
			Glaucoma	01JAN1989		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	26SEP2016	N
		Surgical and medical procedures	Cataract operation	01JAN2009	31DEC2009	N
			Transurethral prostatectomy	26SEP2016	26SEP2016	N
			Vasectomy	01JAN1985	31DEC1985	N
			Cholelithiasis	01JAN1990		Y
	C4591001 1037 10371178	Hepatobiliary disorders	Cholelithiasis	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	04AUG2020		Y
	C4591001 1037 10371181	Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JUL1960		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2018		Y
			Osteoarthritis	01SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tenoplasty	01JAN1995	31DEC1995	N
	C4591001 1037 10371182	Gastrointestinal disorders	Haemorrhoids	01JAN2000	31JAN2000	N
			Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01MAY1990		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2000	31JAN2000	N
			Hysterectomy	01MAR2017	31MAR2017	N
			Inguinal hernia repair	01JAN2010	31JAN2010	N
	C4591001 1037 10371184	Eye disorders	Pigment dispersion syndrome	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
			Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1037 10371185	Gastrointestinal disorders	Splenic artery aneurysm	01SEP2017	30SEP2017	N
		Surgical and medical procedures	Arterial aneurysm repair	01SEP2017	30SEP2017	N
	C4591001 1037 10371186	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Metabolism and nutrition disorders	Postprandial hypoglycaemia	01JAN1960		Y
			Vitamin D deficiency	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01OCT2014	31OCT2014	N
			Osteoarthritis	01JAN2007		Y
		Psychiatric disorders	Anxiety	01FEB2005		Y
			Major depression	01FEB2005		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01OCT2013	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01OCT2014	31DEC2014	N
			Intervertebral disc operation	01JAN2014	31DEC2014	N
			Spinal laminectomy	01OCT2014	31OCT2014	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1037 10371187	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
			Umbilical hernia	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1943		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
		Renal and urinary disorders	Urethral stenosis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Meniscus operation	01JAN1995	31DEC1995	N
			Prostatic urethral lift procedure	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1037 10371188	Blood and lymphatic system disorders	Anaemia	01JAN2001		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2013	31DEC2013	N
		Renal and urinary disorders	Urinary retention	01JAN2013		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2013	31DEC2013	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1037 10371189	Immune system disorders	Seasonal allergy	01JAN1969		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2020	31JAN2020	N
		Psychiatric disorders	Major depression	01JAN2016		Y
		Surgical and medical procedures	Muscle operation	01JAN2015	31DEC2015	N
			Toe operation	01JAN2020	31JAN2020	N
			Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1037 10371190	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2005		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Spinal fusion surgery	01DEC2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1037 10371191	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Sinuplasty	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371193	Cardiac disorders	Myocardial infarction	01JAN1996	31DEC1996	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1037 10371194	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1965		Y
		Renal and urinary disorders	Urinary retention	01JAN2018		Y
	C4591001 1037 10371195	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371196	Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01MAR2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01SEP2000		Y
	C4591001 1037 10371197	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC2000	N
		Psychiatric disorders	Panic attack	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Gastric bypass	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1037 10371203	Gastrointestinal disorders	Rectal prolapse	01JAN2004	31JAN2009	N
		Infections and infestations	Urinary tract infection	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2010		Y
			Overweight	01SEP2015		Y
			Vitamin B12 deficiency	01JAN2012		Y
			Vitamin D deficiency	01JAN2012		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2004	31JAN2009	N
			Urinary tract pain	01JAN2018		Y
		Social circumstances	Postmenopause	01JUN1997		Y
		Surgical and medical procedures	Colporrhaphy	01JAN2009	31JAN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371205	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JUL2020	18SEP2020	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Nephrectomy	01JAN2009	31DEC2009	N
	C4591001 1037 10371206	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1951		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
			Tonsil cancer	01JAN2003	31DEC2003	N
	C4591001 1037 10371207	Eye disorders	Glaucoma	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Migraine	01OCT2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
	C4591001 1037 10371211	Injury, poisoning and procedural complications	Cardiac valve rupture	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Mitral valve repair	01JAN2009	31DEC2009	N
	C4591001 1037 10371212	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2002		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371213	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371217	Gastrointestinal disorders	Umbilical hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Reaction to colouring	01JAN2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Overweight	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1999	31DEC2001	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
				01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2001	31DEC2001	N
			Umbilical hernia repair	01JAN2005	31DEC2005	N
	C4591001 1037 10371218	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371224	Eye disorders	Eye disorder	(b) (6) 1952		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1037 10371226	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Social circumstances	Postmenopause	01MAR2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1037 10371227	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371228	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01OCT2010	31OCT2010	N
		Surgical and medical procedures	Hysterectomy	01OCT2010	31OCT2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAY2000		Y
	C4591001 1037 10371229	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Periodic limb movement disorder	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1037 10371233	Immune system disorders	Seasonal allergy	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
	C4591001 1037 10371234	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JUN1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2006		Y
			Hypokalaemia	01JUN2006		Y
			Obesity	01JUN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAY2017	31MAY2017	N
		Psychiatric disorders	Tobacco abuse	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2006	31JAN2006	N
			Prostatectomy	01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01JUN2006		Y
	C4591001 1037 10371235	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
	C4591001 1037 10371239	Endocrine disorders	Primary hypogonadism	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hyperlipidaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1037 10371242	Gastrointestinal disorders	Dyspepsia	01JAN1972		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Vitamin D deficiency	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1037 10371243	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2011		Y
			Migraine	01JAN2011		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1037 10371244	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1992		Y
			Osteoarthritis	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Shoulder arthroplasty	01JUL2020	31JUL2020	N
	C4591001 1037 10371248	Congenital, familial and genetic disorders	Congenital musculoskeletal anomaly	(b) (6) 1956	31DEC1985	N
		Ear and labyrinth disorders	Vertigo	01JAN2020		Y
		Infections and infestations	Tonsillitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Tenoplasty	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371251	Metabolism and nutrition disorders	Obesity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31JAN2015	N
		Surgical and medical procedures	Cancer surgery	01JAN2015	31JAN2015	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1037 10371252	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1037 10371260	Eye disorders	Dry eye	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371261	Cardiac disorders	Angina pectoris	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01MAR2003		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000	31MAR2003	N
		Social circumstances	Postmenopause	01JAN1988		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Knee arthroplasty	01MAR2003	31MAR2003	N
	C4591001 1037 10371263	Eye disorders	Cataract	01JAN2016	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371264	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1987	31DEC1987	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1037 10371267	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	12AUG2020		Y
		Infections and infestations	Hepatitis C	01JAN1988	31DEC2003	N
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019	11AUG2020	N
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign pancreatic neoplasm	01JAN2003	31DEC2003	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Pancreaticoduodenectomy	01JAN2003	31DEC2003	N
			Spinal decompression	11AUG2020	11AUG2020	N
	C4591001 1037 10371268	Blood and lymphatic system disorders	Anaemia	01MAR2020		Y
		Cardiac disorders	Coronary artery disease	01JUN2010		Y
			Myocardial infarction	01JUN2010	30JUN2010	N
		Eye disorders	Glaucoma	22JUN2013		Y
		Nervous system disorders	Migraine	12MAY2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	22OCT1988	22OCT1988	N
		Vascular disorders	Hypertension	23JAN2009		Y
	C4591001 1037 10371270	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Vitamin A deficiency	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
			Tobacco abuse	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1037 10371273	Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
				01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1037 10371274	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Cholecystitis infective	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN1963		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1037 10371275	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2008		Y
			Major depression	01JAN2005		Y
	C4591001 1037 10371276	Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01AUG2018	31AUG2018	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2019	31JAN2019	N
	C4591001 1037 10371278	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Obesity	01FEB1996	29FEB2004	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	31JAN2004	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2004	31JAN2004	N
			Gastric bypass	01FEB2004	29FEB2004	N
			Hysterectomy	01JAN2009	31JAN2009	N
	C4591001 1037 10371279	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1993		Y
			Obesity	01JAN1990		Y
		Surgical and medical procedures	Coronary artery bypass	04MAY2015	04MAY2015	N
			Vasectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371280	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2008	31MAY2008	N
		Surgical and medical procedures	Spinal fusion surgery	01MAY2008	31MAY2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371281	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
			Bursitis	07SEP2020		Y
			Exostosis	01JAN2008	31DEC2008	N
			Osteopenia	01JAN2019		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2008	31DEC2008	N
			Tenotomy	01JAN2008	31DEC2008	N
	C4591001 1037 10371282	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
			Pancreatic carcinoma	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Mastectomy	01JAN2009	31DEC2009	N
			Pancreatectomy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1037 10371283	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
			Spinal stenosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hip arthroplasty	01DEC2007	31DEC2007	N
				01JAN2015	31JAN2015	N
	C4591001 1037 10371292	Eye disorders	Cataract	01JAN1991	31DEC1991	N
			Retinal detachment	01JAN1994	31DEC1994	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Vertebral foraminal stenosis	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Cataract operation	01JAN1991	31DEC1991	N
			Retinopexy	01JAN1994	31DEC1994	N
			Spinal laminectomy	01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1037 10371293	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1037 10371294	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Surgical and medical procedures	Hip surgery	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1984	31DEC1984	N
	C4591001 1037 10371295	Endocrine disorders	Hyperparathyroidism	01JAN2014	31MAY2015	N
		Immune system disorders	Food allergy	01JAN1961		Y
			Seasonal allergy	01JAN1961		Y
		Metabolism and nutrition disorders	Gout	01JAN2003		Y
			Hyperlipidaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2015	31MAY2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1037 10371297	Eye disorders	Cataract	01JAN2007	31DEC2007	N
			Dry eye	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01MAR2020		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1037 10371299	Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1037 10371303	Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371304	Hepatobiliary disorders	Cholelithiasis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1037 10371305	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JUL2020		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2016		Y
			Rotator cuff repair	01JAN2005	31DEC2005	N
	C4591001 1037 10371311	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1977		Y
	C4591001 1037 10371318	Cardiac disorders	Myocardial infarction	01JAN2009	31DEC2009	N
		Eye disorders	Cataract	01JAN2018		Y
		General disorders and administration site conditions	Chest pain	01JAN2009		Y
		Infections and infestations	Hepatitis B	01JAN1968	31DEC2014	N
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1037 10371320	Cardiac disorders	Tachycardia	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2013	31DEC2013	N
				01NOV2018	30NOV2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1037 10371322	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	03DEC1980	03DEC1980	N
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1037 10371329	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Endocrine disorders	Goitre	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01FEB2020		Y
			Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31MAR2016	N
		Surgical and medical procedures	Myomectomy	01MAR2016	31MAR2016	N
			Percutaneous coronary intervention	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1037 10371333†	Gastrointestinal disorders	Abdominal hernia	01AUG2017	31AUG2017	N
		Immune system disorders	Seasonal allergy	01APR1970		Y
		Infections and infestations	Hepatitis B	01JAN1979	31DEC1979	N
		Investigations	HIV test positive	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
			Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUL2019	31JUL2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Major depression	01JUN1979		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2009		Y
		Surgical and medical procedures	Abdominal hernia repair	01AUG2017	31AUG2017	N
			Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JUL2019	31JUL2019	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1037 10371334	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Investigations	Biopsy breast	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
	C4591001 1037 10371335	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371338	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1037 10371339	Gastrointestinal disorders	Diverticulum	01SEP2000		Y
		Infections and infestations	Diverticulitis	05OCT2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Somnolence	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2015		Y
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1037 10371345	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01FEB1977	28FEB1977	N
		Surgical and medical procedures	Salpingectomy	01FEB1977	28FEB1977	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1037 10371354	Immune system disorders	Drug hypersensitivity	01AUG1980		Y
		Infections and infestations	Appendicitis	01AUG1972	31AUG1972	N
		Nervous system disorders	Intracranial aneurysm	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01MAY2012	30SEP2017	N
			Depression	01JAN2012	30SEP2017	N
		Surgical and medical procedures	Appendicectomy	01AUG1972	31AUG1972	N
			Intra-cerebral aneurysm operation	01FEB2020	29FEB2020	N
	C4591001 1037 10371356	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381007	Hepatobiliary disorders	Hepatic steatosis	15AUG2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal tract adenoma	01JAN2000	31DEC2000	N
			Seborrhoeic keratosis	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1038 10381009	Cardiac disorders	Arteriosclerosis coronary artery	01APR2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2010		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Renal and urinary disorders	Nocturia	01JAN2018		Y
		Surgical and medical procedures	Coronary artery bypass	01JUL2012	31JUL2012	N
	C4591001 1038 10381015	Endocrine disorders	Hypothyroidism	29JAN2002		Y
		Infections and infestations	Sinusitis	01JAN2006		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	17APR2015		Y
			Hyperlipidaemia	15OCT2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	17FEB2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc degeneration	02DEC2014		Y
		Psychiatric disorders	Anxiety disorder	17FEB2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	17FEB2006		Y
	C4591001 1038 10381017	Metabolism and nutrition disorders	Glucose tolerance impaired	29OCT2009		Y
			Hyperlipidaemia	16NOV2011		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	03JUL2017		Y
		Vascular disorders	Essential hypertension	29MAR2019		Y
	C4591001 1038 10381019	Metabolism and nutrition disorders	Hyperlipidaemia	19NOV2007		Y
			Type 2 diabetes mellitus	06NOV2007		Y
		Psychiatric disorders	Generalised anxiety disorder	19NOV2007		Y
			Insomnia	09SEP2009		Y
		Reproductive system and breast disorders	Breast calcifications	10DEC2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	03MAR2009		Y
		Skin and subcutaneous tissue disorders	Granuloma annulare	30MAY2014		Y
		Surgical and medical procedures	Hysterectomy	01FEB2007	28FEB2007	N
		Vascular disorders	Essential hypertension	06NOV2007		Y
	C4591001 1038 10381021	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2011		Y
		Hepatobiliary disorders	Hepatic steatosis	04SEP2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10MAY2006		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	28DEC2011		Y
		Psychiatric disorders	Anxiety	13FEB2014		Y
		Surgical and medical procedures	Anticoagulant therapy	01JAN2004		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	25OCT2018	25OCT2018	N
		Vascular disorders	Hypertension	20APR2006		Y
	C4591001 1038 10381025	Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01OCT2017	31OCT2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01OCT2005		Y
		Surgical and medical procedures	Blepharoplasty	01FEB2019	28FEB2019	N
			Tenoplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1038 10381026	Blood and lymphatic system disorders	Thrombocytopenia	01MAR2013		Y
		Cardiac disorders	Arteriosclerosis coronary artery	06MAR2014		Y
		General disorders and administration site conditions	Oedema peripheral	01MAY2018		Y
		Metabolism and nutrition disorders	Gout	01MAR2013		Y
			Hyperlipidaemia	25JUL2005		Y
			Type 2 diabetes mellitus	06MAR2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	23MAY2018		Y
			Osteoarthritis	08JUN2007		Y
			Pain in extremity	23MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	08FEB2010		Y
		Renal and urinary disorders	Chronic kidney disease	06MAR2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12SEP2017		Y
	C4591001 1038 10381030	Vascular disorders	Essential hypertension	17FEB2012		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1038 10381031	Vascular disorders	Hypertension	01JAN2015		Y
		Eye disorders	Non-proliferative retinopathy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01DEC1993		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01JAN2015		Y
			Skin cancer	01JAN2020	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1038 10381032	Skin and subcutaneous tissue disorders	Actinic keratosis	01FEB2020		Y
		Injury, poisoning and procedural complications	Foot fracture	18MAY2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	14DEC2005		Y
			Spinal osteoarthritis	09OCT2017		Y
	C4591001 1038 10381033	Social circumstances	Postmenopause	01JAN1990		Y
		Cardiac disorders	Atrial flutter	01JAN2010		Y
		Gastrointestinal disorders	Diverticulum intestinal	01JAN2019		Y
			Haemorrhoids	01JAN2019		Y
		Investigations	Carotid bruit	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Osteoporosis	01JAN2019		Y
		Reproductive system and breast disorders	Cystocele	01JAN2017		Y
	C4591001 1038 10381034	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1038 10381035	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Essential tremor	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1038 10381037	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1038 10381040	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN2000		Y
	C4591001 1038 10381041	Blood and lymphatic system disorders	Anaemia	03NOV2017		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN1981		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract diabetic	01JAN2010		Y
			Diabetic retinopathy	01JAN2000		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Large intestine polyp	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1995		Y
			Vitamin B12 deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2014	31JAN2014	N
	C4591001 1038 10381046	Gastrointestinal disorders	Dyspepsia	01DEC2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Vascular disorders	Essential hypertension	01JAN2000		Y
	C4591001 1038 10381047	Immune system disorders	Seasonal allergy	01DEC2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Muscle spasms	01JAN2013		Y
		Social circumstances	Postmenopause	01DEC2006		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2017	31DEC2017	N
			Female sterilisation	01DEC1982	31DEC1982	N
			Wrist surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01DEC2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381050	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Dysaesthesia	01DEC2019		Y
		Psychiatric disorders	Nicotine dependence	01DEC1975		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	07NOV2014		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Fracture treatment	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1038 10381051	General disorders and administration site conditions	Pain	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Facet joint syndrome	01JAN1996	31DEC1996	N
			Osteoarthritis	01JAN2014		Y
			Trigger finger	01FEB2020		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
			Lumbar radiculopathy	01JAN1996		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2019	31DEC2019	N
				01JAN2018	31DEC2018	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal fusion surgery	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1038 10381055	Infections and infestations	Oral herpes	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JUL2020	31JUL2020	N
		Vascular disorders	Essential hypertension	01JAN1980		Y
	C4591001 1038 10381056	Endocrine disorders	Thyroid mass	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	15JUN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	08OCT2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	12MAY2011		Y
		Renal and urinary disorders	Nocturia	24JUL2020		Y
		Surgical and medical procedures	Thyroidectomy	01MAR2010	31MAR2010	N
	C4591001 1038 10381062	Gastrointestinal disorders	Barrett's oesophagus	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1038 10381064	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N
			Ligament operation	01JAN2014	31DEC2014	N
	C4591001 1038 10381066	Cardiac disorders	Coronary artery disease	01JAN1981		Y
			Mitral valve prolapse	01DEC1981		Y
		Ear and labyrinth disorders	Deafness neurosensory	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1987		Y
			Osteoarthritis	01JAN1997		Y
			Osteoporosis	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary granuloma	01JAN1981		Y
		Surgical and medical procedures	Elbow operation	01JAN1999	31DEC1999	N
			Wrist surgery	01JAN1999	31DEC1999	N
		Vascular disorders	Aortic arteriosclerosis	01JAN1981		Y
	C4591001 1038 10381068	General disorders and administration site conditions	Oedema peripheral	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN1974	31DEC1974	N
	C4591001 1038 10381072	Injury, poisoning and procedural complications	Ankle fracture	01MAY2019	01MAY2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Foot operation	01MAY2019	01MAY2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1038 10381073	Immune system disorders	Seasonal allergy	05APR2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	25APR2017		Y
		Nervous system disorders	Tremor	24JUL2019		Y
		Surgical and medical procedures	Lipoma excision	01JAN2017	31DEC2017	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
			Shoulder operation	01JUN2019	30JUN2019	N
	C4591001 1038 10381074	Endocrine disorders	Hypogonadism male	01JAN2017		Y
		Investigations	Arthroscopy	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Metatarsalgia	20MAR2020		Y
		Nervous system disorders	Memory impairment	24FEB2020		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2000	31DEC2000	N
			Wrist surgery	01JAN2017	31DEC2017	N
	C4591001 1038 10381081	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1038 10381084	Blood and lymphatic system disorders	Thrombocytopenia	06APR2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16JUN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16AUG2011		Y
		Nervous system disorders	Sciatica	06APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Snoring	24AUG2011		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	27JUL2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Essential hypertension	16JAN2016		Y
	C4591001 1038 10381086	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
		Nervous system disorders	Ischaemic stroke	01OCT2015	31OCT2015	N
			Migraine with aura	01JAN2018		Y
		Psychiatric disorders	Sleep disorder	01JAN2000		Y
		Surgical and medical procedures	Aortic valve replacement	01FEB2016	29FEB2016	N
			Cardiac ablation	01FEB2020	29FEB2020	N
			Coronary artery bypass	01FEB2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1038 10381089	Eye disorders	Open angle glaucoma	02JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seborrhoeic keratosis	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN1990	31DEC1990	N
			Limb operation	01JAN1995	31DEC1995	N
		Vascular disorders	Aortic arteriosclerosis	01MAR2018		Y
			Essential hypertension	01JAN2017		Y
	C4591001 1038 10381090	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Abdominal migraine	05SEP2008		Y
			Gastroesophageal reflux disease	12AUG2014		Y
			Irritable bowel syndrome	12AUG2014		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
			Rhinitis	05SEP2008		Y
		Injury, poisoning and procedural complications	Incisional hernia	30JAN2017	31DEC2018	N
		Investigations	Blood glucose abnormal	30SEP2019		Y
			Mammogram abnormal	05SEP2017	05SEP2017	N
		Metabolism and nutrition disorders	Hyperglycaemia	15AUG2017		Y
			Hyperlipidaemia	10AUG2016		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2018		Y
		Reproductive system and breast disorders	Breast fibrosis	05SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	30JAN2017	30JUN2017	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	12AUG2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381101	Injury, poisoning and procedural complications	Sports injury	01JAN1963	31DEC2006	N
		Metabolism and nutrition disorders	Hyperlipidaemia	27DEC2018		Y
			Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Bursitis	20JUN2017		Y
			Rotator cuff syndrome	23FEB2017		Y
		Nervous system disorders	Carpal tunnel syndrome	20DEC2017		Y
			Lumbar radiculopathy	22DEC2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01MAR2019	31DEC2019	N
			Knee operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	14MAR2009		Y
	C4591001 1038 10381104	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1038 10381107	Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hyperlipidaemia	01JAN2010		Y
		Renal and urinary disorders	Urine flow decreased	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1038 10381108	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Osteoporosis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1965		Y
			Vertebral artery occlusion	01JAN2017		Y
			Vertebral artery stenosis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2018		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
			Cardiac ablation	01JAN2016	31DEC2016	N
	C4591001 1038 10381113	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	09SEP2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	23MAY2018		Y
		General disorders and administration site conditions	Fatigue	12JUN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	16JAN2017		Y
		Nervous system disorders	Hypersomnia	09APR2018		Y
		Psychiatric disorders	Anxiety	07JUL2020		Y
			Insomnia	09SEP2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1038 10381122	Ear and labyrinth disorders	Vertigo	12FEB2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	30APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	11MAY2009		Y
			Osteopenia	04MAR2019		Y
		Psychiatric disorders	Insomnia	30JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	30APR2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1038 10381123	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2000		Y
			Vitamin B12 deficiency	01JAN1998		Y
			Vitamin D deficiency	01MAY2020		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2000		Y
			Nephropathy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1995	31DEC1995	N
				01JAN1997	31DEC1997	N
		Vascular disorders	Essential hypertension	01JAN2000		Y
	C4591001 1038 10381124	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1038 10381126	Cardiac disorders	Coronary artery disease	13AUG2017		Y
			Myocardial infarction	13AUG2017	13AUG2017	N
		Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Catheterisation cardiac	13AUG2017	31AUG2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	31JUL2020	N
		Psychiatric disorders	Anxiety	01SEP2017		Y
			Depression	01SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Essential hypertension	01JAN1990		Y
	C4591001 1038 10381134	Cardiac disorders	Aortic valve incompetence	01JAN2000		Y
		Investigations	Blood calcium increased	01JAN2010		Y
			Blood cholesterol increased	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1038 10381135	Ear and labyrinth disorders	Tinnitus	22FEB2017		Y
		Endocrine disorders	Hypothyroidism	22MAR2013		Y
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
			Rhinitis	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23FEB2005		Y
			Obesity	17JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	22FEB2017		Y
		Reproductive system and breast disorders	Prostatomegaly	22FEB2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	29AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1038 10381139	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1039 10391001	Endocrine disorders	Hyperthyroidism	01JAN2008	31DEC2008	N
			Hypothyroidism	01JAN2008		Y
		Eye disorders	Myopia	01JAN1963		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2003	N
		Nervous system disorders	Cluster headache	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1955	31DEC1955	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2012		Y
			Varicose vein	01JAN2010		Y
	C4591001 1039 10391005	Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1039 10391006	Ear and labyrinth disorders	Auditory disorder	01JAN1958		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2000	31DEC2015	N
			Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2020		Y
			Osteoporosis	01JAN2020		Y
			Spinal osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2010	31MAY2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010	31MAY2020	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1039 10391010	Cardiac disorders	Coronary artery disease	01JUL2016		Y
		Ear and labyrinth disorders	Auditory disorder	01JAN2020		Y
		Eye disorders	Cataract	01JAN2013	31DEC2013	N
			Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Nervous system disorders	Carotid artery stenosis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1955		Y
		Social circumstances	Corrective lens user	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN1960		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391012	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN1977		Y
		Eye disorders	Cataract	01JAN2003		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2019		Y
			Prostate cancer	01JAN2003		Y
			Skin cancer	01JAN2006		Y
		Nervous system disorders	Essential tremor	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Vascular disorders	Deep vein thrombosis	01JAN1977		Y
	C4591001 1039 10391013	Ear and labyrinth disorders	Auditory disorder	01JAN2012		Y
		Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastrointestinal pain	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2018	31DEC2018	N
		Social circumstances	Hearing aid user	01JAN2012		Y
		Surgical and medical procedures	Cholelithotomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391015	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1975	31DEC1980	N
				01JAN2010	31DEC2010	N
					31DEC2018	N
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Meniscus operation	01JAN1980	31DEC2018	N
				01JAN2010	31DEC2010	N
				01OCT2018	31OCT2018	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
				01OCT2018	31OCT2018	N
	C4591001 1039 10391018	Gastrointestinal disorders	Large intestine perforation	01JAN2008	31DEC2008	N
			Small intestinal perforation	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Neck pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N
			Eye laser surgery	01JAN2008		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01AUG2018	01AUG2018	N
				01JAN2015	31DEC2015	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1039 10391019	Eye disorders	Cataract	01JAN2020		Y
			Presbyopia	01MAR2020		Y
		Gastrointestinal disorders	Colitis microscopic	01JAN2012		Y
			Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1987	31DEC1987	N
			Osteopenia	01JAN2018		Y
			Rheumatoid arthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Blood donor	01JAN1978		Y
	C4591001 1039 10391020	Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	30MAR2018		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN1990	31DEC2005	N
		Surgical and medical procedures	Eye laser surgery	01JAN1983	31DEC2010	N
	C4591001 1039 10391023	Eye disorders	Myopia	01JAN1969		Y
		General disorders and administration site conditions	Cyst	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Knee operation	01JAN2009	31DEC2009	N
			Oophorectomy	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1039 10391024	Eye disorders	Myopia	01JAN2020		Y
		General disorders and administration site conditions	Ulcer	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Muscular weakness	01JAN2019		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391027	Ear and labyrinth disorders	Tinnitus	01JAN1990		Y
		Eye disorders	Cataract	01JAN2005		Y
		General disorders and administration site conditions	Hernia	01JAN1970	31DEC1970	N
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Dental cosmetic procedure	01JAN2019		Y
	C4591001 1039 10391030	Eye disorders	Cataract	01JAN2018		Y
			Glaucoma	01JAN1994		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1993		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperuricaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1989		Y
			Rosacea	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
			Tobacco user	01JAN1975		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391031	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
			Menopause	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
			Cholecystectomy	01JAN1994	31DEC1994	N
	C4591001 1039 10391032	Eye disorders	Cataract	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
			Pharyngo-oesophageal diverticulum	01JAN2010	31DEC2011	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
			Seasonal allergy	01JAN1998		Y
		Infections and infestations	Herpes simplex	01JAN2004		Y
		Investigations	Blood cholesterol increased	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2002		Y
		Renal and urinary disorders	Hypertonic bladder	01FEB2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Eye laser surgery	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Mammoplasty	01JAN1975		Y
				01JUN2019		Y
			Pharyngeal operation	01JAN2011	31DEC2011	N
			Urinary bladder suspension	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391033	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Laparoscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1980	31DEC1992	N
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1039 10391034	Eye disorders	Eyelid ptosis	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Coeliac disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Hepatitis A	01JAN1987	31DEC1987	N
		Investigations	Biopsy skin	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1970	31DEC1970	N
			Squamous cell carcinoma	01JAN1970	31DEC1970	N
		Nervous system disorders	Seizure	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1957		Y
		Social circumstances	Corrective lens user	01JAN1970		Y
			Menopause	01JAN2010		Y
		Surgical and medical procedures	Cartilage operation	01JAN2014	31DEC2014	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Eyelid operation	01JAN2000	31DEC2000	N
	C4591001 1039 10391035	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Ear and labyrinth disorders	Auditory disorder	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vertigo	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Heart rate irregular	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2015	N
			Squamous cell carcinoma of skin	01JAN2010	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012	31DEC2019	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1039 10391037	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2016		Y
			Panic disorder	01JAN1989		Y
		Renal and urinary disorders	Renal impairment	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391038	Ear and labyrinth disorders	Auditory disorder	01JAN1949		Y
		Endocrine disorders	Hypogonadism	01JAN2004		Y
			Hypothyroidism	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Neck pain	01JAN2010		Y
			Osteoarthritis	01JAN2004		Y
			Osteopenia	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015	31DEC2017	N
			Erectile dysfunction	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1958	31DEC1968	N
		Surgical and medical procedures	Prostatic operation	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391039	Eye disorders	Cataract	01JAN2013		Y
		Investigations	Biopsy breast	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1039 10391040	Eye disorders	Presbyopia	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
			Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN1975		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1039 10391041	Investigations	Colonoscopy	23APR2019	23APR2019	N
		Metabolism and nutrition disorders	Gout	01JAN2005	31DEC2005	N
			Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1974		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1996		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1974		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
			Tobacco user	01JAN1966	31DEC2016	N
		Surgical and medical procedures	Carpal tunnel decompression	01AUG2015	31AUG2015	N
			Hernia repair	01JAN2008		Y
			Spinal operation	01DEC1985	31DEC1985	N
	C4591001 1039 10391042	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Eye disorders	Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1966	31DEC1966	N
			Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol	01JAN2006		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1988		Y
			Spinal pain	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Attention deficit hyperactivity disorder	01JAN2011	31DEC2020	N
			Depression	01JAN2011		Y
			Insomnia	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2016		Y
			Rosacea	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Eye laser surgery	01JAN1998	31DEC1998	N
			Hernia repair	01JAN1966	31DEC1966	N
	C4591001 1039 10391043	Cardiac disorders	Angina pectoris	01JAN2010	31DEC2015	N
			Palpitations	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Cataract	27AUG2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Tonsillitis	27AUG2009		Y
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01SEP2017	30SEP2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Respiratory disorder	01JAN2016		Y
			Rhinitis allergic	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2020		Y
		Surgical and medical procedures	Appendectomy	01DEC1986	31DEC2018	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Knee operation	01JAN2018	31DEC2018	N
			Thyroidectomy	01DEC1985	31DEC1985	N
			Tonsillectomy	01MAR2009	31MAR2009	N
		Vascular disorders	Hypertension	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391044	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1956		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	05JUN2019		Y
	C4591001 1039 10391046	Eye disorders	Presbyopia	01JAN2020		Y
		Gastrointestinal disorders	Dysphagia	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1960		Y
		Social circumstances	Corrective lens user	01JAN2020		Y
	C4591001 1039 10391047	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
			Inguinal hernia	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2001		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Neck pain	01JAN2016		Y
			Tendonitis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1969		Y
			Hearing aid user	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1039 10391049	Eye disorders	Macular degeneration	01JAN1997	31DEC1997	N
			Retinal detachment	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Hiatus hernia	01JAN2019		Y
			Oesophageal achalasia	01JAN2007		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2007		Y
		Infections and infestations	Bronchitis	01JAN1979	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1969	31DEC2016	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1988		Y
				01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1962		Y
		Surgical and medical procedures	Cataract operation	01OCT2019	31DEC2019	N
			Ligament operation	01JAN1984	31DEC1984	N
			Vision correction operation	01JAN1962		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1039 10391050	Cardiac disorders	Bradyarrhythmia	01JAN1965		Y
		Eye disorders	Presbyopia	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1970	31DEC1990	N
		Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
			Micrographic skin surgery	01JAN2015	31DEC2015	N
	C4591001 1039 10391051	Congenital, familial and genetic disorders	Ichthyosis	(b) (6) 1951		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Investigations	Blood uric acid increased	01JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Osteopenia	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN1964		Y
		Psychiatric disorders	Anxiety	01JAN1981		Y
			Depression	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2018	31DEC2020	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1039 10391052	Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Glaucoma	01FEB2020		Y
			Myopia	01JAN1967		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1967		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1039 10391053	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Congenital, familial and genetic disorders	Bicuspid aortic valve	01JAN2006		Y
		Eye disorders	Presbyopia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Infections and infestations	Diverticulitis	01JAN2000		Y
			Hepatitis A	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip and/or oral cavity cancer	01JAN2019	31DEC2019	N
			Skin cancer	01JAN2018	31DEC2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1985		Y
		Surgical and medical procedures	Limb operation	01JAN2004	31DEC2004	N
			Tenoplasty	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Thrombosis	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391054	Gastrointestinal disorders	Abdominal hernia	01JAN1960	31DEC1960	N
		Infections and infestations	Hepatitis C	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2003	31DEC2005	N
			Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010		Y
				11APR2017	31DEC2017	N
				23FEB2016	31DEC2016	N
			Squamous cell carcinoma of skin	10NOV2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
				01MAY2013		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015	31MAR2020	N
		Surgical and medical procedures	Hernia repair	01JAN1960	31DEC1960	N
				01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391055	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Glaucoma	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2020	30JUN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1039 10391056	Cardiac disorders	Ventricular extrasystoles	01JAN2018		Y
		Eye disorders	Cataract	01DEC2019	31JAN2020	N
			Glaucoma	01JAN2013		Y
			Myopia	01JAN1958		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Investigations	Biopsy skin	01JAN2002	31DEC2002	N
				01JAN2009	31DEC2009	N
			Colonoscopy	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Gout	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2015		Y
			Tendonitis	29JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2002	N
				01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2007		Y
		Social circumstances	Organ donor	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Nephrectomy	01JAN2009	31DEC2009	N
			Skin neoplasm excision	01JAN2002	31DEC2002	N
				01JAN2009	31DEC2009	N
		Vascular disorders	Aortic dilatation	04MAY2018		Y
	C4591001 1039 10391059	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Herpes simplex	01MAY2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Herpes zoster	01JAN2016		Y
				01MAY2013	31DEC2013	N
		Investigations	Colonoscopy	01JAN2020	31DEC2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	26MAR2015		Y
			Underweight	13MAR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	26MAR2015		Y
		Psychiatric disorders	Anxiety	01JAN2010	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2013		Y
			Postmenopause	01JAN2000		Y
	C4591001 1039 10391060	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Impaired fasting glucose	09JUN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1039 10391061	Cardiac disorders	Bundle branch block right	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Artificial crown procedure	01JAN2016	31DEC2016	N
			Dental implantation	01JAN2016	31DEC2016	N
			Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1039 10391062	Ear and labyrinth disorders	Tinnitus	01MAY2013		Y
		Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN1971		Y
		Gastrointestinal disorders	Diverticulum	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2013	31DEC2015	N
		Surgical and medical procedures	Endodontic procedure	04AUG2020	04AUG2020	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01MAY2013		Y
	C4591001 1039 10391064	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Infections and infestations	Diverticulitis	01JAN2008		Y
		Investigations	Blood glucose increased	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31DEC2016	N
			Squamous cell carcinoma of skin	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Intertrigo	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Colectomy	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1039 10391069	Eye disorders	Cataract	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Denture wearer	01JAN1995		Y
	C4591001 1039 10391070	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Elbow operation	01NOV2017	30NOV2017	N
			Knee arthroplasty	01FEB2020	29FEB2020	N
			Neck surgery	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391072	Immune system disorders	Seasonal allergy	01JAN1966		Y
		Investigations	Blood triglycerides increased	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000	31DEC2000	N
			Prostate cancer	01JAN2012	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1965		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Intraocular lens implant	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1039 10391073	Eye disorders	Cataract	01JAN2017		Y
			Presbyopia	01JAN2018		Y
			Retinal vascular disorder	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2019	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1976	31DEC1976	N
				01JAN1979	31DEC1979	N
	C4591001 1039 10391074	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Glaucoma	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1952		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Tenosynovitis	01JAN2016		Y
		Reproductive system and breast disorders	Testicular mass	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2018		Y
		Surgical and medical procedures	Glaucoma surgery	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2013	31DEC2013	N
			Orchidectomy	01JAN2013	31DEC2013	N
	C4591001 1039 10391075	Cardiac disorders	Cardiac failure congestive	01JAN2019		Y
		Ear and labyrinth disorders	Auditory disorder	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2018		Y
			Irritable bowel syndrome	01JAN2017		Y
		Investigations	Biopsy skin	01JAN1980		Y
			Colonoscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Stent placement	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1039 10391077	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2015		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Diarrhoea	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2007		Y
			Food allergy	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN1953		Y
			Urinary tract infection	01JAN2007		Y
		Investigations	Cardiac murmur	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Impaired fasting glucose	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2004		Y
			Back pain	01AUG1975		Y
			Intervertebral disc degeneration	01JAN1995		Y
			Spondylitis	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1986	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN1968		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2007		Y
		Surgical and medical procedures	Shoulder operation	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1039 10391078	Cardiac disorders	Cardiac valve disease	01JAN2017		Y
			Palpitations	01JAN2009		Y
		Congenital, familial and genetic disorders	Cleft palate	(b) (6) 1950	31DEC1951	N
		Endocrine disorders	Thyroid mass	01JAN1999		Y
		Eye disorders	Cataract	01JAN2009	31DEC2010	N
			Macular degeneration	01JAN2007		Y
			Presbyopia	01JAN1962		Y
		Gastrointestinal disorders	Abdominal hernia	(b) (6) 1950	31DEC1950	N
			Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	(b) (6) 1950		Y
		Infections and infestations	Herpes zoster	01JAN1990	31DEC1990	N
			Sinusitis	01JAN2018		Y
			Urinary tract infection	01JAN2016		Y
		Investigations	Biopsy thyroid gland	01JAN2016	31DEC2016	N
			Cardiac murmur	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip squamous cell carcinoma	01JAN1999	31DEC1999	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1992		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Mammoplasty	01JAN2004	31DEC2004	N
			Nasal operation	06AUG2020	06AUG2020	N
			Nasal septal operation	01MAR2020	31MAR2020	N
			Sinuplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008	31DEC2018	N
	C4591001 1039 10391079	Ear and labyrinth disorders	Meniere's disease	01JAN2012		Y
			Vertigo	01JAN2002		Y
		Immune system disorders	Allergy to metals	01JAN2010		Y
			Drug hypersensitivity	01JAN2000		Y
				01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
			Tendonitis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
			Mechanical urticaria	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1039 10391081	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Infections and infestations	Urinary tract infection	01JAN2016		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Iron deficiency	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2018		Y
		Renal and urinary disorders	Bladder outlet obstruction	01JAN2020		Y
			Chronic kidney disease	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	03MAY2020	03MAY2020	N
			Transurethral prostatectomy	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391082	Blood and lymphatic system disorders	Anaemia	01JAN2011	31DEC2011	N
		Eye disorders	Cataract	01AUG2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2017	31DEC2017	N
			Wrist fracture	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1990	31DEC1990	N
		Nervous system disorders	Migraine	01JAN1971		Y
		Psychiatric disorders	Anxiety	01JAN1960		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2012	31DEC2012	N
			Mastectomy	01JAN1990	31DEC1990	N
			Nasal septal operation	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Wrist surgery	01JAN2008	31DEC2008	N
			Ichthyosis	01JAN2015		Y
	C4591001 1039 10391083	Congenital, familial and genetic disorders				
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2011	31DEC2011	N
			Gastroesophageal reflux disease	01JAN1985		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
		Metabolism and nutrition disorders	Gout	01JAN2010	31DEC2010	N
			Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Rhinitis allergic	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
			Psoriasis	01JAN1985		Y
		Social circumstances	Corrective lens user	01JAN1975		Y
			Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Hernia repair	01JAN2001		Y
			Mammoplasty	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391084	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Pancreatic cyst	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Diverticulitis	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1980		Y
	C4591001 1039 10391089	Eye disorders	Cataract	01JAN2019		Y
			Eyelid ptosis	01JAN2009	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Reproductive system and breast disorders	Breast mass	01JAN2014		Y
			Menstruation irregular	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2008	31DEC2016	N
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Blepharoplasty	01JAN2014	31DEC2014	N
			Caesarean section	01JAN1985	31DEC1985	N
				01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Sinus operation	01MAR2016	31MAR2016	N
	C4591001 1039 10391092	Eye disorders	Hypermetropia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis allergic	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1039 10391094	Eye disorders	Cataract	01JAN2019		Y
			Presbyopia	01JAN1971		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2016		Y
			Irritable bowel syndrome	01JAN2020		Y
		Immune system disorders	Food allergy	01JAN1975		Y
			Milk allergy	01JAN1975		Y
		Infections and infestations	Diverticulitis	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN1971		Y
			Hearing aid user	01JAN2015		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2000	31DEC2000	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
			Intestinal resection	01JAN2016	31DEC2016	N
	C4591001 1039 10391095	Eye disorders	Cataract	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2015		Y
	C4591001 1039 10391098	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Eye disorders	Presbyopia	01JAN1989		Y
		Gastrointestinal disorders	Diverticulum	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1989		Y
		Infections and infestations	Clostridium difficile infection	01JAN2018	31DEC2018	N
			Staphylococcal infection	01JAN2018	31DEC2018	N
		Investigations	Biopsy cervix	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2005		Y
		Reproductive system and breast disorders	Infertility	01JAN1978		Y
		Social circumstances	Corrective lens user	01JAN1989		Y
			Menopause	01JAN2008		Y
		Surgical and medical procedures	Appendectomy	01JAN1977	31DEC1977	N
			Uterine dilation and curettage	01JAN1980	31DEC1980	N
	C4591001 1039 10391100	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2006	31DEC2006	N
		Eye disorders	Conjunctivitis allergic	01JAN2010		Y
			Myopia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
			Plantar fascial fibromatosis	01JAN2017		Y
			Plantar fasciitis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y	
		Social circumstances	Corrective lens user	01JAN1960		Y	
		Surgical and medical procedures	Bunion operation	01JAN2012	31DEC2012	N	
				01JAN2018	31DEC2018	N	
				Caesarean section	01JAN1990	31DEC1990	N
				Cardiac ablation	01JAN2006	31DEC2006	N
				Fracture treatment	01JAN2004	31DEC2004	N
				Cataract	01JAN2019		Y
	C4591001 1039 10391101	Eye disorders					
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y	
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN2010		Y	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y	
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005	31DEC2005	N	
			Skin discolouration		01JAN2000		Y
	C4591001 1039 10391102	Blood and lymphatic system disorders	Anaemia	01JAN1981		Y	
		Ear and labyrinth disorders	Tinnitus	01JAN2000		Y	
		Endocrine disorders	Basedow's disease	01JAN2008		Y	
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y	
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1995		Y	
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y	
		Social circumstances	Menopause	01JAN2008		Y	
	C4591001 1039 10391103	Eye disorders	Presbyopia	01JAN2018		Y	
			Retinal detachment	01JAN2017	31DEC2017	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Diverticulitis	01JAN2005		Y
		Investigations	Biopsy breast	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2010	N
		Social circumstances	Corrective lens user	01JAN2018		Y
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1979	31DEC1979	N
			Dental cosmetic procedure	01JAN2018		Y
			Female sterilisation	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Oophorectomy	01JAN2000	31DEC2000	N
	C4591001 1039 10391105	Cardiac disorders	Bundle branch block left	01JAN2005		Y
			Cardiomyopathy alcoholic	01JAN2015		Y
		Eye disorders	Myopia	01JAN1963		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1988	31DEC2013	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
			Obesity	01JAN1998		Y
			Vitamin B12 deficiency	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
			Osteopenia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2007		Y
			Bipolar I disorder	01JAN1968		Y
			Depression	01JAN1968		Y
			Insomnia	01JAN1968		Y
			Panic disorder	01JAN1968		Y
			Post-traumatic stress disorder	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988	31DEC2013	N
		Surgical and medical procedures	Abdominoplasty	01JAN2000	31DEC2000	N
			Caesarean section	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2001	31DEC2001	N
			Mammoplasty	01JAN2000	31DEC2000	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1039 10391106	Eye disorders	Presbyopia	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1039 10391107	Congenital, familial and genetic disorders	Familial tremor	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
			Osteopenia	01JAN2020		Y
			Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1988		Y
			Rosacea	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Breast operation	01JAN1972	31DEC1972	N
	C4591001 1039 10391111	Eye disorders	Myopia	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1965		Y
		Social circumstances	Tobacco user	01JAN1971	31DEC1977	N
		Surgical and medical procedures	Prostatectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1964	31DEC1964	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1039 10391113	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN1955		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 1 diabetes mellitus	01JAN1965		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1039 10391116	Cardiac disorders	Arrhythmia	01JAN2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Infections and infestations	Urinary tract infection	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
				01JAN1997	31DEC1997	N
			Cholecystectomy	01JAN1997	31DEC1997	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Patent ductus arteriosus repair	01JAN1957	31DEC1963	N
	C4591001 1039 10391117	Cardiac disorders	Palpitations	01JAN2020		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2018	31DEC2018	N
			Appendectomy	01JAN1981	31DEC1981	N
			Brain operation	01JAN1989	31DEC1989	N
			Dental implantation	01JAN2018		Y
			Foot operation	01JAN2020	31DEC2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391122	Gastrointestinal disorders	Gastrointestinal disorder	01JAN2016		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2009	31DEC2014	N
		Investigations	Precancerous cells present	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2015	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1963		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1963		Y
			Eczema	01JAN1963		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				01JAN2000	31DEC2000	N
	C4591001 1039 10391123	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1970		Y
		Infections and infestations	Herpes zoster	01JAN2001	31DEC2001	N
		Investigations	Colonoscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Osteopenia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN1950		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1997	31DEC1997	N
			Rhinoplasty	01JAN1961	31DEC1961	N
	C4591001 1039 10391125	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Food allergy	01JAN2003		Y
			Iodine allergy	01JAN2003		Y
		Infections and infestations	Herpes virus infection	01JAN1961		Y
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
				01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2000		Y
			Seizure	01JAN2004		Y
		Psychiatric disorders	Affective disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1995		Y
		Social circumstances	Corrective lens user	01JAN1996		Y
			Tobacco user	01JAN1983	04JUL2003	N
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
			Blepharoplasty	01JAN2003	31DEC2003	N
				06JUN2003	06JUN2003	N
			Caesarean section	01JAN1976	31DEC1976	N
				01JAN1983	31DEC1983	N
				01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN2002	31DEC2002	N
			Cryotherapy	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1987	31DEC1987	N
			Gastric bypass	01JAN2002	31DEC2002	N
			Gastroenterostomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
			Oesophageal dilation procedure	01JAN2020	31DEC2020	N
			Oophorectomy	01JAN2003	31DEC2003	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Transfusion	01JAN2003	31DEC2003	N
			Uterine operation	01JAN1981	31DEC1981	N
	C4591001 1039 10391126	Cardiac disorders	Tachycardia	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Hiatus hernia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Infections and infestations	Diverticulitis	01JAN2019		Y
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
			Scoliosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1973		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN1986	31DEC1986	N
			Uterine dilation and curettage	01JAN1979	31DEC1979	N
				01JAN2018	31DEC2018	N
	C4591001 1039 10391129	Eye disorders	Cataract	01JAN2018		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
			Dyspepsia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2018	N
			Malignant melanoma	01JAN2016	31DEC2018	N
			Prostate cancer	01JAN2019	31MAY2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2002		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septal operation	01JAN2012	31DEC2012	N
			Prostatectomy	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1039 10391130	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Urinary tract infection	01JAN2020	31MAR2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2002	31DEC2002	N
		Nervous system disorders	Migraine	01JAN1976		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
			Rhinitis allergic	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
			Eczema	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Exeresis	01JAN2013	31DEC2013	N
	C4591001 1039 10391131	Eye disorders	Presbyopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1039 10391132	Endocrine disorders	Hypothyroidism	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1039 10391135	Blood and lymphatic system disorders	Anaemia	01JAN1999		Y
		Cardiac disorders	Angina pectoris	01JAN2010	31DEC2010	N
			Atrial fibrillation	01JAN2018	31DEC2019	N
			Coronary artery disease	01JAN2010		Y
		Ear and labyrinth disorders	Auditory disorder	01JAN2000		Y
			Vertigo	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
			Hiatus hernia	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
		Investigations	Biopsy breast	01JAN2000	31DEC2000	N
			Cardiac murmur	01JAN2020		Y
			Colonoscopy	01JAN2005	31DEC2005	N
			Endoscopy upper gastrointestinal tract	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2005	N
			Transient ischaemic attack	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	01JAN2007	31DEC2007	N
			Depression	01JAN2007	31DEC2007	N
			Obsessive-compulsive disorder	01JAN2007	31DEC2007	N
		Social circumstances	Tobacco user	01JAN1956	31DEC2000	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2005	31DEC2005	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Dental operation	01JAN2015		Y
			Eye operation	01JAN2018	31DEC2018	N
			Foot operation	01JAN2008	31DEC2008	N
			Implantable cardiac monitor insertion	01JAN2016		Y
			Knee operation	01JAN2012	31DEC2012	N
			Oophorectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Peripheral arterial occlusive disease	01JAN2010		Y
	C4591001 1039 10391137	Cardiac disorders	Arteriosclerosis coronary artery	01MAY2020		Y
			Myocardial ischaemia	01JAN2010		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
			Vertigo	01JAN2019		Y
		Endocrine disorders	Hypogonadism male	01JAN2010		Y
		Eye disorders	Cataract	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2019	31DEC2019	N
			Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Tobacco user	01JAN1963	31DEC2004	N
		Surgical and medical procedures	Synovial cyst removal	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391138	Eye disorders	Hypermetropia	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Umbilical hernia repair	01JUN2019	01JUN2019	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1039 10391139	Eye disorders	Myopia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
	C4591001 1039 10391141	Gastrointestinal disorders	Dyspepsia	01JAN1999	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Infections and infestations	Herpes zoster	01JAN2019	31DEC2019	N
		Nervous system disorders	Dizziness	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN1983	31DEC1983	N
			Eye laser surgery	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1039 10391142	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
	C4591001 1039 10391143	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
		Reproductive system and breast disorders	Ovarian fibrosis	01JAN1997	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2018		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1971		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Intraocular lens implant	01JAN2015	31DEC2015	N
	C4591001 1039 10391144	Immune system disorders	Seasonal allergy	01JUN2020		Y
		Infections and infestations	Hepatitis B	01JAN1957	31DEC1957	N
			Herpes zoster	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Bone operation	01JAN2001	31DEC2001	N
			Cataract operation	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN1985	31DEC1985	N
			Hysterectomy	01JAN1999	31DEC1999	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1039 10391146	Immune system disorders	Seasonal allergy	01JAN2015		Y	
		Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N	
		Social circumstances	Postmenopause	01JAN2010		Y	
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N	
				01JAN1984	31DEC1984	N	
				01JAN1989	31DEC1989	N	
				Female sterilisation	01JAN1989	31DEC1989	N
				Hysterectomy	01JAN2015	31DEC2015	N
				Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1039 10391147	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2016		Y	
		Eye disorders	Presbyopia	01JAN2015		Y	
		Gastrointestinal disorders	Diverticulum	01JAN1998		Y	
			Gastroesophageal reflux disease	01JAN2016		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y	
		Infections and infestations	Herpes zoster	01JAN2017	31DEC2017	N	
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y	
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998	31DEC1998	N	
		Psychiatric disorders	Major depression	01JAN2018		Y	
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1968		Y	
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y	
			Urticaria	01JAN1968		Y	
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1999	31DEC1999	N	
			Hip arthroplasty	01JAN2005	31DEC2005	N	
			Hysterectomy	01JAN1983	31DEC1983	N	
			Knee arthroplasty	01JAN2018	31DEC2018	N	
			Limb operation	01JAN1970	31DEC1979	N	

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lung operation	01JAN1982	31DEC1982	N
		Vascular disorders	Essential hypertension	01JAN1997		Y
	C4591001 1039 10391148	Ear and labyrinth disorders	Vertigo	01JAN2017	31DEC2017	N
		Endocrine disorders	Thyroid mass	01JAN2005		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1958		Y
			Drug hypersensitivity	01JAN1966		Y
		Investigations	Biopsy skin	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2014	30SEP2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2020	31JAN2020	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2017	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1998		Y
			Alopecia	01JAN1998		Y
		Social circumstances	Blood donor	01JAN1984	31DEC2000	N
			Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Caesarean section	01JAN1983	31DEC1983	N
			Carpal tunnel decompression	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Micrographic skin surgery	01JAN1998	31DEC1998	N
			Plastic surgery	01JAN1998	31DEC1998	N
			Spinal operation	01JAN1980	31DEC1980	N
			Tendon sheath incision	01JAN2013	31DEC2013	N
	C4591001 1039 10391154	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN1947		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
			Malignant melanoma	01JAN1996	31DEC1996	N
				01JAN2001	31DEC2001	N
				01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Squamous cell carcinoma	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1953	31DEC1971	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2001		Y
		Social circumstances	Corrective lens user	01JAN1968		Y
		Surgical and medical procedures	Artificial crown procedure	01JAN1965	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1039 10391155	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1975		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast operation	01JAN1995	31DEC1995	N
	C4591001 1039 10391158	Endocrine disorders	Goitre	01JAN2015		Y
			Hypothyroidism	01JAN2015		Y
			Thyroiditis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1965		Y
		Infections and infestations	Urinary tract infection	01JAN2018	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Keloid scar	01JAN1987	31DEC1989	N
		Social circumstances	Corrective lens user	01JAN1965		Y
			Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01DEC1987	01DEC1987	N
				23AUG1989	23AUG1989	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1039 10391159	Endocrine disorders	Hypothyroidism	05MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Seasonal allergy	01JAN1964		Y
		Infections and infestations	Herpes zoster	01NOV2015	31DEC2015	N
		Metabolism and nutrition disorders	Gout	05MAY2020		Y
			Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01MAR2018	30NOV2019	N
			Plantar fasciitis	06JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN2000		Y
			Tobacco user	01JAN1970	31DEC1976	N
		Surgical and medical procedures	Photorefractive keratectomy	01JAN2001	31DEC2001	N
	C4591001 1039 10391160	Ear and labyrinth disorders	Hypoacusis	01AUG2020		Y
			Tinnitus	01AUG2020		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2006	31DEC2006	N
			Sleep apnoea syndrome	01JAN1995		Y
	C4591001 1039 10391163	Surgical and medical procedures	Nasal septal operation	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Hepatitis A	01JAN1978	31DEC1978	N
		Investigations	Colonoscopy	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010	31DEC2010	N
		Social circumstances	Corrective lens user	01JAN1975		Y
		Surgical and medical procedures	Hydrocele operation	01JAN2006	31DEC2006	N
			Vasectomy	01JAN2006	31DEC2006	N
			Wisdom teeth removal	01JAN1980	31DEC1980	N
				01JAN2005	31DEC2005	N
	C4591001 1039 10391164	Vascular disorders	Hypertension	01JAN2018		Y
		Eye disorders	Myopia	01JAN1982		Y
		Infections and infestations	Herpes zoster	01MAR2019	31MAR2019	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1982		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1992	31DEC1992	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1039 10391169	Ear and labyrinth disorders	Vertigo positional	01JAN2003	31DEC2003	N
		Endocrine disorders	Hypothyroidism	01JAN1996	31DEC1996	N
			Thyroid mass	13OCT2014		Y
		Eye disorders	Presbyopia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Large intestine polyp	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Chronic sinusitis	01JAN2008	31DEC2012	N
			Chronic tonsillitis	01JAN1970	31DEC2013	N
			Cystitis	01JAN2002		Y
			Laryngitis	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1984	31DEC1986	N
		Renal and urinary disorders	Urge incontinence	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Bartholin's cyst removal	01JAN2002	31DEC2002	N
			Colon operation	01DEC2011	31DEC2011	N
				01JAN2011	31DEC2011	N
			Female sterilisation	01JAN2002	31DEC2002	N
			Haemorrhoid operation	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Ligament operation	01JAN2000	31DEC2000	N
			Limb operation	01JAN1961	31DEC1961	N
			Salpingo-oophorectomy	01JAN2002	31DEC2002	N
			Sinuplasty	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN2013	31DEC2013	N
			Vaginal operation	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391170	Ear and labyrinth disorders	Ear congestion	01JAN1964		Y
		Eye disorders	Diplopia	01JAN1998		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Back disorder	01JAN2016	31AUG2020	N
			Musculoskeletal stiffness	01JAN1965		Y
		Nervous system disorders	Headache	01JAN1965		Y
			Vlth nerve paralysis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN1968		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000	31AUG2020	N
		Social circumstances	Blood donor	01JAN1975	31DEC2019	N
			Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Spinal operation	01AUG2020	31AUG2020	N
			Strabismus correction	01JAN1999	31DEC1999	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N
	C4591001 1039 10391173	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2010		Y
			Ventricular extrasystoles	01JAN2010	31DEC2018	N
		Ear and labyrinth disorders	Hypoacusis	01JAN2014		Y
		Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
				01JAN2019		Y
			Seasonal allergy	01JAN2013		Y
		Investigations	Colonoscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
			Neck pain	01JAN2009		Y
			Osteoarthritis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2017		Y
			Pulmonary fibrosis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1980		Y
		Surgical and medical procedures	Dental implantation	01JAN2014	31DEC2014	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1039 10391174	Cardiac disorders	Atrial fibrillation	01NOV2019		Y
			Bradycardia	01NOV2019		Y
		Endocrine disorders	Testicular failure	01JUN2020		Y
		Eye disorders	Cataract	01JAN2019		Y
			Myopia	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Investigations	Heart rate irregular	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Essential tremor	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Bipolar disorder	01JAN2013		Y
			Depression	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Stevens-Johnson syndrome	01JAN2017		Y
		Surgical and medical procedures	Denture wearer	01JAN2018	31DEC2018	N
			Cardiac pacemaker insertion	01JAN2019		Y
			Knee arthroplasty	01JAN2019	31JAN2019	N
			Limb operation	01JAN2009	31DEC2009	N
		Vascular disorders	Essential hypertension	01JAN1983		Y
	C4591001 1039 10391184	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Osteoporosis	01SEP2020		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1039 10391188	Endocrine disorders	Hypothyroidism	01JAN2014		Y
			Thyroid disorder	01JAN2003	31DEC2008	N
		Eye disorders	Myopia	01JAN1969		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Hypokalaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1969		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Exeresis	01JAN2003	31DEC2003	N
				01JAN2008	31DEC2008	N
			Myomectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Essential hypertension	01JAN2012		Y
	C4591001 1039 10391189	Eye disorders	Hypermetropia	01JAN1990		Y
			Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteopenia	01JAN2018		Y
			Rheumatoid arthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1969		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
			Postmenopause	01JAN2005		Y
	C4591001 1039 10391192	Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Arthroscopy	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal stenosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2000	31DEC2000	N
			Ovarian neoplasm surgery	01JAN1983	31DEC1983	N
			Toe operation	01DEC2019	31DEC2019	N
	C4591001 1039 10391193	Cardiac disorders	Palpitations	01JAN2005	31DEC2010	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1967		Y
		Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995	31DEC2000	N
			Hiatus hernia	01JAN1995	31DEC2000	N
		Infections and infestations	Herpes zoster	01JAN2003	31DEC2003	N
		Investigations	Colonoscopy	01FEB2018	28FEB2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2013		Y
			Plantar fasciitis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01AUG2018	01AUG2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01DEC2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Hip arthroplasty	01JAN2013	31DEC2013	N
			Nasal septal operation	01AUG2020	31AUG2020	N
			Rotator cuff repair	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Aortic arteriosclerosis	01JAN1998		Y
	C4591001 1039 10391197	Blood and lymphatic system disorders	Anaemia	01JAN2006		Y
			Neutropenia	01JAN2008		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2009	29FEB2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
			Rosacea	01JAN1990		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
			Bunion operation	01JAN2013	31JAN2013	N
			Cataract operation	01JAN2015	31JAN2015	N
			Haemorrhoid operation	01JAN2015	31DEC2015	N
			Hernia repair	01JAN2015	31DEC2015	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Rotator cuff repair	23JAN2014	23JAN2014	N
			Spinal decompression	01SEP2004	30SEP2004	N
			Vasectomy	01JAN1975	31DEC1975	N
	C4591001 1039 10391201	Ear and labyrinth disorders	Vertigo	01JAN1980		Y
		Eye disorders	Cataract	01JAN2015		Y
			Presbyopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Herpes zoster	01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
				01JAN2019		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1970		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1958	31DEC1958	N
			Breast conserving surgery	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1039 10391202	Ear and labyrinth disorders	Auditory disorder	01JAN2005		Y
		Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
			Prostate cancer	01JAN2000	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998	31DEC1998	N
			Cerebrovascular accident	01JAN2016	31DEC2016	N
			Mononeuritis	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Dental operation	01OCT2019	31OCT2019	N
			Transfusion	01JAN2000	31DEC2000	N
		Vascular disorders	Essential hypertension	01JAN2005		Y
	C4591001 1039 10391206	Eye disorders	Presbyopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spondylitis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Injection	01JAN2008	31DEC2008	N
			Knee arthroplasty	01AUG2020	31AUG2020	N
				01FEB2020	29FEB2020	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1039 10391211	Cardiac disorders	Arteriosclerosis coronary artery	01AUG2019		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Conjunctivitis allergic	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1989		Y
		Investigations	Blood cholesterol increased	01JAN2003		Y
			Catheterisation cardiac	17JUL2019	17JUL2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01SEP2018		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015	29FEB2020	N
		Surgical and medical procedures	Adenoidectomy	01JAN1950	31DEC1950	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1039 10391213	Endocrine disorders	Hypogonadism	01JAN2012		Y
		Eye disorders	Myopia	01JAN1967		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1995		Y
		Investigations	Colonoscopy	01JAN2001	31DEC2001	N
				01JAN2006	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2016	31DEC2016	N
		Nervous system disorders	Syncope	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Blood donor	01JAN2000		Y
			Corrective lens user	01JAN1967		Y
		Surgical and medical procedures	Craniotomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1039 10391217	Ear and labyrinth disorders	Deafness bilateral	01JAN2014		Y
			Tinnitus	01JAN2015		Y
		Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2019		Y
		Infections and infestations	Laryngitis	01JAN1980	31DEC2010	N
			Pharyngitis	01JAN1980	31DEC2010	N
		Investigations	Biopsy breast	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2005	31DEC2005	N
			Melanocytic naevus	01JAN2000		Y
			Uterine leiomyoma	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC1990	N
			Rhinitis perennial	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Rhinoplasty	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1039 10391221	Eye disorders	Myopia	01JAN1976		Y
		Infections and infestations	Herpes simplex	01JAN1971		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1976		Y
	C4591001 1039 10391227	Cardiac disorders	Palpitations	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1985	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Neck pain	01JAN1998		Y
			Osteoporosis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1973	31DEC2005	N
		Psychiatric disorders	Depression	01JAN1981	31DEC1987	N
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01MAR2010		Y
		Surgical and medical procedures	Hysterectomy	01MAR2010	31MAR2010	N
			Nervous system neoplasm surgery	01MAR1998	31MAR1998	N
	C4591001 1039 10391228	Blood and lymphatic system disorders	Anaemia	01JAN1977	31DEC2002	N
		Cardiac disorders	Palpitations	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1967		Y
		Investigations	Colonoscopy	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020		Y
			Osteoarthritis	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Migraine	01JAN1987	31DEC2012	N
			Syncope	01JAN1963	31DEC1986	N
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	03APR1990	03APR1990	N
				21OCT1987	21OCT1987	N
				24JUL1985	24JUL1985	N
			Cryotherapy	01JAN2001	31DEC2001	N
			Rotator cuff repair	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1039 10391229	Eye disorders	Cataract	01FEB2019		Y
			Myopia	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2005	31DEC2005	N
			Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1039 10391230	Eye disorders	Myopia	01JAN1969		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01SEP2020		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN1969		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1039 10391231	Blood and lymphatic system disorders	Anaemia	01JAN1988	31DEC2001	N
		Cardiac disorders	Mitral valve prolapse	01JAN1977		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Inguinal hernia	01JAN1957		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Osteoarthritis	01JAN2009	31DEC2010	N
			Scoliosis	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1988	31DEC2007	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Arthrodesis	01AUG2010	31AUG2010	N
				01FEB2010	28FEB2010	N
			Eye laser surgery	01JAN2005	31DEC2005	N
			Haemorrhoid operation	01JAN2020	31JAN2020	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN1962	31DEC1962	N
			Mammoplasty	01JAN1989		Y
			Rhinoplasty	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1039 10391238	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1978	31DEC1978	N
			Vitreous injury	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014	31DEC2014	N
			Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN1974		Y
			Insomnia	01JAN2001		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN2006	31DEC2006	N
			Ligament operation	01JAN2016	31DEC2016	N
			Mastectomy	01JAN1993	31DEC1993	N
			Pancreatic cyst	01JAN2012	31DEC2012	N
	C4591001 1042 10421002	Gastrointestinal disorders		01JUL2015	31JUL2015	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01OCT2002		Y
		Nervous system disorders	Migraine	01JUL1987	30JUN2012	N
		Social circumstances	Postmenopause	01JUN2000	30JUN2001	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1042 10421009	Immune system disorders	Food allergy	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01MAR2019	31JUL2019	N
	C4591001 1042 10421010	Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	08DEC1978	08DEC1978	N
				14MAR1983	14MAR1983	N
				17FEB1986	17FEB1986	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1042 10421011	Immune system disorders	Rubber sensitivity	01JAN1989		Y
		Infections and infestations	Herpes simplex	01JUN2019		Y
			Herpes zoster	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1042 10421018	Social circumstances	Tobacco user	01JAN1980	31DEC1985	N
	C4591001 1042 10421023	Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31JAN2000	N
		Social circumstances	Postmenopause	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1042 10421025	Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421026	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Immune system disorders	Seasonal allergy	01JAN1954		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1998	31DEC1998	N
				01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1042 10421032	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2017	N
				01JAN2016		Y
		Nervous system disorders	Amnesia	01MAR2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1042 10421033	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Transplant	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421036	Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2018		Y
			Gastrooesophageal reflux disease	01JUL2020		Y
		Immune system disorders	Food allergy	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2005		Y
			Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1962	31DEC1962	N
			Chondroplasty	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Female sterilisation	31JUL1981	31JUL1981	N
			Mole excision	01JAN1964	31DEC1964	N
		Vascular disorders	Hot flush	01JAN2016	31DEC2020	N
			Hypertension	01JAN2000		Y
	C4591001 1042 10421037	Cardiac disorders	Myocardial infarction	01JAN1987		Y
		Eye disorders	Cataract	01JAN2017	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1982	31DEC1982	N
		Social circumstances	Postmenopause	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
			Spinal deformity correction	14FEB2019	14FEB2019	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1042 10421038	Infections and infestations	Oral herpes	01JAN1985		Y
			Tonsillitis	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1042 10421040	Gastrointestinal disorders	Gastroesophageal reflux disease	14MAR2020		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Injury, poisoning and procedural complications	Sports injury	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Alcoholism	01JAN1980	14MAR2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1042 10421048	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1042 10421052	Metabolism and nutrition disorders	Iron deficiency	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2008	31OCT2008	N
			Intervertebral disc protrusion	01JUN2014	30JUN2014	N
		Nervous system disorders	Hypoaesthesia	01OCT2008	31OCT2008	N
			Neuralgia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JUN2019		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2008	31DEC2008	N
	C4591001 1042 10421054	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Social circumstances	Postmenopause	01MAY2017		Y
		Surgical and medical procedures	Pelvic floor repair	01APR2019	30APR2019	N
	C4591001 1042 10421055	Cardiac disorders	Atrial fibrillation	01APR2015		Y
				01JAN2014	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01AUG2019		Y
		Eye disorders	Cataract	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN2014		Y
		Infections and infestations	Ear infection	01JAN2010		Y
			Tonsillitis	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2017	28FEB2017	N
				01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2017	30NOV2017	N
		Surgical and medical procedures	Cardiac operation	01JAN2008		Y
			Knee arthroplasty	01JAN2014	31DEC2014	N
				01FEB2017	28FEB2017	N
				01NOV2017	30NOV2017	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1042 10421056	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
			Osteoarthritis	01JAN1996		Y
			Spinal osteoarthritis	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1960		Y
		Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1042 10421058	Cardiac disorders	Atrial fibrillation	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2014	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1951	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2005	N
			Nasal polyps	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1950		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1042 10421060	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
			Muscle rupture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN2017	31DEC2017	N
			Muscle operation	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1042 10421062	Gastrointestinal disorders	Dyspepsia	01SEP2008		Y
			Gastroesophageal reflux disease	01SEP2008		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1042 10421064	Metabolism and nutrition disorders	Hypercholesterolaemia	05DEC2014		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1997	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	20JAN2016		Y
		Vascular disorders	Hypertension	05DEC2014		Y
	C4591001 1042 10421066	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1042 10421067	Gastrointestinal disorders	Anal fissure	01JAN2010	31DEC2010	N
			Mouth ulceration	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Food allergy	01JAN2014		Y
		Nervous system disorders	Dizziness	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
			Drug eruption	01JAN2014		Y
	C4591001 1042 10421072	Cardiac disorders	Atrial fibrillation	21JUL1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01SEP2008		Y
		Metabolism and nutrition disorders	Fluid retention	21JUL2000		Y
		Nervous system disorders	Neuropathy peripheral	21JUL2012		Y
			Restless legs syndrome	21JUL2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2000		Y
	C4591001 1042 10421074	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01DEC1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01DEC1999	31DEC1999	N
			Urinary bladder suspension	01JAN1990	31DEC1990	N
		Vascular disorders	Hot flush	01JAN2012		Y
	C4591001 1042 10421075	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1042 10421078	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Investigations	Prostatic specific antigen increased	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Penile prosthesis insertion	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN2015	31DEC2015	N
	C4591001 1042 10421084	Cardiac disorders	Arrhythmia	01JAN1995		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1984		Y
			Gastroesophageal reflux disease	01JAN1984		Y
			Rectal prolapse	01JAN2006		Y
			Umbilical hernia	01JAN2006		Y
		General disorders and administration site conditions	Chest pain	01JAN2017		Y
		Immune system disorders	Contrast media allergy	01JAN1983		Y
			Contrast media reaction	01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Panic attack	01JAN1980		Y
		Renal and urinary disorders	Nephropathy	01APR2020		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1979	31DEC1979	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1962		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1979		Y
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
			Rectal prolapse repair	01JAN2006	31DEC2006	N
		Vascular disorders	Hot flush	01JAN1982		Y
			Hypertension	01JAN1995		Y
	C4591001 1042 10421086	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2014	31DEC2014	N
	C4591001 1042 10421087	Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN1958	31DEC1958	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1960		Y
			Narcolepsy	01JAN2011		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
	C4591001 1042 10421089	Surgical and medical procedures	Hernia repair	01JAN1958	31DEC1958	N
		Endocrine disorders	Hyperthyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2002	31DEC2002	N
			Thyroid cancer	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Thyroidectomy	01APR2011	30APR2011	N
	C4591001 1042 10421090	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	06APR1995	06APR1995	N
				06DEC1993	06DEC1993	N
				24FEB1997	24FEB1997	N
	C4591001 1042 10421091	Cardiac disorders	Arrhythmia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Renal and urinary disorders	Pollakiuria	01JAN2017		Y
	C4591001 1042 10421097	Eye disorders	Cataract	01JAN2018		Y
			Glaucoma	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1978		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN1985		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31JAN2019	N
			Mastectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1042 10421098	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1992	31DEC2000	N
					31DEC2005	N
			Scoliosis	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN2001		Y
		Pregnancy, puerperium and perinatal conditions	Breech delivery	19JUL1989	19JUL1989	N
			Placenta accreta	19JUL1989	19JUL1989	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	19JUL1989	19JUL1989	N
			Hysterectomy	19JUL1989	19JUL1989	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
	C4591001 1042 10421099	Gastrointestinal disorders	Umbilical hernia	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	08OCT2019	08OCT2019	N
		Nervous system disorders	Neuralgia	01OCT2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Rotator cuff repair	08OCT2019	08OCT2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1042 10421101	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2001		Y
				01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hot flush	01JAN2019		Y
			Hypertension	01JAN2000		Y
	C4591001 1042 10421102	Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1042 10421104	Infections and infestations	Herpes simplex	01JAN1983		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	10JUN1988	10JUN1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1042 10421107	Endocrine disorders		14AUG1985	14AUG1985	N	
				Hypothyroidism	01JAN1999		Y
			Eye disorders	Cataract	01JAN1996	31DEC2013	N
			Immune system disorders	Seasonal allergy	01JAN2000		Y
			Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
			Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
				Osteoporosis	01JAN2017		Y
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
			Psychiatric disorders	Depression	01JAN2011		Y
				Insomnia	01JAN2000		Y
			Reproductive system and breast disorders	Endometriosis	01JAN1987	31DEC1987	N
			Social circumstances	Postmenopause	01JAN1999		Y
			Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
				Cataract operation	01JAN2013	31DEC2013	N
				Oophorectomy	01JAN2000	31DEC2000	N
				Tonsillectomy	01JAN1968	31DEC1968	N
				Central vision loss	01JAN1995		Y
	C4591001 1042 10421110	Eye disorders					
			Gastrointestinal disorders	Vomiting	01JAN1973		Y
			Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				Seasonal allergy	01JAN2000		Y
			Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
			Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
				Obesity	01JAN1960		Y
			Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1957	31DEC1957	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Knee arthroplasty	01JAN2004	31DEC2004	N
		Vascular disorders	Hot flush	01JAN1993		Y
	C4591001 1042 10421113	Eye disorders	Cataract	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN1995		Y
		Infections and infestations	Herpes simplex	01JAN2017		Y
			Tonsillitis	01JAN1975	31DEC1975	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hot flush	01JAN2012	31DEC2018	N
			Hypertension	01JAN2010		Y
	C4591001 1042 10421116	Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intervertebral disc operation	01JAN2003	31DEC2003	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1042 10421117	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1042 10421118	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2017	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1042 10421119	Nervous system disorders	Migraine	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1042 10421122	General disorders and administration site conditions	Cyst rupture	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1042 10421127	Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		General disorders and administration site conditions	Vaccination site swelling	01JAN2005		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2018		Y
			Drug hypersensitivity	01JAN1993		Y
				01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2002	31DEC2014	N
		Nervous system disorders	Seizure	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1993		Y
			Rash	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2005	31DEC2005	N
				01JAN2014	31DEC2014	N
	C4591001 1042 10421132	Cardiac disorders	Coronary artery disease	01JAN1970		Y
			Myocardial infarction	01JAN1970	31DEC1970	N
		Eye disorders	Cataract	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Dental caries	01JAN2014	31DEC2014	N
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1960		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01SEP2019	30SEP2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1946	31DEC1960	N
		Surgical and medical procedures	Sleep apnoea syndrome	01JAN2017		Y
			Coronary artery bypass	01JAN1970	31DEC1970	N
			Stent placement	01JAN2020		Y
					31JAN2020	N
		Vascular disorders	Tooth extraction	01JAN2014	31DEC2014	N
			Arterial occlusive disease	01JAN2020	31JAN2020	N
			Hypertension	01JAN1960		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
	C4591001 1042 10421133	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2001	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01SEP2001	30SEP2001	N
			Cholecystectomy	01MAY2018	31MAY2018	N
			Micrographic skin surgery	01JAN2016	31DEC2016	N
	C4591001 1042 10421134	Infections and infestations	Oral herpes	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1042 10421135	Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
	C4591001 1042 10421138	Vascular disorders	Hypertension	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1986	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hot flush	01JAN1986		Y
			Hypertension	01JAN2001		Y
	C4591001 1042 10421139	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2016		Y
			Urticaria	01JAN2016		Y
	C4591001 1042 10421141	Blood and lymphatic system disorders	Anaemia	01JAN2014		Y
		General disorders and administration site conditions	Stenosis	01JAN2014		Y
		Immune system disorders	Dust allergy	01JAN1955		Y
			Iodine allergy	01JAN2014		Y
		Infections and infestations	Appendicitis	01DEC1962	31DEC1962	N
			Tonsillitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01APR2014	30APR2014	N
			Prostate cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN1963		Y
			Migraine	01JAN1963		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
			Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01DEC1962	31DEC1962	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1042 10421145	Immune system disorders	Allergy to arthropod sting	01JAN1975		Y
			Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1973		Y
		Infections and infestations	Otitis media chronic	01MAR2020	31MAR2020	N
			Pharyngitis streptococcal	01JAN1982	31DEC1982	N
			Tonsillitis	01JAN1982	31DEC1982	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hot flush	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421146	Metabolism and nutrition disorders	Fluid retention	01JAN2014		Y
			Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31JAN2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
			Transient ischaemic attack	06JAN2016	06JAN2016	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2015	31JAN2015	N
	C4591001 1042 10421147	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hot flush	01JAN2013		Y
	C4591001 1042 10421150	Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Prostatectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1042 10421152	Investigations	Arthroscopy	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1042 10421153	Cardiac disorders	Coronary artery disease	01JAN2017		Y
			Myocardial infarction	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Overweight	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Vascular stent insertion	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1042 10421154	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1042 10421156	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Splenic rupture	01JUL1970	31JUL1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Infertility	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1042 10421159	Surgical and medical procedures	Splenectomy	01JUL1970	31JUL1970	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Pharyngotonsillitis	01JAN1963	31DEC1963	N
			Tonsillitis	01JAN1962	31DEC1962	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1963	31DEC1963	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1042 10421160	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Cholesterosis	01JAN2016	31DEC2016	N
			Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Thrombosis	01NOV2014	30APR2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421164	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1042 10421166	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Arthroscopic surgery	01JAN2019	31DEC2019	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
	C4591001 1042 10421167	Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2018	30APR2018	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2006		Y
			Panic attack	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Knee arthroplasty	01APR2018	30APR2018	N
		Vascular disorders	Hot flush	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421168	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1042 10421171	Blood and lymphatic system disorders	Iron deficiency anaemia	01FEB2020		Y
		Cardiac disorders	Cardiac failure congestive	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2019		Y
			Obesity	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN1998		Y
			Panic attack	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1042 10421172	Eye disorders	Cataract	01JAN2017	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Neck mass	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Parotidectomy	01JAN2017	31DEC2017	N
	C4591001 1042 10421173	Hepatobiliary disorders	Cholecystitis	01JAN2006	31DEC2006	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2002	31DEC2002	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2002	31DEC2002	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1042 10421174	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Biopsy breast	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1988	31DEC1988	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	12FEB1996	12FEB1996	N
		Vascular disorders	Hot flush	01JAN2008	31DEC2009	N
	C4591001 1042 10421178	Cardiac disorders	Arrhythmia	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Coronary artery bypass	01JUL2014	31JUL2014	N
	C4591001 1042 10421182	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
			Wisdom teeth removal	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1042 10421183	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN1975	31DEC1975	N
			Tenoplasty	01JAN1995	31DEC1995	N
	C4591001 1042 10421186	Blood and lymphatic system disorders	Iron deficiency anaemia	27MAR2020		Y
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1042 10421187	Surgical and medical procedures	Hernia repair	01JAN2019	31DEC2019	N	
		Cardiac disorders	Coronary artery disease	01JAN1993		Y	
				Myocardial infarction	01JAN1988		Y
			Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Gastrointestinal disorders	Haemorrhoids	01JAN2014	31DEC2014	N
			Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
				Obesity	01JAN2017		Y
				Type 2 diabetes mellitus	01JAN2017		Y
			Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
			Reproductive system and breast disorders	Erectile dysfunction	01JAN1989		Y
			Surgical and medical procedures	Coronary artery bypass	01JAN1993	31DEC1993	N
				Haemorrhoid operation	01JAN2014	31DEC2014	N
		C4591001 1042 10421189	Vascular disorders	Hypertension	01JAN1988		Y
	Endocrine disorders		Hypothyroidism	01JAN2000		Y	
			Immune system disorders	Seasonal allergy	01JAN1960		Y
			Injury, poisoning and procedural complications	Vth nerve injury	01JAN2018		Y
			Reproductive system and breast disorders	Ovarian cyst	01JAN1995	31DEC1995	N
			Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1042 10421191		Surgical and medical procedures	Ovarian cystectomy	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1042 10421192	Gastrointestinal disorders	Mouth ulceration	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1042 10421195	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1977	31DEC2001	N
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1042 10421200	Immune system disorders	Allergy to plants	01JAN1989		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1994	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1042 10421202	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1042 10421203	Investigations	Cardiac murmur	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31OCT2019	N
	C4591001 1042 10421208	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Renal stone removal	01JAN2018	31DEC2018	N
	C4591001 1042 10421211	Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Infections and infestations	Anal abscess	01JAN2005	31DEC2005	N
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985	31DEC1985	N
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Abscess drainage	01JAN2005	31DEC2005	N
			Spinal laminectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Deep vein thrombosis	01JAN2015	31DEC2015	N
	C4591001 1042 10421212	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01AUG2019	31JAN2020	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2015		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2020	31JAN2020	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1042 10421215	Cardiac disorders	Coronary artery disease	01JAN2016		Y
			Myocardial infarction	01AUG2016	31AUG2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Coronary angioplasty	01AUG2016	31AUG2016	N
	C4591001 1042 10421218	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2016	31DEC2016	N
			Osteoporosis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	31DEC2019	N
			Rhinitis allergic	01JAN2013		Y
			Upper-airway cough syndrome	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Nasal septal operation	01JAN2018	31DEC2019	N
			Toe operation	01JAN2016	31DEC2016	N
	C4591001 1042 10421220	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1042 10421221	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1042 10421223	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2000		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1042 10421224	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1042 10421225	Blood and lymphatic system disorders	Anaemia	01JAN2008	31DEC2008	N
		Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1950		Y
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1951	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2014	N
			Transient ischaemic attack	01JAN2005	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Coronary artery bypass	01JAN2013	31DEC2013	N
			Mastectomy	01JAN2012	31DEC2012	N
			Transurethral prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1042 10421226	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2010		Y
			Intervertebral disc degeneration	01JAN2016		Y
			Tendonitis	01MAR2020		Y
		Psychiatric disorders	Depression	01MAR2020		Y
			Insomnia	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1042 10421227	Cardiac disorders	Coronary artery disease	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1042 10421230	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1042 10421236	Eye disorders	Cataract	01JAN2015	30SEP2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Bone hypertrophy	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1972	31DEC1972	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Cataract operation	01SEP2018	30SEP2018	N
	C4591001 1042 10421240	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1042 10421241	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1995	31DEC1995	N
		Congenital, familial and genetic disorders	Intestinal malrotation	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1985	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1977	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Intestinal malrotation repair	01JAN2015	31DEC2015	N
			Nasal septal operation	01JAN2018	31DEC2018	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
	C4591001 1042 10421242	General disorders and administration site conditions	Pain	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN1978		Y
			Tonsillitis	01JAN1966	31DEC1966	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1978		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1966	31DEC1966	N
			Vasectomy	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1042 10421244	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2009	N
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basosquamous carcinoma	31JUL2020	31JUL2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Coronary artery bypass	04MAY2010	04MAY2010	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1042 10421254	Immune system disorders	Seasonal allergy	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JUN2020	15JUL2020	N
		Surgical and medical procedures	Skin lesion removal	15JUL2020	15JUL2020	N
	C4591001 1042 10421258	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2002	31DEC2002	N
			Gastrooesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
			Rheumatic fever	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2002	31DEC2002	N
		Vascular disorders	Hot flush	01JAN2012		Y
	C4591001 1042 10421263	Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Allergy to animal	01JAN1986		Y
			Allergy to plants	01JAN1986		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1042 10421268	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
			Hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1042 10421269	Cardiac disorders	Arrhythmia	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2012	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN1982		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN2017		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1984	31DEC1984	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1982		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Knee arthroplasty	01AUG2020	31AUG2020	N
				01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hot flush	01JAN1984	31DEC2018	N
			Thrombosis	01JAN1969		Y
	C4591001 1044 10441002	Cardiac disorders	Coronary artery disease	01NOV1996		Y
			Myocardial infarction	25AUG2019	25AUG2019	N
		General disorders and administration site conditions	Chest pain	01JAN1996	30NOV1996	N
			Hernia	01FEB2000	31MAY2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01NOV1996		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1998		Y
		Surgical and medical procedures	Hernia repair	01MAY2000	31MAY2000	N
			Limb operation	01JAN2018	31DEC2018	N
			Toe amputation	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vascular stent insertion	05NOV1996	05NOV1996	N
				25AUG2019	25AUG2019	N
	C4591001 1044 10441003	Endocrine disorders	Hypothyroidism	19JUN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	18DEC2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10NOV2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Psychiatric disorders	Depression	27FEB2018		Y
	C4591001 1044 10441004	Metabolism and nutrition disorders	Hyperlipidaemia	05MAR2013		Y
			Obesity	15JAN2019		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	10SEP2012	31DEC2012	N
		Psychiatric disorders	Depression	07OCT2016		Y
		Vascular disorders	Hypertension	05MAR2013		Y
	C4591001 1044 10441005	Vascular disorders	Hypertension	21JAN2013		Y
	C4591001 1044 10441006	Endocrine disorders	Hypogonadism	21NOV2012		Y
			Hypothyroidism	02AUG2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02AUG2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2010		Y
			Gouty arthritis	06JUN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	21OCT2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	27JUL2017		Y
		Vascular disorders	Hypertension	21OCT2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1044 10441008	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2020	N
		Surgical and medical procedures	Liposuction	01JAN2000	31DEC2020	N
	C4591001 1044 10441010	Blood and lymphatic system disorders	Anaemia	19FEB2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	23FEB2011		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1970		Y
				01JAN1971		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Hyperlipidaemia	25MAR2013		Y
			Type 2 diabetes mellitus	25MAR2013		Y
			Vitamin D deficiency	25MAR2013		Y
		Nervous system disorders	Transient ischaemic attack	26MAY2017		Y
		Psychiatric disorders	Generalised anxiety disorder	23FEB2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19FEB2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Vascular disorders	Hypertension	25MAR2013		Y
	C4591001 1044 10441012	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2016	20DEC2016	N
			Throat cancer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cancer surgery	01JAN2014	31DEC2014	N
				20DEC2016	20DEC2016	N
	C4591001 1044 10441013	Cardiac disorders	Atrioventricular block	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	22DEC2004	31JAN2005	N
		Surgical and medical procedures	Breast conserving surgery	01FEB2004	28FEB2004	N
				01JAN2005	31JAN2005	N
			Cardiac pacemaker insertion	01JAN2019	31JAN2019	N
			Hysterectomy	01JAN1986	31DEC1986	N
			Hyperlipidaemia	01JAN1970		Y
	C4591001 1044 10441014	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1044 10441016	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1044 10441017	Cardiac disorders	Mitral valve prolapse	01JAN2004	31MAY2004	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Surgical and medical procedures	Mitral valve repair	01MAY2004	31MAY2004	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1044 10441018	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1044 10441020	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441022	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2005		Y
		Immune system disorders	Drug hypersensitivity	01DEC1980		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2018		Y
			Hyperlipidaemia	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1044 10441023	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1044 10441025	General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1044 10441026	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
	C4591001 1044 10441027	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
	C4591001 1044 10441032	Renal and urinary disorders	Nephrolithiasis	01JAN1994		Y
		Surgical and medical procedures	Vasectomy	01FEB1998	28FEB1998	N
	C4591001 1044 10441033	Psychiatric disorders	Anxiety	01JUL2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
	C4591001 1044 10441036	Immune system disorders	Rubber sensitivity	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1975		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1957		Y
	C4591001 1044 10441039	Surgical and medical procedures	Hysterectomy	18JUL1994	18JUL1994	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1044 10441040	Vascular disorders	Hypertension	01JAN2016		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1044 10441041	Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip and/or oral cavity cancer	01JAN2012	31DEC2012	N
			Prostate cancer	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Glossectomy	01JAN2012	31DEC2012	N
	C4591001 1044 10441046		Radiotherapy to prostate	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441047	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAR2014	10DEC2014	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000	31DEC2000	N
			Insomnia	01MAR2020		Y
		Surgical and medical procedures	Radical prostatectomy	10DEC2014	10DEC2014	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1044 10441049	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1044 10441055	Ear and labyrinth disorders	Presbycusis	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2005		Y
	C4591001 1044 10441062	Congenital, familial and genetic disorders	Familial tremor	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1968		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
			Prostate cancer	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Micrographic skin surgery	01JAN2006	31DEC2006	N
			Prostatectomy	01JAN2006	31DEC2006	N
	C4591001 1044 10441064	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2007	30APR2007	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Colectomy	01APR2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1044 10441066	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Attention deficit hyperactivity disorder	01JAN1997		Y
		Renal and urinary disorders	Urge incontinence	01JAN2016		Y
		Vascular disorders	Hypertension	15APR2012		Y
	C4591001 1044 10441067	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
	C4591001 1044 10441070	Gastrointestinal disorders	Diverticulum	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2020		Y
	C4591001 1044 10441072	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1044 10441073	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1044 10441074	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Infections and infestations	Vestibular neuritis	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
	C4591001 1044 10441075	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	30JUN2005	N
		Surgical and medical procedures	Prostatectomy	01JUN2005	30JUN2005	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1044 10441078	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Psychiatric disorders	Seasonal affective disorder	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN1995		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1044 10441080	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1044 10441082	Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1998		Y
	C4591001 1044 10441083	Immune system disorders	Drug hypersensitivity	01JAN1955	31DEC1955	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1999		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1044 10441087	Eye disorders	Retinal vein occlusion	21MAR2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2011		Y
	C4591001 1044 10441090	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Urinary tract infection	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2005	31DEC2005	N
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01DEC2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Gastric bypass	01JAN2005		Y
			Skin neoplasm excision	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1044 10441091	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1044 10441092	Infections and infestations	Urinary tract infection	15FEB2015		Y
		Metabolism and nutrition disorders	Gout	01JAN1992		Y
			Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1992		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1044 10441094	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1044 10441095	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01OCT2007		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441096	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31JUL2016	N
		Surgical and medical procedures	Skin neoplasm excision	01JUL2016	31JUL2016	N
	C4591001 1044 10441098	Endocrine disorders	Hypothyroidism	01JAN1969		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01APR2019	30APR2019	N
		Surgical and medical procedures	Micrographic skin surgery	01APR2019	31DEC2019	N
	C4591001 1044 10441100	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN1957		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1044 10441104	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1044 10441105	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1044 10441106	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2015		Y
		Immune system disorders	Allergy to arthropod sting	18AUG2020	18AUG2020	N
		Psychiatric disorders	Anxiety	01JUN2010		Y
		Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1044 10441108	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1044 10441109	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
	C4591001 1044 10441110	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1044 10441111	Reproductive system and breast disorders	Peyronie's disease	01MAR2020		Y
	C4591001 1044 10441113	Injury, poisoning and procedural complications	Epicondylitis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2015	31DEC2015	N
	C4591001 1044 10441114	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN2018	31DEC2018	N
				01JUN2020	31DEC2020	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2018	31DEC2018	N
			Skin lesion removal	01JUN2020	31DEC2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1044 10441115	Cardiac disorders	Coronary artery disease	01OCT2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
			Type 2 diabetes mellitus	01JAN2020		Y
	C4591001 1044 10441116	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1044 10441117	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1044 10441120	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1044 10441124	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1996	31DEC1996	N
		Psychiatric disorders	Anxiety	01JAN1973		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1044 10441125	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
	C4591001 1044 10441128	Skin and subcutaneous tissue disorders	Dermatitis contact	24AUG2020	30AUG2020	N
		Immune system disorders	Drug hypersensitivity	31JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1044 10441131	Skin and subcutaneous tissue disorders	Rosacea	01JAN1973		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
	C4591001 1044 10441134	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN1988		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1044 10441135	Gastrointestinal disorders	Enteritis	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2015		Y
				01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2020		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1044 10441138	Cardiac disorders	Atrial fibrillation	01SEP2009		Y
		Surgical and medical procedures	Cardiac ablation	01JUL2013	31DEC2013	N
	C4591001 1044 10441145	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2012		Y
	C4591001 1044 10441147	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
	C4591001 1044 10441148	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1044 10441149	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC1992	31DEC1992	N
		Surgical and medical procedures	Mastectomy	01JAN1992	31DEC1992	N
	C4591001 1044 10441150	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
				01JAN2019		Y
		Infections and infestations	Urinary tract infection	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Psychiatric disorders	Insomnia	01DEC2019		Y
		Social circumstances	Menopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1044 10441160	Cardiac disorders	Atrial fibrillation	01JAN2004		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990		Y
			Squamous cell carcinoma	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN1990	31DEC1990	N
				01OCT2016	31DEC2016	N
	C4591001 1044 10441161	General disorders and administration site conditions	Drug intolerance	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUN2018		Y
	C4591001 1044 10441169	Metabolism and nutrition disorders	Hyperlipidaemia	30DEC2019		Y
		Vascular disorders	Hypertension	26JUN2020		Y
	C4591001 1044 10441172	Ear and labyrinth disorders	Meniere's disease	01JAN1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
	C4591001 1044 10441175	General disorders and administration site conditions	Drug intolerance	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
	C4591001 1044 10441178	Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Investigations	Cardiac murmur	15OCT2020		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
	C4591001 1044 10441179	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2017		Y
			Vitamin B12 deficiency	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Brachytherapy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1044 10441180	Immune system disorders	Drug hypersensitivity	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
				01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	30JUL2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1044 10441182	Surgical and medical procedures	Micrographic skin surgery	01JAN2005	31DEC2005	N
	C4591001 1044 10441184	Eye disorders	Dry eye	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1044 10441189	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Psychiatric disorders	Insomnia	01OCT2005		Y
	C4591001 1044 10441194	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1987		Y
				01JAN1995		Y
			Rubber sensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2019		Y
			Polyarthritis	01JAN1990		Y
		Nervous system disorders	Cervical radiculopathy	01JAN1990		Y
			Migraine	01JAN1987		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
	C4591001 1044 10441201	Cardiac disorders	Ventricular extrasystoles	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01SEP2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Vasomotor rhinitis	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Papulopustular rosacea	01JAN2018		Y
			Rosacea	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01DEC2017		Y
	C4591001 1044 10441202	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC1980		Y
	C4591001 1044 10441205	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
	C4591001 1044 10441206	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
	C4591001 1044 10441208	Surgical and medical procedures	Hormone replacement therapy	01JAN2003		Y
			Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1044 10441209	Endocrine disorders	Basedow's disease	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1970		Y
			Myasthenia gravis	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1044 10441214	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Thyroidectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1044 10441217	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1976		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Prophylaxis	01JAN1997		Y
		Vascular disorders	Flushing	01JAN1986		Y
			Hypertension	01MAR2020		Y
	C4591001 1044 10441220	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1993		Y
			Rheumatoid arthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1044 10441221	General disorders and administration site conditions	Drug intolerance	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1044 10441223	General disorders and administration site conditions	Drug intolerance	01JAN1999		Y
	C4591001 1044 10441225	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1995		Y
		Nervous system disorders	Narcolepsy	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1044 10441226	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1046 10461003	Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Angioplasty	15AUG1995	15AUG1995	N
			Coronary artery bypass	08NOV2005	08NOV2005	N
			Fracture treatment	15APR2004	15APR2004	N
			Vasectomy	09MAY1989	09MAY1989	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1046 10461004	Reproductive system and breast disorders	Menstrual disorder	01DEC2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1046 10461007	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
			Heart rate decreased	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461008	Eye disorders	Dry eye	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Mastectomy	01JAN2002	31DEC2002	N
			Pneumonectomy	01JAN2009	31DEC2009	N
	C4591001 1046 10461009	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Nervous system disorders	Petit mal epilepsy	01JAN1961	31DEC1961	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Corneal transplant	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2011	31DEC2011	N
			Renal stone removal	01JAN2018	31DEC2018	N
		Vascular disorders	Aortic aneurysm	01JAN1991	31DEC1991	N
	C4591001 1046 10461012	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Gastrectomy	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461013	Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Bunion operation	01JAN1993	31DEC1993	N
			Toe operation	01JAN2009	31DEC2009	N
	C4591001 1046 10461015	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
	C4591001 1046 10461017	Cardiac disorders	Bundle branch block right	06AUG2020		Y
			Cardiomyopathy	06AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1046 10461019	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016	31DEC2016	N
			Migraine	01JAN1967		Y
			Occipital neuralgia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461021	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	10DEC2000	10DEC2000	N
				19AUG2002	19AUG2002	N
				25AUG2005	25AUG2005	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Oesophagogastric fundoplasty	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461022	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461025	Immune system disorders	Allergic reaction to excipient	01JAN2010		Y
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hodgkin's disease	01JAN2006	31DEC2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Caesarean section	30OCT1993	30OCT1993	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Renal stone removal	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1046 10461032	Cardiac disorders	Coronary artery disease	01JAN2013		Y
			Coronary artery occlusion	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
		Nervous system disorders	Carotid artery disease	01JAN2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461033	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Investigations	Arthroscopy	01JAN2003	31DEC2003	N
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2003	31DEC2019	N
				01JAN2010	31MAY2020	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
				01MAY2020	31MAY2020	N
			Knee operation	01JAN1973	31DEC1973	N
	C4591001 1046 10461035	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		General disorders and administration site conditions	Cyst	01JAN2005	31DEC2005	N
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2010	N
			Intervertebral disc degeneration	01JAN2017		Y
			Osteoarthritis	01JAN1990		Y
			Plantar fasciitis	01JAN2006		Y
			Trigger finger	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN1970		Y
			Neuritis	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2014	31DEC2014	N
			Fascial operation	01JAN2006	31DEC2006	N
			Fracture treatment	01JAN2008	31DEC2008	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN1985	31DEC1985	N
			Spinal operation	01JAN2017	31DEC2017	N
			Tendon sheath incision	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1046 10461036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1978	31DEC1978	N
		Infections and infestations	Herpes ophthalmic	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
				01MAY2020	31MAY2020	N
		Psychiatric disorders	Depression	01JAN2008		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1978	31DEC1978	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
				01MAY2020	31MAY2020	N
	C4591001 1046 10461037	Cardiac disorders	Coronary artery disease	01JAN2004		Y
			Myocardial infarction	01JAN2004	31DEC2004	N
				01JAN2008	31DEC2008	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		General disorders and administration site conditions	Hernia	01JAN2005	31DEC2005	N
		Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hernia repair	01JAN2005	31DEC2005	N
			Shoulder arthroplasty	01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN2004	31DEC2004	N
	C4591001 1046 10461038	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Investigations	Vitamin B12 decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
			Fibromyalgia	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
			Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2013	31DEC2013	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1046 10461041	Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Chronic sinusitis	01JAN2005		Y
			Herpes simplex	01JAN2000		Y
		Investigations	Blood potassium decreased	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Weight increased	01JAN2019		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Blepharoplasty	01JAN2005	31DEC2005	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Rhinoplasty	01JAN2005	31DEC2005	N
	C4591001 1046 10461045	Hepatobiliary disorders	Cholecystitis	01JAN1970	31DEC1970	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Osteoporosis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1970	31DEC1970	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1046 10461047	Eye disorders	Amblyopia	01JAN1974	31DEC1980	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Gout	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2015		Y
		Renal and urinary disorders	Bladder neck obstruction	01JAN1962	31DEC1962	N
	C4591001 1046 10461048	Gastrointestinal disorders	Flatulence	01JAN2010		Y
			Nausea	01JAN2010		Y
			Tooth impacted	01JAN2014	31DEC2014	N
		General disorders and administration site conditions	Hernia	01APR2020	30APR2020	N
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
		Investigations	Arthroscopy	01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
					31DEC2016	N
				01JAN2011	31DEC2016	N
				01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric banding	01JAN2010	31DEC2010	N
			Hernia repair	01APR2020	30APR2020	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Tooth extraction	01JAN2014	31DEC2014	N
			Tracheostomy	01JAN2004		Y
					31DEC2004	N
				01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461056	Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Infections and infestations	Tonsillitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2008		Y
			Restless legs syndrome	01JAN2008		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1987	31DEC1987	N
			Inguinal hernia repair	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN2015	31DEC2015	N
	C4591001 1046 10461057	Cardiac disorders	Angina pectoris	01JAN2000	31DEC2000	N
			Myocardial infarction	01JAN2000	31DEC2000	N
		Eye disorders	Cataract	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2014	31DEC2014	N
			Large intestine polyp	01JAN2007		Y
			Peptic ulcer	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
					31DEC2012	N
			Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2010	31DEC2010	N
			Bladder neoplasm	01JAN2010	31DEC2010	N
			Prostate cancer	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2014	31DEC2014	N
			Bladder neoplasm surgery	01JAN2010	31DEC2010	N
			Cardiac ablation	01JAN2013	31DEC2013	N
			Cataract operation	01JAN2001	31DEC2001	N
			Coronary artery bypass	01JAN2000	31DEC2000	N
			High frequency ablation	01JAN2013	31DEC2013	N
			Transurethral prostatectomy	01JAN2014	31DEC2014	N
	C4591001 1046 10461059	Cardiac disorders	Cardiac failure congestive	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461060	Blood and lymphatic system disorders	Lymphadenopathy	01JAN1995	31DEC1995	N
		Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Nervous system disorders	Cerebrovascular accident	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
			Lymphadenectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
	C4591001 1046 10461061	Eye disorders	Amblyopia	01JAN1960		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Eye operation	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461062	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Investigations	Arthroscopy	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1989	31DEC1989	N
				01JAN2014	31DEC2014	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1046 10461064	Cardiac disorders	Coronary artery occlusion	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	03APR1982	03APR1982	N
				09SEP1986	09SEP1986	N
				23MAY1988	23MAY1988	N
			Coronary artery bypass	01JAN2016	31DEC2016	N
			Gastroplasty	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461065	General disorders and administration site conditions	Chest pain	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Investigations	Catheterisation cardiac	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1975	31DEC1975	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Sebaceous cyst excision	01JAN2016	31DEC2016	N
			Shoulder operation	01JAN1975	31DEC1975	N
	C4591001 1046 10461073	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Renal stone removal	01JAN1989	31DEC1989	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1046 10461074	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020	29FEB2020	N
				01JAN2009	31DEC2012	N
		Nervous system disorders	Migraine	01JAN1988		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Joint arthroplasty	01FEB2020	29FEB2020	N
			Shoulder operation	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1046 10461075	Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1995	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Tenoplasty	01JAN1995	31DEC1995	N
				01JAN1997	31DEC1997	N
				01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461076	Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Laryngitis	01JAN2018		Y
			Tonsillitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Foreign body	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2019		Y
			Tendonitis	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Bronchial hyperreactivity	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Mammoplasty	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Removal of foreign body	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1046 10461077	Eye disorders	Retinopathy	01JAN2002		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
		Infections and infestations	Rhinitis	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2016	31DEC2016	N
		Vascular disorders	Aortic stenosis	01JAN2016		Y
			Hypertension	01JAN2012		Y
	C4591001 1046 10461078	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N
	C4591001 1046 10461079	Gastrointestinal disorders	Diverticulum	01JAN2011		Y
			Irritable bowel syndrome	01JAN1997		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1963	31DEC1963	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005	31DEC2005	N
			Arthritis	01JAN2019		Y
			Back pain	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Colectomy	01JAN2003	31DEC2003	N
				01JAN2011	31DEC2011	N
			Fracture treatment	01JAN1963	31DEC1963	N
			Vertebroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1046 10461080	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1046 10461082	Gastrointestinal disorders	Nausea	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2014		Y
			Neuropathy peripheral	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Lithotripsy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461083	Gastrointestinal disorders	Tonsillectomy	01JAN1970	31DEC1970	N
			Inguinal hernia	01JAN2016	31DEC2016	N
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Gastrectomy	01JAN2016	31DEC2016	N
			Hernia repair	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
		Eye disorders	Eyelid ptosis	01JAN2020	31JAN2020	N
		C4591001 1046 10461084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	
	Investigations		Blood testosterone decreased	01JAN2014		Y
	Metabolism and nutrition disorders		Gluten sensitivity	01JAN2019		Y
			Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
	Musculoskeletal and connective tissue disorders		Foot deformity	01JAN1994	31DEC1994	N
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Benign neoplasm of cornea	01JAN2011	31DEC2011	N
	Respiratory, thoracic and mediastinal disorders		Diaphragmatic disorder	01JAN1996	31DEC1996	N
	Surgical and medical procedures		Bunion operation	01JAN1994	31DEC1994	N
			Corneal operation	01JAN2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diaphragmatic operation	01JAN1996	31DEC1996	N
			Eyelid operation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461085	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Ear and labyrinth disorders	Deafness	01JAN2002		Y
			Vertigo	01JAN2007		Y
		Gastrointestinal disorders	Constipation	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN1980		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
			Arthritis	01JAN2009		Y
			Fibromyalgia	01JAN2017		Y
			Osteoporosis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN1965		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2002		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2002	31DEC2015	N
			Nephropathy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menstrual disorder	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1965		Y
		Surgical and medical procedures	Caesarean section	01JAN1976	31DEC1976	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Gastric bypass	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN1987	31DEC1987	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Nephrectomy	01JAN2005	31DEC2005	N
			Urinary bladder suspension	01JAN2002	31DEC2002	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461086	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1970		Y
			Rectal fissure	01JAN1974	31DEC1974	N
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN1973		Y
				01JAN1999		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1985		Y
			Fibromyalgia	01JAN2008		Y
			Spinal stenosis	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Anorectal operation	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1973	31DEC1973	N
			Neck surgery	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2007	31DEC2007	N
	C4591001 1046 10461087	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Circumcision	01JAN1974	31DEC1974	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461088	Cardiac disorders	Angina pectoris	01JAN2012		Y
			Myocardial infarction	07AUG2012	07AUG2012	N
			Myocardial ischaemia	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
			Peptic ulcer	01JAN2009		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2004		Y
		Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Investigations	Catheterisation cardiac	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1046 10461090	Investigations	Blood cholesterol increased	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1046 10461094	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
			Chronic sinusitis	01JAN2010	31DEC2010	N
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Sinus operation	01JAN2010	31DEC2010	N
	C4591001 1046 10461095	Endocrine disorders	Hyperthyroidism	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461096	Investigations	Arthroscopy	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
				01JAN2015	31DEC2015	N
			Blood uric acid increased	01JAN2000		Y
		Surgical and medical procedures	Gallbladder operation	01JAN1999	31DEC1999	N
			Oesophagogastric fundoplasty	01JAN1999	31DEC1999	N
			Renal stone removal	01JAN2003	31DEC2003	N
				01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2020	31DEC2020	N
			Tendon sheath incision	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1046 10461106	Cardiac disorders	Coronary artery disease	01JAN2006		Y
			Myocardial infarction	01JAN2006	31DEC2006	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		General disorders and administration site conditions	Hernia	01JAN2005	31DEC2005	N
			Oedema peripheral	01JAN2012		Y
		Investigations	Arthroscopy	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2012		Y
			Vitamin D deficiency	01JAN2012		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1989		Y
				01JAN1991		Y
			Back pain	01JAN1970		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2009		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2007	31DEC2007	N
			Coronary artery bypass	01JAN2009	31DEC2009	N
			Hernia repair	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN1989	31DEC1989	N
			Spinal operation	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1046 10461110	Injury, poisoning and procedural complications	Wrist fracture	01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1993	31DEC1993	N
			Ovarian cyst	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Eyelid operation	01JAN2012	31DEC2012	N
			Fracture treatment	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Salpingectomy	01JAN2006	31DEC2006	N
	C4591001 1046 10461114	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Hernia repair	01JAN2012	31DEC2012	N
			Oesophagogastric fundoplasty	01JAN2017	31DEC2017	N
	C4591001 1046 10461121	Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1046 10461122	Cardiac disorders	Aortic valve stenosis	01JAN2017	31DEC2017	N
			Atrial fibrillation	01JAN2014		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1987		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
			Arthritis	01JAN2011		Y
			Back pain	01JAN2008		Y
			Exostosis	01JAN2018	31DEC2018	N
			Trigger finger	01MAR2020	31MAR2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Nervous system disorders	Transient ischaemic attack	01SEP2019	30SEP2019	N
			Tremor	01JAN2014		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bone lesion excision	01JAN2018	31DEC2018	N
			Cardiac pacemaker insertion	05JUN2020	05JUN2020	N
			Cataract operation	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Prostatectomy	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Spinal laminectomy	01JAN2008	31DEC2008	N
			Tendon sheath incision	01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1046 10461126	Cardiac disorders	Angina pectoris	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Nervous system disorders	Headache	01JAN1970		Y
			Nerve compression	01JUN2018	30JUN2018	N
		Reproductive system and breast disorders	Prostatomegaly	01MAR2011	31MAR2011	N
		Surgical and medical procedures	Ankle operation	01AUG2002	31AUG2002	N
			Hip surgery	10DEC2010	10DEC2010	N
			Prostatectomy	01MAR2011	31MAR2011	N
			Spinal decompression	01JUN2018	30JUN2018	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1046 10461128	Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Heart rate irregular	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Arthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01FEB2006	28FEB2006	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cardiac ablation	01JAN2013	31DEC2013	N
			Carpal tunnel decompression	01FEB2006	28FEB2006	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1046 10461129	Infections and infestations	Appendicitis	01JAN1940	31DEC1940	N
			Tonsillitis	01JAN1940	31DEC1940	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2016	30JUN2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2020	31DEC2020	N
			Skin cancer	01FEB2020		Y
			Squamous cell carcinoma	01FEB2020	31DEC2020	N
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1940	31DEC1940	N
			Fascia release	01APR2017	30APR2017	N
				01JAN2016	31JAN2016	N
				01JUN2017	30JUN2017	N
			Spinal fusion surgery	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tenoplasty	01JAN1956	31DEC1956	N
			Tonsillectomy	01JAN1940	31DEC1940	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461132	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2001	31DEC2001	N
				01JAN2016	31DEC2016	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2001	31DEC2001	N
				01JAN2016	31DEC2016	N
	C4591001 1046 10461136	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1046 10461138	Hepatobiliary disorders	Cholecystitis	01FEB2020	29FEB2020	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Caesarean section	19AUG1984	19AUG1984	N
				19AUG1986	19AUG1986	N
			Cholecystectomy	01FEB2020	29FEB2020	N
			Fracture treatment	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Meniscus operation	16MAY2020	16MAY2020	N
	C4591001 1046 10461141	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
				01JAN2012	31DEC2012	N
			Blood testosterone decreased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000	31DEC2012	N
				01JAN2010	31DEC2010	N
	C4591001 1046 10461144	Surgical and medical procedures	Elbow operation	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2006		Y
			Insomnia	01JAN2006		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1046 10461156	Investigations	Blood cholesterol increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
				01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2009	31DEC2009	N
			Turbinoplasty	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1046 10461157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
				01JUN2020	30JUN2020	N
		Psychiatric disorders	Affective disorder	01JAN2017		Y
			Bipolar disorder	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Gastric bypass	01JAN2004	31DEC2004	N
			Hip arthroplasty	01JUN2020	30JUN2020	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1979	31DEC1979	N
	C4591001 1046 10461158	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Nasal polyps	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Sinus operation	01JAN2019	31DEC2019	N
	C4591001 1046 10461160	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Breast cyst excision	01JAN2010	31DEC2010	N
			Fracture treatment	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1046 10461161	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2005	31DEC2005	N
		Investigations	Arthroscopy	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Fracture treatment	01JAN2005	31DEC2005	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
	C4591001 1046 10461165	Cardiac disorders	Cardiomyopathy	01JAN2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Surgical and medical procedures	Abdominal operation	01JAN2010	31DEC2010	N
			Oophorectomy	01JAN1970	31DEC1970	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendon sheath incision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461166	Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Periodic limb movement disorder	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461169	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Nausea	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Subdural haematoma	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 1 diabetes mellitus	01JAN1958		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Coronary artery bypass	01JAN2000	31DEC2000	N
			Keratomileusis	01JAN1980	31DEC1980	N
			Renal stone removal	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461173	Gastrointestinal disorders	Haemorrhoids	01JAN2003	31DEC2003	N
		General disorders and administration site conditions	Hernia	01JAN1964	31DEC1964	N
		Infections and infestations	Tonsillitis	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Back pain	01JAN2000		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2003	31DEC2003	N
			Hernia repair	01JAN1964	31DEC1964	N
			Meniscus operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461178	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Nervous system disorders	Angiopathic neuropathy	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
			Mastectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1046 10461179	Endocrine disorders	Hypothyroidism	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Glaucoma	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1995		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
			Genital herpes	01JAN1979		Y
			Tonsillitis	01JAN1960	31DEC1960	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Fracture treatment	01JAN1974	31DEC1974	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461180	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Cyst removal	01JAN1993	31DEC1993	N
				01JAN1994	31DEC1994	N
			Mammoplasty	01JAN1990	31DEC1990	N
			Uterine irrigation	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461181	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Arthroscopy	01JAN1992	31DEC1992	N
			Biopsy breast	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
			Muscle spasms	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
			Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Abdominoplasty	01JAN1999	31DEC1999	N
			Caesarean section	07APR1978	07APR1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				16NOV1976	16NOV1976	N
				22JUL1981	22JUL1981	N
			Gastric bypass	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Mammoplasty	01JAN1999	31DEC1999	N
	C4591001 1046 10461183	Cardiac disorders	Myocardial infarction	30JUL2017	30JUL2017	N
		Surgical and medical procedures	Coronary arterial stent insertion	30JUL2017	30JUL2017	N
	C4591001 1046 10461184	Endocrine disorders	Hypogonadism	01JAN2013		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2013		Y
		General disorders and administration site conditions	Cyst	01JAN2012		Y
			Pain	01JAN1998		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Investigations	Arthroscopy	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Vitamin B12 deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998	31DEC1998	N
			Back pain	01JAN1990		Y
				01JAN1998		Y
			Intervertebral disc degeneration	01JAN2013		Y
			Muscle spasms	01JAN1998		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dizziness	01JAN2014		Y
			Dysaesthesia	01JAN2013		Y
			Headache	01JAN2012		Y
			Neuralgia	01JAN2013		Y
		Renal and urinary disorders	Haematuria	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Erectile dysfunction	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1046 10461185	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Social circumstances	Menopause	01JAN2003		Y
	C4591001 1046 10461187	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Infections and infestations	Tonsillitis	01JAN1971	31DEC1971	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Salpingoplasty	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1971	31DEC1971	N
	C4591001 1046 10461190	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Multiple allergies	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01FEB2011	28FEB2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Jaw operation	01OCT1993	31OCT1993	N
	C4591001 1046 10461195	Immune system disorders	Multiple allergies	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1989		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2008		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2008	31DEC2008	N
			Stapedectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN1964	31DEC1964	N
	C4591001 1046 10461205	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Hepatobiliary disorders	Hypothyroidism	01JAN1981		Y
		Immune system disorders	Cholecystitis	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Drug hypersensitivity	01JAN1977		Y
		Skin and subcutaneous tissue disorders	Muscle spasms	01JAN2018		Y
		Social circumstances	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Postmenopause	01JAN2006		Y
	C4591001 1046 10461206	Immune system disorders	Cholecystectomy	01JAN2002	31DEC2002	N
		Investigations	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Blood cholesterol increased	01JAN2000		Y
			Hysterectomy	01JAN1990	31DEC1990	N
			Lymphadenectomy	01JAN2005	31DEC2005	N
	C4591001 1046 10461207	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Meniscus operation	15APR2020	15APR2020	N
			Rotator cuff repair	29JAN2020	29JAN2020	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1046 10461208	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2015	31DEC2015	N
			Hernia repair	01JAN1995	31DEC1995	N
			Rhinoplasty	01JAN1970	31DEC1970	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1046 10461212	Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Gout	01JAN1998		Y
			Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N
			Pain in extremity	01JAN1998	31DEC1998	N
		Nervous system disorders	Transient ischaemic attack	01MAY2018	31MAY2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Foot operation	01JAN1998	31DEC1998	N
			Gastrectomy	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee operation	01JAN2003	31DEC2003	N
			Shoulder operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461213	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Eyelid ptosis	01JAN2001	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1993	31DEC1999	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2001	31DEC2001	N
			Rhinoplasty	01JAN1999	31DEC1999	N
	C4591001 1046 10461214	Cardiac disorders	Myocardial infarction	19JUN2019	27JUN2019	N
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back disorder	28JAN2016	31JAN2016	N
	C4591001 1046 10461215	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Impaired gastric emptying	01JAN2017		Y
			Irritable bowel syndrome	01JAN2010		Y
			Malabsorption	01JAN2018		Y
			Nausea	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
			Back pain	01JAN2006		Y
			Bursitis	01JAN2005		Y
			Exostosis	01JAN2017	31DEC2017	N
			Fibromyalgia	01JAN2010		Y
			Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN2005		Y
			Rheumatoid arthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2001	31DEC2001	N
			Dizziness	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2013	31DEC2019	N
		Reproductive system and breast disorders	Endometriosis	01JAN2003	31DEC2003	N
			Menstrual disorder	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2017	31DEC2017	N
			Carpal tunnel decompression	01JAN2001	31DEC2001	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Oophorectomy	01JAN2003	31DEC2003	N
			Shoulder operation	01JAN2019	31DEC2019	N
			Urinary bladder suspension	01JAN2013	31DEC2013	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461216	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1046 10461220	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
			Large intestine polyp	01JAN2013		Y
			Oesophageal stenosis	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN1999		Y
				01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2011		Y
			Vitamin B12 deficiency	01JAN2011		Y
			Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
			Renal mass	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Restrictive pulmonary disease	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Gastric bypass	01JAN2015	31DEC2015	N
			Lithotripsy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1046 10461222	Eye disorders	Cataract	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2012		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2011		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1984	31DEC1984	N
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
			Fibromyalgia	01JAN2016		Y
			Osteoarthritis	01JAN1967		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2013		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N
			Cataract operation	01JAN2001	31DEC2001	N
			Cholecystectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
			Uterine tumour excision	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1046 10461225	Metabolism and nutrition disorders	Obesity	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Gastric bypass	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461226	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1046 10461229	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461230	Hepatobiliary disorders	Gallbladder disorder	02JUL1985	02JUL1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Jaw cyst	22JAN2020	22JAN2020	N
			Plantar fasciitis	01JAN1994	31JAN1994	N
		Nervous system disorders	Headache	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Reproductive system and breast disorders	Menstrual disorder	01JUL1997	31JUL1997	N
		Surgical and medical procedures	Bone cyst excision	22JAN2020	22JAN2020	N
			Cholecystectomy	02JUL1985	02JUL1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Foot operation	01JAN1994	31JAN1994	N
			Hysterectomy	01JUL1997	31JUL1997	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461231	Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005	31DEC2005	N
				01JAN2017	31DEC2018	N
			Osteoarthritis	01JAN1998		Y
		Nervous system disorders	Dementia	01JAN2016		Y
			Myoclonus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1046 10461235	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
			Restless legs syndrome	01JAN2018		Y
	C4591001 1046 10461238	Immune system disorders	Seasonal allergy	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2007	31DEC2007	N
				01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007	31DEC2007	N
				01JAN2011	31DEC2011	N
				01JAN2018	31DEC2018	N
			Pain in extremity	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Shoulder operation	01JAN2011	31DEC2011	N
			Tenoplasty	01JAN2018	31DEC2018	N
	C4591001 1046 10461239	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1046 10461241	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Infections and infestations	Chronic sinusitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Hypometabolism	01MAY2020		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fracture treatment	01JAN1997	31DEC1997	N
			Sinuplasty	01JAN1995	31DEC1995	N
	C4591001 1046 10461243	Eye disorders	Glaucoma	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Breast prosthesis removal	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Mastectomy	01JAN2013	31DEC2013	N
			Muscle flap operation	01JUL2020	31JUL2020	N
	C4591001 1046 10461244	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1985	31DEC1985	N
			Arthritis	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Renal and urinary disorders	Bladder prolapse	01JAN1980	31DEC1980	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
			Knee operation	01JAN1985	31DEC1985	N
			Urinary bladder suspension	01JAN1980	31DEC1980	N
	C4591001 1046 10461245	Cardiac disorders	Coronary artery occlusion	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2010		Y
		Surgical and medical procedures	Cardiac operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1046 10461249	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1046 10461250	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1046 10461251	Gastrointestinal disorders	Inguinal hernia	01JAN1965	31DEC1983	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1965	31DEC1965	N
				01JAN1983	31DEC1983	N
			Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1046 10461253	Cardiac disorders	Atrial fibrillation	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Reproductive system and breast disorders	Prostatic disorder	01DEC2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hernia repair	01AUG2008	31AUG2008	N
			Knee arthroplasty	01JAN2011	31JAN2011	N
			Prostatectomy	01DEC2007	31DEC2007	N
			Urinary tract operation	01FEB2008	29FEB2008	N
		Vascular disorders	Deep vein thrombosis	01JAN2005		Y
			Hypertension	01JAN2014		Y
	C4591001 1046 10461258	Gastrointestinal disorders	Constipation	01JAN1980		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1986	31DEC1986	N
		Infections and infestations	Tonsillitis	01JAN1986	31DEC1986	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
			Cholecystectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1986	31DEC1986	N
	C4591001 1046 10461259	Investigations	Blood cholesterol increased	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
			Skin graft	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461260	Cardiac disorders	Myocardial infarction	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1960		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Chronic obstructive pulmonary disease	01JAN2013		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2011	31DEC2011	N
			Renal stone removal	01JAN1960	31DEC1960	N
			Spinal laminectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1046 10461262	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Sinus operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1046 10461264	Cardiac disorders	Coronary artery disease	01JAN2010		Y
			Coronary artery occlusion	01NOV2010	30NOV2010	N
		Eye disorders	Glaucoma	01JUN2020		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	01NOV2010	30NOV2010	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1046 10461267	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014	31DEC2014	N
			Back pain	29JAN2019		Y
			Fibromyalgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Pain in extremity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1998		Y
			Seizure	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1046 10461277	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Psychiatric disorders	Major depression	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461278	Endocrine disorders	Hyperaldosteronism	01JAN2012		Y
		Eye disorders	Cataract	25FEB2020	25FEB2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Eye injury	01JAN1965	31DEC1965	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	25FEB2020	25FEB2020	N
			Eye muscle operation	01JAN1965	31DEC1965	N
			Uterine dilation and curettage	25JUL1990	25JUL1990	N
	C4591001 1046 10461279	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Face lift	19JUL2020	19JUL2020	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1046 10461282	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Infections and infestations	Onychomycosis	01SEP2020		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003	31DEC2003	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fracture treatment	01JAN1998	31DEC1998	N
			Intervertebral disc operation	01JAN2003	31DEC2003	N
			Uvulopalatopharyngoplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461283	Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Laparotomy	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN1995	31DEC1995	N
	C4591001 1046 10461286	Hepatobiliary disorders	Cholecystitis	01JAN1991	31DEC1991	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2010	N
			Back pain	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2007	31DEC2007	N
			Rectal cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Colectomy	01JAN2007	31DEC2007	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1046 10461293	Cardiac disorders	Myocardial infarction	01JAN1989		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary artery bypass	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1046 10461296	Cardiac disorders	Coronary artery disease	01JAN2004		Y
		Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Hepatobiliary disorders	Cholecystitis	01MAR2020	31MAR2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Vitamin B12 deficiency	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menstrual disorder	01MAY2018	31MAY2018	N
		Surgical and medical procedures	Cholecystectomy	01MAR2020	31MAR2020	N
			Coronary arterial stent insertion	01MAY2009	31MAY2009	N
				01NOV2004	30NOV2004	N
			Hysterectomy	01MAY2018	31MAY2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1046 10461299	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Cardiac disorders	Mitral valve incompetence	01JAN1994		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2016		Y
				01JAN2017		Y
			Seasonal allergy	01JAN2016		Y
		Infections and infestations	Diverticulitis	01JAN2016		Y
		Investigations	Blood potassium decreased	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin B12 deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2000	31DEC2000	N
		Nervous system disorders	Diabetic neuropathy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN2003		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
			Nephrolithiasis	01JAN1991		Y
			Urinary incontinence	01JAN2017		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Proctoplasty	01JAN1991	31DEC1991	N
			Urinary bladder suspension	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1046 10461301	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1965		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1997	31DEC1997	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ligament operation	01JAN1997	31DEC1997	N
			Mastoidectomy	01JAN1967	31DEC1967	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1046 10461305	Ear and labyrinth disorders	Deafness	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Neuralgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1046 10461309	Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
			Venous operation	01JAN2017	31DEC2017	N
		Vascular disorders	Peripheral venous disease	01JAN2017		Y
	C4591001 1046 10461310	Hepatobiliary disorders	Cholelithiasis	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1970		Y
	C4591001 1046 10461316	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1046 10461317	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
			Arthritis	01JAN2000		Y
			Spinal stenosis	01JAN1981		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Chronic obstructive pulmonary disease	01JAN2013		Y
		Surgical and medical procedures	Lithotripsy	01JAN2007	31DEC2007	N
			Shoulder operation	01JAN2001	31DEC2001	N
				01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Deep vein thrombosis	01JAN2008	31DEC2008	N
			Hypertension	01JAN2019		Y
	C4591001 1046 10461320	Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
			Foot deformity	01JAN1980	31DEC1980	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1990	31DEC1990	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal fracture treatment	01JAN2018	31DEC2018	N
			Toe operation	01JAN1974	31DEC1974	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1046 10461322	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1975		Y
		Reproductive system and breast disorders	Menstrual disorder	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1046 10461326	Gastrointestinal disorders	Gastrointestinal hypomotility	01JAN2020		Y
			Tooth impacted	01JAN1978	31DEC1978	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N
			Face lift	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Mammoplasty	01JAN2016	31DEC2016	N
			Sterilisation	01JAN1993	31DEC1993	N
			Tympanomastoidectomy	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN1978	31DEC1978	N
	C4591001 1046 10461328	Gastrointestinal disorders	Inguinal hernia	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Hernia repair	01JAN2013	31DEC2013	N
	C4591001 1046 10461335	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	25JAN2018	25JAN2018	N
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rotator cuff repair	25JAN2018	25JAN2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471001	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Nervous system disorders	Ageusia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1047 10471002	Surgical and medical procedures	Neurectomy	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1954	31DEC1954	N
			Vasectomy	01JAN1978	31DEC1978	N
			Wisdom teeth removal	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1047 10471003	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Nervous system disorders	Thoracic outlet syndrome	01JAN2002		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Fracture treatment	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
	C4591001 1047 10471005	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2005	31DEC2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
			Renal infarct	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Toe amputation	01JAN1976	31DEC1976	N
	C4591001 1047 10471006	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1970	31DEC1970	N
		Endocrine disorders	Hypogonadism	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Haemorrhoids	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Haemorrhoid operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471008	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2005	31DEC2005	N
					31DEC2007	N
		Nervous system disorders	Parkinson's disease	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471011	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Eye disorders	Hypermetropia	01JAN2004		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2002	31DEC2002	N
			Foot fracture	01JAN2002	31DEC2002	N
			Joint dislocation	01JAN2000	31DEC2000	N
		Investigations	Biopsy larynx normal	01JAN2016	31DEC2016	N
			Blood cholesterol increased	01JAN2017		Y
		Nervous system disorders	Sciatica	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Laryngeal disorder	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Joint dislocation reduction	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1047 10471012	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2018	28FEB2018	N
			Gastric bypass	01JUN2001	30JUN2001	N
			Hysterectomy	01DEC2003	31DEC2003	N
	C4591001 1047 10471014	Gastrointestinal disorders	Inguinal hernia	01JAN1974	31DEC1974	N
			Large intestine polyp	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood triglycerides increased	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2012	31DEC2012	N
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Renal and urinary disorders	Nocturia	01JAN2010		Y
			Pollakiuria	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1974	31DEC1974	N
			Tendon sheath incision	01JAN2012	31DEC2012	N
	C4591001 1047 10471016	Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
	C4591001 1047 10471019	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Dry eye	01JAN2016		Y
			Macular fibrosis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC1999	N
		Investigations	Arthroscopy	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999	31DEC1999	N
			Osteoarthritis	01JAN1995		Y
			Osteopenia	01JAN2018		Y
		Nervous system disorders	Essential tremor	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Menopausal depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Spinal corpectomy	01JAN1999	31DEC1999	N
			Vitrectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1047 10471022	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1984		Y
			Rotator cuff syndrome	01JAN2017	31DEC2017	N
			Temporomandibular joint syndrome	01JAN1984	31DEC1984	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1996	31DEC1996	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1990	31DEC1990	N
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2015		Y
		Social circumstances	Menopause	01JAN2011		Y
		Vascular disorders	Hypertension	22DEC2017		Y
	C4591001 1047 10471023	Endocrine disorders	Hyperparathyroidism	01JAN1998	31DEC2001	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1996	31DEC1996	N
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000	31DEC2001	N	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2012	N	
		Nervous system disorders	Migraine	01JAN2005		Y	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	21AUG1995	31DEC2005	N	
		Surgical and medical procedures	Inguinal hernia repair	01JAN1996	31DEC1996	N	
			Parathyroidectomy	01JAN2001	31DEC2001	N	
			Skin neoplasm excision	01JAN2012	31DEC2012	N	
			Spinal fusion surgery	01JAN2001	31DEC2001	N	
			Uvulopalatopharyngoplasty	01JAN2005	31DEC2005	N	
			Vascular disorders	Hypertension	01JAN2002		Y
			Gastrointestinal disorders	Constipation	01JAN2005		Y
	C4591001 1047 10471024	General disorders and administration site conditions	Oedema peripheral	01JAN1990		Y	
		Immune system disorders	Contrast media allergy	01JAN1990		Y	
			Drug hypersensitivity	01JAN2018		Y	
				01MAR2020		Y	
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2014	31DEC2016	N	
				01JAN2016	31DEC2016	N	
			Meniscus injury	01JAN2014	31DEC2016	N	
		Investigations	Blood potassium decreased	01JUN2020		Y	
		Metabolism and nutrition disorders	Fluid retention	01JAN1990		Y	
			Hypercholesterolaemia	01JAN2010		Y	
			Vitamin B12 deficiency	01JUN2020		Y	
			Vitamin D deficiency	01SEP2019		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2000	31DEC2000	N
			Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1960		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1983		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2000	31DEC2000	N
			Carpal tunnel decompression	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Knee arthroplasty	15JUN2016	15JUN2016	N
			Meniscus operation	01JAN2015	31DEC2015	N
			Spinal fusion surgery	15JUN2016	15JUN2016	N
				21AUG2014	21AUG2014	N
	C4591001 1047 10471026	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471027	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Streptococcal infection	01JAN1960	31DEC1962	N
		Investigations	Biopsy breast	01JAN1999	31DEC1999	N
				01JAN2016	31DEC2016	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2013	N
			Migraine	01JAN1991		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1988	31DEC1988	N
				01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ectopic pregnancy	01JAN1999	31DEC1999	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
			Peripheral nerve transposition	01JAN2013	31DEC2013	N
			Rhinoplasty	01JAN1972	31DEC1972	N
			Salpingostomy	01JAN1999	31DEC1999	N
			Spinal fusion surgery	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1047 10471031	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
					31DEC2000	N
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1961	31DEC1961	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN1997		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Systemic lupus erythematosus	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1961	31DEC1961	N
			Caesarean section	01JAN1987	31DEC1987	N
				01JAN1992	31DEC1992	N
			Open reduction of fracture	01JAN2014	31DEC2014	N
	C4591001 1047 10471032	Eye disorders	Cataract	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Osteoporosis	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Breast conserving surgery	01JUN2007	30JUN2007	N
			Bunion operation	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Cataract operation	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Surgery	01JUN1998	30JUN1998	N
	C4591001 1047 10471039	Endocrine disorders	Adrenal cyst	01JAN2003	31DEC2003	N
		Eye disorders	Astigmatism	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Chronic sinusitis	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Surgical and medical procedures	Adrenalectomy	01JAN2003	31DEC2003	N
			Carpal tunnel decompression	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinus operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1047 10471043	Endocrine disorders	Goitre	01JAN2003	31DEC2003	N
			Hyperthyroidism	01JAN2002	31DEC2003	N
			Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1964	31DEC1969	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN1982		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Endometriosis ablation	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN2002	31DEC2002	N
			Thyroidectomy	01JAN2003	31DEC2003	N
			Umbilical hernia repair	01JAN1969	31DEC1969	N
	C4591001 1047 10471045	Cardiac disorders	Cardiac disorder	01JAN1999		Y
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1990	31DEC1990	N
		Investigations	Arthroscopy	01JAN1990	31DEC1990	N
			Catheterisation cardiac	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Bone lesion excision	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1047 10471055	Infections and infestations	Tonsillitis	01JAN1960	31DEC1962	N
		Injury, poisoning and procedural complications	Femur fracture	01OCT2018	31OCT2018	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01OCT2018		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Surgical and medical procedures	Gastric bypass	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1047 10471060	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1999		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2005		Y
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
				01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1998		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Large intestine benign neoplasm	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Small intestinal resection	01JAN2010	31DEC2010	N
	C4591001 1047 10471062	Investigations	Blood cholesterol increased	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN1969	31DEC1969	N
		Reproductive system and breast disorders	Ovarian cyst	01JUN2017	30JUN2017	N
		Social circumstances	Organ donor	06DEC2018	06DEC2018	N
		Surgical and medical procedures	Limb operation	01JAN1969	31DEC1969	N
	C4591001 1047 10471063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2003		Y
			Osteoarthritis	01JAN1998		Y
	C4591001 1047 10471066	Eye disorders	Dry eye	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01JUN2011	30JUN2011	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JUN2016	30JUN2016	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01OCT2012	31OCT2012	N
			Tenosynovitis stenosans	01OCT2012	31OCT2012	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2004		Y
				01JAN2005		Y
		Reproductive system and breast disorders	Cervical polyp	01FEB2017	28FEB2017	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	25AUG2011	25AUG2011	N
			Cervical polypectomy	01FEB2017	28FEB2017	N
			Cholecystectomy	01JUN2011	30JUN2011	N
			Synovial cyst removal	01OCT2012	31OCT2012	N
			Tenoplasty	01JUN2016	30JUN2016	N
			Tenotomy	01OCT2012	31OCT2012	N
	C4591001 1047 10471072	Cardiac disorders	Bradycardia	01JAN2014		Y
		Endocrine disorders	Goitre	01JAN2005	31DEC2005	N
			Hypothyroidism	01JAN2005	31DEC2005	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Investigations	Arthroscopy	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN1987	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1986	31DEC1986	N
		Reproductive system and breast disorders	Menstruation irregular	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Cardiac ablation	01FEB2019	28FEB2019	N
				01JUL2020	31JUL2020	N
			Cardiac pacemaker insertion	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Renal stone removal	01JAN2006	31DEC2006	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
			Thyroidectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Raynaud's phenomenon	01JAN1997		Y
	C4591001 1047 10471073	Gastrointestinal disorders	Gastric ulcer	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN1990		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2000	31DEC2000	N
			Shoulder arthroplasty	01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N
				01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1047 10471090	Infections and infestations	Herpes zoster	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemochromatosis	01JAN2017		Y
			Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2018	N
				01JAN2018		Y
			Trigger finger	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
			Tendon sheath incision	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1047 10471091	Blood and lymphatic system disorders	Pernicious anaemia	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1988		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Reproductive system and breast disorders	Endometriosis	01JAN1980		Y
			Infertility	01JAN1980	31DEC1987	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fallopian tube operation	01JAN1988	31DEC1988	N
			Gastric banding	01JAN2010	31DEC2010	N
			Lithotripsy	01JAN2001	31DEC2001	N
			Open reduction of fracture	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1047 10471092	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Investigations	Catheterisation cardiac	01OCT2015	31OCT2015	N
	C4591001 1047 10471096	Congenital, familial and genetic disorders	Developmental hip dysplasia	(b) (6) 1958	31DEC1998	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN1999		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteonecrosis	01JAN1998	31DEC1998	N
		Product issues	Device breakage	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Bone operation	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN1998	31DEC1998	N
			Hip surgery	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471097	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1981		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471098	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Asthenopia	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1967		Y
		Surgical and medical procedures	Eye muscle operation	01JAN2018	31DEC2018	N
	C4591001 1047 10471099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Neck injury	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
			Intervertebral disc operation	01JAN2006	31DEC2006	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471101	Hepatobiliary disorders	Gallbladder disorder	01JAN1995	31DEC1995	N
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Vitamin D deficiency	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Cholecystectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471102	Infections and infestations	Tonsillitis	01JAN1956	31DEC1958	N
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1047 10471103	Investigations	Biopsy prostate normal	01JAN2019	31DEC2019	N
			Blood cholesterol increased	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2009	31DEC2009	N
			Lithotripsy	01JAN2010	31DEC2010	N
	C4591001 1047 10471104	Ear and labyrinth disorders	Ear disorder	01JAN1964	31DEC1971	N
		Endocrine disorders	Hyperthyroidism	01JAN1973	31DEC1977	N
				01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Infections and infestations	Adenoiditis	01JAN1964	31DEC1971	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2012	31DEC2012	N
			Meniscus injury	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1991		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	01JAN1964	31DEC1971	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1047 10471105	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastrointestinal disorder	01JAN1981	31DEC1981	N
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN1975		Y
			Vitamin B12 deficiency	01JAN2011		Y
		Nervous system disorders	Tension headache	01JAN1990		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
			Gastroplasty	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Salpingectomy	01JAN1981	31DEC1981	N
			Small intestinal resection	01JAN1998	31DEC1998	N
	C4591001 1047 10471108	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Injury, poisoning and procedural complications	Femur fracture	01AUG2014	31AUG2014	N
				01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1953	31DEC1953	N
	C4591001 1047 10471110	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
			Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1993	31DEC1999	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Intervertebral disc operation	01JAN1993	31DEC1993	N
				01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1047 10471113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Sarcoidosis	01JAN2003		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1967	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
		Psychiatric disorders	Depression	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Caesarean section	01JAN1983	31DEC1983	N
			Mastectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471114	Cardiac disorders	Cardiac failure congestive	01JAN2000		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Blindness unilateral	01APR2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1953	31DEC1953	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Surgical and medical procedures	Angioplasty	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471121	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Gastrointestinal disorders	Colitis ischaemic	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC1990		Y
			Obesity	01JAN1996		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Gastrectomy	01JAN2014	31DEC2014	N
			Renal stone removal	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
			Tenoplasty	01JAN2002	31DEC2002	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1047 10471122	Ear and labyrinth disorders	Vertigo	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Colitis microscopic	24FEB2020		Y
			Irritable bowel syndrome	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471123	Congenital, familial and genetic disorders	Congenital musculoskeletal anomaly	(b) (6) 1960	31DEC1982	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid neoplasm	01JAN2017	31DEC2017	N
		Nervous system disorders	Carotid artery disease	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1047 10471130	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Ear and labyrinth disorders	Tinnitus	01JAN1968	31DEC1968	N
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1994	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertriglyceridaemia	01JAN1968		Y
			Obesity	01JAN2008	31DEC2011	N
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006	31DEC2006	N
			Osteoarthritis	01JAN2003		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN1965		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008		Y
			Nephropathy	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2003	31DEC2003	N
			Sleep apnoea syndrome	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Gastrectomy	01JAN2011	31DEC2011	N
			Nasal septal operation	01JAN2003	31DEC2003	N
			Renal stone removal	01JAN2008	31DEC2018	N
			Spinal laminectomy	01JAN2006	31DEC2006	N
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN1968		Y
	C4591001 1047 10471132	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1978		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb injury	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Osteoarthritis	01JAN2019		Y
			Rotator cuff syndrome	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
		Renal and urinary disorders	Hypertonic bladder	01JAN1978		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Limb reattachment surgery	01JAN1993	31DEC1993	N
			Rotator cuff repair	01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
				01JAN2006	31DEC2006	N
			Urinary control neurostimulator implantation	01JAN2019	31DEC2019	N
	C4591001 1047 10471135	Gastrointestinal disorders	Umbilical hernia	01JUN2020	30JUN2020	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JUN2020	30JUN2020	N
			Vasectomy	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1047 10471136	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1047 10471137	Ear and labyrinth disorders	Meniere's disease	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1951		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2003	31OCT2003	N
			Colon cancer	01DEC2011	31DEC2011	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01OCT2003	31OCT2003	N
			Colectomy	01DEC2011	31DEC2011	N
	C4591001 1047 10471138	Cardiac disorders	Coronary artery disease	01JAN2017		Y
			Myocardial infarction	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
	C4591001 1047 10471139	Cardiac disorders	Angina pectoris	01JAN1992	31DEC1992	N
		Ear and labyrinth disorders	Tinnitus	01JAN1988		Y
		Eye disorders	Cataract	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN1972		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Lyme disease	01JAN2018	31DEC2018	N
			Sinusitis	01JAN1970		Y
			Tuberculosis	01JAN1982		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2011		Y
			Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1988		Y
		Psychiatric disorders	Insomnia	01JAN1988		Y
		Renal and urinary disorders	Urge incontinence	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2011		Y
		Surgical and medical procedures	Genitourinary operation	01JAN1998	31DEC1998	N
			Haemorrhoid operation	01OCT2017	31OCT2017	N
			Plastic surgery	01JAN1988	31DEC1988	N
			Sinus operation	01JAN2010	31DEC2010	N
			Spinal laminectomy	01JUN2016	30JUN2016	N
		Vascular disorders	Hypertension	01JAN2009	31DEC2015	N
	C4591001 1047 10471140	Cardiac disorders	Bradycardia	01JAN2000		Y
		Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Injury, poisoning and procedural complications	Stab wound	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Renal and urinary disorders	Renal failure	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471141	Gastrointestinal disorders	Barrett's oesophagus	01JAN2012		Y
			Diverticulum	01JAN2004		Y
			Diverticulum intestinal	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Aneurysm repair	01JAN1992	31DEC1992	N
			Sigmoidectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Aneurysm	01JAN1992	31DEC1992	N
			Hypertension	01JAN2010		Y
	C4591001 1047 10471142	Eye disorders	Cataract	01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1983	31DEC1983	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
	C4591001 1047 10471145	Ear and labyrinth disorders	Vertigo	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1975		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Cough	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471152	Eye disorders	Cataract	01JAN2002	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015	31DEC2015	N
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1961	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1047 10471154	Eye disorders	Glaucoma	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Typhoid fever	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1988	31DEC1988	N
		Investigations	Pelvic laparoscopy	01JAN1988	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Osteopenia	01JAN2003		Y
		Reproductive system and breast disorders	Infertility	01JAN1972	31DEC1972	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Ligament operation	01JAN1988	31DEC1988	N
		Vascular disorders	Varicose vein	01JAN2009	31DEC2009	N
	C4591001 1047 10471156	Hepatobiliary disorders	Cholelithiasis	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Injury, poisoning and procedural complications	Nerve injury	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2020	31JUL2020	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1047 10471157	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2020	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1940		Y
			Serum sickness	01JAN1940		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1968	31DEC1968	N
		Psychiatric disorders	Depression	01JAN1989		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Cancer surgery	01JAN1968	31DEC1968	N
			Cholecystectomy	01JAN2020	31JAN2020	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Knee arthroplasty	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1973		Y
			Thrombosis	01JAN2004	31DEC2004	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471158	Eye disorders	Blepharospasm	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007	31DEC2008	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2000	31DEC2002	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2008	31DEC2008	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2000	31DEC2010	N
			Limb operation	01JAN2002	31DEC2002	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1047 10471160	Gastrointestinal disorders	Gastritis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN2002		Y
				01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01APR2020	30APR2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N
			Female sterilisation	01JAN1989	31DEC1989	N
			Hysterectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendon sheath incision	01APR2020	30APR2020	N
	C4591001 1047 10471161	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
			Coronary artery disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1982	10DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cardiac ablation	01OCT2019	31OCT2019	N
			Coronary artery bypass	01DEC2011	31DEC2011	N
			Joint debridement	01JAN2018	31JAN2018	N
			Rhinoplasty	01MAR2018	31MAR2018	N
			Skin neoplasm excision	10DEC2019	10DEC2019	N
	C4591001 1047 10471165	Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
	C4591001 1047 10471169	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2013		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1047 10471170	Cardiac disorders	Ventricular extrasystoles	01JAN2018		Y
		Infections and infestations	Diverticulitis	01JAN1982	31DEC1982	N
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Surgical and medical procedures	Colectomy	01JAN1982	31DEC1982	N
			Large intestine anastomosis	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1047 10471173	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1952		Y
			Seasonal allergy	01JAN1962		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1983		Y
		Surgical and medical procedures	Ligament operation	01JAN1974	31DEC1974	N
			Umbilical hernia repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471175	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Hypertrichosis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bladder operation	01JAN2012	31DEC2012	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1047 10471177	Infections and infestations	Sinusitis	01JAN2005	31DEC2012	N
			Tonsillitis	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Bone cyst	01JAN1977	31DEC1977	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Bone cyst excision	01JAN1977	31DEC1977	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Sinus operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1047 10471178	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1955		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
	C4591001 1047 10471182	Eye disorders	Cataract	01JAN2010	31AUG2020	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN1996	31DEC1996	N
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471183	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Seasonal allergy	01JAN1951		Y
			Arthritis	01JAN1980		Y
			Back pain	01JAN1980		Y
			Rotator cuff syndrome	01JAN2010		Y
	C4591001 1047 10471184	Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1047 10471185	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471187	Cardiac disorders	Coronary artery disease	01JAN1980		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Diverticulum	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN1950		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Infections and infestations	Appendicitis perforated	01JAN1970	31DEC1970	N
			Oral herpes	01JAN1950		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
			Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Nervous system disorders	Essential tremor	01JAN2019		Y
			Myasthenia gravis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN1981		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1985		Y
			Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
			Cholecystectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1047 10471188	Gastrointestinal disorders	Abdominal hernia	(b) (6) 1950	31DEC1952	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1994	31DEC1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2019	15NOV2019	N
		Nervous system disorders	Syncope	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1985		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Papilloma excision	01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Orthostatic hypotension	01JAN2020		Y
	C4591001 1047 10471190	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	10OCT2011	02DEC2011	N
		Surgical and medical procedures	Breast reconstruction	02DEC2011	02DEC2011	N
			Knee arthroplasty	23JAN2020	23JAN2020	N
			Mastectomy	02DEC2011	02DEC2011	N
	C4591001 1047 10471191	Cardiac disorders	Aortic valve incompetence	01JAN2015	31DEC2016	N
			Cardiac failure congestive	01JAN2014		Y
			Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Eye disorders	Macular degeneration	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Bronchitis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
			Lower limb fracture	01JAN2000	31DEC2000	N
			Vascular pseudoaneurysm	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1975		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Back pain	01JAN1978		Y
			Scoliosis	01JAN2008		Y
		Nervous system disorders	Cerebrovascular accident	01JAN1993	31DEC1993	N
			Dementia	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Restless legs syndrome	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Renal and urinary disorders	Renal failure	01JAN2014		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1973	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
			Chronic obstructive pulmonary disease	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Aneurysm repair	01JAN2014	31DEC2014	N
			Aortic valve replacement	01APR2016	30APR2016	N
			Coronary artery bypass	01APR2016	30APR2016	N
			Fracture treatment	01JAN2000	31DEC2000	N
			Ostectomy	11AUG2016	11AUG2016	N
			Wound treatment	11AUG2016	11AUG2016	N
		Vascular disorders	Hypertension	01JAN1976		Y
	C4591001 1047 10471193	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
			Peptic ulcer	01JAN1980	31DEC1981	N
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2000		Y
				01JAN2010		Y
		Nervous system disorders	Dystonia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1980		Y
			Erectile dysfunction	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	10JAN1998	10JAN1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471194	Injury, poisoning and procedural complications	Hip fracture	01JAN2019	31DEC2019	N
			Joint injury	01JAN2011	31DEC2011	N
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Surgical and medical procedures	Gastric bypass	01JAN1993	31DEC1993	N
			Gastric bypass reversal	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
			Ligament operation	01JAN2011	31DEC2011	N
	C4591001 1047 10471195	Cardiac disorders	Atrial fibrillation	01JAN1995		Y
			Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Nausea	30MAY2020	06JUN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Ureteroscopy	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Nervous system disorders	Dizziness	30MAY2020	06JUN2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1988		Y
		Surgical and medical procedures	Angioplasty	01JAN2016	31DEC2016	N
			Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Lithotripsy	01JAN2005	31DEC2005	N
				01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1047 10471197	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Ligament operation	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1047 10471204	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
			Transurethral prostatectomy	01JAN2017	31DEC2017	N
	C4591001 1047 10471205	Hepatobiliary disorders	Gallbladder disorder	01MAY2019	31MAY2019	N
		Infections and infestations	Bronchitis	01DEC2018	31DEC2018	N
			Tonsillitis	01JAN1950	31DEC1955	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc protrusion	01JAN1991	31DEC1991	N
			Spondylitis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	16NOV1974	16NOV1974	N
				31OCT1968	31OCT1968	N
			Cholecystectomy	01MAY2019	31MAY2019	N
			Spinal laminectomy	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1955	31DEC1955	N
			Genital herpes	01JAN1988		Y
	C4591001 1047 10471206	Infections and infestations				
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1996	31DEC1996	N
			Osteoarthritis	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1996	31DEC1996	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
	C4591001 1047 10471208	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1991	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1946	31DEC1975	N
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Mammoplasty	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinoplasty	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1047 10471209	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2020	31JAN2020	N
		Injury, poisoning and procedural complications	Arterial injury	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2020	31JAN2020	N
			Nephrectomy	01SEP1972	30SEP1972	N
		Vascular disorders	Hypertension	01JAN1972		Y
	C4591001 1047 10471213	Cardiac disorders	Coronary artery disease	01JAN2003		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Heart rate irregular	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin D deficiency	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Coronary artery bypass	01JAN2003	31DEC2003	N
			Implantable defibrillator insertion	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1047 10471214	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1047 10471215	Vascular disorders	Hypertension	01JAN2002		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAY2005	31MAY2005	N
		Nervous system disorders	Restless legs syndrome	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Surgical and medical procedures	Penile prosthesis insertion	01JAN2010	31DEC2010	N
			Proctectomy	01JAN2005	31DEC2005	N
	C4591001 1047 10471216	Vascular disorders	Hypertension	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Varicose vein operation	01JAN2012	31DEC2012	N
		Vascular disorders	Deep vein thrombosis	01JAN2011	31DEC2011	N
			Hypertension	01JAN2000		Y
			Varicose vein	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471218	Nervous system disorders	Migraine	01JAN1960	31DEC1960	N
		Psychiatric disorders	Insomnia	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1047 10471222	Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2018		Y
			Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1047 10471224	Gastrointestinal disorders	Colitis	01JAN2012	31DEC2012	N
			Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Contrast media allergy	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01FEB2020	29FEB2020	N
			Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN1980		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Rotator cuff repair	01FEB2020	29FEB2020	N
	C4591001 1047 10471228	Eye disorders	Retinal detachment	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Colitis ulcerative	01JAN2012		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Meniscus injury	01MAY2020	01OCT2020	N
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Meniscus operation	01MAY2020	01OCT2020	N
			Retinopexy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1047 10471230	Cardiac disorders	Atrial fibrillation	01JAN2008		Y
		Congenital, familial and genetic disorders	Pyloric stenosis	(b) (6) 1956	(b) (6) 1956	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Chronic sinusitis	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1965	31DEC1965	N
			Tonsillar hypertrophy	01JAN1965	31DEC1965	N
		Surgical and medical procedures	Adenoidectomy	01JAN1965	31DEC1965	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Sinus operation	01JAN2005	31DEC2005	N
			Spinal laminectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1047 10471235	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Arthroscopy	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sinonasal papilloma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Sphenoid sinus operation	01JAN2016	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1047 10471239	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004	31DEC2004	N
	C4591001 1047 10471242	Cardiac disorders	Myocardial infarction	01JAN2012	31DEC2012	N
				01JAN2018	31DEC2018	N
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Coronary angioplasty	01JAN2012	31DEC2012	N
			Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1047 10471247	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2010	31DEC2010	N
	C4591001 1047 10471248	Cardiac disorders	Cardiomyopathy	01JAN2009		Y
			Coronary artery disease	01JAN2009		Y
		Endocrine disorders	Hypogonadism	01JAN2011		Y
			Hypothyroidism	01JAN1980		Y
		Eye disorders	Cataract	01JAN2014		Y
			Dry eye	01JAN1988		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glaucoma	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
			Haemorrhoids	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Infections and infestations	Oral herpes	01JAN1967		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1973	31DEC1973	N
			Tibia fracture	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1992		Y
			Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN1980		Y
			Vitamin B12 deficiency	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1972		Y
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC2000	N
			Neuropathy peripheral	01JAN1983		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Depression	01JAN1991		Y
			Insomnia	01JAN1991		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2014		Y
			Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
			Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1962		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fracture treatment	01JAN1973	31DEC1973	N
				01JAN1983	31DEC1983	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1047 10471249	Cardiac disorders	Ventricular tachycardia	01JAN2016		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Investigations	Catheterisation cardiac	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Gout	01JAN1982		Y
			Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN2016		Y
		Surgical and medical procedures	Implantable cardiac monitor insertion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1047 10471250	Cardiac disorders	Cardiac failure	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1946	31DEC1946	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2005	31DEC2005	N
			Hip fracture	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010	31DEC2010	N
	C4591001 1047	Surgical and medical procedures	Tonsillectomy	01JAN1946	31DEC1946	N
	10471252	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Arthrodesis	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
	C4591001 1047	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
	10471260		Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Mammoplasty	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1962	31DEC1962	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471261	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Tonsillectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1047 10471263	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Tenosynovitis stenosans	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Knee arthroplasty	01JAN1995	31DEC1995	N
	C4591001 1047 10471265	Eye disorders	Cataract	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
				01JAN2016		Y
				01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Appendicitis perforated	01JAN2003	31DEC2003	N
			Pneumonia	01JAN2018	31DEC2018	N
			Sepsis	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carotid artery occlusion	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Renal artery stenosis	10NOV2014	10NOV2014	N
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Carotid artery stent insertion	01JAN2005	31DEC2005	N
			Cataract operation	01JAN2007	31DEC2007	N
			Renal artery stent placement	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1047 10471268	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Infections and infestations	Herpes zoster	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Synovial cyst	01JAN1985	31DEC1985	N
		Nervous system disorders	Epilepsy	01JAN2015		Y
			Restless legs syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471269	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
			Escherichia infection	01APR2020	30APR2020	N
			Sepsis	01APR2020	30APR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Pain in extremity	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Hip arthroplasty	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1047 10471272	Cardiac disorders	Cardiac failure congestive	01JAN2009	31DEC2009	N
			Tachyarrhythmia	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2004		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1047 10471273	Eye disorders	Glaucoma	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1981	31DEC1981	N
			Meniscus injury	01JAN2007	31DEC2007	N
				01JAN2011	31DEC2011	N
		Investigations	Heart rate decreased	23JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
			Type 2 diabetes mellitus	01JAN1988		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUL2020		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JUN2020	30JUN2020	N
			Ligament operation	01JAN1981	31DEC1981	N
			Meniscus operation	01JAN2007	31DEC2007	N
				01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1047 10471274	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1047 10471276	Investigations	Blood cholesterol increased	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1047 10471277	Vascular disorders	Hypertension	01JAN2017		Y	
		Cardiac disorders	Atrial fibrillation	01JAN2006		Y	
				Atrial flutter	01JAN2019	31DEC2019	N
				Coronary artery disease	01JAN2006		Y
				Supraventricular tachycardia	01JAN2019	31DEC2019	N
			Eye disorders	Cataract	01JAN1989	31DEC1991	N
						31DEC1993	N
			Gastrointestinal disorders	Duodenal ulcer	01JAN1961	31DEC1962	N
				Gastroesophageal reflux disease	01JAN2000		Y
				Inguinal hernia	01JAN1974	15JUN1974	N
			Investigations	Angiocardiogram	19OCT2006	19OCT2006	N
				Catheterisation cardiac	01JUN2019	01JUN2019	N
			Metabolism and nutrition disorders	Gout	01JAN2019		Y
				Obesity	01JAN1970		Y
				Type 2 diabetes mellitus	01JAN2017		Y
			Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1991	22JUL1991	N
					01JAN2009	29JAN2009	N
				Osteoarthritis	01JAN1991		Y
				Rotator cuff syndrome	01JAN2009	31DEC2009	N
				Spinal stenosis	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of testis	01JAN1999	31DEC1999	N	
		Psychiatric disorders	Anxiety	01JAN1979		Y	
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y	



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JAN2019		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	03JUN2019	03JUN2019	N
			Cataract operation	02DEC1993	02DEC1993	N
				12SEP1991	12SEP1991	N
			Coronary arterial stent insertion	01JUN2019	01JUN2019	N
			Coronary artery bypass	26DEC2006	26DEC2006	N
			Inguinal hernia repair	15JUL1974	15JUL1974	N
			Intervertebral disc operation	29JAN2009	29JAN2009	N
			Knee arthroplasty	21APR2017	21APR2017	N
				21MAY2007	21MAY2007	N
			Rotator cuff repair	28SEP2009	28SEP2009	N
			Spinal laminectomy	07JUL2005	07JUL2005	N
			Testicular operation	04MAY1999	04MAY1999	N
			Vasectomy	15JUL1974	15JUL1974	N
				22MAY1987	22MAY1987	N
			Vasectomy reversal	20OCT1979	20OCT1979	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1047 10471280	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Diverticulitis	01SEP2009	30SEP2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma benign	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1047 10471281	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypolipidaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	01APR2020	30APR2020	N
		Surgical and medical procedures	Exeresis	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1047 10471282	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1940		Y
		Investigations	Arteriogram	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1047 10471283	Injury, poisoning and procedural complications	Meniscus injury	01JAN1979	31DEC1979	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Surgical and medical procedures	Meniscus operation	01JAN1979	31DEC1979	N
	C4591001 1047 10471290	Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
			Osteoarthritis	01JAN2010		Y
				01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Fracture treatment	01JAN1978	31DEC1978	N
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1047 10471298	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1047 10471299	Surgical and medical procedures	Caesarean section	11JAN1994	11JAN1994	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2005	N
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1047 10471300	Surgical and medical procedures	Carpal tunnel decompression	01JAN2005	31DEC2005	N
		Eye disorders	Cataract	01JAN2009		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Localised infection	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperkalaemia	01JAN2008		Y
			Hyperlipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2007		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Skin ulcer	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	23APR2013	23APR2013	N
			Toe amputation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1047 10471302	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
	C4591001 1047 10471309	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2018		Y
	C4591001 1047 10471311	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1965	31DEC1965	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2013		Y
			Reaction to colouring	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1985	31DEC1985	N
		Psychiatric disorders	Anxiety	01JAN1978		Y
			Depression	01JAN1978		Y
			Insomnia	01JAN1978		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Gastrectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oesophagogastric fundoplasty	01JAN1985	31DEC1985	N
				01JAN2018	31DEC2018	N
	C4591001 1047 10471313	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1047 10471315	Eye disorders	Dry eye	01MAY2019		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1047 10471320	General disorders and administration site conditions	Cyst	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1984		Y
			Spinal pain	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1984		Y
			Insomnia	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Post-traumatic stress disorder	01JAN1983		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Foot operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1047 10471323	Injury, poisoning and procedural complications	Thermal burn	01JAN2012	31DEC2012	N
	C4591001 1047 10471324	Injury, poisoning and procedural complications	Lower limb fracture	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Fracture treatment	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1047 10471330	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01FEB2019	28FEB2019	N
		Surgical and medical procedures	Inguinal hernia repair	01FEB2019	28FEB2019	N
	C4591001 1048 10481002	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Pain in extremity	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1048 10481003	Eye disorders	Myopia	01JAN1964		Y
			Presbyopia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020	10AUG2020	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1048 10481005	Cardiac disorders	Atrial fibrillation	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1048 10481006	Immune system disorders	Vitamin D deficiency	01JAN2016		Y
			Drug hypersensitivity	01FEB2013		Y
				01FEB2019		Y
				01JAN1980		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	08FEB2019	N
		Psychiatric disorders	Depression	01DEC2000		Y
		Reproductive system and breast disorders	Vaginal cyst	05MAY2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2013	31DEC2013	N
			Knee arthroplasty	08FEB2019	08FEB2019	N
	C4591001 1048 10481007	Cardiac disorders	Myocardial infarction	01JAN1992	31DEC1992	N
		Congenital, familial and genetic disorders	Factor V Leiden mutation	01SEP2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1964		Y
			Umbilical hernia	01DEC2019	31DEC2019	N
		General disorders and administration site conditions	Oedema peripheral	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2020	21OCT2020	N
			Back pain	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2019	N
			Malignant melanoma	01MAR2019	31MAR2019	N
		Nervous system disorders	Neuralgia	01JUL2020		Y
		Reproductive system and breast disorders	Prostatic mass	05JUL2018		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01SEP2016	30SEP2016	N
			Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Angioplasty	01JAN1984	31DEC1993	N
			Cardiac ablation	01NOV2011	30NOV2011	N
			Coronary artery bypass	01NOV1994	30NOV1994	N
			Skin neoplasm excision	01MAR2019	31MAR2019	N
			Umbilical hernia repair	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1048 10481008	Eye disorders	Angle closure glaucoma	06AUG2020		Y
			Presbyopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Hypersensitivity	01JAN1970		Y
			Rubber sensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Sinusitis	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01MAY2020		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481009	Eye disorders	Myopia	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2002	31DEC2002	N
		Nervous system disorders	Headache	01JAN1967		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1048 10481010	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2010		Y
			Myopia	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
			Tobacco user	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1048 10481012	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1980		Y
				01JAN1986		Y
				01JAN1995		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015		Y
		Infections and infestations	Chronic sinusitis	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
				01JAN2019		Y
		Social circumstances	Postmenopause	01NOV2011		Y
	C4591001 1048 10481013	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1979	31DEC2015	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Intervertebral disc operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1048 10481014	Eye disorders	Myopia	01JAN1975		Y
			Presbyopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01APR2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2019		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1048 10481015	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2013	31JUL2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Urinary bladder suspension	01JUL2018	31JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN1970		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1048 10481022	Cardiac disorders	Bradycardia	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2015	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2015	31DEC2015	N
	C4591001 1048 10481023	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2015		Y
	C4591001 1048 10481026	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01DEC2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1048 10481028	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01FEB2000		Y
		Social circumstances	Tobacco user	01JAN1967		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1048 10481029	Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1977		Y
		Social circumstances	Tobacco user	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481031	Cardiac disorders	Coronary artery disease	01JAN2002		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2005	10AUG2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
			Obesity	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
			Haemorrhoid operation	10AUG2020	10AUG2020	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1048 10481033	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1048 10481034	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Muscle strain	10AUG2020		Y
		Investigations	Smear cervix abnormal	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N
	C4591001 1048 10481036	Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Hypersensitivity	01JAN1954		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
			Trigger finger	01JAN2002		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1048 10481038	Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1048 10481039	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1048 10481041	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1995		Y
				01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017	28FEB2018	N
			Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Nasal septal operation	01FEB2018	28FEB2018	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481042	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1048 10481043	Eye disorders	Cataract	01JAN2008	05AUG2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010	01JAN2018 12AUG2020	Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1969		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Intraocular lens implant	05AUG2020	05AUG2020	N
				12AUG2020	12AUG2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1048 10481045	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid adenoma	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1048 10481047	Blood and lymphatic system disorders	Thrombocytopenia	01JAN1990		Y
		Immune system disorders	Hypersensitivity	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	11MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2005		Y
		Social circumstances	Postmenopause	01AUG2013		Y
	C4591001 1048 10481049	Eye disorders	Cataract	01FEB2020	30JUN2020	N
		Psychiatric disorders	Depression	01JAN1998		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2005	N
		Surgical and medical procedures	Cataract operation	01JUN2020	30JUN2020	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1048 10481051	Reproductive system and breast disorders	Endometriosis	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1048 10481053	Cardiac disorders	Atrial fibrillation	01AUG2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2009		Y
			Gastroesophageal reflux disease	01JAN1995		Y
			Oesophageal motility disorder	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Infections and infestations	Fungal skin infection	01JAN2004		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2010	31DEC2010	N
		Investigations	Blood testosterone decreased	01JAN2018		Y
			Cardiac murmur	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Nervous system disorders	Arachnoid cyst	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN1997		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1048 10481058	Investigations	Blood cholesterol increased	01DEC1980		Y
			Blood testosterone decreased	01AUG2015		Y
	C4591001 1048 10481060	Endocrine disorders	Goitre	01OCT2019		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01OCT2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1990		Y
			Eczema	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1048 10481062	Cardiac disorders	Mitral valve prolapse	01JAN1994	31DEC2017	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020	31AUG2020	N
		Psychiatric disorders	Affective disorder	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
	C4591001 1048 10481063	Surgical and medical procedures	Mitral valve repair	01JAN2017	31DEC2017	N
		Endocrine disorders	Goitre	01JAN2012	30NOV2012	N
			Hypothyroidism	01OCT2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1048 10481066	Eye disorders	Dry eye	01JAN2015		Y
		Nervous system disorders	Nerve compression	01JAN2011		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
	C4591001 1048 10481067	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2002		Y
			Vulvovaginal dryness	01JAN2017		Y
	C4591001 1048 10481068	Surgical and medical procedures	Shoulder arthroplasty	01JAN2020	31JAN2020	N
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Obesity	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Gastrectomy	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN2007	31DEC2007	N
	C4591001 1048 10481069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2019	N
			Hepatic steatosis	01JAN2016		Y
		Immune system disorders	Allergy to metals	01JAN2015		Y
			Food allergy	01JAN2015		Y
			Seasonal allergy	01DEC1977		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1048 10481071	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Surgical and medical procedures	Hip arthroplasty	01NOV2019	30NOV2019	N
	C4591001 1048 10481072	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1048 10481073	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
			Muscle spasms	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1048 10481074	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1999	31DEC1999	N
				01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
	C4591001 1048 10481077	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1992	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1048 10481078	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1048 10481081	Nervous system disorders	Guillain-Barre syndrome	01JAN1991	31DEC1991	N
			Neuropathy peripheral	01JAN1991		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1048 10481082	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	17AUG2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1048 10481084	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2019	31MAY2020	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hip arthroplasty	01MAY2020	31MAY2020	N
	C4591001 1048 10481087	Blood and lymphatic system disorders	Pernicious anaemia	01OCT2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Glaucoma	01SEP2019		Y
			Macular fibrosis	01OCT2019		Y
		Gastrointestinal disorders	Chronic gastritis	01JAN2019		Y
			Gastrointestinal haemorrhage	01JAN2019	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acrochordon	01JAN2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Prostatic urethral lift procedure	01FEB2020	31DEC2020	N
			Vitrectomy	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1048 10481089	Investigations	Blood cholesterol increased	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Polyarthritits	01JAN2004		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1048 10481090	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1048 10481091	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Gout	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN2019		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cardiac pacemaker insertion	01MAR2020	31MAR2020	N
			Spinal laminectomy	01JAN1971	31DEC1971	N
	C4591001 1048 10481096	Metabolism and nutrition disorders	Obesity	01JAN1980	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
			Uterine leiomyoma	01JAN1990	31DEC1991	N
		Nervous system disorders	Essential tremor	01JAN2000		Y
		Psychiatric disorders	Depression	01JUL2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Mastectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1048 10481099	Injury, poisoning and procedural complications	Vascular pseudoaneurysm	20JAN2014	20JAN2014	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Intracranial aneurysm	20JAN2014	20JAN2014	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2010	31DEC2010	N
			Peripheral artery stent insertion	20JAN2014	20JAN2014	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1048 10481100	Gastrointestinal disorders	Dyspepsia	01JAN1992		Y
		Renal and urinary disorders	Nocturia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481102	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1048 10481104	Endocrine disorders	Immune-mediated thyroiditis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1048 10481105	Skin and subcutaneous tissue disorders	Alopecia	01JAN1971		Y
	C4591001 1048 10481111	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01OCT2004		Y
		Surgical and medical procedures	Hysterectomy	11OCT2004	11OCT2004	N
	C4591001 1048 10481112	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Rubber sensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1978		Y
		Psychiatric disorders	Anxiety	01JAN1971		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1048 10481113	Endocrine disorders	Autoimmune thyroiditis	01JAN1990		Y
			Hypoparathyroidism	01JAN2010		Y
			Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2010	31DEC2010	N
			Thyroidectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1048 10481115	Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
	C4591001 1048 10481117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1048 10481118	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Toothache	01JAN2014		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Injury, poisoning and procedural complications	Stress fracture	01JUN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1999	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1048 10481119	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
	C4591001 1048 10481120	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1981		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1048 10481122	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1048 10481123	Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01AUG2020		Y
		Eye disorders	Cataract	01JAN2020	31JAN2020	N
				01NOV2019	30NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1967		Y
		Gastrointestinal disorders	Constipation	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
	C4591001 1048 10481124	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1048 10481127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1048 10481128	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1048 10481129	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1048 10481130	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Gastritis	01JAN1963		Y
			Gastrooesophageal reflux disease	01JAN1963		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1963		Y
			Insomnia	01JAN1963		Y
	C4591001 1048 10481133	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Petit mal epilepsy	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1048 10481134	General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1052 10521001	Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	01JAN1992	31DEC1992	N
	C4591001 1052 10521002	Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Tracheostomy	01NOV1979	31JAN1980	N
	C4591001 1052 10521008	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1052 10521010	Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
	C4591001 1052 10521023	Vascular disorders	Hypertension	01DEC2015		Y
	C4591001 1052 10521024	Investigations	Blood pressure measurement	01JAN2009		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2019		Y
	C4591001 1052 10521025	Surgical and medical procedures	Eye laser surgery	01JAN1970	31DEC1970	N
			Knee arthroplasty	01JAN1980	31DEC1980	N
			Wrist surgery	01JAN1974	31DEC1974	N
	C4591001 1052 10521033	Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1052 10521042	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Renal and urinary disorders	Nephropathy	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1052 10521045	Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1052 10521047	Social circumstances	Postmenopause	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1052 10521048	Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1052 10521059	Nervous system disorders	Sciatica	10APR2008		Y
	C4591001 1052 10521060	Investigations	Blood cholesterol	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1052 10521067	Surgical and medical procedures	Wrist surgery	01JAN1990	31DEC1990	N
	C4591001 1052 10521069	Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hip arthroplasty	12MAR2020	12MAR2020	N
	C4591001 1052 10521078	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2000	29FEB2000	N
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Tonsillectomy	03FEB1961	03FEB1961	N
	C4591001 1052 10521085	Investigations	Blood pressure measurement	01JAN2019		Y
			Colonoscopy	15SEP2018	15SEP2018	N
	C4591001 1052 10521088	Surgical and medical procedures	Gastric bypass	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1052 10521089	Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1052 10521095	Surgical and medical procedures	Knee operation	15JUL2017	15OCT2017	N
	C4591001 1052 10521098	Endocrine disorders	Hyperthyroidism	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Tenoplasty	01JUN2001	30JUN2001	N
			Thyroidectomy	01JUN1993	30JUN1993	N
	C4591001 1052 10521108	Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1052 10521115	Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1052 10521118	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1052 10521122	Injury, poisoning and procedural complications	Epicondylitis	01JAN2013	31DEC2013	N
			Fall	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2005	31DEC2005	N
	C4591001 1052 10521127	Surgical and medical procedures	Large intestine operation	20MAR2015	20JAN2016	N
	C4591001 1052 10521128	Vascular disorders	Hypertension	15FEB2020		Y
	C4591001 1052 10521136	Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Knee operation	01JAN2000	31DEC2000	N
			Shoulder operation	01JAN2007	31DEC2007	N
			Wrist surgery	01JAN2010	31DEC2010	N
	C4591001 1052 10521137	Surgical and medical procedures	Female sterilisation	11AUG1992	15AUG1992	N
	C4591001 1052 10521138	Psychiatric disorders	Depression	17AUG2020	17AUG2020	N
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	17AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1052 10521142	Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1052 10521144	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN1984		Y
	C4591001 1052 10521147	Eye disorders	Glaucoma	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2014	16OCT2019	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2014	16OCT2019	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1052 10521151	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1052 10521156	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1052 10521171	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1054 10541009	Injury, poisoning and procedural complications	Scar	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Overweight	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Varicose vein	01JAN2000		Y
	C4591001 1054 10541015	Gastrointestinal disorders	Umbilical hernia	01JAN1957		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Overweight	01JAN2019		Y
	C4591001 1054 10541021	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1054 10541024	Social circumstances	Menopause	01JAN2004		Y
	C4591001 1054 10541030	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1968	31DEC1970	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2017		Y
		Infections and infestations	Bronchitis	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1992	31DEC1992	N
			Scar	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1986		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000		Y
		Nervous system disorders	Hypoaesthesia	01JAN2018		Y
			Neuropathy peripheral	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1054 10541031	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
			Polypectomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1054 10541036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Social circumstances	Limb prosthesis user	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
	C4591001 1054 10541045	Gastrointestinal disorders	Large intestine polyp	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1983	31DEC1983	N
		Investigations	Colonoscopy	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Surgical and medical procedures	Laparotomy	01JAN1983	31DEC1983	N
			Polypectomy	01JAN2013	31DEC2013	N
	C4591001 1054 10541046	Congenital, familial and genetic disorders	Thalassaemia minor	(b) (6) 1952		Y
		Infections and infestations	Onychomycosis	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Bone operation	01JAN2015	31DEC2015	N
	C4591001 1054 10541056	Injury, poisoning and procedural complications	Scar	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1992		Y
			Back pain	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Ligament operation	01JAN1992	31DEC1992	N
				01JAN1995	31DEC1995	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1054 10541059	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Inguinal hernia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Nasal congestion	01JAN2020		Y
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
			Limb operation	01JAN2018	31DEC2018	N
	C4591001 1054 10541063	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Scar	01JAN1995		Y
				28JAN1994		Y
			Skin laceration	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	28JAN1994	28JAN1994	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1054 10541071	Investigations	Cardiac murmur	28AUG2020		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1054 10541072	Gastrointestinal disorders	Inguinal hernia	01JAN1975	31DEC1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Onychomycosis	01JAN2015		Y
		Injury, poisoning and procedural complications	Scar	01JAN1975		Y
	C4591001 1054 10541075	Surgical and medical procedures	Inguinal hernia repair	01JAN1975	31DEC1975	N
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Glaucoma	01JAN2018	31DEC2018	N
		Infections and infestations	Onychomycosis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Pruritus	01FEB2020		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Glaucoma surgery	01JAN2018	31DEC2018	N
	C4591001 1054 10541077	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
			Pneumonia	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Scar	01JAN1969		Y
				01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01APR2020		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
			Bipolar disorder	01JAN2004		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1054 10541079	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1054 10541082	Infections and infestations	Onychomycosis	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2000		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1054 10541083	Infections and infestations	Onychomycosis	01JAN2018		Y
		Investigations	Cardiac murmur	28AUG2020		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1054 10541093	Injury, poisoning and procedural complications	Scar	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1983		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Depression	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1054 10541095	Cardiac disorders	Ventricular extrasystoles	01JAN1972		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Inguinal hernia	01JAN1955	31DEC1955	N
		Infections and infestations	Onychomycosis	01JAN2002		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1993	31DEC1993	N
			Scar	01JAN1955		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wrist fracture	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2003	31DEC2003	N
				01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1054 10541099	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Injury, poisoning and procedural complications	Scar	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1054 10541102	Blood and lymphatic system disorders	Polycythaemia	01JAN2018		Y
			Thrombocytopenia	01OCT2018		Y
		Cardiac disorders	Sinus node dysfunction	01JAN2000		Y
		Endocrine disorders	Hypogonadism	01JAN1952		Y
			Hypothyroidism	01JAN1952		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Scar	01JAN1981		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2001	31DEC2001	N
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Radical prostatectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Aortic dilatation	01JAN2000		Y
			Hypertension	01JAN2010		Y
	C4591001 1054 10541103	Social circumstances	Menopause	01JAN2002		Y
	C4591001 1054 10541105	Eye disorders	Cataract	01JAN2019		Y
		Injury, poisoning and procedural complications	Fibula fracture	01FEB2019	28FEB2019	N
			Scar	01APR1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian dysgerminoma stage unspecified	01APR1990	30APR1990	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
			Urticaria	01JAN1990		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01APR1990	30APR1990	N
			Fracture treatment	01FEB2019	28FEB2019	N
			Oophorectomy	01APR1990	30APR1990	N
		Vascular disorders	Hot flush	01JAN2001		Y
	C4591001 1054 10541112	Injury, poisoning and procedural complications	Scar	01JAN1968		Y
			Skin laceration	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle twitching	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1054 10541114	Injury, poisoning and procedural complications	Scar	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010		Y
			Muscle spasms	01JAN2019	31DEC2010	N
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1054 10541116	Investigations	Cardiac murmur	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Limb deformity	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1054 10541118	Injury, poisoning and procedural complications	Gun shot wound	01JAN1990	31DEC1990	N
			Scar	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Finger deformity	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1054 10541124	Ear and labyrinth disorders	Vertigo	24APR2020	28APR2020	N
		Endocrine disorders	Hypothyroidism	01MAR2019		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Infections and infestations	Conjunctivitis	09MAR2019	16MAR2019	N
		Investigations	Prostatic specific antigen increased	09MAR2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020	30JUN2020	N
			Back pain	01JAN2020	30JUN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	07APR2015	30APR2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Spermatocele	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Epididymal cyst removal	01JAN2005	31DEC2005	N
			Haemorrhoid operation	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
			Skin neoplasm excision	01APR2015	30APR2015	N
	C4591001 1054 10541126	General disorders and administration site conditions	Oedema peripheral	01AUG2020		Y
		Injury, poisoning and procedural complications	Skin abrasion	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2017		Y
		Psychiatric disorders	Depression	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Skin exfoliation	01JUN2020		Y
	C4591001 1054 10541128	Injury, poisoning and procedural complications	Scar	07JUN1992		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2016	31DEC2016	N
				01OCT2014	31OCT2014	N
		Social circumstances	Menopause	01JUN2010		Y
		Surgical and medical procedures	Caesarean section	07JUN1992	07JUN1992	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
				01OCT2014	31OCT2014	N
			Mammoplasty	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541129	Infections and infestations	Oral herpes	01JAN2010		Y
		Injury, poisoning and procedural complications	Scar	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1973	31DEC2009	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1054 10541132	Injury, poisoning and procedural complications	Scar	01AUG2010		Y
		Surgical and medical procedures	Intervertebral disc operation	01AUG2010	31AUG2010	N
	C4591001 1054 10541133	Infections and infestations	Appendicitis	01JAN1961	31DEC1961	N
		Injury, poisoning and procedural complications	Scar	01JAN1961		Y
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
	C4591001 1054 10541134	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1054 10541136	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1976	31DEC1976	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN2015		Y
			Oesophageal ulcer	01JAN2015	31DEC2015	N
			Rectal prolapse	01JAN1990	31DEC1990	N
		Immune system disorders	Hypersensitivity	01JAN1965		Y
		Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1974	31DEC1974	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Back pain	01JAN1964		Y
			Osteoarthritis	01JAN1980		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01OCT2019	31OCT2019	N
			Squamous cell carcinoma	01JUN2020	30NOV2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950	31DEC1980	N
			Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Fracture treatment	01JAN1974	31DEC1974	N
			Micrographic skin surgery	01OCT2019	31OCT2019	N
			Rectal prolapse repair	01JAN1990	31DEC1990	N
			Varicose vein operation	01JAN2017	31JAN2017	N
		Vascular disorders	Essential hypertension	01JAN2017		Y
			Varicose vein	01JAN2010		Y
	C4591001 1054 10541139	Gastrointestinal disorders	Oesophagitis	01JUL2020		Y
		Injury, poisoning and procedural complications	Scar	08JAN1980		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	05FEB1984	05FEB1984	N
				08JAN1980	08JAN1980	N
	C4591001 1054 10541142	Infections and infestations	Genital herpes	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinusitis	01JAN1992	31DEC1995	N
			Urinary tract infection	01JAN2005	31DEC2005	N
		Nervous system disorders	Headache	01JAN2000		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Sinus operation	01JAN1995	31DEC1995	N
	C4591001 1054 10541143	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
			Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Scar	01JAN1996		Y
				01JAN2010		Y
				01JAN2017		Y
				01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008	31DEC2010	N
				01JAN2010		Y
			Bone erosion	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid neoplasm	01JAN1996	31DEC1996	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Menopause	01JAN1959		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
			Thyroidectomy	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urinary bladder suspension	01JAN2016	31DEC2016	N
	C4591001 1054 10541146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2020	31JAN2020	N
			Lymphoma	01JAN1998	31DEC1998	N
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Lymphoma operation	01JAN1998	31DEC1998	N
			Micrographic skin surgery	01JAN2020	31JAN2020	N
			Skin lesion removal	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1054 10541149	Eye disorders	Pterygium	10SEP2020		Y
		Investigations	Weight increased	01JUN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	27SEP2019	27SEP2019	N
		Surgical and medical procedures	Transurethral prostatectomy	27SEP2019	27SEP2019	N
	C4591001 1054 10541151	Gastrointestinal disorders	Small intestinal obstruction	01JAN2009	31DEC2009	N
		Immune system disorders	Hypersensitivity	01JAN1965		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Scar	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Bursitis	29DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc degeneration	05MAR2020		Y
			Osteoarthritis	09JAN2020		Y
			Osteoporosis	02JAN2006		Y
		Nervous system disorders	Radiculopathy	05MAR2020		Y
		Psychiatric disorders	Depression	01JUN2020		Y
			Panic disorder	01JAN1989		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1992	31DEC1992	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Surgical and medical procedures	Appendectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Small intestinal resection	01JAN2009	31DEC2009	N
	C4591001 1054 10541156	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1054 10541159	Injury, poisoning and procedural complications	Scar	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1054 10541164	Psychiatric disorders	Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2015		Y
	C4591001 1054 10541166	Psychiatric disorders	Depression	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541167	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 1 diabetes mellitus	01JAN1974		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1054 10541168	Injury, poisoning and procedural complications	Scar	22MAR1976		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	22MAR1976	22MAR1976	N
				26OCT1979	26OCT1979	N
	C4591001 1054 10541169	Infections and infestations	Abscess limb	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1978	31DEC1978	N
			Scar	01JAN1978		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Surgical and medical procedures	Abscess drainage	01JAN2000	31DEC2000	N
			Knee operation	01JAN1978	31DEC1978	N
	C4591001 1054 10541173	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Infections and infestations	Appendicitis	01MAY2005	31MAY2005	N
			Onychomycosis	01JAN2015		Y
		Injury, poisoning and procedural complications	Scar	01MAY2005		Y
		Nervous system disorders	Neuralgia	11SEP2020		Y
		Surgical and medical procedures	Appendicectomy	01MAY2005	31MAY2005	N
	C4591001 1054 10541177	Gastrointestinal disorders	Dyspepsia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia	01JAN1951		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Glucose tolerance impaired	15JUL2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2018	30NOV2019	N
		Surgical and medical procedures	Prostatectomy	01JUN2019	30JUN2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1054 10541180	Infections and infestations	Onychomycosis	01JAN2018		Y
		Injury, poisoning and procedural complications	Scar	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1992	31DEC1993	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Spinal laminectomy	01JAN1993	31DEC1993	N
	C4591001 1054 10541181	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2011	31DEC2011	N
			Scar	01JUL2007		Y
				01SEP2011		Y
			Stab wound	01JUL2007	31JUL2007	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Knee operation	01SEP2011	30SEP2011	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541183	Blood and lymphatic system disorders	Iron deficiency anaemia	27AUG2019	16OCT2019	N
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1999	31DEC1999	N
			Scar	01JAN1999		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Neck mass	01JAN2004		Y
		Nervous system disorders	Syncope	15OCT2019	15OCT2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2009	31DEC2009	N
	C4591001 1054 10541185	Gastrointestinal disorders	Inguinal hernia	01JAN1997		Y
				01JAN2010		Y
			Umbilical hernia	01DEC2019		Y
		Injury, poisoning and procedural complications	Scar	01JAN1997		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1054 10541186	General disorders and administration site conditions	Cyst	01JAN2019		Y
		Infections and infestations	Appendicitis	14FEB2017	14FEB2017	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	14FEB2017	14FEB2017	N
	C4591001 1054 10541187	Eye disorders	Eyelid ptosis	01JAN2014		Y
		Investigations	Cardiac murmur	23SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1054 10541188	Infections and infestations	Onychomycosis	01JAN2019		Y
		Injury, poisoning and procedural complications	Scar	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	16AUG1984		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2012	31DEC2013	N
		Surgical and medical procedures	Caesarean section	01JAN1996		Y
				06OCT1991	06OCT1991	N
				16AUG1984	16AUG1984	N
				22AUG1994	22AUG1994	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
	C4591001 1054 10541194	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
		Hepatobiliary disorders	Cholecystitis	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Scar	11AUG1992		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	11AUG1992	11AUG1992	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Gastric bypass	01JAN1998	31DEC1998	N
			Inguinal hernia repair	01JAN2004	31DEC2004	N
	C4591001 1054 10541195	Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1974	31DEC1974	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Obesity	01JAN2010		Y
	C4591001 1054 10541196	Infections and infestations	Onychomycosis	01JAN2010		Y
		Injury, poisoning and procedural complications	Scar	01FEB2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	10JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01FEB2000	29FEB2000	N
		Surgical and medical procedures	Hysterectomy	01FEB2000	29FEB2000	N
	C4591001 1054 10541198	Injury, poisoning and procedural complications	Fibula fracture	01JAN1977	31DEC1977	N
			Road traffic accident	01JAN2003	31DEC2003	N
			Scar	01JAN2003	31DEC2003	N
			Tibia fracture	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Closed fracture manipulation	01JAN1977	31DEC1977	N
	C4591001 1054 10541202	Infections and infestations	Sinusitis	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1054 10541205	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1054 10541209†	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Glaucoma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN1995	31DEC2018	N
			Syphilis	01JAN2000	31DEC2000	N
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N
			HIV test positive	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
	C4591001 1054 10541210	General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Infections and infestations	Onychomycosis	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Drug dependence	01JAN2018		Y
	C4591001 1054 10541211	Ear and labyrinth disorders	Deafness bilateral	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Scar	01JAN2010	31DEC2010	N
				16NOV1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Caesarean section	16NOV1994	16NOV1994	N
			Cochlea implant	01JAN2017	31DEC2017	N
			Synovial cyst removal	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1054 10541213†	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Infections and infestations	Hepatitis C	01JAN2005		Y
		Investigations	HIV test positive	01JAN1988		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1055 10551002	Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
				01JAN2015		Y
	C4591001 1055 10551004	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1055 10551005	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Ear and labyrinth disorders	Deafness bilateral	01APR2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1055 10551006	Endocrine disorders	Hypothyroidism	01SEP1988		Y
		Eye disorders	Keratoconus	01JAN1969		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP1993		Y
		Immune system disorders	Reaction to preservatives	01JAN1999		Y
			Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2018		Y
			Lactose intolerance	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary granuloma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01DEC2010		Y
	C4591001 1055 10551008	Cardiac disorders	Mitral valve prolapse	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Raynaud's phenomenon	01JAN1985		Y
	C4591001 1055 10551009	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Surgical and medical procedures	Vasectomy	01JAN1991	01JAN1991	N
	C4591001 1055 10551010	Social circumstances	Postmenopause	01OCT2013		Y
	C4591001 1055 10551011	Ear and labyrinth disorders	Vertigo positional	01JAN2018		Y
		Vascular disorders	Hypertension	01JUL1985		Y
	C4591001 1055 10551014	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551015	Ear and labyrinth disorders	Deafness bilateral	(b) (6) 1957		Y
		Eye disorders	Cataract	01JAN2015		Y
			Glaucoma	01JAN2008		Y
	C4591001 1055 10551017	Gastrointestinal disorders	Constipation	01JAN2019		Y
		Social circumstances	Postmenopause	01JUN2013		Y
	C4591001 1055 10551018	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1055 10551019	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Lactose intolerance	14JAN1986		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551023	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Lactose intolerance	(b) (6) 1949		Y
		Musculoskeletal and connective tissue disorders	Back pain	27DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1959		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2000		Y
		Social circumstances	Postmenopause	01MAR2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN1979	31DEC1979	N
	C4591001 1055 10551024	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN1961		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1971		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Nocturia	01JAN1995		Y
	C4591001 1055 10551027	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1055 10551030	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL1990		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1055 10551031	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1055 10551033	Immune system disorders	Drug hypersensitivity	01JAN1953		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1055 10551035	Immune system disorders	Seasonal allergy	01MAR2017		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1055 10551036	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Social circumstances	Postmenopause	01DEC2010		Y
	C4591001 1055 10551038	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	13AUG2015		Y
	C4591001 1055 10551039	Eye disorders	Glaucoma	03JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1055 10551041	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1055 10551048	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2012		Y
	C4591001 1055 10551052	Immune system disorders	Seasonal allergy	01MAR1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15JAN2010		Y
	C4591001 1055 10551053	Endocrine disorders	Hypothyroidism	25MAR1995		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1055 10551055	Eye disorders	Cataract	01JAN2018		Y
			Uveitis	01JAN2018		Y
		Immune system disorders	Sarcoidosis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551059	Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
	C4591001 1055 10551060	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1055 10551062	Immune system disorders	Seasonal allergy	14APR1970		Y
		Social circumstances	Postmenopause	01AUG2015		Y
		Vascular disorders	Hypertension	18APR2016		Y
	C4591001 1055 10551064	Immune system disorders	Food allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1055 10551065	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1965		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1055 10551068	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551069	Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01APR2000		Y
	C4591001 1055 10551070	Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1055 10551079	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1055 10551081	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1055 10551083	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
	C4591001 1055 10551088	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	15AUG2015	29SEP2015	N
		Nervous system disorders	Migraine	01JAN1964	31DEC2020	N
		Surgical and medical procedures	Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1055 10551091	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Vascular disorders	Peripheral arterial occlusive disease	01JAN2016		Y
	C4591001 1055 10551093	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	20JUL1987	15SEP2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551094	Skin and subcutaneous tissue disorders	Dermatomyositis	01JAN1995	31DEC1998	N
	C4591001 1055 10551095	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1055 10551096	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1055 10551098	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2010	31AUG2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1055 10551101	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01SEP1997	31DEC1997	N
			Malignant melanoma	01JUL2019	20AUG2020	N
		Surgical and medical procedures	Mastectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1055 10551102	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Hepatitis C	01JAN2010	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1055 10551106	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	10FEB2020		Y
	C4591001 1055 10551107	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1055 10551108	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2010		Y
	C4591001 1055 10551109	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1055 10551110	Metabolism and nutrition disorders	Hyperlipidaemia	10JAN2005		Y
	C4591001 1055 10551111	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	17JUN2013		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Peripheral vascular disorder	20APR2010		Y
	C4591001 1055 10551113	Endocrine disorders	Hypogonadism	01JAN1990		Y
	C4591001 1055 10551114	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551120	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1055 10551122	Cardiac disorders	Mitral valve prolapse	01JAN1991		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
	C4591001 1055 10551123	Cardiac disorders	Atrial fibrillation	01JAN2009		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2019	31DEC2019	N
	C4591001 1055 10551124	Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2018		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01FEB2018	28FEB2018	N
			Intracranial aneurysm	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1055 10551126	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1055 10551127	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2003	31MAY2008	N
	C4591001 1055 10551130	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1055 10551137	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Thyroidectomy	01APR2018	30APR2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551140	Cardiac disorders	Mitral valve prolapse	01JAN1996		Y
	C4591001 1055 10551141	Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1055 10551142	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1981		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1055 10551147	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01DEC2007		Y
	C4591001 1055 10551148	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1055 10551149	Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2008		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1055 10551153	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01FEB2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551154	Infections and infestations	Herpes simplex	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1055 10551155	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551158	Immune system disorders	Seasonal allergy	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
	C4591001 1055 10551159	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2007		Y
			Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1055 10551160	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1055 10551164	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1055 10551166	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1950		Y
	C4591001 1055 10551167	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1055 10551170	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1055 10551172	Endocrine disorders	Hypothyroidism	01JAN1967		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01SEP1999		Y
	C4591001 1055 10551178	Cardiac disorders	Supraventricular extrasystoles	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1970		Y
	C4591001 1055 10551180	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung carcinoma cell type unspecified stage IV	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Pneumonectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1055 10551182	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1055 10551185	Cardiac disorders	Supraventricular tachycardia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01MAR2019		Y
	C4591001 1055 10551187	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1055 10551191	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551194	Nervous system disorders	Migraine	01JAN2002		Y
	C4591001 1055 10551197	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle twitching	01SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV1998	31DEC1999	N
		Surgical and medical procedures	Mastectomy	01JAN1999	31DEC1999	N
	C4591001 1055 10551199	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1055 10551201	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
	C4591001 1055 10551205	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1055 10551209	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
	C4591001 1055 10551210	Endocrine disorders	Hypothyroidism	20JUL2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20JUL1995		Y
	C4591001 1055 10551212	Endocrine disorders	Hypothyroidism	01JUL1978		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL1999		Y
		Vascular disorders	Hypertension	01JUL1999		Y
	C4591001 1055 10551216	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01AUG2017	31OCT2018	N
		Surgical and medical procedures	Mastectomy	01OCT2018	31OCT2018	N
	C4591001 1055 10551227	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1055 10551236	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1055 10551248	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1056 10561005	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Gout	01JAN2006		Y
			Overweight	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
	C4591001 1056 10561008	Vascular disorders	Hypertension	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	17JUN2020	17JUN2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Reproductive system and breast disorders	Breast cyst	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1056 10561011	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561014	Congenital, familial and genetic disorders	Spina bifida	(b) (6) 1943	31DEC1960	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Spinal cord operation	01JAN1960	31DEC1960	N
	C4591001 1056 10561015	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561018	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561023	Congenital, familial and genetic disorders	Renal aplasia	(b) (6) 1950		Y
		Gastrointestinal disorders	Lumbar hernia	01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1056 10561024	Metabolism and nutrition disorders	Overweight	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign salivary gland neoplasm	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Salivary gland operation	01JAN2000	31DEC2000	N
	C4591001 1056 10561030	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1056 10561032	Hepatobiliary disorders	Cholecystitis	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N
			Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1056 10561034	Cardiac disorders	Mitral valve prolapse	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Infections and infestations	Pelvic inflammatory disease	01JAN1999	31DEC2003	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1056 10561035	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2011		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	10FEB1987	10FEB1987	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1056 10561036	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Thyroid nodule removal	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561037	Injury, poisoning and procedural complications	Limb injury	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Limb operation	01JAN2015	31DEC2015	N
			Shoulder arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1056 10561043	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Mammoplasty	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561044	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561045	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Fracture treatment	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561047	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
			Foot operation	01JAN2008	31DEC2008	N
	C4591001 1056 10561048	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
	C4591001 1056 10561049	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
	C4591001 1056 10561051	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1975	31DEC1975	N
	C4591001 1056 10561052	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1056 10561055	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561056	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
	C4591001 1056 10561057	Metabolism and nutrition disorders	Gout	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Prostatectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1056 10561062	Hepatobiliary disorders	Cholelithiasis	01MAY2019	30JUN2019	N
		Metabolism and nutrition disorders	Overweight	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2019	30JUN2019	N
	C4591001 1056 10561063	Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Overweight	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
			Emphysema	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561064	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1056 10561066	Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561067	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561068	Injury, poisoning and procedural complications	Limb injury	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Shoulder operation	01JAN2004	31DEC2004	N
	C4591001 1056 10561070	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
			Insomnia	01JAN2015		Y
	C4591001 1056 10561074	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561075	Metabolism and nutrition disorders	Overweight	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2008		Y
	C4591001 1056 10561078	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1056 10561079	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Nervous system disorders	Epilepsy	01JAN1960		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561080	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
	C4591001 1056 10561083	Gastrointestinal disorders	Gastritis	01JAN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1056 10561084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y
	C4591001 1056 10561085	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
	C4591001 1056 10561086	Congenital, familial and genetic disorders	Cataract congenital	(b) (6) 1961	31DEC2016	N
		Eye disorders	Retinal detachment	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561091	Gastrointestinal disorders	Umbilical hernia	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561093	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1056 10561095	Vascular disorders	Hypertension	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561096	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561099	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1056 10561105	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1056 10561106	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561107	Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Surgical and medical procedures	Tonsillectomy	01JAN1957	31DEC1957	N
	C4591001 1056 10561109	Metabolism and nutrition disorders	Overweight	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561114	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561120	Cardiac disorders	Myocardial infarction	01JAN2004	31DEC2004	N
		Eye disorders	Strabismus	(b) (6) 1955		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1056 10561122	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561123	Metabolism and nutrition disorders	Overweight	01JAN2013		Y
	C4591001 1056 10561124	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561125	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1056 10561127	Gastrointestinal disorders	Umbilical hernia	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561128	Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Salpingectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561133	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	13JUN1990	13JUN1990	N
	C4591001 1056 10561134	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561136	Cardiac disorders	Angina pectoris	01JAN2017		Y
			Myocardial infarction	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Angioplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561137	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1964		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561140	Endocrine disorders	Hypothyroidism	01JAN1967		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1056 10561141	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
			Myocardial infarction	07JUL2016	07JUL2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Overweight	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	07JUL2016	07JUL2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1056 10561143	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Sinus node dysfunction	01JAN2013		Y
		Gastrointestinal disorders	Gastritis	01JAN2016		Y
			Haemorrhoids	01JAN2015		Y
			Oesophagitis	01JAN2016	31DEC2016	N
		Infections and infestations	Diverticulitis	01JAN2012	31DEC2012	N
			Hepatitis A	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
		Investigations	Cardiac murmur	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Psychiatric disorders	Colon adenoma	01JAN2012	31DEC2012	N
			Depression	01JAN1994		Y
			Drug dependence	01JAN1998		Y
			Schizophrenia	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Mastectomy	01JAN2009	31DEC2009	N
			Open reduction of fracture	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2013		Y
			Peripheral vascular disorder	01JAN2013		Y
			Obesity	01JAN2000		Y
	C4591001 1056 10561144	Metabolism and nutrition disorders				
	C4591001 1056 10561148	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Gout	01JAN2018		Y
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561150	Cardiac disorders	Arrhythmia	01JAN1996	26OCT1996	N
		Infections and infestations	Appendicitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Nervous system disorders	Amnesia	01JAN2019		Y
			Carpal tunnel syndrome	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neuralgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1972		Y
			Depression	01JAN1972		Y
			Major depression	01JAN1972		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1958	31DEC1958	N
		Surgical and medical procedures	Appendicectomy	01JAN1958	31DEC1958	N
			Cardiac pacemaker insertion	26OCT1996	26OCT1996	N
			Gastric bypass	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1056 10561159	Cardiac disorders	Myocardial infarction	01JUN2016	30JUN2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUN2016	30JUN2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561162	Endocrine disorders	Thyroid mass	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1992	31DEC1993	N
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Thyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1056 10561163	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1955	31DEC1955	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561164	Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1993	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Caesarean section	27OCT1992	27OCT1992	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Oophorectomy	01JAN1994	31DEC1994	N
			Salpingectomy	01JAN1994	31DEC1994	N
	C4591001 1056 10561167	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1056 10561168	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1056 10561175	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561176	Gastrointestinal disorders	Inguinal hernia	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1972	31DEC1972	N
	C4591001 1056 10561179	Cardiac disorders	Myocardial infarction	01JUN2017	30JUN2017	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01OCT2019	31JAN2020	N
		Nervous system disorders	Cerebrovascular accident	01JUN2017	30JUN2017	N
		Surgical and medical procedures	Angioplasty	01JUN2017	30JUN2017	N
			Appendicectomy	01JAN1990	31DEC1990	N
			Prostate cryoablation	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561180	Endocrine disorders	Hypothyroidism	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Abdominoplasty	01JAN2006	31DEC2006	N
			Caesarean section	22MAY1995	22MAY1995	N
			Female sterilisation	22MAY1995	22MAY1995	N
			Mammoplasty	01JAN2007	31DEC2007	N
			Rhinoplasty	01JAN1981	31DEC1981	N
			Thyroidectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561181	Injury, poisoning and procedural complications	Ligament rupture	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1056 10561183	Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N
	C4591001 1056 10561184	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561198	Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561199	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2006		Y
	C4591001 1056 10561200	Vascular disorders	Hypertension	01JAN2006		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2000	31DEC2000	N
	C4591001 1056 10561201	Vascular disorders	Hypertension	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1056 10561202	Vascular disorders	Hypertension	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
			Umbilical hernia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Overweight	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
	C4591001 1056 10561204	Injury, poisoning and procedural complications	Clavicle fracture	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561207	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561209	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561211	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN1976	31DEC1976	N
			Meniscus operation	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561220	Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2008	31DEC2008	N
			Caesarean section	19SEP1999	19SEP1999	N
			Open reduction of fracture	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561221	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1056 10561222	Ear and labyrinth disorders	Vertigo	01JAN2009		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Umbilical hernia	01JAN2005	31DEC2005	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1056 10561229	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2013		Y
			Peripheral arterial occlusive disease	01JAN2005		Y
	C4591001 1056 10561231	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Spinal laminectomy	01JAN1988	31DEC1988	N
	C4591001 1056 10561232	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Nervous system disorders	Sciatica	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Open reduction of fracture	01JAN2016	31DEC2016	N
	C4591001 1056 10561236	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561237	Eye disorders	Retinal detachment	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Surgical and medical procedures	Retinopexy	01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1056 10561238	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561239	Cardiac disorders	Cardiomegaly	01JAN2015		Y
			Left ventricular hypertrophy	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2006		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Coronary artery bypass	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2012		Y
			Peripheral vascular disorder	01JAN2017		Y
	C4591001 1056 10561242	Injury, poisoning and procedural complications	Meniscus injury	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
			Meniscus operation	01JAN2003	31DEC2003	N
	C4591001 1056 10561247	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Caesarean section	27MAY2000	27MAY2000	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1056 10561248	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561249	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Appendectomy	01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Salpingectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561254	Injury, poisoning and procedural complications	Ankle fracture	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Overweight	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31JAN2013	N
		Psychiatric disorders	Major depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1994	31DEC1994	N
			Prostatectomy	01JAN2013	31JAN2013	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561257	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561258	Eye disorders	Cataract	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N
			Cataract operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561259	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561260	Eye disorders	Cataract	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
			Major depression	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561261	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Lithotripsy	01JAN2000	31DEC2000	N
	C4591001 1056 10561265	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bipolar disorder	01JAN2015		Y
			Insomnia	01JAN2015		Y
	C4591001 1056 10561266	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1056 10561267	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2002	31DEC2002	N
		Psychiatric disorders	Major depression	01JAN2018		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2002	31DEC2002	N
	C4591001 1056 10561269	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2013	N
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1985		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1056 10561270	Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561275	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561276	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561280	Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1056 10561281	Cardiac disorders	Arrhythmia	01JAN2009		Y
			Myocardial infarction	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	14NOV1991	14NOV1991	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary arterial stent insertion	01JAN2008	31DEC2008	N
			Implantable defibrillator replacement	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1056 10561285	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Caesarean section	02MAR1982	02MAR1982	N
				27OCT1986	27OCT1986	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1056 10561294	Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Peripheral arterial occlusive disease	01JAN2015		Y
	C4591001 1056 10561296	Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1056 10561298	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561301	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
	C4591001 1056 10561302	Cardiac disorders	Angina pectoris	01JAN2010		Y
			Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2001	31DEC2001	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Coronary artery bypass	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561303	Injury, poisoning and procedural complications	Humerus fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2005	31DEC2005	N
	C4591001 1056 10561305	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2019	20MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	20SEP2000	20SEP2000	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	20MAY2020	20MAY2020	N
	C4591001 1056 10561306	Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2019	31DEC2019	N
	C4591001 1056 10561310	Endocrine disorders	Hypothyroidism	01JAN1978		Y
			Thyroid mass	01JAN1978	31DEC1978	N
		Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN1978	31DEC1978	N
	C4591001 1056 10561311	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01MAR2004	31MAR2004	N
		Surgical and medical procedures	Caesarean section	19DEC1992	19DEC1992	N
			Hysterectomy	01MAR2004	31MAR2004	N
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1056 10561324	Metabolism and nutrition disorders	Obesity	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561334	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561339	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1056 10561342	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Lipoma excision	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561343	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561349	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561351	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1056 10561353	Cardiac disorders	Cardiac failure congestive	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myocardial infarction	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561355	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1056 10561362	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561368	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2000		Y
			Insomnia	01JAN2000		Y
			Major depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561370	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561371	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561374	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561379	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y
		Infections and infestations	Helicobacter infection	01JAN2015	31DEC2015	N
			Hepatitis C	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Overweight	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561380	Cardiac disorders	Coronary artery disease	01JAN2015		Y
			Myocardial infarction	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Overweight	01JAN2015		Y
		Psychiatric disorders	Major depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561381	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
			Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561382	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2019		Y
			Generalised anxiety disorder	01JAN2019		Y
			Major depression	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561387	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
			Major depression	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
			Caesarean section	16AUG1988	16AUG1988	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561389	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561390	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Oophorectomy	01JAN2013	31DEC2013	N
	C4591001 1056 10561399	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	07NOV2003	07NOV2003	N
			Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561404	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561409	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561410	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Aortic dilatation	21AUG2020		Y
			Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561412	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561415	Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
			Hepatitis A	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Prostatectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1056 10561416	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1056 10561418	Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
	C4591001 1056 10561420	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1056 10561423	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561424	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	02JUL1980	02JUL1980	N
	C4591001 1056 10561426	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561428	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	06DEC1980	06DEC1980	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1056 10561429	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	29JAN2015	29JAN2015	N
		Psychiatric disorders	Major depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561430	Gastrointestinal disorders	Haemorrhoids	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561433	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561436	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1056 10561439	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561446	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561447	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1056 10561449	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561450	Psychiatric disorders	Major depression	01JAN2016		Y
	C4591001 1056 10561454	Injury, poisoning and procedural complications	Femur fracture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561455	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
			Major depression	01JAN2014		Y
	C4591001 1056 10561458	Surgical and medical procedures	Mastectomy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1056 10561459	Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1056 10561460	Hepatobiliary disorders	Cholelithiasis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	15MAY1965	15MAY1965	N
				20FEB1964	20FEB1964	N
				21JUL1962	21JUL1962	N
			Cholecystectomy	01JAN1966	31DEC1966	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1056 10561461	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1056 10561462	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Major depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Caesarean section	08DEC1972	08DEC1972	N
				21SEP1974	21SEP1974	N
	C4591001 1056 10561463	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Social circumstances	Postmenopause	31JUL2000		Y
	C4591001 1056 10561464	Gastrointestinal disorders	Lumbar hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1056 10561465	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561470	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
	C4591001 1056 10561478	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1056 10561479	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1056 10561483	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1056 10561485	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2005	31DEC2005	N
	C4591001 1056 10561486	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1056 10561487	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561492	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	07OCT1985	07OCT1985	N
				26AUG1986	26AUG1986	N
	C4591001 1056 10561496	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	10JAN1985	10JAN1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561498	Injury, poisoning and procedural complications	Tibia fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Overweight	01JAN1998		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN1990	31DEC1990	N
	C4591001 1056 10561500	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561501	Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Surgical and medical procedures	Appendectomy	01JAN1987	31DEC1987	N
	C4591001 1056 10561502	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1056 10561504	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1056 10561509	Gastrointestinal disorders	Umbilical hernia	23JUL2020	23JUL2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Surgical and medical procedures	Umbilical hernia repair	23JUL2020	23JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561515	Cardiac disorders	Palpitations	01JAN2000		Y
		Infections and infestations	Pharyngitis	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	07DEC1998	07DEC1998	N
				26NOV1993	26NOV1993	N
				30SEP2000	30SEP2000	N
			Tonsillectomy	01JAN1971	31DEC1971	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561522	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	11MAR1987	11MAR1987	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Open reduction of fracture	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561523	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1056 10561524	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561527	Psychiatric disorders	Major depression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561537	Metabolism and nutrition disorders	Overweight	01JAN2018		Y
	C4591001 1056 10561538	Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2005	31DEC2005	N
	C4591001 1056 10561551	Injury, poisoning and procedural complications	Abdominal injury	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Surgical and medical procedures	Splenectomy	01JAN1970	31DEC1970	N
	C4591001 1056 10561552	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1056 10561556	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561557	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561561	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1056 10561571	Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendectomy	01JAN1955	31DEC1955	N
			Meniscus operation	01JAN1967	31DEC1967	N
	C4591001 1056 10561573	Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01JAN1983	31DEC1983	N
			Cholecystectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1056 10561574	Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2019		Y
	C4591001 1056 10561577	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1056 10561578	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Investigations	Catheterisation cardiac	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Vascular disorders	Arteriosclerosis	01JAN2016	31DEC2018	N
			Hypertension	01JAN2005		Y
	C4591001 1056 10561580	Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1056 10561589	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561597	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
	C4591001 1056 10561598	Nervous system disorders	Transient ischaemic attack	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1056 10561603	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Major depression	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Coronary arterial stent insertion	22AUG2016	22AUG2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561604	Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
	C4591001 1056 10561605	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2001		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1056 10561607	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1056 10561615	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
	C4591001 1056 10561619	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Lipoma excision	01JAN2019	31DEC2019	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
	C4591001 1056 10561620	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1056 10561625	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1056 10561628	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Parathyroid gland operation	01JAN1973	31DEC1973	N
			Renal stone removal	01JAN1971	31DEC1971	N
			Vasectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561630	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1056 10561637	Gastrointestinal disorders	Abdominal hernia	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1056 10561640	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1056 10561641	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
			Umbilical hernia	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
			Major depression	01JAN2008		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
	C4591001 1057 10571003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lumbar spinal stenosis	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1970		Y
			Major depression	01JAN1999		Y
		Social circumstances	Postmenopause	01AUG2014		Y
	C4591001 1057 10571004	Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2008	31DEC2008	N
	C4591001 1057 10571010	Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1975	31DEC1975	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1980	31DEC1980	N
			Limb operation	01JAN1975	31DEC1975	N
	C4591001 1057 10571011	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004	31DEC2005	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Depression	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1057 10571021	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1057 10571022	Gastrointestinal disorders	Hiatus hernia	07JUN2003	07JUN2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1998		Y
				01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1958	31DEC1958	N
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	24AUG2005		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1996		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1958	31DEC1958	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
			Chronic obstructive pulmonary disease	01JAN2003		Y
		Surgical and medical procedures	Appendicectomy	01JAN1958	31DEC1958	N
			Hernia hiatus repair	07JUN2003	07JUN2003	N
			Hysterectomy	01NOV1972	30NOV1972	N
			Urinary bladder suspension	01JAN1996	31DEC1996	N
	C4591001 1057 10571023	Cardiac disorders	Coronary artery disease	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Catheterisation cardiac	01MAR2019	31MAR2019	N
		Metabolism and nutrition disorders	Gout	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Pulmonary embolism	01JAN1995	31DEC1995	N
			Cataract operation	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Coronary arterial stent insertion	01MAR2019	31MAR2019	N
			Parathyroidectomy	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
			Vena cava filter insertion	01JAN2013	31DEC2013	N
			Vascular disorders	Deep vein thrombosis	01JAN1995	31DEC1995
			Hypertension	01JAN2015		Y
	C4591001 1057 10571026	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1992	31DEC1992	N
		Social circumstances	Postmenopause	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1995	31DEC1995	N
			Female sterilisation	01JAN1983	31DEC1983	N
	C4591001 1057 10571029	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1057 10571034	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2007	N
		Renal and urinary disorders	Bladder prolapse	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01OCT2019		Y
		Surgical and medical procedures	Caesarean section	29DEC1986	29DEC1986	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Urinary bladder suspension	01JAN2017	31DEC2017	N
	C4591001 1057 10571038	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1057 10571039	Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1057 10571040	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15OCT2014	15OCT2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	15OCT2019	15OCT2019	N
	C4591001 1057 10571041	Metabolism and nutrition disorders	Obesity	01JAN1999		Y
			Type 2 diabetes mellitus	01AUG2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1975		Y
		Social circumstances	Postmenopause	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1057 10571047	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JUL2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1057 10571052	Cardiac disorders	Coronary artery disease	19AUG2018		Y
			Myocardial infarction	19AUG2018	19AUG2018	N
		Endocrine disorders	Hypothyroidism	18MAR1993		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
			Pain	18MAR2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	19AUG2018		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	18MAR1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	18MAR2003		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Coronary artery bypass	19AUG2018	19AUG2018	N
			Thyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	19AUG2018		Y
	C4591001 1057 10571053	Metabolism and nutrition disorders	Hyperlipidaemia	15APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN1976	31DEC1976	N
			Uterine dilation and curettage	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1057 10571055	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Pilonidal cyst	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Joint injury	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2018		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN1979	31DEC1979	N
			Pilonidal sinus repair	01JAN1998	31DEC1998	N
			Umbilical hernia repair	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	15JUN2020		Y
	C4591001 1057 10571057	Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2020		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1965		Y
	C4591001 1057 10571061	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1057 10571062	Cardiac disorders	Coronary artery disease	01MAY2014		Y
		Eye disorders	Cataract	01FEB2009	28FEB2009	N
		Metabolism and nutrition disorders	Gout	01AUG2019		Y
			Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01MAR2013	31MAR2013	N
		Nervous system disorders	Transient ischaemic attack	01OCT2017	31OCT2017	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01AUG2012		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01FEB2009	28FEB2009	N
			Coronary arterial stent insertion	01MAY2015	31MAY2015	N
			Hysterectomy	01JUN1976	30JUN1976	N
			Lung lobectomy	01MAY2013	31MAY2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1057 10571063	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
			Seasonal allergy	01DEC1960		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1996		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1057 10571064	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1057 10571066	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01JAN1988	31DEC1988	N
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Cholecystectomy	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Meningioma surgery	01JAN1988	31DEC1988	N
			Palatoplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1057 10571069	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glucose tolerance impaired	01JAN2006		Y
			Gout	01JAN1985		Y
		Nervous system disorders	Essential tremor	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
		Surgical and medical procedures	Appendicectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1057 10571072	Endocrine disorders	Thyroid mass	01JAN1985	31DEC1985	N
		Eye disorders	Cataract	01JAN2014		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Rib fracture	01JAN2019	31DEC2019	N
			Road traffic accident	01JAN2019	31DEC2019	N
			Spinal column injury	01JAN2016	31DEC2016	N
				01JAN2020	31DEC2020	N
			Sternal fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Knee operation	01JAN1957	31DEC1957	N
				01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571073	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1057 10571076	Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Cataract	01NOV2018	30NOV2019	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cataract operation	01NOV2019	30NOV2019	N
			Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1057 10571077	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1057 10571084	Metabolism and nutrition disorders	Gout	15AUG2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	10AUG2020		Y
		Vascular disorders	Hypertension	15AUG2015		Y
	C4591001 1057 10571086	Endocrine disorders	Hyperthyroidism	01JAN1974	31DEC1980	N
			Hypothyroidism	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01MAR2013		Y
		Surgical and medical procedures	Caesarean section	15AUG1986	15AUG1986	N
			Radioactive iodine therapy	01JAN1980	31DEC1980	N
	C4591001 1057 10571087	Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN1985	31DEC1990	N
		Surgical and medical procedures	Synovial cyst removal	01JAN1990	31DEC1990	N
	C4591001 1057 10571094	Eye disorders	Glaucoma	01JAN2020		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Infections and infestations	Tonsillitis	01JAN1949	31DEC1950	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005	31DEC2014	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
			Prostatic operation	01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1057 10571096	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
	C4591001 1057 10571097	General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholecystitis	01JAN2004	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Caesarean section	09JUN2003	09JUN2003	N
				11JAN1995	11JAN1995	N
				29AUG1990	29AUG1990	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN2013	31DEC2013	N
			Oophorectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1057 10571098	Nervous system disorders	Migraine without aura	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1057 10571099	Immune system disorders	Food allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1057 10571101	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 1 diabetes mellitus	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01FEB2010	28FEB2010	N
				01JAN2015	31JAN2015	N
	C4591001 1057 10571102	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571105	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1057 10571107	Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1057 10571108	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
	C4591001 1057 10571110	Eye disorders	Cataract	01JAN2020	25AUG2020	N
		Surgical and medical procedures	Cataract operation	25AUG2020	25AUG2020	N
	C4591001 1057 10571112	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2015		Y
			Back pain	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Uterine leiomyoma embolisation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1057 10571114	Cardiac disorders	Coronary artery occlusion	01JAN2013	31DEC2013	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
			Obesity	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2013	31DEC2013	N
	C4591001 1057 10571115	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Salpingo-oophorectomy bilateral	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1057 10571116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Umbilical hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Surgical and medical procedures	Prostatectomy	01JAN2013	31DEC2013	N
			Tenoplasty	01JAN1991	31DEC1991	N
			Umbilical hernia repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1057 10571119	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1057 10571126	Injury, poisoning and procedural complications	Tendon injury	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1057 10571128	Surgical and medical procedures	Tendon operation	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
			Spinal osteoarthritis	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
	C4591001 1057 10571130	Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2012		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010	31DEC2013	N
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Joint arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1057 10571131	Eye disorders	Glaucoma	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1983	31DEC1983	N
	C4591001 1057 10571133	Surgical and medical procedures	Spinal laminectomy	01JAN1988	31DEC1988	N
		Immune system disorders	Contrast media allergy	01JAN2004		Y
			Drug hypersensitivity	01JAN1972		Y
		Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2020	30JUN2020	N
			Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Skin mass	01JUL2020		Y
	C4591001 1057 10571134	Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
		Cardiac disorders	Atrial fibrillation	01MAR2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2010	N
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Prostate ablation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1057 10571135	Immune system disorders	Seasonal allergy	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
	C4591001 1057 10571138	Ear and labyrinth disorders	Hypoacusis	01JAN1973		Y
			Otosclerosis	01JAN1973		Y
		Reproductive system and breast disorders	Pelvic prolapse	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1057 10571141	Injury, poisoning and procedural complications	Tendon rupture	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Tenoplasty	01JAN1988	31DEC1988	N
	C4591001 1057 10571143	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1998	31DEC1998	N
		Psychiatric disorders	Major depression	01JAN1980		Y
	C4591001 1057 10571149	Surgical and medical procedures	Rotator cuff repair	01JAN1998	31DEC1998	N
		Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01NOV2018	30NOV2018	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1057 10571150	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Oesophagogastric fundoplasty	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1057 10571151	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1979		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
	C4591001 1057 10571157	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Major depression	01JAN1989		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1057 10571159	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1986		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1986	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1057 10571166	Endocrine disorders	Hypothyroidism	01SEP1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	10FEB2020		Y
		Nervous system disorders	Migraine	01SEP2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1057 10571167	Eye disorders	Dry eye	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1057 10571168	Gastrointestinal disorders	Crohn's disease	01JAN1970	31DEC1996	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Ileostomy	01JAN1995	31DEC1995	N
			Proctocolectomy	01JAN1995	31DEC1995	N
	C4591001 1057 10571172	Eye disorders	Macular degeneration	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Dyslipidaemia	01NOV2018		Y
		Surgical and medical procedures	Tenoplasty	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1057 10571174	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1057 10571175	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN2002	31DEC2002	N
		Nervous system disorders	Restless legs syndrome	01JAN1971		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Ligament operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1057 10571178	Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
			Systemic lupus erythematosus	01JAN2008		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2008		Y
			Major depression	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571179	Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1057 10571180	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1057 10571181	Vascular disorders Metabolism and nutrition disorders	Hypertension Dyslipidaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571183	Eye disorders	Glaucoma	01SEP2001		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2000		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Vascular disorders	Hypertension	01SEP2000		Y
	C4591001 1057 10571184	Cardiac disorders	Atrial fibrillation	17JUN2015		Y
		Nervous system disorders	Transient ischaemic attack	17JUN2015	17JUN2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1057 10571189	Hepatobiliary disorders	Cholecystitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
	C4591001 1057 10571190	Cardiac disorders	Coronary artery disease	01JAN2002		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Deafness bilateral	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Nervous system disorders	Dementia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1990		Y
			Sleep apnoea syndrome	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1057 10571192	Cardiac disorders	Coronary artery disease	01FEB2017		Y
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2010		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Coronary arterial stent insertion	01FEB2017	28FEB2017	N
		Vascular disorders	Hypertension	01SEP2012		Y
	C4591001 1057 10571196	Psychiatric disorders	Major depression	01SEP2011	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1057 10571197	Gastrointestinal disorders	Crohn's disease	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1975	31DEC1975	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N
	C4591001 1057 10571199	General disorders and administration site conditions	Hernia	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hernia repair	01JAN1980	31DEC1980	N
	C4591001 1057 10571209	Hepatobiliary disorders	Cholelithiasis	01MAY2020	31MAY2020	N
		Psychiatric disorders	Major depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2020	31MAY2020	N
	C4591001 1057 10571221	Eye disorders	Glaucoma	01JAN2011		Y
		Injury, poisoning and procedural complications	Back injury	01NOV2012	30NOV2012	N
		Investigations	Cardiac murmur	01JAN1975		Y
		Surgical and medical procedures	Spinal operation	01NOV2012	30NOV2012	N
	C4591001 1057 10571224	Hepatobiliary disorders	Cholelithiasis	01JAN1977	31DEC1977	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005		Y
			Migraine	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Cholecystectomy	01JAN1977	31DEC1977	N
	C4591001 1057 10571225	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Osteoarthritis	01NOV2019	28JAN2020	N
		Psychiatric disorders	Depression	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
			Hip arthroplasty	28JAN2020	28JAN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1057 10571228	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571231	Gastrointestinal disorders	Umbilical hernia	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
			Joint injury	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
			Knee operation	01JAN1975	31DEC1975	N
			Umbilical hernia repair	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1057 10571237	Congenital, familial and genetic disorders	Neurofibromatosis	(b) (6) 1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2012	31DEC2012	N
	C4591001 1057 10571242	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1057 10571250	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Cardiac murmur	01SEP2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01FEB2019		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2017		Y
			Blount's disease	01JAN1960		Y
			Intervertebral disc degeneration	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Restless legs syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01SEP2012		Y
	C4591001 1057 10571251	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Nausea	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2005		Y
			Intervertebral disc degeneration	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1980	31DEC1980	N
			Gastric bypass	01JAN2010	31DEC2010	N
	C4591001 1057 10571254	Injury, poisoning and procedural complications	Gun shot wound	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Abdominal operation	01JAN1986	31DEC1986	N
	C4591001 1057 10571256	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	31DEC2015	N
			Spinal osteoarthritis	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Gastric bypass	01JAN1998	31DEC1998	N
			Knee operation	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Spinal fusion surgery	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1057 10571260	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2019		Y
			Obesity	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1057 10571264	Injury, poisoning and procedural complications	Limb crushing injury	01MAR1988	31MAR1988	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR1988		Y
		Surgical and medical procedures	Knee arthroplasty	01FEB2013	28FEB2013	N
				01SEP2013	30SEP2013	N
	C4591001 1057 10571275	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Psychiatric disorders	Major depression	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1057 10571285	Cardiac disorders	Angina pectoris	01AUG1992		Y
			Cardiac failure congestive	01JAN2015		Y
			Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1995	31DEC1995	N
				01JAN2010		Y
			Diverticulum	01JAN2001		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
			Rubber sensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01MAR2005		Y
		Nervous system disorders	Cerebrovascular accident	23JAN2016	23JAN2016	N
			Diabetic neuropathy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Hernia repair	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01AUG1992		Y
	C4591001 1057 10571289	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1999	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Oophorectomy bilateral	01JAN2000	31DEC2000	N
	C4591001 1057 10571290	Cardiac disorders	Coronary artery disease	01JUN2018		Y
			Myocardial infarction	01JUN2018	30JUN2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Surgical and medical procedures	Coronary artery bypass	01JUN2018	30JUN2018	N
			Implantable defibrillator insertion	01JUN2018	30JUN2018	N
	C4591001 1057 10571292	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571296	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2005		Y
	C4591001 1057 10571297	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2010		Y
		Psychiatric disorders	Insomnia	01NOV2016		Y
			Post-traumatic stress disorder	01JAN1966		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2017		Y
		Vascular disorders	Hypertension	01OCT2018		Y
	C4591001 1057 10571300	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2009		Y
			Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Intracranial aneurysm	01MAR2013		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
	C4591001 1057 10571302	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
			Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571303	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1057 10571306	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1982	31DEC1982	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2020		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1982	31DEC1982	N
	C4591001 1057 10571308	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950	31DEC1950	N
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1980	31DEC1980	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Generalised anxiety disorder	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571310	Cardiac disorders	Cardiac failure congestive	01JAN2003		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Investigations	Cardiac murmur	01JAN1958		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Bladder prolapse	01JUN2018	30JUN2018	N
			Renal failure	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	01JAN2003		Y
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Breast conserving surgery	01JAN2009	31DEC2009	N
			Central venous catheterisation	01MAR2020		Y
			Female sterilisation	01JAN1975	31DEC1975	N
			Hysterectomy	01JUN2018	30JUN2018	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1057 10571323	Injury, poisoning and procedural complications	Hip fracture	01MAY2001	31MAY2001	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2001		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2013	31DEC2013	N
				01MAY2001	31MAY2001	N
	C4591001 1057 10571327	Cardiac disorders	Myocardial infarction	28MAY2017	28MAY2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
			Chronic obstructive pulmonary disease	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	23SEP2002	23SEP2002	N
				27JUL1999	27JUL1999	N
			Carpal tunnel decompression	01MAR2020	31MAR2020	N
				01OCT2019	31OCT2019	N
			Cholecystectomy	01JAN1985	31DEC1985	N
			Coronary arterial stent insertion	28MAY2017	28MAY2017	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1057 10571330†	Infections and infestations	HIV infection	01JAN1989		Y
	C4591001 1057 10571334	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Investigations	Cardiac murmur	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hyperlipidaemia	01AUG2020		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1057 10571335†	Gastrointestinal disorders	Abdominal hernia	01JAN2015	31DEC2015	N
		Infections and infestations	HIV infection	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1057 10571346	Surgical and medical procedures	Abdominal hernia repair	01JAN2015	31DEC2015	N
		Cardiac disorders	Mitral valve incompetence	01JAN2017		Y
	C4591001 1057 10571349	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Cardiac disorders	Mitral valve incompetence	01JAN2012		Y
			Myocardial infarction	01JUN2012	30JUN2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2000		Y
			Hypersensitivity	01JAN1990		Y
		Investigations	Cardiac murmur	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31JUL2002	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2000		Y
		Surgical and medical procedures	Coronary artery bypass	01JUN2012	30JUN2012	N
			Hysterectomy	01JUL2002	31JUL2002	N
			Spinal laminectomy	01JUL2020	31JUL2020	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1057 10571351†	Infections and infestations	HIV infection	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1057 10571354†	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
			HIV infection	01JAN1988		Y
			Hepatitis C	01JAN1999		Y
			Tonsillitis	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
			Intervertebral disc degeneration	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1057 10571359	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1980		Y
			Rubber sensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Investigations	Hepatitis C antibody positive	01JAN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
			Intervertebral disc degeneration	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1057 10571361†	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	HIV infection	01JAN2003		Y
	C4591001 1066 10661001	Endocrine disorders	Hypothyroidism	01FEB2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Investigations	Biopsy	01MAR2019	31MAR2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01MAR2019	31MAR2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01MAR2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Hernia repair	01JAN1963	31DEC1963	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1066 10661003	Cardiac disorders	Angina pectoris	01JAN2006		Y
		Ear and labyrinth disorders	Deafness	01JAN1991		Y
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2010	31DEC2013	N
			Limb injury	01JAN2008	31DEC2008	N
			Patella fracture	01JAN2001	31DEC2001	N
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2005		Y
		Psychiatric disorders	Depression	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Carpectomy	01JAN2013	31DEC2013	N
			Coronary arterial stent insertion	01JAN2006	31DEC2006	N
			Gastric banding	01JUL2010	31DEC2010	N
			Knee arthroplasty	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Orthopaedic procedure	01JAN2001	31DEC2001	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2002	31DEC2002	N
			Shoulder arthroplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1066 10661004	Cardiac disorders	Angina pectoris	01JAN2005		Y
			Coronary artery disease	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JUN2016	30JUN2016	N
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1994		Y
			Obesity	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1996		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2016	30JUN2016	N
			Coronary arterial stent insertion	01JAN2005	31DEC2005	N
			Coronary artery bypass	01JAN2016	31DEC2016	N
			Metabolic surgery	01DEC2014	31DEC2014	N
			Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1066 10661005	Gastrointestinal disorders	Abdominal hernia	01JAN2007	31DEC2007	N
			Inguinal hernia	01JAN1970	31DEC1970	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Investigations	Blood cholesterol increased	01JAN2003		Y
			Blood testosterone decreased	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Nervous system disorders	Essential tremor	01JAN2009		Y
			Migraine with aura	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Bipolar disorder	01JAN2008		Y
			Depression	01JAN1977		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1066 10661006	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2001	N
			Ovarian neoplasm	01JAN1995	31DEC1995	N
		Psychiatric disorders	Depression	01JUL2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Lymphoedema	01JAN2001		Y
	C4591001 1066 10661007	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01NOV2018	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2005		Y
		Surgical and medical procedures	Prostatectomy	01JAN2019	31DEC2019	N
			Shoulder operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661008	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1066 10661009	Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01SEP2013		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1066 10661010	Cardiac disorders	Atrial fibrillation	01OCT2019		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Acquired oesophageal web	19APR2013	19APR2013	N
			Gastrooesophageal reflux disease	26DEC2014		Y
			Haemorrhoids	01JAN1971	31DEC1971	N
		Investigations	Oesophagogastroduodenoscopy	19JAN2017	19JAN2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2018		Y
			Sinus polyp	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1997	31DEC1997	N
			Cataract operation	01JAN2018	31DEC2018	N
			Haemorrhoid operation	01JAN1971	31DEC1971	N
			Hysterectomy	01JAN1970	31DEC1970	N
			Sinus operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1066 10661011	General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Shoulder operation	01JAN2010	31DEC2010	N
			Skin lesion removal	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661012	Hepatobiliary disorders	Gallbladder disorder	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
			Herpes zoster	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Nervous system disorders	Epilepsy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Social circumstances	Menopause	01JAN1986		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1066 10661013	Ear and labyrinth disorders	Deafness bilateral	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2017	31DEC2017	N
			Prostate cancer	01JAN2013	31DEC2015	N
		Surgical and medical procedures	Lung lobectomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661014	Investigations	Blood cholesterol increased	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Prostatectomy	16JUL2019	16JUL2019	N
	C4591001 1066 10661016	Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661017	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2007	31DEC2007	N
			Spinal fracture	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003	31DEC2019	N
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Choroid melanoma	01JAN2014	31DEC2014	N
			Renal cancer	01JAN2007	31DEC2007	N
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN1990		Y
			Drug dependence	01JAN2007		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
			Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Nephrectomy	01JAN2007	31DEC2007	N
			Radiotherapy to eye	01JAN2014	31DEC2014	N
			Spinal operation	01JAN2007	31DEC2007	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2003		Y
			Hypertension	01JAN2003		Y
	C4591001 1066 10661018	Reproductive system and breast disorders	Prostatitis	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1066 10661021	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
			Large intestine polyp	01DEC2016	31DEC2016	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
			Gallbladder disorder	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Rubber sensitivity	01JAN1990		Y
			Rubber sensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2001		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2010	31DEC2010	N
			Joint injury	01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N
			Limb injury	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
			Endoscopic retrograde cholangiopancreatography	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1960		Y
		Surgical and medical procedures	Ankle operation	01JAN2003	31DEC2003	N
			Cancer surgery	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Fracture treatment	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1982	31DEC1982	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Large intestinal polypectomy	01DEC2016	31DEC2016	N
			Shoulder operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1066 10661023	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Haemorrhoids	01JAN1989	31DEC1989	N
			Hiatus hernia	01JAN2017	31DEC2017	N
		Infections and infestations	Appendicitis	01NOV2019	31DEC2019	N
			Diverticulitis	01JAN1976	31DEC1976	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Investigation	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01NOV2019	31DEC2019	N
			Haemorrhoid operation	01JAN1989	31DEC1989	N
			Hernia hiatus repair	01JAN2017	31DEC2017	N
			Renal stone removal	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661024	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck pain	01JAN1980		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1968		Y
		Surgical and medical procedures	Prostate ablation	23SEP2019	23SEP2019	N
	C4591001 1066 10661029	Eye disorders	Corneal disorder	01JAN2005	31DEC2014	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1985	31DEC1985	N
			Road traffic accident	01JAN1985	31DEC1985	N
			Wrist fracture	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Corneal operation	01JAN2014	31DEC2014	N
			Transurethral prostatectomy	01JAN2006	31DEC2006	N
	C4591001 1066 10661030	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2005	31DEC2005	N
			Upper limb fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Bone operation	01JAN2005	31DEC2005	N
			Limb operation	01JAN2010	31DEC2010	N
	C4591001 1066 10661031	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Vertebral osteophyte	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Shoulder operation	01JAN1999	31DEC1999	N
			Spinal operation	01JAN2007	31DEC2007	N
			Synovial cyst removal	17JUL2013	17JUL2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1066 10661032	General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2015	N
		Nervous system disorders	Post stroke seizure	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01MAY2014		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1066 10661033	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAY2020	16JUN2020	N
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Radical prostatectomy	16JUN2020	16JUN2020	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661034	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema peripheral	01JAN2008		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Gout	01NOV2019		Y
			Obesity	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1985		Y
		Nervous system disorders	Facial paralysis	01JAN1985	31DEC1985	N
			Restless legs syndrome	01JAN2008		Y
			Sciatica	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Deep vein thrombosis	01JAN2008	31DEC2008	N
			Hypertension	01JAN2003		Y
	C4591001 1066 10661038	Injury, poisoning and procedural complications	Hand fracture	01JAN1992	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1993	31DEC1993	N
		Skin and subcutaneous tissue disorders	Urticaria chronic	23APR2011		Y
		Surgical and medical procedures	Bone graft	01JAN1993	31DEC1993	N
			Nasal septal operation	01JAN1993	31DEC1993	N
	C4591001 1066 10661039	Injury, poisoning and procedural complications	Joint injury	01JAN2012	31DEC2012	N
			Limb injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2009		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1999	N
			Mammoplasty	01JAN1998	31DEC1998	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
			Shoulder operation	01JUN2016	30JUN2016	N
			Tenoplasty	01JAN2012	31DEC2012	N
	C4591001 1066 10661040	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1986	31DEC1986	N
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
			Diverticulitis	01JAN2018	31DEC2018	N
			Oral herpes	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
			Cardiac murmur	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2005		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN2018	31DEC2018	N
		Nervous system disorders	Diabetic neuropathy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Psychiatric disorders	Insomnia	01JAN2015		Y	
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1982	31DEC1982	N	
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y	
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N	
			Cholecystectomy	01JAN1986	31DEC1986	N	
			Hysterectomy	01JAN1982	31DEC1982	N	
			Neurosurgery	01JAN2007	31DEC2007	N	
			Vascular disorders	Hypertension	01JAN2005		Y
			Varicose vein	01JAN2017		Y	
	C4591001 1066 10661041	Injury, poisoning and procedural complications	Meniscus injury	01JAN2003	31DEC2003	N	
		Metabolism and nutrition disorders	Obesity	01JAN2003	30NOV2018	N	
			Type 2 diabetes mellitus	01JAN2002		Y	
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y	
		Renal and urinary disorders	Nephrolithiasis	01NOV2019	31DEC2019	N	
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2019	31DEC2019	N	
		Surgical and medical procedures	Knee arthroplasty	01JAN2007	31DEC2007	N	
			Knee operation	01JAN2003	31DEC2003	N	
					01JAN2004	31DEC2004	N
					01JAN2005	31DEC2005	N
					01JAN2006	31DEC2006	N
					01JAN2007	31DEC2007	N
				Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1991		Y	
	C4591001 1066 10661042	Endocrine disorders	Hypothyroidism	01JAN1990		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2012		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661043	Cardiac disorders	Tachycardia paroxysmal	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Injury, poisoning and procedural complications	Mallet finger	01JAN2016	31DEC2016	N
		Investigations	Angiogram	24MAY2018	24MAY2018	N
			Blood cholesterol increased	01JAN2018		Y
			Catheterisation cardiac	24MAY2018	24MAY2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2004	31DEC2004	N
		Social circumstances	Organ donor	01JAN2003		Y
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
			Neurectomy	01JAN2004	31DEC2004	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Aortic dilatation	12APR2018		Y
			Deep vein thrombosis	01JAN2012	31DEC2012	N
			Hypertension	01JAN2019	31DEC2019	N
			Hypertension	01JAN2019		Y
	C4591001 1066 10661045	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Pancreatitis	01JAN2017		Y
		General disorders and administration site conditions	Pain	01JAN2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01FEB2020		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01FEB2020		Y
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1066 10661046	Cardiac disorders	Atrial fibrillation	01JAN1978		Y
		Eye disorders	Cataract	01JAN2017	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2013		Y
		Social circumstances	Menopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1066 10661047	Eye disorders	Cataract	01JUN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JUN2015	30JUN2015	N
			Limb operation	01JAN2005	31DEC2005	N
			Wrist surgery	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1066 10661048	Ear and labyrinth disorders	Deafness bilateral	01JAN2019		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2019	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2018		Y
		Psychiatric disorders	Alcoholism	01JAN2010		Y
		Renal and urinary disorders	Lower urinary tract symptoms	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2004	31DEC2020	N
		Surgical and medical procedures	Fasciotomy	01MAR2020	31DEC2020	N
			Inguinal hernia repair	01NOV2019	30NOV2019	N
			Ligament operation	01JAN2006	31DEC2006	N
			Sinus operation	01JAN2004	31DEC2004	N
	C4591001 1066 10661049	Gastrointestinal disorders	Large intestine polyp	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Social circumstances	Menopause	01JAN2003		Y
		Vascular disorders	Raynaud's phenomenon	01JAN1978		Y
	C4591001 1066 10661050	Endocrine disorders	Hypogonadism	01JAN2010		Y
			Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Dental caries	01FEB2020	29FEB2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Bone graft	01FEB2020	31DEC2020	N
			Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1066 10661051	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2003		Y
		Eye disorders	Presbyopia	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Investigations	Biopsy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Angioplasty	01DEC2012	31DEC2012	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1066 10661052	Eye disorders	Cataract	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Investigations	Biopsy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	31DEC2004	N
			Migraine	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Social circumstances	Menopause	01JAN2005		Y
	C4591001 1066 10661053	Surgical and medical procedures	Carpal tunnel decompression	01JAN2004	31DEC2004	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1996		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1990	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1996		Y
	C4591001 1066 10661054	Surgical and medical procedures	Umbilical hernia repair	01JAN2013	31DEC2013	N
		Cardiac disorders	Atrial fibrillation	01JAN2019		Y
			Coronary artery disease	01JAN2019		Y
		Ear and labyrinth disorders	Deafness	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1974	31DEC1974	N
			Tendonitis	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661055	Blood and lymphatic system disorders	Polycythaemia	01JAN2013		Y
		Endocrine disorders	Hypothyroidism	01JAN1979		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Blood testosterone decreased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN1979	31DEC1979	N
		Psychiatric disorders	Depression	01JAN2017		Y
			Drug dependence	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Ankle operation	01JAN2007	31DEC2007	N
			Coronary artery bypass	01JUN2018	30JUN2018	N
			Toe amputation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661056	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Menopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661057	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2002		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01APR2019		Y
			Trigger finger	01JAN2011	31DEC2011	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2011	31DEC2011	N
			Diabetic neuropathy	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2011	31DEC2011	N
			Tendon sheath incision	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661058	Ear and labyrinth disorders	Deafness bilateral	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2018	31DEC2018	N
		Investigations	Blood testosterone decreased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Restless legs syndrome	01JAN1980		Y
			Somnolence	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1066 10661061	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN1990	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1990		Y
		Renal and urinary disorders	Incontinence	01JAN2005	31DEC2007	N
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Urinary bladder suspension	01JAN2007	31DEC2007	N
	C4591001 1066 10661063	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Smear cervix abnormal	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2001	31DEC2001	N
		Social circumstances	Menopause	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1066 10661065	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Chronic sinusitis	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1970	31DEC1970	N
				01JAN2019		Y
			Osteopenia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2013	31DEC2013	N
		Social circumstances	Menopause	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bunion operation	01JAN1970	31DEC1970	N
			Cancer surgery	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1066 10661066	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2013		Y
			Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Metabolic surgery	01MAR2013	31MAR2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661067	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	05FEB2020		Y
		Investigations	Biopsy breast	01JAN1982	31DEC1982	N
			Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
				27NOV2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	30MAR2017	30MAR2017	N
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Urge incontinence	02JUL2014		Y
		Reproductive system and breast disorders	Breast pain	05FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2020		Y
			Rhinitis allergic	01JAN2000		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Bone operation	01JAN2016	31DEC2016	N
			Hip surgery	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Large intestinal polypectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	13JUN2017		Y
	C4591001 1066 10661068	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2012		Y
			Synovial cyst	01JAN2018	31DEC2018	N
		Nervous system disorders	Cauda equina syndrome	01JAN2018	31DEC2018	N
			Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Alcohol withdrawal syndrome	01FEB2020		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ligament operation	01JAN2010	31DEC2010	N
			Synovial cyst removal	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661069	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1992		Y
		Eye disorders	Cataract	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Gout	01JAN2010	31DEC2014	N
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2017	31DEC2019	N
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Vascular disorders	Aortic aneurysm	01JAN2010	31DEC2015	N
			Hypertension	01JAN2004		Y
	C4591001 1066 10661070	Cardiac disorders	Cardiomyopathy	01JAN2007		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Spinal operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661074	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN1970		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN1998		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Acidosis	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Intracranial aneurysm	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
			Renal cyst	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Artificial menopause	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Renal cyst excision	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1066 10661076	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2005		Y
			Hyperlipidaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2000		Y
	C4591001 1066 10661077	Gastrointestinal disorders	Umbilical hernia	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
			Meniscus injury	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N
		Surgical and medical procedures	Ligament operation	01JAN1998	31DEC1998	N
			Meniscus operation	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N
	C4591001 1066 10661079	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN1998	31DEC1998	N
				01JAN2012	31DEC2012	N
			Shoulder operation	01JAN2008	31DEC2008	N
	C4591001 1066 10661080	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Raynaud's phenomenon	01JAN2014		Y
	C4591001 1066 10661083	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2017		Y
			Umbilical hernia	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
			Hypertriglyceridaemia	01JAN1997		Y
			Obesity	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1066 10661084	Ear and labyrinth disorders	Deafness bilateral	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2018		Y
	C4591001 1066 10661087	Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neuropathy peripheral	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Breast mass	01JAN2003	31DEC2003	N
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Breast operation	01JAN2003	31DEC2003	N
			Cataract operation	01JAN2014	31DEC2014	N
			Cholecystectomy	01MAR2013	31MAR2013	N
	C4591001 1066 10661088	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
			Haemorrhoids	01JAN1998	31DEC1998	N
		Investigations	Cystoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017		Y
			Spinal osteoarthritis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of bladder	01JAN2017	31DEC2017	N
			Colon adenoma	01JAN2011	31DEC2016	N
			Schwannoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Nervous system neoplasm surgery	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1066 10661089	Immune system disorders	Drug hypersensitivity	01JAN1954		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Arthrodesis	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Raynaud's phenomenon	01JAN2017		Y
	C4591001 1066 10661091	Injury, poisoning and procedural complications	Meniscus injury	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Meniscus operation	01JAN2019	31DEC2019	N
	C4591001 1066 10661092	Gastrointestinal disorders	Constipation	01JAN2005		Y
			Gastric ulcer	01JAN1994	31DEC1994	N
			Gastroesophageal reflux disease	01JAN1993		Y
			Inguinal hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Injury, poisoning and procedural complications	Patella fracture	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1985		Y
			Insomnia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y	
		Surgical and medical procedures	Bone operation	01JAN2005	31DEC2005	N	
			Inguinal hernia repair	01JAN2009	31DEC2009	N	
			Knee arthroplasty	01JAN2010	31DEC2010	N	
			Shoulder arthroplasty	01JAN2017	31DEC2017	N	
			Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1066 10661093		Blood and lymphatic system disorders	Thrombocytopenia	01JAN2018		Y
			Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2002		Y	
	C4591001 1066 10661094	Ear and labyrinth disorders	Deafness bilateral	01JAN2014		Y	
		Eye disorders	Cataract	01JAN2014		Y	
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y	
		Investigations	Blood cholesterol increased	01JAN2014		Y	
			Cardiac murmur	01JAN1942		Y	
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y	
			Osteopenia	01JAN2018		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2000	31DEC2000	N	
			Uterine leiomyoma	01JAN1990	31DEC1990	N	
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y	
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y	
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN1990		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endometriosis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
			Mammoplasty	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1066 10661096	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1954		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2019		Y
			Plantar fasciitis	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Trigeminal neuralgia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2012		Y
	C4591001 1066 10661099	Ear and labyrinth disorders	Deafness bilateral	01JAN2002		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661100	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Umbilical hernia	01JAN2010	31DEC2010	N
		Investigations	Biopsy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Spinal operation	01JAN2013	31DEC2013	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1066 10661102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Seasonal allergy	01JAN1971		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1066 10661103	Injury, poisoning and procedural complications	Road traffic accident	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Wrist surgery	01JAN1995	31DEC1995	N
	C4591001 1066 10661104	Ear and labyrinth disorders	Deafness	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1997	31DEC1997	N
			Wrist fracture	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Rotator cuff syndrome	01JAN2002	31DEC2002	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2003	31DEC2003	N
			Fracture treatment	01JAN1995	31DEC1995	N
				01JAN1997	31DEC1997	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Knee arthroplasty	01JAN2019	31JAN2019	N
			Rotator cuff repair	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1066 10661105	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1066 10661107	Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Glaucoma	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Inguinal hernia	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Aortic aneurysm	01JAN2010		Y
			Hypertension	01JAN2008		Y
	C4591001 1066 10661108	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
			Thyroid mass	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
				01JAN2014	31DEC2014	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Renal and urinary disorders	Incontinence	01MAR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661109	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				01JAN2015		Y
				01JUN2020		Y
			Seasonal allergy	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
	C4591001 1066 10661110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1994		Y
		Hepatobiliary disorders	Gallbladder disorder	01FEB2003	31DEC2003	N
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Nervous system disorders	Headache	01JAN1974		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Appendectomy	01JAN1976	31DEC1976	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Tenoplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1066 10661111	Ear and labyrinth disorders	Deafness bilateral	01OCT2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2005	31DEC2005	N
		Investigations	Blood testosterone decreased	01OCT2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2006		Y
			Obesity	01JAN2016	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Alcohol abuse	01JAN1994	31DEC1997	N
		Renal and urinary disorders	Neurogenic bladder	01JAN2005		Y
		Surgical and medical procedures	Spinal operation	01JAN2005	31DEC2005	N
			Urinary tract operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01OCT2016	31DEC2018	N
	C4591001 1066 10661112	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
			Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2013		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2018	31OCT2018	N
			Transient ischaemic attack	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Carotid endarterectomy	01OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
	C4591001 1066 10661114	Cardiac disorders	Myocardial infarction	01FEB2011	28FEB2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Immune system disorders	Contrast media allergy	01JAN1988		Y
		Investigations	Blood testosterone decreased	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1066 10661117	Ear and labyrinth disorders	Deafness	01JAN2020		Y
		Eye disorders	Glaucoma	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Cardiac murmur	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Round cell liposarcoma	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Shoulder operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2018		Y
			Hypertension	01JAN2010		Y
	C4591001 1066 10661118	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Diverticulitis	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Fibromyalgia	01JAN2005		Y
			Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Carpal tunnel decompression	01MAY2020	31MAY2020	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Colon operation	01JAN2017	31DEC2017	N
			Metabolic surgery	01JAN2018	31DEC2018	N
	C4591001 1066 10661119	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
			Meniere's disease	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01FEB2020	29FEB2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN1997		Y
		Nervous system disorders	Migraine	01DEC2019		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1066	Surgical and medical procedures	Cholecystectomy	01FEB2020	29FEB2020	N
	10661120	Eye disorders	Borderline glaucoma	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
			Tendonitis	01JUL2010	31JUL2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Elbow operation	01JUL2010	31JUL2010	N
			Prostatectomy	01OCT2018	31OCT2018	N
			Shoulder operation	01AUG2010	31AUG2010	N
				01JUL2010	31JUL2010	N
	C4591001 1066	Vascular disorders	Hypertension	01JAN2010		Y
	10661122	Ear and labyrinth disorders	Deafness bilateral	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN1997	31DEC1997	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
			Erectile dysfunction	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Knee operation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1066	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
	10661124					
		Nervous system disorders	Essential tremor	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661125	Social circumstances	Menopause	01JAN1999		Y
		Cardiac disorders	Ventricular arrhythmia	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2002	31DEC2002	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Pancreatitis acute	01JAN1979	31DEC1979	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Cardiac murmur	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1974		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2013	31DEC2013	N
			Lung neoplasm malignant	01JAN2017	31DEC2017	N
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1974		Y
			Depression	01JAN1974		Y
			Insomnia	01JAN1990		Y
	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y	
		Chronic obstructive pulmonary disease	01JAN2006		Y	
		Sleep apnoea syndrome	01JAN2010		Y	
	Social circumstances	Menopause	01JAN2009		Y	
	Surgical and medical procedures	Appendectomy	01JAN1977	31DEC1977	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast conserving surgery	01OCT2013	31OCT2013	N
			Cataract operation	01JAN2002	31DEC2002	N
			Lung lobectomy	01JAN2017	31DEC2017	N
			Metabolic surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661127	Cardiac disorders	Atrial fibrillation	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Ovarian fibrosis	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1990	31DEC1990	N
			Myomectomy	01JAN2007	31DEC2007	N
	C4591001 1066 10661128	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV2016	31DEC2016	N
		Nervous system disorders	Partial seizures	01JUL2013	31JUL2013	N
				01JUN2012	30JUN2012	N
		Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Breast conserving surgery	01DEC2016	31DEC2016	N
			Ligament operation	01JAN2003	31DEC2003	N
			Varicose vein operation	01JUL2017	31JUL2017	N
		Vascular disorders	Varicose vein	01JUN2017	31JUL2017	N
	C4591001 1066 10661131	Congenital, familial and genetic disorders	Limb reduction defect	01JAN1946		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
				01JAN2000		Y
				01JAN2013	31DEC2013	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Periodic limb movement disorder	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
			Shoulder arthroplasty	01JAN2013	31DEC2013	N
		Ear and labyrinth disorders	Tinnitus	01JAN2020		Y
	C4591001 1066 10661134	Immune system disorders	Drug hypersensitivity	01JAN1953		Y
				01JAN1970		Y
				01JAN1975		Y
				01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1982	31DEC1982	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1066 10661135	Ear and labyrinth disorders	Deafness bilateral	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2016		Y
			Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1066 10661140	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2008	31DEC2008	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1960		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2015	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac ablation	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1066 10661141	Investigations	Platelet count decreased	01JAN2019	31AUG2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1975		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1066 10661143	Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Cardiac disorders	Bundle branch block right	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN1995	31DEC1995	N
			Spinal laminectomy	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1066 10661144	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661145	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1066 10661146	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2009	31DEC2009	N
			Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1066 10661148	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Tendonitis	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2016	31DEC2016	N
	C4591001 1066 10661150	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2010	31DEC2010	N
			Lipoma of breast	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Lipoma excision	01JAN2010	31DEC2010	N
		Vascular disorders	Deep vein thrombosis	01JAN2018	31DEC2018	N
	C4591001 1066 10661153	Cardiac disorders	Coronary artery disease	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myocardial infarction	01JAN2003	31DEC2003	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Cataract	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
			Erectile dysfunction	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1066 10661154	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Rotator cuff syndrome	01JAN2001	31DEC2001	N
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1988	31DEC1988	N
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Keratomileusis	01JAN1990	31DEC1990	N
			Knee operation	01JAN2010	31DEC2010	N
			Nasal septal operation	01JAN1988	31DEC1988	N
			Shoulder operation	01JAN2001	31DEC2001	N
			Vasectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661155	Investigations	Biopsy breast	01JAN2016	31DEC2016	N
			Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Tenosynovitis	01JAN2008	31DEC2008	N
			Tenosynovitis stenosans	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2019	31DEC2019	N
			Squamous cell carcinoma	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Breast mass	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Micrographic skin surgery	01JAN2012	31DEC2012	N
			Sinus operation	01JAN2013	31DEC2013	N
			Spinal operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1066 10661156	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1982		Y
			Inguinal hernia	01JAN1999	31DEC1999	N
			Intestinal obstruction	01MAY2015	31DEC2015	N
			Umbilical hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Intestinal operation	01MAY2015	31DEC2015	N
			Rotator cuff repair	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Transurethral prostatectomy	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N
	C4591001 1066 10661157	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2007	31DEC2007	N
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Nasal septal operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661158	Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1066 10661159	Cardiac disorders	Myocardial infarction	01AUG2015	31AUG2015	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Stent placement	01AUG2015	31DEC2015	N
	C4591001 1066 10661161	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Muscle operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Renal stone removal	01JAN2018	31DEC2018	N
	C4591001 1066 10661162	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
			Osteoporosis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
			Knee arthroplasty	01OCT2013	31DEC2013	N
	C4591001 1066 10661164	Investigations	Biopsy breast	01JAN1970	31DEC1970	N
			Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Social circumstances	Menopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661165	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Psychiatric disorders	Alcohol abuse	01JAN1995	31DEC2005	N
			Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661169	Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Impaired fasting glucose	01JAN2017		Y
		Renal and urinary disorders	Hypertensive nephropathy	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661170	Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
				01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Renal and urinary disorders	Incontinence	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
			Mastectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661171	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1985		Y
			Insomnia	01JAN1985		Y
			Post-traumatic stress disorder	01JAN1992		Y
			Tic	01JAN2013		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
			Hiatus hernia	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Nervous system disorders	Headache	01JAN1970		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1992	31DEC1992	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric banding	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1066 10661174	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1066 10661175	Immune system disorders	Drug hypersensitivity	01FEB2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01FEB2020		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
			Headache	01FEB2020	30JUN2020	N
			Transient ischaemic attack	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1066 10661176	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
			Empyema	01JAN2015	31DEC2015	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Traumatic lung injury	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1066 10661177	Hepatobiliary disorders	Gallbladder disorder	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
			Diverticulitis	01JUL2010	31JUL2010	N
			Oral herpes	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2017	31DEC2017	N
			Meniscus injury	01JAN2017	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Ligament operation	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1066 10661179	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2016	31DEC2017	N
		Social circumstances	Menopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661180	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Diverticulum intestinal	01JAN2018	31DEC2018	N
			Gastroesophageal reflux disease	01JAN2000		Y
			Large intestinal obstruction	01JAN2018	31DEC2018	N
			Large intestine polyp	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carotid artery disease	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2000		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
			Cataract operation	01JAN2015	31DEC2015	N
			Colectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1066 10661181	Blood and lymphatic system disorders	Thrombocytopenia	01JAN1982	31DEC1982	N
		Cardiac disorders	Atrial fibrillation	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Hiatus hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
			Carpal tunnel decompression	01JAN1990	31DEC1990	N
			Gastrectomy	01JAN2020	31JAN2020	N
			Knee arthroplasty	01JAN2003	31DEC2003	N
			Oesophagogastric fundoplasty	01JAN2015	31DEC2015	N
			Splenectomy	01JAN1982	31DEC1982	N
	C4591001 1066 10661188	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inflammatory bowel disease	01MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1066 10661189	Gastrointestinal disorders	Constipation	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JAN1978	31DEC1978	N
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2009	31DEC2009	N
			Bunion operation	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1066 10661191	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2009	31DEC2009	N
			Foot deformity	01JAN2001		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Bunion operation	01JAN2001	31DEC2001	N
			Dental implantation	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Rotator cuff repair	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661196	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1974	31DEC1975	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1066 10661199	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1990		Y
		Eye disorders	Cataract	01AUG2019	31AUG2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1951		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1996		Y
			Erectile dysfunction	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2014	31DEC2014	N
			Cardiac pacemaker insertion	01JAN2014	31DEC2014	N
			Cataract operation	01AUG2019	31AUG2019	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661200	Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
			Plantar fasciitis	01JAN2019		Y
		Renal and urinary disorders	Incontinence	01JAN2015		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1066 10661201	Cardiac disorders	Myocardial infarction	01JAN1996	31DEC1996	N
				01JAN2000	31DEC2000	N
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN2003	31DEC2005	N
			Monoclonal gammopathy	01JAN2005		Y
		Renal and urinary disorders	Incontinence	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1996	31DEC1996	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1066 10661204	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661205	Injury, poisoning and procedural complications	Thoracic vertebral fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2014	31DEC2014	N
	C4591001 1066 10661206	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2014	31DEC2014	N
			Ligament rupture	01JAN2010	31DEC2010	N
			Limb injury	01JAN2012	31DEC2012	N
			Muscle rupture	01JAN2017	31DEC2017	N
			Spinal fracture	01JAN2014	31DEC2014	N
			Splenic injury	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Facial operation	01JAN2014	31DEC2014	N
			Knee operation	01JAN2010	31DEC2010	N
			Shoulder operation	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
			Splenectomy	01JAN1976	31DEC1976	N
	C4591001 1066 10661207	Investigations	Biopsy skin	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661208	Ear and labyrinth disorders	Meniere's disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1066 10661209	Surgical and medical procedures	Knee operation	01JAN1990	31DEC1990	N
		Hepatobiliary disorders	Gallbladder disorder	01MAY2020	31JUL2020	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2020	31JUL2020	N
			Knee operation	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
	C4591001 1066 10661210	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2009	31DEC2009	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Arteriosclerosis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN2002		Y
	C4591001 1066 10661211	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
	C4591001 1066 10661212	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Cataract	01JAN2011	31DEC2011	N
				01JAN2019	31DEC2019	N
			Retinal detachment	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1998	31DEC1999	N
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
				01JAN2019	31DEC2019	N
			Female sterilisation	01JAN1976	31DEC1976	N
			Retinal operation	01JAN2017	31DEC2017	N
			Spinal laminectomy	01JAN1998	31DEC1998	N
			Varicose vein operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2013		Y
			Varicose vein	01JAN2006	31DEC2006	N
	C4591001 1066 10661213	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Eye disorders	Cataract	01JAN2000	31DEC2000	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to vaccine	01JAN1961		Y
			Drug hypersensitivity	01JAN1963		Y
				01JAN2005		Y
				01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Social circumstances	Menopause	01JAN1975		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1977	31DEC1977	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Knee arthroplasty	01JAN2001	31DEC2001	N
				01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
	C4591001 1066 10661215	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN1983		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN1983	31DEC1983	N
				01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
				01JAN1987	31DEC1987	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1066 10661216	Injury, poisoning and procedural complications	Cartilage injury	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661218	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1988		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01NOV2019	30NOV2019	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1066 10661220	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Rhinoplasty	01JAN1989	31DEC1989	N
			Rotator cuff repair	01JAN2004	31DEC2004	N
	C4591001 1066 10661221	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1985	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1066 10661222	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2008		Y
			Spinal stenosis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2019	31DEC2019	N
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Affective disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2005	31DEC2005	N
			Large intestinal polypectomy	01JAN2019	31DEC2019	N
			Peripheral nerve decompression	01JAN2008	31DEC2008	N
			Spinal fusion surgery	01JAN2007	31DEC2007	N
			Stent placement	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1066 10661223	Cardiac disorders	Angina pectoris	01APR2018		Y
			Coronary artery disease	01NOV2014		Y
			Myocardial infarction	01NOV2014	31DEC2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2012		Y
		Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1066 10661224	Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1967		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2013		Y
		Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Glaucoma surgery	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2000	31DEC2000	N
	C4591001 1066 10661225	Gastrointestinal disorders	Inguinal hernia	01JAN1961	31DEC1961	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1961	31DEC1961	N
	C4591001 1066 10661227	Ear and labyrinth disorders	Deafness unilateral	01JAN1958		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1990	31DEC1990	N
	C4591001 1066 10661228	Cardiac disorders	Cardiac failure congestive	01JAN2018	31DEC2019	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
			Irritable bowel syndrome	01JAN2020		Y
			Large intestine polyp	01JAN2020	31MAR2020	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephropathy	01JAN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
			Large intestinal polypectomy	01MAR2020	31MAR2020	N
			Limb operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1970		Y
	C4591001 1066 10661229	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
				01JAN2019		Y
			Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2001	N
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Knee arthroplasty	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
			Mastectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661230	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661231	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
			Insomnia	01JAN2008		Y
		Renal and urinary disorders	Incontinence	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Social circumstances	Menopause	01JAN1980		Y
	C4591001 1066 10661232	Endocrine disorders	Hypothyroidism	01JAN1974		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
			Migraine	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric bypass	01JAN2006	31DEC2006	N
	C4591001 1066 10661234	Endocrine disorders	Thyroid disorder	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Chronic sinusitis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1972		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1066 10661236	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1066 10661237	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Investigations	Smear cervix abnormal	01JAN1982	31DEC1983	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1996	31DEC1996	N
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1066 10661238	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2015		Y
	C4591001 1066 10661239	Investigations	Blood cholesterol increased	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1066 10661240	Investigations	Blood testosterone decreased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1995	31DEC1997	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1997	31DEC1997	N
	C4591001 1066 10661241	Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Investigations	Biopsy skin	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1066 10661244	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Plantar fasciitis	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Foot operation	01JAN2003	31DEC2003	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
			Knee operation	01JAN2019	31DEC2019	N
			Stem cell transplant	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661245	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1938		Y
				01JAN2000		Y
			Rubber sensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2001	31DEC2001	N
		Investigations	Angiogram	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteoporosis	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Oesophageal dilation procedure	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1066 10661248	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Eye injury	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2007	31DEC2007	N
			Vitrectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661250	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Obesity	01JAN2004		Y
	C4591001 1066 10661252	Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985	31DEC2018	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Deep vein thrombosis	01DEC2016	31DEC2016	N
	C4591001 1066 10661254	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Glucose tolerance impaired	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1970	31DEC1970	N
		Reproductive system and breast disorders	Breast cyst	01JAN1970	31DEC1970	N
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1970	31DEC1970	N
			Cholecystectomy	01JAN1980	31DEC1980	N
			Female sterilisation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1066 10661255	Endocrine disorders	Thyroid disorder	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
			Hiatus hernia	01OCT2019	11FEB2020	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2015	N
		Surgical and medical procedures	Breast conserving surgery	01APR2010	30APR2010	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1066 10661256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2017	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1977		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1992		Y
			Depression	01JAN2017		Y
		Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Breast conserving surgery	01FEB2017	28FEB2017	N
			Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1066 10661257	Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2016	31DEC2016	N
		Infections and infestations	Diverticulitis	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Large intestinal polypectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661258	Cardiac disorders	Arrhythmia	01JAN2014		Y
			Atrial fibrillation	01JAN2018		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Arthrodesis	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Atrial appendage closure	01MAY2019	31MAY2019	N
			Cholecystectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1066 10661263	Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1066 10661266	Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1991	31DEC1991	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1975	31DEC1975	N
			Parathyroid tumour	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Thyroid nodule removal	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661268	Cardiac disorders	Cardiac flutter	01JAN2007	31DEC2007	N
		Eye disorders	Cataract	01JAN2014	31DEC2014	N
			Strabismus	01JAN2003		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2001	31DEC2001	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2007	31DEC2007	N
			Cataract operation	01JAN2014	31DEC2014	N
			Inguinal hernia repair	01JAN2009	31DEC2009	N
			Nasal septal operation	01JAN2001	31DEC2001	N
			Strabismus correction	01JAN2003	31DEC2003	N
	C4591001 1066 10661269	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Cellulitis	01JAN2007	31DEC2007	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Skin ulcer	01JAN2007		Y
		Surgical and medical procedures	Venous stent insertion	01JAN2011	31DEC2011	N
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
	C4591001 1066 10661271	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1066 10661274	Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
		Investigations	Cardiac murmur	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1066 10661281	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1947	31DEC1947	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1993	31DEC1993	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1947	31DEC1947	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Tenoplasty	01JAN1993	31DEC1993	N
	C4591001 1066 10661283	Injury, poisoning and procedural complications	Wrist fracture	01APR2020	30APR2020	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Wrist surgery	01APR2020	30APR2020	N
	C4591001 1066 10661288	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661292	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Infections and infestations	Diverticulitis	01JAN2018	31JAN2018	N
		Investigations	Hepatic enzyme increased	01NOV2016	30APR2020	N
		Psychiatric disorders	Alcoholism	01JAN2014	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Colectomy	01JAN2018	31JAN2018	N
			Colostomy	01APR2018	30APR2018	N
				01JAN2018	31JAN2018	N
	C4591001 1066 10661297	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1990	31DEC1992	N
				01JAN2016	31OCT2018	N
		Nervous system disorders	Diabetic neuropathy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Menopause	01JAN2001		Y
		Surgical and medical procedures	Mastectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016	31DEC2016	N
	C4591001 1066 10661298	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1066 10661302	Vascular disorders	Hypertension	01APR2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2012		Y
				01JAN2017		Y
		Infections and infestations	Hepatitis C	01JAN1990	31DEC1997	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Haemochromatosis	01JAN2013		Y
			Impaired fasting glucose	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Bipolar disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2012	31DEC2012	N
	C4591001 1066 10661303	Vascular disorders	Hypertension	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1066 10661304	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
				01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	01JAN2009	31DEC2009	N
			Hip arthroplasty	01JAN2011	31DEC2011	N
				01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Mastectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1066 10661306	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN1982	31DEC1982	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
			Osteopenia	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Breast mass	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Appendectomy	01JAN2019	31DEC2019	N
			Breast conserving surgery	01JAN2008	31DEC2008	N
			Cataract operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Knee operation	01JAN2014	31DEC2014	N
			Splenectomy	01JAN1982	31DEC1982	N
	C4591001 1066 10661311	Congenital, familial and genetic disorders	Hydrocele	01JAN2012	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
			Large intestine polyp	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
			Osteoarthritis	01JAN2013		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nephrolithiasis	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Varicocele	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N
			Varicocele repair	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1066 10661313	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Joint injury	01JAN1991	31DEC1991	N
		Psychiatric disorders	Depression	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Surgical and medical procedures	Ankle operation	01JAN1991	31DEC1991	N
			Appendectomy	01JAN2017	31DEC2017	N
	C4591001 1066 10661314	Hepatobiliary disorders	Gallbladder disorder	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1066 10661316	Eye disorders	Cataract	01JAN2017	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Joint range of motion decreased	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Arthrodesis	01JAN2015	31DEC2015	N
			Cataract operation	01JAN2018	31DEC2018	N
			Ligament operation	01JAN2015	31DEC2015	N
	C4591001 1066 10661318	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01MAR2020		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN1995	31DEC1995	N
	C4591001 1066 10661319	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	31DEC2000	N
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1066 10661320	Ear and labyrinth disorders	Vertigo	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1066 10661325	Cardiac disorders	Cardiomyopathy	01AUG2018		Y
			Ventricular tachycardia	01AUG2018		Y
		Investigations	Catheterisation cardiac	01NOV2018	30NOV2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1066 10661326	Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
	C4591001 1066 10661327	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Chronic sinusitis	01JAN2018		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1066 10661328	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01MAY2020	31MAY2020	N
		Nervous system disorders	Migraine	01JAN2000		Y
			Morton's neuralgia	01JAN2017	31JAN2017	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Surgical and medical procedures	Foot operation	01JAN2017	31JAN2017	N
			Lithotripsy	01MAY2018	31MAY2018	N
			Spinal operation	01MAY2020	31MAY2020	N
	C4591001 1066 10661329	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Hypersensitivity	01JAN1945		Y
		Injury, poisoning and procedural complications	Patella fracture	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2017		Y
			Osteopenia	01JAN2005		Y
		Social circumstances	Menopause	01JAN1990	31DEC1991	N
		Surgical and medical procedures	Knee operation	01JAN2007	31DEC2007	N
	C4591001 1066 10661334	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Arthritis infective	01MAR2017	31MAY2017	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	30NOV2010	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01NOV2010	30NOV2010	N
			Knee arthroplasty	01MAY2017	31MAY2017	N
	C4591001 1066 10661339	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Hypersensitivity	01JAN2011		Y
		Social circumstances	Menopause	01JAN2005	31DEC2006	N
	C4591001 1066 10661343	Social circumstances	Menopause	01JAN2013	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1066 10661347	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
			Atrial flutter	01JAN2013		Y
			Supraventricular extrasystoles	01JAN2012		Y
			Ventricular extrasystoles	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Gallbladder disorder	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN1940		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01AUG2017		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
				15JUL2020	15JUL2020	N
			Gallbladder operation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661349	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Inguinal hernia	01MAY2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Kyphosis	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01AUG2012	31DEC2012	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN1995	31DEC1995	N
			Inguinal hernia repair	01MAY2012	31DEC2012	N
			Knee arthroplasty	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01AUG2012	31AUG2012	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661350	Cardiac disorders	Cardiomyopathy	01MAR2018		Y
			Myocardial infarction	01MAR2018	31MAR2018	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1985		Y
		Metabolism and nutrition disorders	Hyponatraemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2012	31DEC2012	N
		Nervous system disorders	Seizure	01JAN2015	31DEC2015	N
		Psychiatric disorders	Alcohol abuse	01JAN2018	31DEC2018	N
			Anxiety	01JAN1990		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661351	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Investigations	Biopsy skin	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2001	31DEC2001	N
	C4591001 1066 10661352	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN1980	31DEC1980	N
		Infections and infestations	Hepatitis C	01JAN1975	31DEC1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Menopause	01JAN2005	31DEC2006	N
		Surgical and medical procedures	Bone lesion excision	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1066 10661353	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1968	31DEC1968	N
				01JAN1975	31DEC1975	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1968	31DEC1968	N
				01JAN1975	31DEC1975	N
			Nasal septal operation	01JAN2012	31DEC2012	N
			Renal stone removal	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1066 10661354	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1066 10661356	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Infections and infestations	Pilonidal cyst	01JAN1975	31DEC1975	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN1980	31DEC1980	N
		Nervous system disorders	Essential tremor	06JUN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Large intestinal polypectomy	01JAN1980	31DEC1980	N
			Pilonidal sinus repair	01JAN1975	31DEC1975	N
	C4591001 1066 10661357	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN1995	31DEC1995	N
	C4591001 1066 10661359	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Attention deficit hyperactivity disorder	01JAN1981		Y
			Insomnia	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Knee arthroplasty	01AUG2020	31AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661361	Vascular disorders	Hypertension	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JUN2019	31AUG2020	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2010	N
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Investigations	Biopsy skin	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Cataract operation	01AUG2020	31AUG2020	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1974	31DEC1974	N
	C4591001 1066 10661362	Endocrine disorders	Hypothyroidism	01JAN1962		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Coeliac disease	01JAN1992		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteochondroma	01JAN1961	31DEC1961	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1972	31DEC1972	N
		Social circumstances	Menopause	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2011	31DEC2011	N
		C4591001 1066 10661365	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004
	Social circumstances		Menopause	01JAN2004		Y
	Surgical and medical procedures		Breast conserving surgery	01JAN2004	31DEC2004	N
			Lymphadenectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661367	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1999	N
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1066 10661368	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
			Obesity	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Tenoplasty	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1066 10661369	Cardiac disorders	Palpitations	01JAN2019		Y
			Sinus bradycardia	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1990		Y
		Injury, poisoning and procedural complications	Musculoskeletal foreign body	01JUL2018	31JUL2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Hypoglycaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Renal and urinary disorders	Micturition urgency	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2012	31DEC2012	N
			Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2017		Y
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
			Nasal septal operation	01JAN2012	31DEC2012	N
			Removal of foreign body from joint	01JUL2018	31JUL2018	N
	C4591001 1066 10661373	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1066 10661374	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Psychiatric disorders	Alcohol abuse	01JAN2013	31DEC2019	N
			Anxiety	01JAN1979		Y
			Depression	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1066 10661375	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01SEP2014		Y
			Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
	C4591001 1066 10661376	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Eye disorders	Blindness unilateral	01JAN2015		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Colectomy	01JAN1983	31DEC1983	N
			Gallbladder operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1066 10661377	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2019		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2000		Y
			Spinal deformity	01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2014		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2014	31DEC2014	N
	C4591001 1066 10661378	Surgical and medical procedures	Sterilisation	01JAN1980	31DEC1980	N
			Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1066 10661380	Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Diverticulum	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Pancreatitis	01JAN2014		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1992	31DEC1992	N
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Nervous system disorders	Migraine	01JAN1971		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1066 10661381	Cardiac disorders	Vaginal prolapse repair	01JAN2018	31DEC2018	N
			Bundle branch block right	01JAN2005		Y
			Ventricular extrasystoles	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2016		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Epilepsy	01JAN2002		Y
			Migraine	01JAN1986		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
			Urinary incontinence	01JUL2020		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		C4591001 1066 10661382	Eye disorders	Intraocular lens implant	01JAN2017	31DEC2017
	Cataract			01MAY2020	31JUL2020	N
			Glaucoma	01MAY2020		Y
	Immune system disorders		Seasonal allergy	01JAN2010		Y
	Investigations		Blood testosterone decreased	01JAN2009		Y
	Musculoskeletal and connective tissue disorders		Back pain	01JAN2009		Y
	Psychiatric disorders		Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
			Insomnia	01JAN2005		Y
	Reproductive system and breast disorders		Benign prostatic hyperplasia	01JAN2012		Y
		Erectile dysfunction	01JAN2009		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JUL2020	31JUL2020	N
			Vasectomy	01JAN1986	31DEC1986	N
	C4591001 1066 10661383	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1985	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1066 10661384	Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1066 10661385	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1066 10661387	Gastrointestinal disorders	Inguinal hernia	01JAN1970	31DEC1970	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N
			Hernia repair	01JAN1970	31DEC1970	N
	C4591001 1068 10681001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease nodular sclerosis	01AUG2014	13FEB2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1068 10681004	Endocrine disorders	Hypothyroidism	01JAN2015		Y
			Thyroid mass	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	14JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681007	Infections and infestations	Sinusitis	01JAN2020	31JUL2020	N
		Investigations	Blood pressure increased	01JAN2018		Y
		Nervous system disorders	Essential tremor	01JAN2011		Y
	C4591001 1068 10681008	Congenital, familial and genetic disorders	Asymptomatic gene carrier	(b) (6) 1942		Y
			Type IIa hyperlipidaemia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Aphthous ulcer	01APR2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
			Tendonitis	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN2010		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2009		Y
			Insomnia	01JAN1960		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JAN1976	31DEC1977	N
			Restrictive pulmonary disease	01JAN1976	31DEC1977	N
		Vascular disorders	Essential hypertension	01JAN1980		Y
	C4591001 1068 10681009	Cardiac disorders	Coronary artery disease	01JAN1995	31DEC1995	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cutaneous T-cell lymphoma	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
	C4591001 1068 10681014	Surgical and medical procedures	Coronary arterial stent insertion	01JAN1999	31DEC1999	N
		Psychiatric disorders	Sleep disorder	01JAN2000		Y
	C4591001 1068 10681015	Social circumstances	Menopause	01SEP2010		Y
		Metabolism and nutrition disorders	Gout	22JUN2020		Y
	C4591001 1068 10681019	Cardiac disorders	Ventricular extrasystoles	01JAN2014		Y
		Immune system disorders	Sarcoidosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2006	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2006	31DEC2006	N
			Lipoma excision	01JAN2010	31DEC2010	N
			Mastectomy	01JAN2006	31DEC2006	N
	C4591001 1068 10681020	Infections and infestations	Onychomycosis	14DEC2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Gout	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	(b) (6) 1952		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	22NOV2019		Y
		Skin and subcutaneous tissue disorders	Nail dystrophy	14DEC2017	14DEC2017	N
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1068 10681022	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2015	N
			Limb asymmetry	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Scoliosis	01JAN2015		Y
			Temporomandibular joint syndrome	01JAN1990		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1068 10681023	Gastrointestinal disorders	Abdominal pain lower	01JAN2018	31DEC2018	N
		Nervous system disorders	Paraesthesia	01JAN2020		Y
		Psychiatric disorders	Sleep disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Hypoxia	01JAN2018		Y
			Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1068 10681029	Endocrine disorders	Hypogonadism	01JAN1995		Y
		Gastrointestinal disorders	Large intestine polyp	11AUG2019	31DEC2020	N
		Vascular disorders	Essential hypertension	01JAN2013		Y
	C4591001 1068 10681030	Ear and labyrinth disorders	Tinnitus	03OCT2014		Y
		Endocrine disorders	Thyroid mass	22FEB2014	31DEC2014	N
		General disorders and administration site conditions	Chest discomfort	27MAR2018	27APR2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	27FEB2014		Y
			Vitamin D deficiency	02FEB2018	16MAR2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10JAN2019		Y
			Rheumatic fever	01JAN1952	31DEC1952	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Large intestine benign neoplasm	02JUN2014		Y
		Skin and subcutaneous tissue disorders	Rosacea	03OCT2014	31DEC2019	N
		Social circumstances	Familial risk factor	01JAN1945		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	27OCT2019		Y
	C4591001 1068 10681032	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	31OCT2016	11JAN2018	N
		Psychiatric disorders	Depression	01AUG1997		Y
		Social circumstances	Alcoholic	01JAN1995		Y
		Vascular disorders	Essential hypertension	01AUG1997		Y
	C4591001 1068 10681033	Endocrine disorders	Hypothyroidism	01JAN1974		Y
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10AUG2019	31DEC2019	N
		Psychiatric disorders	Major depression	01JAN1985	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976	31DEC2015	N
	C4591001 1068 10681040	Hepatobiliary disorders	Cholecystitis	14MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1068 10681041	Musculoskeletal and connective tissue disorders	Osteopenia	20APR2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	11MAR2019		Y
	C4591001 1068 10681043	Social circumstances	Postmenopause	01JAN2017	31DEC2017	N
	C4591001 1068 10681044	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
				03SEP2018		Y
			Osteoarthritis	06MAR2017	31DEC2020	N
	C4591001 1068 10681051	Ear and labyrinth disorders	Tinnitus	01FEB2018		Y
		Social circumstances	Menopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Angiopathy	16NOV2016		Y
	C4591001 1068 10681054	Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	29MAR2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	05MAY2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1068 10681055	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1956		Y
		Infections and infestations	Onychomycosis	01JAN1956		Y
		Injury, poisoning and procedural complications	Seroma	01APR2018	30APR2018	N
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	30APR2018	N
		Nervous system disorders	Carpal tunnel syndrome	01OCT2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01APR2018	30APR2018	N
	C4591001 1068 10681056	Cardiac disorders	Bundle branch block left	01JAN1995		Y
			Supraventricular tachycardia	01JAN1995		Y
		Ear and labyrinth disorders	Deafness neurosensory	15JUL2020		Y
		Endocrine disorders	Hypothyroidism	28MAR2016		Y
		Eye disorders	Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Gastritis	28MAR2016		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	28MAR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	28MAR2016		Y
			Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1966	31DEC1966	N
		Nervous system disorders	Carpal tunnel syndrome	06JUL2018		Y
			Polyneuropathy	03JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01OCT2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	09MAY2017		Y
			Rosacea	01JAN1995		Y
		Vascular disorders	Essential hypertension	01JAN2015		Y
	C4591001 1068 10681057	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2004	31DEC2008	N
		Eye disorders	Cataract nuclear	06DEC2017	24APR2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Bronchitis bacterial	01JAN1974		Y
			Nocardiosis	04DEC2019	27AUG2020	N
			Pulmonary tuberculosis	01JAN1974	31DEC1975	N
		Injury, poisoning and procedural complications	Post procedural haemorrhage	31MAY2020	31MAY2020	N
		Investigations	Endoscopy	26APR2018	26APR2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	19DEC2015	04SEP2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2003	26APR2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	19DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cough	01JAN1974		Y
			Interstitial lung disease	01JAN1974		Y
			Sleep apnoea syndrome	19DEC2015	31DEC2015	N
		Surgical and medical procedures	Continuous positive airway pressure	19DEC2015	31DEC2015	N
	C4591001 1068 10681059	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
			Major depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2013	31DEC2013	N
	C4591001 1068 10681062	Endocrine disorders	Thyroid mass	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Chronic pigmented purpura	06JAN2020	06MAR2020	N
	C4591001 1068 10681063	Metabolism and nutrition disorders	Obesity	01JAN2017	14MAY2020	N
	C4591001 1068 10681065	Endocrine disorders	Hypothyroidism	05NOV2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	19JUN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	19JUN2013	31DEC2015	N
		Psychiatric disorders	Depression	05NOV2018		Y
		Renal and urinary disorders	Dysuria	02MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Cough	19JUN2013		Y
			Pulmonary mass	23AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681068	Eye disorders	Open angle glaucoma	11JUN2013		Y
			Posterior capsule opacification	12MAY2016	31DEC2016	N
		General disorders and administration site conditions	Oedema peripheral	22DEC2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	22DEC2016	31DEC2017	N
			Pain in extremity	27DEC2017		Y
		Renal and urinary disorders	Chronic kidney disease	29FEB2016		Y
	C4591001 1068 10681069	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	08AUG2015		Y
		Gastrointestinal disorders	Diarrhoea	13JAN2020	15JAN2020	N
		Infections and infestations	Herpes simplex	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	15JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1979		Y
	C4591001 1068 10681075	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	16JUL2018		Y
		Gastrointestinal disorders	Diverticulum intestinal	07AUG2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	16JUL2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	06NOV2017	31DEC2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	29MAY2018		Y
			Pulmonary mass	29MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Essential hypertension	10DEC2013		Y
	C4591001 1068 10681078	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Gastrointestinal disorders	Coeliac disease	01JAN1997		Y
			Colitis microscopic	09JUN2019	30JUN2019	N
			Gastritis erosive	09JUN2019		Y
		Nervous system disorders	Depressed level of consciousness	09JUN2016	09JUN2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	10JAN1995		Y
			Nicotine dependence	04APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012	31DEC2014	N
			Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1068 10681079	Congenital, familial and genetic disorders	Type V hyperlipidaemia	18FEB2020		Y
		Gastrointestinal disorders	Crohn's disease	01JAN1969		Y
		Reproductive system and breast disorders	Female genital tract fistula	09MAR2020		Y
	C4591001 1068 10681082	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020	30APR2020	N
			Obstructive pancreatitis	19OCT2017	31DEC2017	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	31OCT2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	18SEP2019		Y
		Psychiatric disorders	Anxiety	30APR2020		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Insomnia	12APR2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	31OCT2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681084	Cardiac disorders	Sinus node dysfunction	05JUL2007	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	11JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
			Sciatica	01JUN2018	30SEP2018	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
			Seasonal affective disorder	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2017	31DEC2017	N
	C4591001 1068 10681088	Blood and lymphatic system disorders	Activated protein C resistance	12SEP2015		Y
			Hypercoagulation	12SEP2015		Y
		Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Congenital, familial and genetic disorders	Factor V Leiden mutation	12SEP2015		Y
			Type V hyperlipidaemia	21OCT2016		Y
		Investigations	Anticoagulation drug level	08MAY2017		Y
		Metabolism and nutrition disorders	Hypophosphataemia	13DEC2016	13DEC2018	N
			Impaired fasting glucose	28OCT2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	13NOV2012		Y
			Prostate cancer	03JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Gastric bypass	01JAN2014	31DEC2014	N
			Vena cava filter insertion	01JAN2014		Y
		Vascular disorders	Aortic aneurysm	01JAN1980	31DEC1980	N
			Aortic stenosis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN1990		Y
	C4591001 1068 10681090	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN1980	31DEC2009	N
			Gastrooesophageal reflux disease	01JAN1980	31DEC2009	N
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1996		Y
			Spinal osteoarthritis	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2004	31DEC2004	N
		Psychiatric disorders	Depression	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Caesarean section	01OCT2002	31OCT2002	N
	C4591001 1068 10681091	Infections and infestations	Oral herpes	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2018		Y
		Reproductive system and breast disorders	Menopausal symptoms	28JAN2018	22JUN2018	N
	C4591001 1068 10681092	Cardiac disorders	Aortic valve stenosis	25NOV2019		Y
			Tachycardia	07NOV2019		Y
		Congenital, familial and genetic disorders	Hereditary haemochromatosis	(b) (6) 1948		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	24OCT2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Nervous system disorders	Lumbosacral radiculopathy	08DEC2015		Y
			Radiculopathy	08DEC2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	12DEC2016		Y
				24OCT2017		Y
	C4591001 1068 10681093	Cardiac disorders	Atrioventricular block complete	26MAY2013	26MAY2013	N
		Endocrine disorders	Hyperparathyroidism	03JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1940		Y
		Investigations	Blood parathyroid hormone abnormal	03JUN2020		Y
		Metabolism and nutrition disorders	Hypercalcaemia	06NOV2017	02JUN2020	N
			Hyponatraemia	14OCT2017	16OCT2017	N
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Cognitive disorder	01AUG2019		Y
			Parkinsonism	10FEB2020		Y
		Renal and urinary disorders	Pollakiuria	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1940		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01NOV2017	01NOV2017	N
			Cataract operation	13JAN2020	13JAN2020	N
				20JAN2020	20JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681094	Vascular disorders	Essential hypertension	01JAN2010		Y
		Cardiac disorders	Coronary artery disease	01JAN2002		Y
			Palpitations	01JAN2003	31DEC2015	N
		Congenital, familial and genetic disorders	Thalassaemia minor	01JAN2018		Y
		Ear and labyrinth disorders	Deafness neurosensory	01JAN1990		Y
		Gastrointestinal disorders	Abdominal pain	01JAN2000		Y
			Diverticulum intestinal	01JAN1972		Y
			Gastritis	01JAN2009		Y
			Irritable bowel syndrome	01JAN1980		Y
		General disorders and administration site conditions	Pain	01JAN1990		Y
		Hepatobiliary disorders	Liver disorder	01JAN2009		Y
		Investigations	Catheterisation cardiac	07APR2015	07APR2015	N
			Full blood count	17JAN2020		Y
			Glycosylated haemoglobin	17JAN2020		Y
			Lipids	17JAN2020		Y
			Liver function test increased	01JAN1995		Y
			Metabolic function test	17JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
			Iron deficiency	20JUN2018		Y
			Type 2 diabetes mellitus	01JAN2003		Y
			Vitamin B complex deficiency	01JAN2007		Y
			Vitamin D deficiency	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	16OCT2019		Y
			Lumbar spinal stenosis	01JAN1960		Y
			Neck pain	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carotid artery stenosis	01JUL2009	31JUL2009	N
			Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1960		Y
			Insomnia	01JAN1990	31DEC2000	N
			Sleep disorder	01JAN1990	31DEC2000	N
		Renal and urinary disorders	Nocturia	01JAN2016		Y
			Pollakiuria	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1945		Y
			Rhinitis allergic	01JAN1945		Y
			Sleep apnoea syndrome	01JAN1999		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2003	31JAN2003	N
			Spinal nerve stimulator implantation	01JAN2015		Y
		Vascular disorders	Essential hypertension	01JAN1980		Y
			Venous haemorrhage	01JAN2003	31JAN2003	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
	C4591001 1068 10681095					
	C4591001 1068 10681096	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN2000		Y
	C4591001 1068 10681101	Immune system disorders	Seasonal allergy	02NOV2018		Y
		Social circumstances	Postmenopause	01JAN2011	31DEC2011	N
	C4591001 1068 10681104	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2016		Y
			Vitamin D deficiency	01FEB2016		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01FEB2016		Y
	C4591001 1068 10681105	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1068 10681107	Infections and infestations	Diverticulitis	21MAY2020		Y
	C4591001 1068 10681108	Blood and lymphatic system disorders	Thrombocytopenia	13AUG2014		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2000		Y
		Eye disorders	Blindness unilateral	(b) (6) 1948		Y
			Glaucoma	01JAN1980		Y
		Investigations	Endoscopy	25JUL2019	25JUL2019	N
		Metabolism and nutrition disorders	Impaired fasting glucose	05OCT2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	16JUL2012		Y
		Surgical and medical procedures	Large intestinal polypectomy	25JUL2019	25JUL2019	N
	C4591001 1068 10681118	Metabolism and nutrition disorders	Hyperlipidaemia	07JUN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	18OCT2016		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	02JUN2020		Y
	C4591001 1068 10681120	Gastrointestinal disorders	Gastroesophageal reflux disease	29APR2016	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	29APR2016		Y
			Intervertebral disc degeneration	29APR2016		Y
			Osteoporosis	28APR2016		Y
			Temporomandibular joint syndrome	29APR2018		Y
		Nervous system disorders	Migraine without aura	29APR2016		Y
		Psychiatric disorders	Anxiety	11SEP2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep disorder	29APR2016		Y
	C4591001 1068 10681122	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2010	31OCT2010	N
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN1992	31DEC1992	N
		Psychiatric disorders	Depression	25SEP1969		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2005		Y
	C4591001 1071 10711001	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1071 10711002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017	31DEC2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Fracture treatment	01JAN1990	31DEC1990	N
			Limb operation	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711009	Cardiac disorders	Bundle branch block left	22AUG2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1972		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	15MAY2015		Y
		Renal and urinary disorders	Nocturia	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Aortic dilatation	01AUG2017		Y
	C4591001 1071 10711010	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711011	Endocrine disorders	Hypogonadism	01JAN2007		Y
		Gastrointestinal disorders	Diverticulum	01FEB2008		Y
		General disorders and administration site conditions	Fatigue	01FEB2008		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2008	31DEC2018	N
				01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
			Erectile dysfunction	01FEB2008		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1071 10711013	Cardiac disorders	Heart valve incompetence	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711014	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
			Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Hernia repair	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1071 10711015	Nervous system disorders	Migraine	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1071 10711016	Cardiac disorders	Coronary artery disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Umbilical hernia	11AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y
					23OCT2019	N
		Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	01JAN2005	31DEC2006	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2001		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN2005	31DEC2008	N
			Rhinitis allergic	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2005	31JAN2006	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1071 10711017	Gastrointestinal disorders	Faeces hard	01NOV2019		Y
			Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1985		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711023	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
			Coronary artery disease	01JAN2019		Y
		Eye disorders	Blindness	01FEB2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
				01JUN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1071 10711025	Cardiac disorders	Supraventricular extrasystoles	19JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JUL2015		Y
		Eye disorders	Cataract	01MAY2005	31MAY2005	N
		General disorders and administration site conditions	Fatigue	19JAN2015	31DEC2016	N
			Oedema peripheral	01JAN2014	31DEC2015	N
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	29DEC2016		Y
			Diastasis recti abdominis	12AUG2020		Y
			Osteoarthritis	29DEC2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff syndrome	01JAN1985	31DEC1985	N
		Nervous system disorders	Memory impairment	01OCT2013		Y
		Renal and urinary disorders	Lower urinary tract symptoms	21OCT2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
			Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01MAY2005	31MAY2005	N
			Muscle operation	01JAN2004	31DEC2004	N
			Rotator cuff repair	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1945	31DEC1945	N
			Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1071 10711029	Metabolism and nutrition disorders	Hyperlipidaemia	05JUL2017		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01SEP1961		Y
		Reproductive system and breast disorders	Erectile dysfunction	04APR2017		Y
		Vascular disorders	Hypertension	04APR2017		Y
	C4591001 1071 10711031	Eye disorders	Macular degeneration	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN1974		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2008	N
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1071 10711032	Congenital, familial and genetic disorders	Myoclonic dystonia	01JAN2015		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1980		Y
		Renal and urinary disorders	Nocturia	01JUN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1071 10711033	Ear and labyrinth disorders	Eustachian tube dysfunction	01JAN1997		Y
			Tinnitus	01JAN2015		Y
			Vertigo	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Constipation	15SEP2015		Y
			Haemorrhoids	07MAR2012		Y
			Umbilical hernia	05AUG2016		Y
		General disorders and administration site conditions	Chronic fatigue syndrome	10JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Diverticulitis	07MAY2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21AUG2017		Y
			Hypertriglyceridaemia	14JUL2017		Y
			Obesity	09OCT2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2004		Y
			Muscle spasms	01JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2013		Y
				30SEP2013		Y
			Rotator cuff syndrome	04JUN2018		Y
		Nervous system disorders	Dizziness	01JAN2015		Y
		Psychiatric disorders	Depression	06NOV2018		Y
		Renal and urinary disorders	Nocturia	01JAN1989		Y
			Pollakiuria	17JUL2018		Y
		Reproductive system and breast disorders	Prostatitis	15JUN2010		Y
		Vascular disorders	Aortic dilatation	18MAY2016		Y
			Arteriosclerosis	18MAY2016		Y
			Hypertension	01JAN2016		Y
	C4591001 1071 10711035	Musculoskeletal and connective tissue disorders	Fibromyalgia	11JUN2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711038	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1071 10711043	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Attention deficit hyperactivity disorder	01JAN2018		Y
			Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1071 10711044	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1999		Y
	C4591001 1071 10711048	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Irritable bowel syndrome	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2018		Y
			Osteoarthritis	01JAN2006		Y
			Osteoporosis	03MAY2006		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1071 10711049	Cardiac disorders	Coronary artery disease	01APR2019		Y
			Myocardial infarction	01APR2019	30APR2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	17AUG2020		Y
			Type 2 diabetes mellitus	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
			Cough	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1071 10711050	Gastrointestinal disorders	Gastrooesophageal reflux disease	27NOV2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholesteatoma	27NOV2017		Y
		Nervous system disorders	Tremor	04JUN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	27NOV2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis	06DEC2018		Y
	C4591001 1071 10711051	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hot flush	01JAN2009		Y
	C4591001 1071 10711052	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2013		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711053	Gastrointestinal disorders	Constipation	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Reproductive system and breast disorders	Dyspareunia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1071 10711054	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1993		Y
			Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1071 10711058	Endocrine disorders	Hypothyroidism	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1949		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1981		Y
			Obesity	01JAN1994		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1071 10711059	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Paraesthesia	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711060	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1071 10711063	Eye disorders	Glaucoma	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
			Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Bipolar disorder	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
	C4591001 1071 10711064	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2017		Y
	C4591001 1071 10711066	Eye disorders	Conjunctivitis allergic	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	09APR2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN1985		Y
			Insomnia	26OCT2017		Y
		Renal and urinary disorders	Urinary incontinence	25JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	19JAN2017		Y
			Rhinitis allergic	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1071 10711067	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1071 10711068	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1071 10711069	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1071 10711071	Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2018		Y
				01MAR2015		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1071 10711072	Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
			Erectile dysfunction	01JAN2018		Y
	C4591001 1071 10711073	Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Oral herpes	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2002		Y
			Osteoarthritis	01JAN2017		Y
			Pain in extremity	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2001		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711074	Blood and lymphatic system disorders	Anaemia	27MAY2020		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Glomerular filtration rate decreased	27MAY2020		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1071 10711075	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1995		Y
			Plantar fasciitis	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hot flush	01JAN2016		Y
			Hypertension	01JAN2014		Y
	C4591001 1071 10711076	Ear and labyrinth disorders	Deafness bilateral	01JAN1995		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1071 10711077	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1978		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711078	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711084	Metabolism and nutrition disorders	Gout	01JAN2000		Y
	C4591001 1071 10711085	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2010		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1998		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hypercholesterolaemia	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1071 10711088	Cardiac disorders	Arteriosclerosis coronary artery	06JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Type 2 diabetes mellitus	06JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2015		Y
		Vascular disorders	Hypertension	06JAN2017		Y
	C4591001 1071 10711089	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711091	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Multiple allergies	01JAN1958		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1071 10711093	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1984		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711096	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Stress	01MAY2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1071 10711099	Psychiatric disorders	Schizoaffective disorder	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
	C4591001 1071 10711101	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1071 10711103	Endocrine disorders	Hypothyroidism	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diverticulum intestinal	18APR2017		Y
			Large intestine polyp	18APR2017		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1991		Y
		Infections and infestations	Oral herpes	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	18APR2017		Y
			Vitamin B complex deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Back pain	01APR2016		Y
			Intervertebral disc degeneration	01JAN2017		Y
			Intervertebral disc displacement	01APR2016		Y
			Osteoarthritis	01JAN2008		Y
				01JAN2016		Y
			Pain in extremity	01JAN2015		Y
			Spinal osteoarthritis	01APR2016		Y
		Nervous system disorders	Lumbar radiculopathy	01APR2016		Y
			Neuropathy peripheral	01JAN2017		Y
			Radiculopathy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	18APR2017		Y
		Social circumstances	Postmenopause	18APR2017		Y
	C4591001 1071 10711104	Infections and infestations	Oral herpes	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1071 10711105	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	08AUG2015		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1071 10711106	Ear and labyrinth disorders	Hypoacusis	27AUG2020		Y
		Eye disorders	Glaucoma	01APR2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Gout	20JUL2018		Y
			Hyperlipidaemia	01JAN1972		Y
		Nervous system disorders	Headache	01JAN1965		Y
			Migraine	01JAN1965		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1071 10711108	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
			Osteoporosis	01JAN2000		Y
			Scoliosis	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01DEC1999	31DEC1999	N
	C4591001 1071 10711109	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2014		Y
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1071 10711110	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2009		Y
			Emphysema	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
	C4591001 1071 10711111	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1071 10711112	Immune system disorders	Drug hypersensitivity	01JAN1949		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
	C4591001 1071 10711117	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1071 10711120	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1985		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01AUG2011		Y
			Seasonal allergy	01JAN1979		Y
		Infections and infestations	Urinary tract infection	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1977		Y
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN1968		Y
	C4591001 1071 10711121	General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
			Narcolepsy	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01AUG2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1071 10711122	Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
	C4591001 1071 10711126	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN1988		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1071 10711129	Gastrointestinal disorders	Umbilical hernia	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1071 10711130	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	05MAY1990	05MAY1990	N
	C4591001 1071 10711132	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	12AUG2020		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711134	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Vascular disorders	Hypertension	03MAR2015		Y
	C4591001 1071 10711135	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1071 10711142	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN1979		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1071 10711143	Cardiac disorders	Bundle branch block left	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1991		Y
				01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2014		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1071 10711144	Endocrine disorders	Hypothyroidism	08MAY1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1071 10711145	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1071 10711147	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	05MAY2015		Y
	C4591001 1071 10711163	Endocrine disorders	Hypothyroidism	01MAY2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Sarcoidosis	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2009		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1071 10711165	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
	C4591001 1071 10711169	Hepatobiliary disorders	Cholelithiasis	01JAN2018		Y
			Hepatic steatosis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Ataxia	01JAN2018		Y
			Neuropathy peripheral	01JAN2018		Y
			Seizure	01JAN1986		Y
		Psychiatric disorders	Alcohol abuse	01JAN1982		Y
			Depression	01JAN1982		Y
			Drug abuse	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970		Y
	C4591001 1071 10711172	Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01AUG2007	31AUG2007	N
	C4591001 1071 10711174	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1071 10711178	Blood and lymphatic system disorders	Lymphadenopathy	01JAN1994		Y
		Ear and labyrinth disorders	Cerumen impaction	01JAN2019		Y
			Deafness	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01MAY2019		Y
	C4591001 1071 10711179	Skin and subcutaneous tissue disorders	Lichen planus	01MAR2020		Y
		Social circumstances	Postmenopause	07MAR2001		Y
		Surgical and medical procedures	Hysterectomy	07MAR2001	07MAR2001	N
	C4591001 1071 10711180	Cardiac disorders	Coronary artery disease	01NOV2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01APR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
				01JAN2016		Y
				01JAN2018		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01NOV2016		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01NOV2016		Y
	C4591001 1071 10711181	Gastrointestinal disorders	Abdominal hernia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN1981		Y
			Type 2 diabetes mellitus	08OCT2006		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1071 10711184	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1071 10711187	Ear and labyrinth disorders	Endolymphatic hydrops	12JUN2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1071 10711190	Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1071 10711191	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2020		Y
	C4591001 1071 10711192	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1071 10711195	Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1071 10711196	Eye disorders	Blindness	01JAN1954		Y
			Eye pruritus	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Impaired gastric emptying	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
			Intervertebral disc degeneration	01JAN2012		Y
			Osteoarthritis	01JAN2013		Y
			Osteopenia	01JAN2006		Y
		Nervous system disorders	Neuralgia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Renal and urinary disorders	Nocturia	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1071 10711197	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Neck pain	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1071 10711201	Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	07MAR2009	07MAR2009	N
	C4591001 1071 10711207	Ear and labyrinth disorders	Tympanic membrane scarring	01JAN1965		Y
		Gastrointestinal disorders	Tooth loss	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1071 10711214	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1071 10711216	Endocrine disorders	Hypothyroidism	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1071 10711220	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1995		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
			Osteoarthritis	01MAR2008		Y
		Vascular disorders	Deep vein thrombosis	01JAN2002	31DEC2002	N
	C4591001 1071 10711221	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Dyspepsia	01JAN1984		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Obesity	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Vascular disorders	Hypertension	01OCT2014		Y
	C4591001 1071 10711226	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1071 10711228	Gastrointestinal disorders	Abdominal hernia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUL2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1071 10711238	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
	C4591001 1071 10711240	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1071 10711243	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1071 10711245	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2000		Y
			Muscle spasms	10DEC2019		Y
			Osteoarthritis	01JAN2000		Y
				01JAN2010		Y
		Nervous system disorders	Headache	01JAN1974		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01FEB2014		Y
	C4591001 1072 10721002	Surgical and medical procedures	Gastric bypass	01JAN2012	31DEC2012	N
	C4591001 1072 10721003	Metabolism and nutrition disorders	Gout	01JAN2012		Y
			Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1072 10721004	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1072 10721005	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1072 10721006	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1072 10721007	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JUN2016	30JUN2016	N
			Non-Hodgkin's lymphoma	01JUN2016	30JUN2016	N
		Nervous system disorders	Carotid artery disease	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1072 10721010	Injury, poisoning and procedural complications	Postoperative thrombosis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01AUG2010	31AUG2010	N
		Surgical and medical procedures	Prostatectomy	01SEP2010	30SEP2010	N
	C4591001 1072 10721011	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Nervous system disorders	Cluster headache	01JAN1990		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1072 10721014	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Surgical and medical procedures	Knee arthroplasty	01AUG2017	31AUG2017	N
				01NOV2017	30NOV2017	N
			Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1072 10721015	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1072 10721016	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1072 10721017	Cardiac disorders	Mitral valve prolapse	01JAN1984		Y
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Investigations	Hormone level abnormal	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1987		Y
			Depression	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01APR1991	30APR1991	N
	C4591001 1072 10721018	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1072 10721019	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Hormone level abnormal	01SEP2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01SEP2012		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1072 10721020	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1957		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1072 10721021	Psychiatric disorders	Anxiety	01OCT1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01DEC2015	31DEC2015	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1072 10721025	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1965		Y
			Depression	01JAN1990		Y
	C4591001 1072 10721026	Metabolism and nutrition disorders	Gout	01JAN1986		Y
			Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1986		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1072 10721027	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Sinusitis	01JAN2005	31MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1072 10721028	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Radical prostatectomy	01MAY2017	31MAY2017	N
	C4591001 1072 10721032	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	18JAN1998	31AUG1998	N
		Surgical and medical procedures	Hysterectomy	01AUG1998	31AUG1998	N
			Oophorectomy	01AUG1998	31AUG1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1072 10721036	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
			Muscle spasms	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1072 10721037	Congenital, familial and genetic disorders	Cerebrovascular arteriovenous malformation	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Endometrial ablation	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1072 10721038	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Investigations	Hormone level abnormal	01JAN2000		Y
		Social circumstances	Menopause	01JAN1995		Y
	C4591001 1072 10721039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer stage I	01JAN2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01APR2007	30APR2007	N
	C4591001 1072 10721041	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1072 10721043	Investigations	Heart rate irregular	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1072 10721044	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Gastric bypass	01JAN2008	31DEC2008	N
	C4591001 1072 10721045	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
	C4591001 1072 10721048	Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1072 10721053	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1072 10721054	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Hypertriglyceridaemia	01JAN2015		Y
		Surgical and medical procedures	Percutaneous coronary intervention	08JUL2019	08JUL2019	N
			Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1072 10721055	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN1974	31DEC1974	N
	C4591001 1072 10721056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1072 10721057	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1984	31DEC2014	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1979		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1072 10721059	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1072 10721060	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
		Surgical and medical procedures	Hysterectomy	01JUN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1072 10721061	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN1966		Y
			Vitamin B12 deficiency	01JAN2005		Y
			Vitamin D deficiency	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2001		Y
			Osteoarthritis	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1992	31DEC1992	N
			Uterine leiomyoma	01JAN1985	31DEC1985	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Renal and urinary disorders	Bladder spasm	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1966		Y
	C4591001 1072 10721062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1072 10721064	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1072 10721065	Musculoskeletal and connective tissue disorders	Back pain	01NOV2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1072 10721066	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1072 10721067	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Reproductive system and breast disorders	Vulvovaginal pain	01JAN2015		Y
		Social circumstances	Menopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1072 10721068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Gout	01JAN2004		Y
			Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Dizziness	01JAN2016		Y
			Neuropathy peripheral	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1072 10721073	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01FEB2006	31DEC2009	N
		Nervous system disorders	Cerebrovascular accident	01APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
	C4591001 1072 10721075	Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1072 10721076	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1072 10721078	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1072 10721079	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Hypersensitivity	01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Nervous system disorders	Dizziness	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
	C4591001 1072 10721080	Vascular disorders	Hypertension	01JAN2006		Y
		Cardiac disorders	Myocardial infarction	01JAN1997	31DEC1997	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2005	31DEC2005	N
	C4591001 1072 10721081	Vascular disorders	Hypertension	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1997		Y
	C4591001 1072 10721082	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JUL2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Cerebrovascular accident	01SEP2018	30SEP2018	N
			Neuropathy peripheral	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT1994		Y
			Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Corneal transplant	01MAY2019	31MAY2019	N
			Knee arthroplasty	01JUN2012	30JUN2012	N
				01JUN2015	30JUN2015	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01SEP1999		Y
	C4591001 1072 10721088	Surgical and medical procedures	Appendicectomy	11SEP2001	11SEP2001	N
			Vasectomy	01SEP1993	30SEP1993	N
	C4591001 1072 10721092	Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1072 10721095	Investigations	Blood glucose increased	01MAR2020		Y
		Metabolism and nutrition disorders	Gout	01MAY2017		Y
			Hypercholesterolaemia	01MAY2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUL2001		Y
		Surgical and medical procedures	Brain operation	01JUL2001	31JUL2001	N
		Vascular disorders	Aneurysm	01APR2001	31JUL2001	N
			Hypertension	01APR2001		Y
	C4591001 1072 10721096	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
			Prostatomegaly	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1072 10721097	Vascular disorders	Hypertension	01JAN2010		Y
		Cardiac disorders	Ventricular extrasystoles	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1072 10721098	Social circumstances	Postmenopause	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Surgical and medical procedures	Gastric bypass	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1072 10721101	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2010	31DEC2010	N
			Thyroidectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1073 10731001	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2010		Y
		Psychiatric disorders	Insomnia	01FEB2013		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB1996		Y
		Surgical and medical procedures	Hysterectomy	15MAY1999	15MAY1999	N
		Vascular disorders	Hot flush	01FEB2013		Y
			Hypertension	30JAN2010		Y
	C4591001 1073 10731002	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2015	31JAN2016	N
		Ear and labyrinth disorders	Deafness	01JAN1999		Y
		Eye disorders	Cataract	01JUN2017		Y
			Glaucoma	01JAN2002		Y
		Infections and infestations	Appendicitis	01JAN1972	31JAN1972	N
			Diverticulitis	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1972	31JAN1972	N
			Corneal operation	01JAN2016	31JAN2016	N
			Glaucoma surgery	01JAN2016	31JAN2016	N
			Trabeculectomy	01JAN2002	31JAN2002	N
	C4591001 1073 10731003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1949		Y
		Infections and infestations	Appendicitis	01JAN1972		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Hypoaesthesia	01AUG2019		Y
			Paraesthesia	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731004	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
			Milk allergy	01JAN1962		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Epilepsy	01JAN1963		Y
			Neuropathy peripheral	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1073 10731005	Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
	C4591001 1073 10731010	Cardiac disorders	Coronary artery disease	01JAN2004		Y
			Myocardial infarction	15APR2004	15APR2004	N
		Immune system disorders	Drug hypersensitivity	(b) (6) 1942		Y
		Surgical and medical procedures	Coronary arterial stent insertion	15FEB2005	15FEB2005	N
	C4591001 1073 10731011	Eye disorders	Cataract	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	09JAN2020		Y
			Osteoarthritis	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1073 10731014	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
	C4591001 1073 10731015	Investigations	Blood cholesterol increased	01FEB2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2010		Y
		Psychiatric disorders	Depression	01JUN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01SEP2007		Y
		Surgical and medical procedures	Hysterectomy	01SEP2006	01SEP2006	N
	C4591001 1073 10731017	Vascular disorders	Hypertension	01SEP2003		Y
		Gastrointestinal disorders	Constipation	01JAN1958		Y
			Dyspepsia	01JAN1970		Y
		Immune system disorders	Contrast media allergy	01JAN1984		Y
			Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1967		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1073 10731018	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Ear and labyrinth disorders	Deafness	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1073 10731019	Cardiac disorders	Arrhythmia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Kidney infection	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN2020		Y
			Hypertension	01JAN2012		Y
	C4591001 1073 10731023	Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1073 10731024	Congenital, familial and genetic disorders	Arnold-Chiari malformation	(b) (6) 1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	01JAN2018		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01AUG2010	31AUG2010	N
				01DEC2010	31DEC2010	N
			Rotator cuff repair	01DEC2011	31DEC2011	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1073 10731025	Ear and labyrinth disorders	Tinnitus	01OCT2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01APR2004		Y
		Surgical and medical procedures	Caesarean section	13JAN2004	13JAN2004	N
			Rhinoplasty	01FEB1991		Y
		Vascular disorders	Hot flush	01MAY2004		Y
	C4591001 1073 10731026	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Cataract	01APR2009	01APR2009	N
		Immune system disorders	Hypersensitivity	10FEB2005		Y
		Social circumstances	Menopause	01JAN1995		Y
	C4591001 1073 10731030	Ear and labyrinth disorders	Deafness	01SEP2015		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Herpes simplex	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01SEP2015	01SEP2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2019	N
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2020	31DEC2020	N
			Endometrial ablation	01JAN2000	31DEC2000	N
			Uterine dilation and curettage	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1073 10731031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1952		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
			Uterine leiomyoma	01JAN2014		Y
		Social circumstances	Menopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1073 10731033	Infections and infestations	Pertussis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2020		Y
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1073 10731035	Endocrine disorders	Hypothyroidism	01JUN2000		Y
		Infections and infestations	Kidney infection	01JAN1956	31DEC1956	N
			Sinusitis	01JAN1980	31DEC1980	N
			Tonsillitis	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2004	31DEC2004	N
		Psychiatric disorders	Insomnia	01JUL2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1982	31DEC1982	N
			Hysterectomy	10AUG1999	10AUG1999	N
		Vascular disorders	Hot flush	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731037	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Sinusitis	01JAN2000	31DEC2018	N
			Tonsillitis	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01FEB2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Vascular disorders	Hypertension	01FEB2018		Y
	C4591001 1073 10731039	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2007		Y
		Social circumstances	Menopause	01APR2005	30APR2006	N
	C4591001 1073 10731040	Ear and labyrinth disorders	Vertigo	01JAN2007		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Gout	01JAN2011		Y
		Social circumstances	Menopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1073 10731041	Infections and infestations	Diverticulitis	24FEB2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	14JUL1992		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Cough	06OCT2006		Y
		Surgical and medical procedures	Cataract operation	14JUL1999	14JUL1999	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia repair	20APR2020	20APR2020	N
	C4591001 1073 10731042	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Hiatus hernia	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1073 10731043	Cardiac disorders	Coronary artery disease	01DEC2014		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	06OCT2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Coronary arterial stent insertion	24DEC2014	24DEC2014	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN1984	31DEC1984	N
			Rhinoplasty	01JAN1978	31DEC1978	N
	C4591001 1073 10731044	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2018		Y
			Vitamin D deficiency	10FEB2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2016		Y
			Osteopenia	01MAY2016		Y
		Psychiatric disorders	Anxiety	10FEB2020		Y
		Social circumstances	Postmenopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731047	Hepatobiliary disorders	Cholelithiasis	04APR2019	05APR2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2006		Y
		Social circumstances	Menopause	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	10APR2019	10APR2019	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1073 10731049	Hepatobiliary disorders	Cholelithiasis	01FEB1985	20JUL1985	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Cystitis	01NOV2019	20NOV2019	N
			Sinusitis	10OCT1986	10OCT2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2012		Y
			Type 2 diabetes mellitus	01JUL2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	10SEP2003	10SEP2003	N
				24MAY1996	24MAY1996	N
		Psychiatric disorders	Anxiety	01JUN1996		Y
			Depression	01JUN1996		Y
		Skin and subcutaneous tissue disorders	Acne	09SEP1975		Y
		Surgical and medical procedures	Cholecystectomy	01JUL1985	31JUL1985	N
		Vascular disorders	Hypertension	01JUL2012		Y
	C4591001 1073 10731051	Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	04JAN2006		Y
	C4591001 1073	Surgical and medical procedures	Vasectomy	01APR2000	30APR2000	N
	10731052	Endocrine disorders	Hypothyroidism	01MAR2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Injury, poisoning and procedural complications	Humerus fracture	10MAY2010	30JUN2010	N
		Psychiatric disorders	Anxiety	20JUL2012	15AUG2015	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1977	31JAN1986	N
			Rosacea	01JUL2010		Y
	C4591001 1073	Surgical and medical procedures	Joint debridement	01SEP2010	30SEP2010	N
	10731053	Investigations	Heart rate irregular	15JAN2011		Y
		Surgical and medical procedures	Knee arthroplasty	01OCT2010	31OCT2010	N
	C4591001 1073	Endocrine disorders	Hyperthyroidism	01NOV1999		Y
	10731054	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV1999		Y
		Psychiatric disorders	Depression	01JUN2014		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1073	General disorders and administration site conditions	Pain	01JUL2010		Y
	10731055	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1995		Y
	C4591001 1073	Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	10731058					
	C4591001 1073	Gastrointestinal disorders	Constipation	10FEB2019		Y
	10731061					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Pain	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Investigations	Blood cholesterol	01MAR2000		Y
		Psychiatric disorders	Depression	21SEP2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01MAR2000		Y
	C4591001 1073 10731066	Eye disorders	Cataract	01OCT2017		Y
		Hepatobiliary disorders	Cholelithiasis	05OCT2019		Y
		Psychiatric disorders	Bipolar disorder	09MAY2000		Y
	C4591001 1073 10731069	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Social circumstances	Menopause	01JAN2003		Y
		Surgical and medical procedures	Bunion operation	01JAN1989	31DEC1989	N
			Cataract operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Ear operation	01JAN2017	31DEC2017	N
	C4591001 1073 10731071	Investigations	Blood cholesterol increased	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2017	31MAY2019	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
	C4591001 1073 10731072	Eye disorders	Strabismus	01JAN1982	31DEC1982	N
				01JAN1993	31DEC1993	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	18FEB2000		Y
			Vitamin D deficiency	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1992		Y
		Psychiatric disorders	Depression	01JAN1992		Y
			Insomnia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Gastric bypass	01JAN2019	31DEC2019	N
			Hernia repair	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1976	31DEC1976	N
			Mammoplasty	01JAN2004	31DEC2004	N
			Strabismus correction	01JAN1982	31DEC1982	N
				01JAN1993	31DEC1993	N
			Urinary bladder suspension	01JAN2003	31DEC2003	N
		Vascular disorders	Hot flush	01JAN2002		Y
	C4591001 1073 10731073	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1073 10731074	Investigations	Blood cholesterol	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01NOV2013		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2010	31DEC2010	N
			Spinal decompression	01NOV2013	30NOV2013	N
	C4591001 1073 10731075	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Radical prostatectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1073 10731076	Endocrine disorders	Hypothyroidism	01FEB2006		Y
		Eye disorders	Glaucoma	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01APR2009	30APR2009	N
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Knee arthroplasty	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731080	Investigations	Blood cholesterol increased	15JUL2015	15JUL2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	02JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	15JUL2018	20JUL2018	N
		Vascular disorders	Hypertension	15JUL2019	20JUL2019	N
	C4591001 1073 10731082	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1073 10731086	Immune system disorders	Allergy to chemicals	01JAN1943		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Psychiatric disorders	Depression	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1073 10731087	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Cataract	01JUL2019	31JUL2019	N
		Infections and infestations	Herpes simplex	01SEP2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1950		Y
		Social circumstances	Menopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1073 10731088	Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1073 10731090	Endocrine disorders	Hypothyroidism	10MAR2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Surgical and medical procedures	Keratomileusis	01FEB2006	28FEB2006	N
			Knee operation	01JAN1978	31DEC1978	N
		Vascular disorders	Hot flush	01NOV2017		Y
	C4591001 1073 10731092	Infections and infestations	Oral herpes	01JAN1980	31DEC1992	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01FEB2015		Y
		Nervous system disorders	Migraine	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01MAY1990		Y
	C4591001 1073 10731094	Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Glaucoma	01JAN2008		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2019		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAR2018		Y
			Scoliosis	(b) (6) 1951		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Dental implantation	01JAN2012	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
	C4591001 1073 10731095	Immune system disorders	Allergy to animal	01DEC2018		Y
		Infections and infestations	Pulmonary mycosis	01JAN2002	31DEC2002	N
			Sinusitis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Lung lobectomy	01JAN2002	31DEC2002	N
	C4591001 1073 10731096	Ear and labyrinth disorders	Deafness	01NOV2010		Y
		Investigations	Blood cholesterol	01FEB2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
			Vasectomy	01JAN1978		Y
	C4591001 1073 10731097	Infections and infestations	Appendicitis	20APR1999	20APR1999	N
			Herpes simplex	10MAR1995		Y
		Injury, poisoning and procedural complications	Meniscus injury	09AUG2020	09AUG2020	N
		Investigations	Biopsy breast	20JUL2020	20JUL2020	N
		Reproductive system and breast disorders	Breast hyperplasia	20JUL2020		Y
		Social circumstances	Menopause	01JAN1970		Y
		Surgical and medical procedures	Appendicectomy	20APR1999	20APR1999	N
			Endometrial ablation	01JAN2005	31DEC2005	N
			Meniscus operation	09AUG2020	09AUG2020	N
	C4591001 1073 10731098	Cardiac disorders	Atrial fibrillation	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	14JUL2009		Y
			Glaucoma	15FEB2015		Y
		Gastrointestinal disorders	Dyspepsia	24FEB2020		Y
		Infections and infestations	Diverticulitis	24FEB2020		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	14JUL1992		Y
		Reproductive system and breast disorders	Prostatomegaly	24FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Cough	06OCT2006		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1073 10731100	Gastrointestinal disorders	Dyspepsia	15JUN2017		Y
			Gastroesophageal reflux disease	30JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2005		Y
		Investigations	Blood cholesterol increased	01FEB2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	20JUN2018		Y
		Surgical and medical procedures	Female sterilisation	01JUN1985		Y
			Hip arthroplasty	01FEB2017	28FEB2017	N
		Vascular disorders	Hypertension	15JUN2017		Y
	C4591001 1073 10731105	Gastrointestinal disorders	Dyspepsia	01NOV2014		Y
			Gastroesophageal reflux disease	01NOV2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2014		Y
		Surgical and medical procedures	Vasectomy	01SEP2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731107	Cardiac disorders	Angina pectoris	01JAN2000		Y
			Atrial fibrillation	01JAN1950		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
			Squamous cell carcinoma	01FEB2020	29FEB2020	N
				01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1949		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
			Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
				01JAN2020	31DEC2020	N
			Cardiac pacemaker insertion	01OCT2015	31OCT2015	N
			Hernia repair	01JAN1995	31DEC1995	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Uterine leiomyoma	01NOV2001		Y
	C4591001 1073 10731108	Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
		Surgical and medical procedures	Hysterectomy	01NOV2001		Y
			Oophorectomy bilateral	01NOV2001		Y
	C4591001 1073 10731111	Ear and labyrinth disorders	Vertigo	01APR2017	01OCT2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hyperthyroidism	01SEP2019	30SEP2019	N
		Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN1985		Y
			Hiatus hernia	01JAN2015		Y
			Irritable bowel syndrome	01JAN1981		Y
		Immune system disorders	Drug hypersensitivity	11JUN1962		Y
		Infections and infestations	Sinusitis	15DEC2019	15MAR2020	N
		Investigations	Arthroscopy	01JAN1994	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Floating patella	01JAN2004	31DEC2004	N
			Muscle spasms	01JAN2018	31DEC2019	N
			Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN2020		Y
			Rotator cuff syndrome	01JAN1994	31DEC1994	N
				01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1981	01JAN1981	N
			Malignant melanoma	21JAN2020	21JAN2020	N
			Squamous cell carcinoma	01APR2015	01APR2015	N
		Nervous system disorders	Nerve compression	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JUN2020	31JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981	31DEC1998	N
			Bronchitis chronic	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Rash	01JUN2017	01DEC2019	N
		Surgical and medical procedures	Cancer surgery	01APR2015	01APR2015	N
			Knee operation	01JAN2004	31DEC2004	N
			Peripheral nerve operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN2018	31DEC2018	N
			Skin neoplasm excision	01JAN1981	01JAN1981	N
				21JAN2020	31DEC2020	N
			Thyroidectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1073 10731115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Hiatus hernia	01JAN2017		Y
			Umbilical hernia	01JAN2018	31DEC2018	N
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	06APR2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1956	31DEC1956	N
			Umbilical hernia repair	01JAN2018		Y
	C4591001 1073 10731118	Endocrine disorders	Hypothyroidism	01NOV2008		Y
		Eye disorders	Cataract	01MAR2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15MAR2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
			Transient ischaemic attack	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	30NOV2008	30NOV2008	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1073 10731121	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Renal and urinary disorders	Pollakiuria	01JAN2018		Y
		Social circumstances	Menopause	01JAN2004	31DEC2004	N
	C4591001 1073 10731122	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
		Nervous system disorders	Essential tremor	01JAN1990		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1073 10731123	Ear and labyrinth disorders	Deafness	01SEP2019		Y
		Infections and infestations	Urinary tract infection	01JUL2020	06JUL2020	N
		Injury, poisoning and procedural complications	Multiple fractures	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01SEP2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	05JAN2007	15MAY2007	N
		Nervous system disorders	Headache	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	28FEB2017		Y
		Surgical and medical procedures	Breast conserving surgery	15MAY2017	15MAY2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1073 10731124	Eye disorders	Cataract	01MAR2010		Y
	C4591001 1073 10731125	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2002		Y
	C4591001 1073 10731127	Reproductive system and breast disorders	Prostatomegaly	05FEB2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1073 10731128	Nervous system disorders	Seizure	01JAN1985		Y
		Surgical and medical procedures	Brain tumour operation	01JAN1990	31DEC1990	N
			Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1073 10731129	General disorders and administration site conditions	Pain	15MAR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2005		Y
		Nervous system disorders	Neuropathy peripheral	01OCT2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUN2010		Y
		Vascular disorders	Hypertension	01NOV2005		Y
	C4591001 1073 10731130	Surgical and medical procedures	Appendicectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	15APR2011		Y
	C4591001 1077 10771005	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
	C4591001 1077 10771006	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771011	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
	C4591001 1077 10771012	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Investigations	Prostatic specific antigen increased	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
	C4591001 1077 10771016	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN1980		Y
			Reaction to preservatives	01JAN1980		Y
		Investigations	Arthroscopy	01JAN1960	31DEC1974	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1960		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1997		Y
			Insomnia	01APR2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Urinary control neurostimulator implantation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1077 10771017	Endocrine disorders	Hyperthyroidism	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN1962		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1987	31DEC1987	N
			Thyroidectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771021	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Allergy to animal	01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
	C4591001 1077 10771022	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1077 10771024	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	10AUG2020		Y
	C4591001 1077 10771025	Endocrine disorders	Hypothyroidism	01DEC2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2011		Y
			Type 2 diabetes mellitus	01AUG2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cutaneous T-cell lymphoma	01JUN2014		Y
		Vascular disorders	Hypertension	01JUL2016		Y
	C4591001 1077 10771026	Blood and lymphatic system disorders	Pernicious anaemia	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Dry eye	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Adverse drug reaction	01JAN1978		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1992		Y
				01JAN2016		Y
			Hypersensitivity	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1077 10771033	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1077 10771034	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
	C4591001 1077 10771039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
	C4591001 1077 10771040	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Investigations	Cardiac murmur	01JAN1958		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1077 10771043	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Joint range of motion decreased	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771046	Cardiac disorders	Mitral valve prolapse	01JAN1994		Y
		Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1077 10771047	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Nervous system disorders	Facial neuralgia	01JAN2018		Y
			Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1077 10771048	Immune system disorders	Allergy to arthropod sting	01JAN2018		Y
			Drug hypersensitivity	01JAN1977		Y
	C4591001 1077 10771049	Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
			Chronic sinusitis	01JAN1960	31DEC1960	N
		Nervous system disorders	Facial paralysis	01JAN2013	31DEC2013	N
			Transient ischaemic attack	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1077 10771050	Vascular disorders	Hypertension	01JAN2005		Y
		Cardiac disorders	Atrial fibrillation	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1951		Y
				01JAN1958		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Pulmonary fibrosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1077 10771051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1077 10771052	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
	C4591001 1077 10771053	Immune system disorders	Allergy to arthropod sting	01JAN1960		Y
			Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771055	Investigations	Intraocular pressure increased	01JAN2017		Y
	C4591001 1077 10771056	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1077 10771057	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Immune system disorders	Allergy to animal	01JAN1970		Y
			Seasonal allergy	01JAN1964		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
	C4591001 1077 10771059	Immune system disorders	Drug hypersensitivity	01JAN1957		Y
				01JAN2000		Y
				01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1077 10771060	Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1077 10771062	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1077 10771063	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
	C4591001 1077 10771064	Gastrointestinal disorders	Colitis	01JAN2010	31OCT2016	N
		Immune system disorders	Rubber sensitivity	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1077 10771065	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
			Hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Transient ischaemic attack	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1077 10771072	Hepatobiliary disorders	Cholelithiasis	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1077 10771075	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1077 10771078	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1985		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
			Seasonal allergy	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Depression	01JAN1988		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
	C4591001 1077 10771081	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Thyroidectomy	01JAN2013	31DEC2013	N
	C4591001 1077 10771088	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
	C4591001 1077 10771090	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1077 10771091	Infections and infestations	Hepatitis C	01JAN1990	31DEC2016	N
		Investigations	Biopsy bone	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01MAR1997	31DEC1997	N
		Psychiatric disorders	Drug dependence	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771092	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2000	31DEC2000	N
		Nervous system disorders	Tremor	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01JAN1995	31DEC1995	N
			Prostatectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1077 10771093	Hepatobiliary disorders	Cholecystitis	01JAN1963	31DEC1963	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal stenosis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Cataract operation	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN1963	31DEC1963	N
			Intervertebral disc operation	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1077 10771094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Noninfective gingivitis	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
	C4591001 1077 10771095	Eye disorders	Glaucoma	01APR2019		Y
		Immune system disorders	Hypersensitivity	01JAN1960		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
	C4591001 1077 10771098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01OCT2017	31OCT2017	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1077 10771099	Immune system disorders	Hypersensitivity	01JAN1949		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1972		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1949		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1077 10771102	Immune system disorders	Rubber sensitivity	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
	C4591001 1077 10771104	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1077 10771105	Endocrine disorders	Hypothyroidism	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Nervous system disorders	Migraine	01JAN1969		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JUN1995	30JUN1995	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1077 10771106	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Dry eye	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2011	31DEC2011	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1077 10771107	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Transient ischaemic attack	01MAR2019	31MAR2019	N
		Psychiatric disorders	Anxiety	01MAR2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1077 10771109	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Sinus operation	01JAN1995	31DEC1995	N
	C4591001 1077 10771110	Infections and infestations	Poliomyelitis	01JAN1956	31DEC1957	N
		Nervous system disorders	Hyporeflexia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
	C4591001 1077 10771111	Immune system disorders	Hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Rotator cuff syndrome	01JAN2008	24JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
			Rotator cuff repair	24JAN2020	24JAN2020	N
	C4591001 1077 10771112	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771113	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1077 10771115	General disorders and administration site conditions	Adverse drug reaction	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771116	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2005	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2005	31DEC2005	N
	C4591001 1077 10771119	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
	C4591001 1077 10771121	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2000		Y
		Immune system disorders	Seasonal allergy	29JAN2020		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN2008		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2000		Y
			Hypokalaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31OCT2008	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Pulmonary mass	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	29JAN2020	29JAN2020	N
			Mastectomy	01AUG2008	01AUG2008	N
	C4591001 1077 10771127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1077 10771130	Gastrointestinal disorders	Constipation	01JAN2010		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1077 10771141	Immune system disorders	Drug hypersensitivity	01JAN1952		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
	C4591001 1077 10771143	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN1997	31DEC1997	N
		Reproductive system and breast disorders	Endometriosis	01JAN1999	31DEC1999	N
	C4591001 1077 10771144	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2010	N
		Surgical and medical procedures	Spinal operation	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1077 10771145	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1077 10771146	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1077 10771147	Immune system disorders	Seasonal allergy	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	30JUN2020		Y
		Surgical and medical procedures	Hysterectomy	28DEC2012	28DEC2012	N
	C4591001 1077 10771148	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
	C4591001 1077 10771149	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1077 10771151	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Brain tumour operation	01JAN2015	31DEC2015	N
	C4591001 1077 10771154	General disorders and administration site conditions	Adverse drug reaction	01JAN2000		Y
	C4591001 1077 10771155	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Thoracic vertebral fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2013	31DEC2013	N
	C4591001 1077 10771160	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Cancer surgery	01JAN2009	31DEC2009	N
			Endometrial ablation	01JAN2010	31DEC2010	N
	C4591001 1077 10771161	Eye disorders	Strabismus	01JAN1959		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1077 10771162	Congenital, familial and genetic disorders	Hereditary haemochromatosis	01MAY2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2016		Y
			Rhinitis allergic	01DEC2008		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1077 10771163	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1995		Y
			Seasonal allergy	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hot flush	01JAN2017		Y
			Hypertension	01JUN2009		Y
	C4591001 1077 10771164	Gastrointestinal disorders	Constipation	01JAN2010		Y
			Diverticulum	01JAN2015		Y
			Haemorrhoids	01JAN2000		Y
			Irritable bowel syndrome	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15JUN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2000		Y
			Meningioma	01JAN2012		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN1986		Y
			Depression	01JAN1986		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2017	31DEC2017	N
	C4591001 1077 10771167	Infections and infestations	Clostridium difficile infection	06MAY2020	06JUN2020	N
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1077 10771168	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Investigations	Gene mutation identification test positive	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2007		Y
		Surgical and medical procedures	Gastric bypass	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1077 10771170	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1077 10771172	Gastrointestinal disorders	Gastric ulcer	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1077 10771173	Cardiac disorders	Angina pectoris	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2007		Y
		Surgical and medical procedures	Sigmoidectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1077 10771175	Gastrointestinal disorders	Umbilical hernia	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1077 10771176	Vascular disorders	Hypertension	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
	C4591001 1077 10771177	Social circumstances	Postmenopause	01JAN2011		Y
		Immune system disorders	Allergy to arthropod bite	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1077 10771179	Vascular disorders	Lymphoedema	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Contrast media allergy	01JAN2010		Y
			Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2017		Y
	C4591001 1077 10771180	Psychiatric disorders	Post-traumatic stress disorder	01JAN2019		Y
		Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1077 10771182	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1077 10771185	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1077 10771187	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1077 10771191	Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1077 10771194	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771195	Cardiac disorders	Supraventricular tachycardia	01JAN2015		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1077 10771196	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Prostatectomy	01JAN2017	31DEC2017	N
	C4591001 1077 10771197	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1077 10771199	Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1077 10771205	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2016	N
		Nervous system disorders	Generalised tonic-clonic seizure	01JAN2015		Y
			Tremor	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Chemotherapy	01JAN2015	31DEC2016	N
	C4591001 1077 10771206	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal cancer	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Chemotherapy	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1077 10771208	Congenital, familial and genetic disorders	Factor XII deficiency	(b) (6) 1955		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1077 10771210	Eye disorders	Corneal scar	01JAN2010	31DEC2014	N
		General disorders and administration site conditions	Adverse food reaction	01JAN1959		Y
		Immune system disorders	Hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Surgical and medical procedures	Corneal transplant	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1077 10771211	Cardiac disorders	Mitral valve prolapse	01JAN1988		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Pancreatic cyst	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	15APR2020	15APR2020	N
		Surgical and medical procedures	Knee operation	01JAN2016	31DEC2016	N
			Skin neoplasm excision	15APR2020	15APR2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1077 10771215	Immune system disorders	Drug hypersensitivity	01JUN2020		Y
		Injury, poisoning and procedural complications	Limb injury	14JUL2020	09SEP2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Deep vein thrombosis	01JAN2012	31DEC2012	N
			Hypertension	01JAN2017		Y
	C4591001 1077 10771216	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771217	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771219	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1077 10771220	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1077 10771223	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Renal and urinary disorders	Nephropathy	01JAN2015		Y
		Vascular disorders	Peripheral arterial occlusive disease	01JAN2008		Y
	C4591001 1077 10771226	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2016		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1965		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771227	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Transurethral prostatectomy	01DEC2019	31DEC2019	N
			Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1077 10771228	Cardiac disorders	Palpitations	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Electrocardiogram QT prolonged	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1077 10771229	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
			Myocardial infarction	01DEC2019	31DEC2019	N
				01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2001	31DEC2001	N
			Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Cardioversion	01DEC2019	31DEC2019	N
				01JAN2015	31DEC2015	N
			Coronary artery bypass	01DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc operation	01JAN2001	31DEC2001	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1077 10771231	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
				01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
	C4591001 1077 10771232	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1077 10771233	Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
	C4591001 1077 10771241	Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1077 10771249	Investigations	Arthroscopy	01DEC2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01SEP2015	31AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Prostatectomy	01DEC2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1077 10771251	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1077 10771255	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Hepatitis A	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1077 10771256	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Eye disorders	Cataract	01JAN2014	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1077 10771257	Injury, poisoning and procedural complications	Pelvic fracture	01JAN1968	31DEC1968	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1077 10771259	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1077 10771263	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2019		Y
	C4591001 1077 10771264	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
				01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31DEC2009	N
			Hysterectomy	20MAR2020	20MAR2020	N
	C4591001 1077 10771265	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Iodine allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1077 10771266	Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1077 10771267	Immune system disorders	Food allergy	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoporosis	01JAN2018		Y
			Plantar fasciitis	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1077 10771270	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1077 10771271	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
		Surgical and medical procedures	Hernia repair	01JAN1992	31DEC1992	N
			Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1079 10791001	Cardiac disorders	Sinus arrhythmia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1079 10791006	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Tremor	01JAN2015		Y
	Depression		01JAN2005		Y	
	Insomnia		01JAN2005		Y	
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791009	Eye disorders	Hypermetropia	01JAN1960		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
	C4591001 1079 10791011	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1079 10791012	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Type 2 diabetes mellitus	01JAN2000		Y
			Hypertension	01JAN2016		Y
	C4591001 1079 10791014	Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
	C4591001 1079 10791015	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		General disorders and administration site conditions	Oedema	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01OCT2018	31OCT2019	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1079 10791016	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2005		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1988		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1079 10791019	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1079 10791020	Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2008		Y
	C4591001 1079 10791023	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1079 10791024	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Hiatus hernia	01JAN2013		Y
		Infections and infestations	Upper respiratory tract infection	17APR2019	24APR2019	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2006		Y
		Investigations	Endoscopy	01OCT2019	31OCT2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1999		Y
		Nervous system disorders	Complex regional pain syndrome	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
			Depression	01JAN2004		Y
	C4591001 1079 10791025	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1079 10791026	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1974	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1079 10791027	Infections and infestations	Herpes zoster	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2016		Y
		Nervous system disorders	Cerebrovascular accident	01DEC2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1079 10791028	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Adenoiditis	01JAN1962	31DEC1962	N
			Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Tibia fracture	27SEP1968	27SEP1968	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
			Phlebitis	01JAN1968	31DEC1987	N
	C4591001 1079 10791029	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1079 10791030	Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
			Tonsillitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1079 10791031	Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Spinal operation	01JAN2016	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1079 10791032	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791033	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
	C4591001 1079 10791034	Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1982	31DEC1982	N
	C4591001 1079 10791035	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
			Tonsillitis	01JAN1960	31DEC1960	N
	C4591001 1079 10791036	Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791038	Eye disorders	Hypermetropia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791041	Cardiac disorders	Myocardial infarction	01JUN2001	30JUN2001	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
	C4591001 1079 10791042	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1996		Y
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1079 10791043	Gastrointestinal disorders	Gastroesophageal reflux disease	03AUG2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1079 10791044	Gastrointestinal disorders	Haemorrhoids	18JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Skin hyperpigmentation	01JAN1980		Y
		Social circumstances	Menopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791045	Gastrointestinal disorders	Dyspepsia	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2019		Y
			Myalgia	01OCT2019		Y
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN2015		Y
	C4591001 1079 10791049	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Genital herpes	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1988		Y
		Nervous system disorders	Sciatica	01JAN1979		Y
		Psychiatric disorders	Depression	01JAN1975		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1079 10791051	Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y
			Non-alcoholic steatohepatitis	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of the tongue	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791052	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1079 10791055	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Nervous system disorders	Migraine	01JAN1976	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1079 10791056	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Renal and urinary disorders	Lower urinary tract symptoms	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791057	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1079 10791065	Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2020		Y
			Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Mood swings	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791067	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Gout	01JAN1990		Y
			Hyperlipidaemia	01JAN1990		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1079 10791068	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1079 10791070	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1079 10791071	Cardiac disorders	Supraventricular tachycardia	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791074	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791076	Eye disorders	Blindness unilateral	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hot flush	01JUL2020		Y
			Hypertension	01JAN2015		Y
	C4591001 1079 10791078	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Sciatica	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1079 10791080	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
			Osteopenia	01JAN1995		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Female sterilisation	01JAN1974	31DEC1974	N
	C4591001 1079 10791081	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
	C4591001 1079 10791083	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1079 10791085	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2008	N
		Nervous system disorders	Headache	01JAN1980		Y
			Hydrocephalus	01JAN2000		Y
			Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1980		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1079 10791092	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1079 10791093	Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1079 10791094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
			Prostatomegaly	01JAN2016		Y
		Vascular disorders	Hypertension	11AUG2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791101	Blood and lymphatic system disorders	Anaemia	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791103	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Arthritis		01JAN2010		Y
	C4591001 1079 10791104	Psychiatric disorders	Insomnia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1079 10791105	Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Deep vein thrombosis	01JAN2018		Y
	C4591001 1079 10791108	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1079 10791111	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Pancreatic failure	01FEB2020		Y
			Vomiting	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Restless legs syndrome	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1079 10791119	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1079 10791121	Endocrine disorders	Hypothyroidism	01JAN1969		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1079 10791122	Renal and urinary disorders	Urinary retention	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1079 10791123	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1079 10791128	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1079 10791131	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791132	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1079 10791136	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1978		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Infections and infestations	Escherichia infection	01JAN2012	31DEC2012	N
			Staphylococcal infection	01JAN2012	31DEC2012	N
	C4591001 1079 10791138	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
	C4591001 1079 10791139	Cardiac disorders	Myocardial infarction	01DEC2000	31DEC2000	N
				01MAY1998	31MAY1998	N
				01SEP1999	30SEP1999	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN2004		Y
		Gastrointestinal disorders	Dry mouth	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Nervous system disorders	Narcolepsy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neuropathy peripheral	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN1958		Y
			Depression	01JAN1958		Y
			Rapid eye movements sleep abnormal	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1079 10791140	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1079 10791141	Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN1995		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1079 10791145	Infections and infestations	Herpes virus infection	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1079 10791148	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1079 10791149	Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1079 10791150	Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
	C4591001 1079 10791151	Eye disorders	Macular degeneration	01JAN1970		Y
	C4591001 1079 10791152	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1079 10791155	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1079 10791156	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1079 10791158	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791159	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2014	N
		Nervous system disorders	Migraine	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1079 10791160	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1992	31DEC1992	N
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
				01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1079 10791161	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1079 10791163	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1079 10791165	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1079 10791167	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1079 10791168	Surgical and medical procedures	Hydrocele operation	01JAN2018	31DEC2018	N
	C4591001 1079 10791168	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1079 10791180	Investigations	Heart rate irregular	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2015	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791185	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Food allergy	01JAN1999		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN1999		Y
			Hypercholesterolaemia	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1079 10791189	Surgical and medical procedures	Skin neoplasm excision	01JUL2020	31JUL2020	N
	C4591001 1079 10791190	Endocrine disorders	Hypothyroidism	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1079 10791191	Infections and infestations	Vestibular neuronitis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Prostatic operation	01JAN2018	31DEC2018	N
	C4591001 1079 10791193	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN1992	31DEC1992	N
	C4591001 1079 10791194	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN1978		Y
		Surgical and medical procedures	Female sterilisation	01JAN1976	31DEC1976	N
			Meniscus operation	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2019	31DEC2019	N
			Wrist surgery	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1079 10791196	Infections and infestations	Diverticulitis	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	01JAN2009	31DEC2009	N
			Colectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1079 10791198	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma of liver	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hepatectomy	01JAN2000	31DEC2000	N
			Knee operation	01JAN2014	31DEC2014	N
	C4591001 1079 10791200	Cardiac disorders	Angina pectoris	01JAN2015		Y
			Cardiac failure congestive	01JAN2010		Y
			Myocardial infarction	01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 1 diabetes mellitus	01JAN1995		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Renal and urinary disorders	Nephropathy	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2005	31DEC2005	N
				01JAN2011	31DEC2011	N
				01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1079 10791201	Psychiatric disorders	Anxiety	01DEC2019		Y
		Social circumstances	Postmenopause	28AUG1998		Y
	C4591001 1079 10791204	Blood and lymphatic system disorders	Anaemia	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Obesity	01JAN2013		Y
		Nervous system disorders	Sciatica	01FEB2020		Y
		Psychiatric disorders	Anxiety	01AUG2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1079 10791207	Metabolism and nutrition disorders	Hypokalaemia	01JAN2009		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Gastric bypass	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Parathyroidectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791208	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1079 10791209	Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Ankle operation	01JAN2003	31DEC2003	N
	C4591001 1079 10791210	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2002		Y
	C4591001 1079 10791212	Cardiac disorders	Myocardial infarction	01JAN2008	31DEC2009	N
		Eye disorders	Cataract	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2010		Y
				01JAN2011		Y
		Infections and infestations	Herpes virus infection	01SEP2019		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Coronary arterial stent insertion	01JAN2008	31DEC2008	N
			Thymectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Raynaud's phenomenon	01JAN1992		Y
	C4591001 1079 10791213	Eye disorders	Glaucoma	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	26AUG2020		Y
		Nervous system disorders	Generalised tonic-clonic seizure	01JAN1978	31DEC1978	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1979	31DEC2020	N
		Surgical and medical procedures	Renal stone removal	01JAN1981	31DEC1981	N
				01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
	C4591001 1079 10791214	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1079 10791215	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1079 10791216	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Investigations	Biopsy breast normal	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2005	31DEC2005	N
	C4591001 1079 10791217	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1079 10791218	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Surgical and medical procedures	Chondroplasty	01JAN2005	31DEC2005	N
	C4591001 1079 10791219	Eye disorders	Glaucoma	01JAN2018		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Dry mouth	01JAN2005		Y
			Gastrooesophageal reflux disease	01JAN2005		Y
			Oesophageal spasm	01JAN2005		Y
			Oral lichen planus	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1952		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Parkinson's disease	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Erythema	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Arthrodesis	01JAN2019	31DEC2019	N
			Cataract operation	01JAN2015	31DEC2015	N
			Haemorrhoid operation	01JAN1982		Y
			Shoulder operation	01JAN2008	31DEC2008	N
			Tendon sheath incision	01JAN2019	31DEC2019	N
	C4591001 1079 10791220	Congenital, familial and genetic disorders	Duodenal atresia	01JAN1954		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Intestinal obstruction	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1972	31DEC1972	N
			Cataract operation	01JAN2006	31DEC2006	N
			Intestinal resection	01JAN2015	31DEC2015	N
	C4591001 1079 10791221	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Pneumonia	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1079 10791222	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Investigations	Arthroscopy	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1079 10791223	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Herpes virus infection	01JAN2018		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2018	31DEC2018	N
			Hip fracture	01JAN2018	31DEC2018	N
			Nerve injury	01JAN2017	31DEC2017	N
			Procedural pain	01JAN2018		Y
			Road traffic accident	01JAN2018	31DEC2018	N
			Spinal fracture	01JAN2018	31DEC2018	N
		Nervous system disorders	Tension headache	01JAN1985		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Bone operation	01JAN2018	31DEC2018	N
			Fracture treatment	01JAN2018	31DEC2018	N
			Neck surgery	01JAN2017	31DEC2017	N
	C4591001 1079 10791225	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791226	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2001		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Inguinal hernia repair	01JAN1959	31DEC1959	N
				01JAN2006	31DEC2006	N
	C4591001 1079 10791227	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Dry eye	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
			Osteoporosis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1079 10791228	Eye disorders	Ocular discomfort	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Blood testosterone decreased	01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1964	31DEC1964	N
			Hernia repair	01JAN1970	31DEC1970	N
				01JAN1978	31DEC1978	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Deep vein thrombosis	01JAN2010		Y
			Hypertension	01JAN2000		Y
	C4591001 1079 10791229	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
				01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Hernia repair	01JAN1994	31DEC1994	N
			Spinal operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1079 10791231	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
			Limb operation	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791233	Surgical and medical procedures	Prostatectomy	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1079 10791234	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1079 10791236	Immune system disorders	Allergy to plants	01JAN2010		Y
			Contrast media allergy	01JAN1999		Y
			Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood testosterone decreased	01DEC2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004		Y
		Surgical and medical procedures	Colectomy	01JAN1994	31DEC1994	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2001		Y
			Spinal operation	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
				17AUG2020	17AUG2020	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1079 10791237	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN1990		Y
				01JAN1995		Y
			Seasonal allergy	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Paraovarian cystectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	01JAN1998		Y
	C4591001 1079 10791240	Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1079 10791242	Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1079 10791243	Endocrine disorders	Hypothyroidism	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1969	31DEC1969	N
	C4591001 1079 10791246	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1079 10791247	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791248	General disorders and administration site conditions	Hernia	01JAN1992		Y
				01JAN1995		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2005		Y
			Ligament rupture	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Nervous system disorders	Tonic convulsion	01JAN1990	31DEC1992	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Elbow operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791254	Injury, poisoning and procedural complications	Tendon rupture	01JAN1990	31DEC1990	N
		Nervous system disorders	Facial paralysis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Tenoplasty	01JAN1990	31DEC1990	N
			Transurethral prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791255	Surgical and medical procedures	Knee operation	01JAN2002	31DEC2002	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1079 10791258	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Investigations	Intraocular pressure increased	01JAN2004		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1079 10791259	Eye disorders	Macular oedema	01JAN2019		Y
			Retinal vein occlusion	01OCT2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1980	31DEC1980	N
				01JAN1994	31DEC1994	N
	C4591001 1079 10791260	Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791261	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
	C4591001 1079 10791264	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791266	Blood and lymphatic system disorders	Thrombocytosis	01JAN2017	31DEC2017	N
		Endocrine disorders	Hypogonadism	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1079 10791268	General disorders and administration site conditions	Pain	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
	C4591001 1079 10791270	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1981	31DEC1981	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791271	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Bunion operation	01JAN1997		Y
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Oophorectomy bilateral	01JAN2014	31DEC2014	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2016	31DEC2016	N
	C4591001 1079 10791273	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791274	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
				01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
			Restless legs syndrome	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1079 10791276	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2009	31DEC2009	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Shoulder arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791278	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Exeresis	01JAN2018	31DEC2018	N
	C4591001 1079 10791279	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	01DEC2019	01MAR2020	N
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1079 10791280	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Metabolism and nutrition disorders	Obesity	15SEP2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Endometrial ablation	01JAN2007	31DEC2007	N
			Female sterilisation	18JAN2000	18JAN2020	N
			Knee operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01FEB2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791282	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Arthropod bite	12SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Renal and urinary disorders	Renal mass	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
			Nephrectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1079 10791283	Cardiac disorders	Palpitations	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Contrast media allergy	01JAN2005		Y
			Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Gastrectomy	01JAN2006	31DEC2006	N
	C4591001 1079 10791284	Endocrine disorders	Thyroid mass	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
		Social circumstances	Organ donor	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2002	31DEC2002	N
	C4591001 1079 10791285	General disorders and administration site conditions	Hernia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Renal and urinary disorders	Micturition urgency	01JAN2000		Y
		Surgical and medical procedures	Urinary bladder suspension	01AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1079 10791286	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1956	31DEC1956	N
			Wrist surgery	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1079 10791287	Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
	C4591001 1079 10791299	Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791301	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2006	31DEC2006	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Intraocular lens implant	01JAN2006	31DEC2006	N
			Lower oesophageal sphincter magnetic augmentation	01JAN2017		Y
			Prostatic operation	01JAN2016	31DEC2016	N
	C4591001 1079 10791302	Nervous system disorders	Parkinson's disease	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Deep brain stimulation	01JAN2018	31DEC2018	N
	C4591001 1079 10791306	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Spinal operation	01JAN2010	31DEC2010	N
	C4591001 1079 10791307	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
	C4591001 1079 10791308	Eye disorders	Dry eye	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1079 10791309	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2007	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2013	31DEC2013	N
	C4591001 1079 10791310	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1079 10791312	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01AUG2020		Y
				01JAN1985		Y
				01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1079 10791314	Immune system disorders	Drug hypersensitivity	01JAN1952		Y
	C4591001 1080 10801005	Cardiac disorders	Angina pectoris	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01FEB2019	28FEB2019	N
		Investigations	Biopsy breast normal	01JAN2019	31JAN2019	N
			Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Meniscus operation	01FEB2019	28FEB2019	N
	C4591001 1080 10801006	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Panic attack	01JAN2014		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801007	Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801008	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1960		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Epiglottic oedema	01DEC1951	31DEC1951	N
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2010		Y
			Rash	01JAN2010		Y
	C4591001 1080 10801011	Cardiac disorders	Atrial fibrillation	01JAN1993		Y
		Nervous system disorders	Restless legs syndrome	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2017		Y
			Thrombosis	01JAN2016	31DEC2016	N
	C4591001 1080 10801012	Gastrointestinal disorders	Pancreatic cyst	01JAN2010		Y
		Immune system disorders	Perennial allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N
		Nervous system disorders	Tension headache	01JAN2000		Y
	C4591001 1080 10801013	Eye disorders	Dry eye	01JAN2019		Y
		Gastrointestinal disorders	Abdominal discomfort	01JAN2012		Y
			Inguinal hernia	01JUL2006		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
			Osteoarthritis	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Mechanical urticaria	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31JAN2011	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1080 10801014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2009		Y
			Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Rib fracture	19DEC2018		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1080 10801016	Vascular disorders	Hypertension	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
	C4591001 1080 10801020	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Impaired gastric emptying	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1967	31DEC2004	N
		Psychiatric disorders	Depression	01JAN1991		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
			Nephrolithiasis	01JAN2005		Y
		Reproductive system and breast disorders	Ovarian failure	01FEB1991	28FEB1991	N
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Cholecystectomy	01MAR2008	31MAR2008	N
			Gastric bypass	01FEB2004	29FEB2004	N
			Hysterectomy	01FEB1991	28FEB1991	N
			Intestinal operation	01NOV2006	30NOV2006	N
			Wrist surgery	01JUN2019	30JUN2019	N
	C4591001 1080 10801021	Eye disorders	Glaucoma	01JAN2007		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801024	Blood and lymphatic system disorders	Anaemia	01JAN1986		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hair follicle tumour benign	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1080 10801025	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1984	31DEC2004	N
		Renal and urinary disorders	Proteinuria	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1080 10801028	Endocrine disorders	Hyperthyroidism	01JAN1995		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2016	31DEC2019	N
			Abdominal pain	01JAN1981		Y
			Gastroesophageal reflux disease	01JUN2020		Y
			Inguinal hernia	01JAN1949	31DEC2002	N
			Pancreatic failure	01JAN2001		Y
			Pancreatic mass	01NOV1981	30NOV1981	N
		Hepatobiliary disorders	Portal vein thrombosis	01JUN2020		Y
		Infections and infestations	Tonsillitis	01JAN1949	31DEC1949	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2001		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Bladder outlet obstruction	01JAN1993		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
			Nasal septum deviation	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1949	31DEC1949	N
			Explorative laparotomy	01NOV1981	30NOV1981	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1080 10801029	Eye disorders	Glaucoma	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2003		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801030	Infections and infestations	Urinary tract infection	22JUL2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1080 10801034	Ear and labyrinth disorders	Tinnitus	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801035	Vascular disorders	Hypertension	01JAN2017	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
	C4591001 1080 10801037	Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Eye disorders	Cataract	01SEP2019	30SEP2019	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Eczema vaccinatum	01JAN1961	31DEC1961	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2009	31DEC2009	N
			Muscle strain	01NOV2019		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Cardiac murmur	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Intervertebral disc protrusion	01NOV2000	30NOV2000	N	
		Muscle spasms	01JAN2010		Y	
	Skin and subcutaneous tissue disorders	Eczema	01JAN1955	31DEC1985	N	
	Surgical and medical procedures	Caesarean section	01JAN1976	31DEC1976	N	
			01JAN1981	31DEC1981	N	
			01JAN1982	31DEC1982	N	
			01JAN1984	31DEC1984	N	
		Cataract operation	01SEP2019	30SEP2019	N	
		Hysterosalpingo-oophorectomy	01JAN2004	31DEC2004	N	
		Incisional hernia repair	01JAN2009	31DEC2009	N	
		Spinal fusion surgery	01NOV2000	30NOV2000	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1080 10801038	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Tenosynovitis stenosans	01MAR2020		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1080 10801039	Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1080 10801044	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
				01JAN2003		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980	31DEC1980	N
			Neuralgia	01JAN1992	31DEC1992	N
		Psychiatric disorders	Bipolar disorder	01JAN1969		Y
			Depression	01JAN1969		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1958		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1983	31DEC1983	N
			Fracture treatment	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Peripheral nerve transposition	01JAN1992	31DEC1992	N
			Simple mastectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1080 10801046	Endocrine disorders	Thyroid mass	01JUN2013	08JUL2013	N
		Eye disorders	Cataract	01APR2015	29JUL2015	N
		Gastrointestinal disorders	Nausea	01JAN2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
				01JAN2016		Y
			Reaction to colouring	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	24JAN2013	N
		Investigations	Arthroscopy	24JAN2013	24JAN2013	N
			Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Appendix cancer	01APR2016	21JUL2016	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1999	01DEC1999	N
		Reproductive system and breast disorders	Endometriosis	01JAN1987	31MAY1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	13APR2016	13APR2016	N
			Cataract operation	05JUN2015	05JUN2015	N
				29JUN2015	29JUN2015	N
			Hyperthermic chemotherapy	21JUL2016	21JUL2016	N
			Hysterectomy	01MAY1990	31MAY1990	N
			Metabolic surgery	14AUG2017	14AUG2017	N
			Thyroidectomy	08JUL2013	08JUL2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801047	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN1998		Y
			Seasonal allergy	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Abscess drainage	01JAN1984	31DEC1984	N
			Finger repair operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1080 10801048	Endocrine disorders	Hypoprogesteronism	01JUN2020		Y
			Hypothyroidism	01JAN2005		Y
			Oestrogen deficiency	01JUN2020		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2000		Y
		Immune system disorders	Food allergy	01JAN1975		Y
		Infections and infestations	Pneumonia	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Fluid retention	01JAN2015		Y
			Vitamin D deficiency	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1080	Surgical and medical procedures	Thoracotomy	01JAN2002	31DEC2002	N
	10801049	Gastrointestinal disorders	Dental caries	22JUL2020		Y
			Nausea	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN1988	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1992	31DEC1992	N
		Nervous system disorders	Vocal cord paresis	01JAN2009		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Aneurysm repair	01JAN2016	31DEC2016	N
			Bone graft	22JUL2020	22JUL2020	N
			Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Oophorectomy	01JAN1992	31DEC1992	N
			Therapeutic embolisation	01JAN2016	31DEC2016	N
	C4591001 1080	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
	10801052					
	C4591001 1080	Cardiac disorders	Supraventricular tachycardia	01JAN2005		Y
	10801056					
		Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Vascular pseudoaneurysm	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN1998		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1080 10801060	Investigations	Blood cholesterol increased	01JAN2010		Y
			Blood glucose increased	01JAN2008	31DEC2009	N
		Surgical and medical procedures	Abdominoplasty	01APR2013	31DEC2013	N
	C4591001 1080 10801061	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Migraine	01JAN1998		Y
		Pregnancy, puerperium and perinatal conditions	HELLP syndrome	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01OCT2017		Y
	C4591001 1080 10801062	Infections and infestations	Appendicitis	01JAN1952	31DEC1952	N
			Staphylococcal infection	01JAN1974	31DEC1974	N
			Tonsillitis	01JAN1943	31DEC1943	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2013	31DEC2014	N
		Nervous system disorders	Sciatica	01JAN2011	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Surgical and medical procedures	Appendectomy	01JAN1952	31DEC1952	N
			Benign breast lump removal	01JAN2014	31DEC2014	N
			Limb operation	01JAN1974	31DEC1974	N
			Spinal laminectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1943	31DEC1943	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801063	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN1960		Y
			Dyspepsia	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1960		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1988		Y
	C4591001 1080 10801064	Cardiac disorders	Atrial fibrillation	01JAN2017	31AUG2017	N
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
			Tonsillitis	01JAN1967	31DEC1967	N
		Injury, poisoning and procedural complications	Ligament rupture	26OCT2006	26OCT2006	N
		Investigations	Blood cholesterol increased	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1985		Y
			Synovial cyst	01JAN1975	31DEC1975	N
				01JAN1998	31DEC1998	N
		Psychiatric disorders	Depression	01OCT2006		Y
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
			Cardiac ablation	01AUG2017	31DEC2017	N
			Ligament operation	26OCT2006	26OCT2006	N
			Synovial cyst removal	01JAN1975	31DEC1975	N
				01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1967	31DEC1967	N
			Vasectomy	01JAN1978	31DEC1978	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801066	Eye disorders	Glaucoma	01JAN2017		Y
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
	C4591001 1080 10801067	Eye disorders	Myopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01SEP2017		Y
			Hypokalaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2015	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1080 10801069	Endocrine disorders	Hyperthyroidism	01JAN1981	31DEC1983	N
			Hypothyroidism	01JAN1985		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Extraocular muscle disorder	01JAN2015		Y
				01JUN2020		Y
			Eyelid ptosis	01JAN2019	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2017	N
			Spinal pain	01JAN1973	31DEC1973	N
		Nervous system disorders	Neuralgia	01JAN1978	31DEC1978	N
		Social circumstances	Postmenopause	01JAN2002	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801070	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Surgical and medical procedures	Prostatectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801071	Cardiac disorders	Atrial flutter	06OCT2017	06OCT2017	N
			Myocardial infarction	01APR2017	01APR2017	N
		Congenital, familial and genetic disorders	Arterial tortuosity syndrome	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Angioplasty	02APR2017	02APR2017	N
			Cardiac ablation	06OCT2017	06OCT2017	N
			Coronary arterial stent insertion	02APR2017	02APR2017	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1080 10801073	Gastrointestinal disorders	Diarrhoea	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Large intestine benign neoplasm	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN1993	31DEC1996	N
			Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Colectomy	01JAN2016	31DEC2016	N
	C4591001 1080 10801074	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801075	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	29FEB2020	N
		Surgical and medical procedures	Knee arthroplasty	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1080 10801076	Cardiac disorders	Arrhythmia	01JAN2000		Y
		Endocrine disorders	Hyperthyroidism	01JAN1968		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1080 10801077	Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Arthralgia	03AUG2020	09AUG2020	N
			Dupuytren's contracture	01OCT2018	31JUL2019	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801080	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
			Cardiac disorder	01JAN1999		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1960	31DEC1960	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN1999	31DEC1999	N
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN1999	31DEC1999	N
			Bone operation	01JAN1960	31DEC1960	N
			Coronary arterial stent insertion	01JAN1999	31DEC1999	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1080 10801083	Eye disorders	Retinal detachment	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Retinopexy	01JAN2010	31DEC2010	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1080 10801084	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1987		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
				01JAN2020	31DEC2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1990		Y
		Social circumstances	Menopause	01JAN1997	31DEC1998	N
			Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Face lift	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Meniscus operation	01JAN2013	31DEC2013	N
				01JAN2020	31DEC2020	N
			Myomectomy	01JAN1992	31DEC1992	N
			Wisdom teeth removal	01JAN1974	31DEC1974	N
	C4591001 1080 10801085	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
			Prostate cancer	01JAN2006	31DEC2006	N
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1080 10801086	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1080 10801088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Food allergy	(b) (6) 1949		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1983	31DEC1988	N
			Neuralgia	01JAN1982	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1988	31DEC1988	N
			Cholecystectomy	01JAN1988	31DEC1988	N
			Limb operation	01JAN2007	31DEC2007	N
			Peripheral nerve transposition	01JAN1987	31DEC1987	N
			Sinus operation	01JAN1988	31DEC1988	N
		Vascular disorders	Deep vein thrombosis	01JAN2008		Y
			Hypertension	01JAN2017		Y
	C4591001 1080 10801090	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Hypertriglyceridaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1969		Y
			Insomnia	01JAN1971		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1961	31DEC1979	N
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801091	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2014	31DEC2014	N
	C4591001 1080 10801093	Eye disorders	Dry eye	01JAN2015		Y
		Infections and infestations	Ear infection	01JAN1960	31DEC1962	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteopenia	01JAN2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2012		Y
		Social circumstances	Menopause	01JAN2009	31DEC2010	N
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1962	31DEC1962	N
			Caesarean section	01JAN1988	31DEC1988	N
			Fracture treatment	01JAN2004	31DEC2004	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1080 10801094	Blood and lymphatic system disorders	Pernicious anaemia	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
	C4591001 1080 10801098	Metabolism and nutrition disorders	Obesity	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1080 10801099	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
			Peripheral arterial occlusive disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801101	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
		General disorders and administration site conditions	Hernia	01JAN1959	31DEC1959	N
		Infections and infestations	Appendicitis perforated	01JAN1960	31DEC1960	N
			Tonsillitis	01JAN1963	31DEC1963	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1976	31DEC1976	N
			Joint dislocation	01JAN1976	31DEC1976	N
			Meniscus injury	01JAN1982	31DEC1982	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1958	31DEC2000	N
		Surgical and medical procedures	Appendectomy	01JAN1960	31DEC1960	N
			Hernia repair	01JAN1959	31DEC1959	N
				01JAN2000	31DEC2000	N
			Knee operation	01JAN1976	31DEC1976	N
				01JAN1982	31DEC1982	N
			Rhinoplasty	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1080 10801103	Gastrointestinal disorders	Tooth impacted	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2012	31DEC2012	N
			Muscle spasms	01JAN2018		Y
		Nervous system disorders	Tremor	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1080 10801105	Eye disorders	Cataract	01DEC2019	29FEB2020	N
					30JUN2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1989	31DEC2005	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1952	31DEC1952	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
	C4591001 1080 10801106	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2012		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2002	31DEC2002	N
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1080 10801110	Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN1980	31DEC1980	N
				01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801112	Gastrointestinal disorders	Inguinal hernia	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2013		Y
	C4591001 1080 10801113	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2005	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2011		Y
	C4591001 1080 10801116	Gastrointestinal disorders	Inguinal hernia	01NOV2003	30NOV2003	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Inguinal hernia repair	01NOV2003	30NOV2003	N
			Ovarian cystectomy	01JAN1976	31DEC1976	N
	C4591001 1080 10801118	Eye disorders	Cataract	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
			Sciatica	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01JAN2000	31DEC2000	N
			Hernia repair	01JAN1999	31DEC1999	N
			Intervertebral disc operation	01JUN2016	30JUN2016	N
	C4591001 1080 10801121	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1080 10801123	Injury, poisoning and procedural complications	Hand fracture	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Finger repair operation	01JAN2018	31DEC2018	N
	C4591001 1080 10801124	Gastrointestinal disorders	Pancreatitis chronic	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Nervous system disorders	Paraplegia	(b) (6) 1954		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1080 10801125	Infections and infestations	Genital herpes	01JAN1980		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Chondroplasty	01JAN1995	31DEC1995	N
	C4591001 1080 10801126	Blood and lymphatic system disorders	Pancytopenia	01JAN2019		Y
		Eye disorders	Dry eye	01MAY2020		Y
		Gastrointestinal disorders	Abdominal discomfort	01JAN2016		Y
			Barrett's oesophagus	01JAN1995		Y
			Vomiting	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Occipital neuralgia	01JAN2018		Y
		Psychiatric disorders	Somnambulism	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN1980		Y
	C4591001 1080 10801127	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Endocrine disorders	Hypogonadism	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017	31DEC2019	N
		Psychiatric disorders	Depression	01JAN1980		Y
		Surgical and medical procedures	Aortic aneurysm repair	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
		Vascular disorders	Aortic aneurysm	01JAN2014	31DEC2018	N
			Hypertension	01JAN2015		Y
	C4591001 1080 10801128	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	C4591001 1080 10801129	Endocrine disorders	Hypothyroidism	01JAN2020		Y
			Thyroid mass	01JAN2019	31JAN2020	N
		Eye disorders	Glaucoma	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01AUG2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Intervertebral disc operation	01OCT2017	31OCT2017	N
			Thyroidectomy	01JAN2020	31JAN2020	N
	C4591001 1080 10801130	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1080 10801133	Gastrointestinal disorders	Malocclusion	01JAN1985	31DEC1985	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
			Caesarean section	01JAN1999	31DEC1999	N
			Jaw operation	01JAN1985	31DEC1985	N
	C4591001 1080 10801134	Endocrine disorders	Basedow's disease	01JAN2003	31DEC2007	N
			Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salivary gland calculus	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01MAY2020		Y
		Nervous system disorders	Intention tremor	01JAN2003		Y
			Migraine	01JAN1994		Y
		Psychiatric disorders	Insomnia	01JAN2004		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
			Salivary gland resection	01JAN1976	31DEC1976	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1080 10801138	Musculoskeletal and connective tissue disorders	Myalgia	01JUL2019		Y
			Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Toe operation	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
	C4591001 1080 10801139	Immune system disorders	Seasonal allergy	01JUN2017		Y
		Infections and infestations	Appendicitis	01JAN1991	31DEC1991	N
		Injury, poisoning and procedural complications	Cartilage injury	01JUL2019		Y
				01MAR2020		Y
		Surgical and medical procedures	Appendectomy	01JAN1991	31DEC1991	N
	C4591001 1080 10801143	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1080 10801146	Eye disorders	Glaucoma	01MAR2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1995	31DEC1995	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1080 10801147	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2017	N
	C4591001 1080 10801148	Cardiac disorders	Myocardial infarction	01OCT2005	31OCT2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1967	31DEC1967	N
			Ligament rupture	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Dehydration	01JAN2010	31DEC2010	N
			Type 2 diabetes mellitus	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary artery bypass	01OCT2005	31OCT2005	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
			Ligament operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1080 10801150	Gastrointestinal disorders	Constipation	01JAN2005		Y
		General disorders and administration site conditions	Pain	01JAN2005		Y
		Nervous system disorders	Sinus headache	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1080 10801152	Cardiac disorders	Atrial fibrillation	01JAN1996		Y
		Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
			Hiatus hernia	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid neoplasm	01JAN1974	31DEC1975	N
		Surgical and medical procedures	Uterine leiomyoma	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1974	31DEC1974	N
			Knee arthroplasty	01JAN1998	31DEC1998	N
				01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1080 10801154	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
			Pain	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1080 10801156	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Myopia	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Periodic limb movement disorder	01JAN2016		Y
		Psychiatric disorders	Irritability	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Keratomileusis	01JAN1995	31DEC1995	N
	C4591001 1080 10801157	Gastrointestinal disorders	Constipation	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
	C4591001 1080 10801158	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Desmoid tumour	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUN2019		Y
		Surgical and medical procedures	Tumour excision	01JAN2005	31DEC2005	N
	C4591001 1080 10801161	Cardiac disorders	Palpitations	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1991		Y
	C4591001 1080 10801164	Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01SEP2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2020		Y
	C4591001 1080 10801165	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1943		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN1988		Y
	C4591001 1080 10801166	Immune system disorders	Food allergy	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Intention tremor	01JAN2000		Y
		Renal and urinary disorders	Urinary retention	01JAN2016		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1080 10801167	Gastrointestinal disorders	Hiatus hernia	01JAN2003	31DEC2003	N
		Infections and infestations	Hepatitis B	01JAN1961	31DEC1961	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010		Y
				01JAN2014		Y
			Spinal osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hernia hiatus repair	01JAN2003	31DEC2003	N
			Prostatic operation	01JAN2007	31DEC2007	N
	C4591001 1080 10801168	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01DEC2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2005	31DEC2005	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
		Surgical and medical procedures	Benign tumour excision	01JAN2005	31DEC2005	N
	C4591001 1080 10801169	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
	C4591001 1080 10801170	Infections and infestations	Hepatitis B	01JAN2010	31DEC2014	N
		Psychiatric disorders	Insomnia	01JUN2000		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1080 10801171	Infections and infestations	Herpes simplex	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1080 10801172	Infections and infestations	Urinary tract infection	01SEP2019	30SEP2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Nervous system disorders	Sciatica	01JUL2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Urinary retention	01MAY2019		Y
	C4591001 1080 10801173	Cardiac disorders	Mitral valve prolapse	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
	C4591001 1080 10801175	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1080 10801176	General disorders and administration site conditions	Pain	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN1971		Y
		Injury, poisoning and procedural complications	Snake bite	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2019		Y
	C4591001 1080 10801177	Infections and infestations	Tonsillitis	01JAN1945	31DEC1945	N
			Urinary tract infection	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2019		Y
			Osteoarthritis	01JAN2017	31DEC2017	N
			Osteopenia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1974	31DEC1974	N
		Psychiatric disorders	Insomnia	01SEP2014		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01JAN1974	31DEC1974	N
			Spinal operation	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1945	31DEC1945	N
	C4591001 1080 10801178	Blood and lymphatic system disorders	Anaemia	01JAN1999	31DEC1999	N
		Eye disorders	Macular degeneration	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JUL2020		Y
	C4591001 1080 10801181	Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Infections and infestations	Oral herpes	01SEP2020	04SEP2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2005	31DEC2005	N
			Osteopenia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Bone operation	01JAN2005	31DEC2005	N
			Hip surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801184	General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2019	30APR2020	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01APR2020	30APR2020	N
				01JAN1992	31DEC1992	N
			Intervertebral disc operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1988	31DEC1988	N
	C4591001 1080 10801188	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2000		Y
				01JAN2001		Y
		Investigations	High density lipoprotein decreased	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1080 10801189	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Gallbladder enlargement	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1080 10801190	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1975		Y
		Surgical and medical procedures	Fracture treatment	01JAN1997	31DEC1997	N
	C4591001 1080 10801191	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2012	31DEC2012	N
			Wrist fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2012	31DEC2012	N
			Wrist surgery	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1080 10801198	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	01SEP1997	31OCT1997	N
		Surgical and medical procedures	Brain tumour operation	01OCT1997	31OCT1997	N
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1080 10801199	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
				01JAN1995	31DEC1995	N
	C4591001 1080 10801200	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1986	31DEC1986	N
				01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1080 10801203	Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1976	31DEC1976	N
		Reproductive system and breast disorders	Ovarian haemorrhage	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1080 10801206	Eye disorders	Dry eye	01JAN2010		Y
		Gastrointestinal disorders	Dry mouth	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Polydipsia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1080 10801207	Endocrine disorders	Hyperthyroidism	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1975	31DEC1975	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN1975	31DEC1975	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1080 10801208	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1994		Y
	C4591001 1080 10801209	Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1961	31DEC1961	N
		Investigations	Blood triglycerides increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1080 10801210	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Atopy	(b) (6) 1949		Y
			Hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
				01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
				01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Erythema multiforme	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1985	31DEC1985	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1080 10801211	Blood and lymphatic system disorders	Pernicious anaemia	01JAN1984		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoporosis	01JAN2010		Y
		Nervous system disorders	Nervous system disorder	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1080 10801215	Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1080 10801216	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Limb reattachment surgery	01JAN2012	31DEC2012	N
	C4591001 1080 10801217	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
				01JAN2011		Y
			Seasonal allergy	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2013	31DEC2013	N
	C4591001 1080 10801218	Social circumstances	Postmenopause	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1080 10801220	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Perennial allergy	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31JAN2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Surgical and medical procedures	Lithotripsy	01JAN2019	31JAN2019	N
	C4591001 1080 10801222	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1080 10801223	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1081 10811002	Eye disorders	Open angle glaucoma	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Splenectomy	01JAN1966	01JAN1966	N
			Tonsillectomy	01JAN1971	01JAN1971	N
	C4591001 1081 10811004	Infections and infestations	Hepatitis A	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Gout	01SEP2011		Y
			Impaired fasting glucose	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Osteoarthritis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811005	Gastrointestinal disorders	Constipation	01JAN2012		Y
			Irritable bowel syndrome	01AUG2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Infections and infestations	Chronic sinusitis	01JAN1983		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1957		Y
			Psoriasis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1081 10811007	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Allergy to animal	01JAN1941		Y
			Mite allergy	01JAN1941		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Bronchitis chronic	01JAN2013		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Hernia repair	01JAN2013	31DEC2013	N
			Pharyngeal operation	01JAN2017	31DEC2017	N
			Radiotherapy to prostate	01JUN2014	31DEC2019	N
	C4591001 1081 10811011	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1081 10811014	Social circumstances	Postmenopause	01JAN2013		Y	
		Cardiac disorders	Angina pectoris	01DEC2009		Y	
			Coronary artery disease		01DEC2009		Y
			Myocardial infarction		01DEC2009	01DEC2009	N
		Ear and labyrinth disorders	Deafness bilateral		01JAN2010		Y
			Tinnitus		01JAN2010		Y
		Eye disorders	Cataract		01JAN2003		Y
						01JUN2011	N
		Gastrointestinal disorders	Gastroesophageal reflux disease		01JUN2011		Y
		Infections and infestations	Tonsillitis		01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Dyslipidaemia		01JAN2010		Y
			Obesity		01JAN2010		Y
			Type 2 diabetes mellitus		01JAN2010		Y
		Nervous system disorders	Headache		01JAN2018		Y
			Neuropathy peripheral		01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis		01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Erectile dysfunction		01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma		01JAN1962		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact		01JAN2010		Y
		Surgical and medical procedures	Cataract operation		01JUN2011	01JUN2011	N
		Coronary artery bypass		01JAN2010	31DEC2010	N	
		Tonsillectomy		01JAN1966	31DEC1966	N	
	Vascular disorders	Hypertension		01JAN2010		Y	
		Intermittent claudication		01JAN2010		Y	
		Peripheral vascular disorder		01JAN2010		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811015	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Rosacea	01DEC2019		Y
		Surgical and medical procedures	Meniscus removal	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
	C4591001 1081 10811016	Cardiac disorders	Cardiomyopathy	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN1978		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Bipolar disorder	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Keratomileusis	01JAN2004	31DEC2004	N
			Mammoplasty	01JAN1978	31DEC1978	N
	C4591001 1081 10811017	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Prostatectomy	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
	C4591001 1081 10811019	Cardiac disorders	Coronary artery disease	01JAN2007		Y
			Myocardial infarction	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2007	31DEC2007	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Intestinal resection	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1081 10811021	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980	31DEC2017	N
				01JAN2009		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01APR2019	01APR2019	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Varicocele repair	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1081 10811022	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1983	30JUN1983	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Renal and urinary disorders	Proteinuria	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	26JUL2016	30SEP2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JUN1983	30JUN1983	N
			Transurethral prostatectomy	01SEP2017	30SEP2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1081 10811024	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Gout	01DEC2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1081 10811026	Blood and lymphatic system disorders	Anaemia	01JAN2011	31DEC2015	N
		Endocrine disorders	Hyperplasia adrenal	01JAN1997		Y
			Hypothyroidism	01JAN1984		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2011	31DEC2011	N
		Hepatobiliary disorders	Cholelithiasis	01FEB2002	28FEB2003	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002		Y
			Obesity	01JAN1962		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2010	31DEC2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2002	31DEC2002	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Knee arthroplasty	01JAN2003	31DEC2009	N
			Large intestinal polypectomy	01DEC2011	01DEC2011	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1081 10811027	Cardiac disorders	Angina pectoris	01DEC2012	31DEC2012	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1951	31DEC1951	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1081 10811028	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Eye disorders	Myopia	01JAN1952		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Large intestine polyp	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Infections and infestations	Diverticulitis	21JUL2015	21JUL2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1967		Y
			Osteopenia	01JAN2005		Y
	C4591001 1081 10811029	Cardiac disorders	Coronary artery disease	01JAN2016		Y
			Myocardial infarction	08SEP2016	08SEP2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Nervous system disorders	Sciatica	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	13SEP2016	13SEP2016	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1081 10811030	Cardiac disorders	Angina pectoris	01JAN2006		Y
			Coronary artery disease	01JAN2006		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1970		Y
			Hand fracture	01JAN1965		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
			Obesity	01JAN2009		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1081 10811031	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Eye disorders	Cataract	01JAN2015	31DEC2017	N
			Presbyopia	01JAN1984		Y
		Gastrointestinal disorders	Constipation	01JAN2011		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01DEC2013		Y
			Osteoarthritis	01JAN2002	31DEC2005	N
			Spinal osteoarthritis	01JAN2013		Y
		Nervous system disorders	Dizziness postural	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neuropathy peripheral	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1081 10811034	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
			Obesity	01JAN2015		Y
			Type 2 diabetes mellitus	18JAN2016	18JAN2016	N
		Nervous system disorders	Cerebrovascular accident	17MAY2014	17MAY2014	N
		Surgical and medical procedures	Female sterilisation	25FEB1983	25FEB1983	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1081 10811035	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1081 10811037	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
	C4591001 1081 10811039	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	30NOV2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
		Surgical and medical procedures	Hip arthroplasty	01NOV2019	30NOV2019	N
	C4591001 1081 10811040	Eye disorders	Strabismus	01JAN1961	01JAN1961	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pilonidal cyst	01JAN1965	01JAN1965	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1965	01JAN1965	N
			Strabismus correction	01JAN1961	01JAN1961	N
			Thromboembolectomy	01APR1971	01APR1971	N
		Vascular disorders	Aneurysm ruptured	01APR1971	01APR1971	N
			Hypertension	01JAN2004		Y
	C4591001 1081 10811041	Eye disorders	Myopia	01JAN1968		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2011		Y
			Gout	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2009		Y
			Urticaria	01JAN1970		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Large intestinal polypectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1081 10811043	Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
			Tonsillitis	01JAN1975	31DEC1975	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2001	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Pruritus allergic	(b) (6) 1962		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Breast reconstruction	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1081 10811045	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2018	N
		Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Injury, poisoning and procedural complications	Fall	01JAN1995	31DEC1995	N
			Wrist fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1998	31DEC1998	N
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1998	31DEC1998	N
			Caesarean section	01JAN1988	31DEC1988	N
				01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1081 10811048	Endocrine disorders	Hypothyroidism	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Glaucoma	01JAN2013	31DEC2017	N
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1944		Y
			Irritable bowel syndrome	01JAN2014		Y
			Large intestine polyp	01JAN2002		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1966	31DEC1966	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Infections and infestations	Tonsillitis	01JAN1940	31DEC1940	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2004		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN1966	31DEC1966	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
			Meniscus removal	01JAN2002	31DEC2002	N
			Ovarian cystectomy	01JAN1960	31DEC1960	N
			Tonsillectomy	01JUL1940	31JUL1940	N
	C4591001 1081 10811049	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1081 10811050	Eye disorders	Myopia	01JAN1998		Y
			Presbyopia	01JAN1947		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN1967		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1991	31DEC1991	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Conjunctivitis viral	14AUG2020	17AUG2020	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2000		Y
			Osteoarthritis	01JAN1996		Y
					05JUN2020	N
			Osteoporosis	01JAN2006		Y
		Nervous system disorders	Headache	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
				05JUN2020	05JUN2020	N
			Spinal laminectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1081 10811051	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2013		Y
			Type 2 diabetes mellitus	01AUG2013		Y
		Psychiatric disorders	Depression	01AUG2013		Y
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1081 10811052	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1964		Y
			Tinnitus	01SEP1964		Y
		Endocrine disorders	Hypothyroidism	01JAN1967		Y
		Eye disorders	Cataract	01JAN2013		Y
			Presbyopia	01JAN1953		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
			Seasonal allergy	(b) (6) 1945		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Myopathy	01JAN1953		Y
			Osteoarthritis	01JAN2000	31DEC2005	N
		Psychiatric disorders	Bipolar disorder	01JAN1988		Y
			Depression	01JAN1998		Y
			Gambling disorder	01MAY2020		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1081 10811053	Eye disorders	Cataract	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Radiotherapy to prostate	01JAN2014	31DEC2014	N
	C4591001 1081 10811054	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01APR2018		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	01JAN2015	N
			Large intestinal polypectomy	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN1998	31DEC1998	N
	C4591001 1081 10811055	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1081 10811056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811057	Ear and labyrinth disorders	Hypoacusis	01JAN1978		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Abdominal hernia	01SEP2010	30SEP2010	N
			Gastroesophageal reflux disease	01JAN2008		Y
		Infections and infestations	Rhinitis	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2010		Y
			Type 2 diabetes mellitus	01AUG2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01DEC2012		Y
			Nasal polyps	01JAN2010	31DEC2010	N
			Nasal septum deviation	01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2014		Y
		Surgical and medical procedures	Abdominal hernia repair	01SEP2010	30SEP2010	N
			Cataract operation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Nasal polypectomy	01NOV2010	31DEC2010	N
			Nasal septal operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811058	Cardiac disorders	Coronary artery disease	01JUN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2017	15NOV2017	N
			Sleep apnoea syndrome	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2000		Y
			Venous thrombosis	01NOV2017	15NOV2017	N
	C4591001 1081 10811059	Immune system disorders	Drug hypersensitivity	01JAN1954		Y
	C4591001 1081 10811060	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1965		Y
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1081 10811061	Congenital, familial and genetic disorders	Dolichocolon	01JAN2011	31JAN2011	N
		Gastrointestinal disorders	Constipation	01JAN2011		Y
			Gastrooesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Small intestinal obstruction	01JUL2011	31OCT2011	N
		General disorders and administration site conditions	Pelvic mass	01JUN2007	30JUN2007	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Tendon rupture	01JAN1988	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Dyslipidaemia	01JAN2015		Y
			Foot deformity	01JAN1998	31DEC1998	N
				01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Vaginal cyst	01JUN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Caesarean section	01MAY1983	31MAY1983	N
			Cataract operation	01JUL2017	31JUL2017	N
			Hysterosalpingo-oophorectomy	01JUL1993	31JUL1993	N
	C4591001 1081 10811063	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN2001		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
				01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
			Tension headache	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811064	Endocrine disorders	Goitre	01JAN1995	31DEC1995	N
			Hypothyroidism	01JAN1995		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2010	28FEB2010	N
		Nervous system disorders	Balance disorder	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Fracture treatment	01JAN1980	31DEC1980	N
			Spinal fusion surgery	01FEB2010	28FEB2010	N
			Spinal laminectomy	01FEB2010	31DEC2010	N
			Thyroidectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1081 10811065	Cardiac disorders	Coronary artery disease	01JAN1998		Y
			Myocardial infarction	01JAN1997	31DEC1997	N
		Eye disorders	Cataract	01JAN2017		Y
		Infections and infestations	Herpes zoster	05SEP2019	30SEP2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
			Foot deformity	01JAN2007	31DEC2007	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2015		Y
			Osteonecrosis	01JAN2005	31DEC2005	N
			Rotator cuff syndrome	01AUG2018	31AUG2018	N
				01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Vocal cord cyst	01JAN2013	31DEC2013	N
			Wheezing	01JAN2006		Y
		Surgical and medical procedures	Bunion operation	01JAN2007	31DEC2007	N
			Coronary angioplasty	01JAN1997	31DEC1997	N
			Hip arthroplasty	01JAN2005	31DEC2005	N
			Laryngeal cyst removal	01JAN2013	31DEC2013	N
			Rotator cuff repair	01AUG2018	31AUG2018	N
				01JAN2019	31DEC2019	N
	C4591001 1081 10811068	Eye disorders	Presbyopia	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2012		Y
			Spinal osteoarthritis	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
	C4591001 1081 10811069	Immune system disorders	Drug hypersensitivity	(b) (6) 1955		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1081 10811072	Cardiac disorders	Ventricular extrasystoles	01JAN2009		Y
		Hepatobiliary disorders	Cholelithiasis	01JUL2003	01JUL2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Infections and infestations	Chronic sinusitis	01JAN2003		Y
			Peritonitis	01JAN2002	01JAN2002	N
				01JAN2013	01JAN2013	N
		Injury, poisoning and procedural complications	Tendon rupture	01MAY2018	01MAY2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer stage IV	01JAN2003	01JAN2003	N
			Hepatic cancer	01JUL2003	01MAY2005	N
		Surgical and medical procedures	Colectomy	01JAN2003	01JAN2003	N
			Hepatectomy	01MAY2005	01MAY2005	N
			Liver ablation	01APR2005	01MAY2005	N
			Tenoplasty	01MAY2017	01MAY2017	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1081 10811073	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811076	Cardiac disorders	Atrial fibrillation	15FEB2020		Y
			Palpitations	01JAN1983		Y
		Eye disorders	Myopia	01JAN1962		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2007	31DEC2007	N
			Gastroesophageal reflux disease	01JAN2002		Y
			Irritable bowel syndrome	01JAN2016		Y
			Large intestine polyp	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2013		Y
		Infections and infestations	Chronic sinusitis	01JAN1957		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Diverticulitis	01MAY2018	01MAY2018	N
			Pneumonia	01JAN1984	31DEC1984	N
			Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1988		Y
			Type 2 diabetes mellitus	01JUN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Bone cyst	01AUG2012	31AUG2012	N
			Intervertebral disc protrusion	01FEB2013		Y
			Osteoarthritis	01JAN2006		Y
				01JAN2009		Y
			Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC1990	N
				01JAN2010	31DEC2010	N
			Diabetic neuropathy	01JUN2012		Y
			Nerve compression	01JAN2010	31DEC2010	N
			Restless legs syndrome	01JAN1960		Y
			Sinus headache	01JAN1965		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018		Y
			Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2007	31DEC2007	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Carpal tunnel decompression	01JAN1990	31DEC1990	N
				01JAN2010	31DEC2010	N
			Ligament operation	01JAN2006	31DEC2006	N
			Neurectomy	01JAN2010	31DEC2010	N
			Polypectomy	01JAN2001	31DEC2001	N
			Prostatectomy	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01MAR2017	31MAR2017	N
			Spinal operation	01AUG2012	31AUG2012	N
			Tonsillectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	23MAY2013		Y
	C4591001 1081 10811078	Injury, poisoning and procedural complications	Fall	01JAN2000	31DEC2000	N
		Investigations	Arthroscopy	01JAN1993	31DEC1993	N
				01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Intervertebral disc protrusion	01JAN2000	31DEC2000	N
			Osteoarthritis	01JAN1993		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
			Depression	01JAN1993		Y
			Insomnia	01JAN1993		Y
			Post-traumatic stress disorder	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2000	31DEC2000	N
	C4591001 1081 10811080	Eye disorders	Amblyopia	(b) (6) 1959	31DEC1999	N
			Presbyopia	01JAN1961		Y
		Infections and infestations	Appendicitis	24NOV2019	24NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1969	31DEC1969	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Myopathy	01JAN1961		Y
			Rotator cuff syndrome	01NOV1999	01NOV1999	N
			Synovial cyst	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01APR2009	30APR2009	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1987	31DEC1987	N
			Migraine	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	24NOV2019	24NOV2019	N
			Carpal tunnel decompression	01JAN1987	31DEC1987	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Rotator cuff repair	01NOV1999	30NOV1999	N
			Thyroid nodule removal	01APR2009	30APR2009	N
			Tonsillectomy	01JAN1969	31DEC1969	N
			Vision correction operation	31DEC1993	31DEC1993	N
	C4591001 1081 10811082	Endocrine disorders	Hypothyroidism	01DEC1998		Y
		Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1998		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2011		Y
				01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01DEC2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2019	N
			Spinal osteoarthritis	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tenosynovitis stenosans	01JAN2019	30NOV2019	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005	31DEC2005	N
			Tenotomy	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1081 10811084	Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2019		Y
			Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Allergic oedema	01JAN2011		Y
			Drug hypersensitivity	01JAN2009		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Angioedema	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811088	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN1964		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2012	31DEC2016	N
	C4591001 1081 10811090	Congenital, familial and genetic disorders	Cerebral palsy	(b) (6) 1964		Y
		Nervous system disorders	Transient ischaemic attack	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1081 10811091	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1081 10811093	Cardiac disorders	Atrial fibrillation	18AUG2020		Y
		Eye disorders	Glaucoma	01JAN2004		Y
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Epilepsy	01JAN1989	31DEC2005	N
			Narcolepsy	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1081 10811097	Psychiatric disorders	Depression	01JAN2012		Y
	C4591001 1081 10811099	Cardiac disorders	Coronary artery disease	01MAY2007		Y
			Myocardial infarction	01MAY2007	31MAY2007	N
		Immune system disorders	Drug hypersensitivity	01MAY2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01MAY2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01SEP2013	30SEP2013	N
		Skin and subcutaneous tissue disorders	Urticaria	01MAY2007		Y
		Surgical and medical procedures	Coronary angioplasty	01MAY2007	31MAY2007	N
			Prostatectomy	01SEP2013	30SEP2013	N
		Vascular disorders	Hypertension	01MAY2007		Y
	C4591001 1081 10811100	Investigations	Heart rate increased	01JAN2017		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2016		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1081 10811102	Immune system disorders	Food allergy	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2001		Y
	C4591001 1081 10811107	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1081 10811110	Endocrine disorders	Hypothyroidism	01AUG2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1957		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Urinary tract infection	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
			Osteopenia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2014	31DEC2014	N
					31DEC2015	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01APR2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Raynaud's phenomenon	01JAN2016		Y
	C4591001 1081 10811111	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Female sterilisation	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811112	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2015		Y
		Nervous system disorders	Cerebrovascular accident	24DEC2015	24DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1081 10811113	Endocrine disorders	Hyperaldosteronism	01JAN2007		Y
		Gastrointestinal disorders	Constipation	01JAN1955		Y
			Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Obesity	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1999		Y
			Intervertebral disc degeneration	01FEB2020		Y
			Osteoarthritis	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1081 10811115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1997		Y
	C4591001 1081 10811116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1081 10811117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
				01JAN2017		Y
	C4591001 1081 10811120	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1081 10811122	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					27MAY2016	N
		Social circumstances	Postmenopause	15MAR2016		Y
		Vascular disorders	Hypertension	08DEC2017		Y
	C4591001 1081 10811123	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811124	Metabolism and nutrition disorders	Gout	01JAN2000		Y
	C4591001 1081 10811125	Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
	C4591001 1081 10811128	Immune system disorders	Food allergy	01JAN1970		Y
			Rubber sensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
			Bronchitis chronic	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JUL1998	31JUL1998	N
		Vascular disorders	Hypertension	01JAN1976		Y
	C4591001 1081 10811136	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002		Y
			Obesity	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1991		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2002	01JAN2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	01JAN2002	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1081 10811137	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	01JAN1992	N
	C4591001 1081 10811139	Cardiac disorders	Cardiomyopathy	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Pancreatitis chronic	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Psychiatric disorders	Anxiety	01DEC2012		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1999		Y
		Social circumstances	Postmenopause	01JUN2013		Y
	C4591001 1081 10811142	Psychiatric disorders	Depression	01JAN2013	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1081 10811144	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	25NOV2013		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1081 10811149	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2019		Y
		Surgical and medical procedures	Foot amputation	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1081 10811150	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1081 10811151	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Abdominal infection	01JAN2015	01JAN2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1081 10811152	Immune system disorders	Drug hypersensitivity	01JAN1954		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1994		Y
			Osteoarthritis	01JAN2003	31DEC2016	N
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN1977		Y
	C4591001 1081 10811153	Cardiac disorders	Palpitations	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811154	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1989		Y
		Social circumstances	Menopause	01JAN1996		Y
		Vascular disorders	Hypertension	01DEC1996		Y
	C4591001 1081 10811155	Endocrine disorders	Hypothyroidism	01SEP2003		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1081 10811156	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Impaired fasting glucose	10MAY2016		Y
			Obesity	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1081 10811157	Blood and lymphatic system disorders	Anaemia	01JAN2011		Y
		Cardiac disorders	Arrhythmia	01NOV2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
			Impaired fasting glucose	20JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811158	Endocrine disorders	Hyperthyroidism	01JAN2014	31MAY2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
			Urticaria	01JAN1977		Y
		Social circumstances	Menopause	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Mastectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	13NOV2019		Y
	C4591001 1081 10811159	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01FEB2020	01FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Productive cough	01FEB2020		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01FEB2020	01FEB2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1081 10811162	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1081 10811163	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
	C4591001 1081 10811165	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1081 10811166	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1081 10811167	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811168	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1081 10811169	Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1978	31DEC1983	N
	C4591001 1081 10811170	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Obesity	17MAR2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2013		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1081 10811171	Immune system disorders	Drug hypersensitivity	(b) (6) 1945		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1081 10811173	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2015		Y
	C4591001 1081 10811174	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2018		Y
			Type 2 diabetes mellitus	01JUN2018		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1081 10811175	Metabolism and nutrition disorders	Dyslipidaemia	01DEC2004		Y
				01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01AUG2009		Y
			Obsessive-compulsive disorder	01JAN1952		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1081 10811176	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1081 10811177	Eye disorders	Macular degeneration	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1968		Y
	C4591001 1081 10811178	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1081 10811179	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Infections and infestations	Urinary tract infection	01JAN2006		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
			Obesity	18MAR2014		Y
			Type 2 diabetes mellitus	01OCT2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1081 10811180	Renal and urinary disorders	Nephrolithiasis	01JAN2020		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1081 10811181	Infections and infestations	Diverticulitis	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Bipolar disorder	01SEP2010		Y
	C4591001 1081 10811182	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1081 10811184	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
					06JUL2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1081 10811188	Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1081 10811189	Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Dyslipidaemia	02SEP2018		Y
		Vascular disorders	Hypertension	02SEP2013		Y
	C4591001 1081 10811191	Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2005		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1081 10811195	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31MAR2015	N
		Nervous system disorders	Diabetic neuropathy	18NOV2014		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1980	01JAN1980	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1081 10811201	Endocrine disorders	Hypothyroidism	01APR2019		Y
	C4591001 1081 10811203	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01APR2020	20APR2020	N
		Surgical and medical procedures	Spinal operation	20APR2020	20SEP2020	N
		Vascular disorders	Hypertension	12SEP2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811204	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
			Cardiac failure congestive	01JAN1993		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2006		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1988		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01SEP2011		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2020		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Peripheral nerve operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1081 10811205	Renal and urinary disorders	Bladder prolapse	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Urinary bladder suspension	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1081 10811208	Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1081 10811211	Cardiac disorders	Myocardial infarction	01JUN2013	30JUN2013	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01DEC2014	31DEC2014	N
	C4591001 1081 10811212	Infections and infestations	Hepatitis C	01JAN2000	31DEC2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1081 10811213	Nervous system disorders	Neuropathy peripheral	06AUG2012	31DEC2013	N
	C4591001 1081 10811214	Endocrine disorders	Hypothyroidism	01APR2013		Y
		Eye disorders	Dermatochalasis	20JUL2020		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01FEB2013		Y
			Large intestine polyp	01APR2013	30APR2013	N
		Immune system disorders	Allergy to arthropod sting	01JAN1964		Y
			Anaphylactic reaction	01JAN1964	31DEC1964	N
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JUN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Polypectomy	01APR2013	30APR2013	N
		Vascular disorders	Hypertension	01MAY2014		Y
	C4591001 1082 10821001	Eye disorders	Hypermetropia	01JAN2015	31DEC2015	N
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1986	31DEC1986	N
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Neck surgery	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1082 10821002	Eye disorders	Borderline glaucoma	01JAN2015		Y
			Myopia	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Reproductive system and breast disorders	Prostatomegaly	01JUN2005	30JUN2005	N
		Surgical and medical procedures	Transurethral prostatectomy	01JUN2005	30JUN2005	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821005	Eye disorders	Myopia	01JAN1965		Y
			Strabismus	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Constipation	01JAN1996		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1986	31DEC1986	N
		Infections and infestations	Candida infection	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	09JUL2019	09JUL2019	N
		Social circumstances	Postmenopause	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Cholecystectomy	01JAN1986	31DEC1986	N
			Eye operation	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Hip arthroplasty	09JUL2019	09JUL2019	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1082 10821007	Eye disorders	Myopia	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1987	31DEC1987	N
			Joint dislocation	01JAN1984	31DEC1984	N
			Ligament rupture	01JAN1981	31DEC1981	N
				01JAN1985	31DEC1985	N
			Muscle rupture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
			Spinal stenosis	01JAN1991		Y
		Surgical and medical procedures	Chondroplasty	01JAN1987	31DEC1987	N
			Joint dislocation reduction	01JAN1984	31DEC1984	N
			Ligament operation	01JAN1981	31DEC1981	N
				01JAN1985	31DEC1985	N
			Muscle operation	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821012	Eye disorders	Hypermetropia	01JAN2008		Y
			Myopia	01JAN2008		Y
		Gastrointestinal disorders	Inguinal hernia	21OCT2019	21OCT2019	N
		Surgical and medical procedures	Inguinal hernia repair	21OCT2019	21OCT2019	N
	C4591001 1082 10821017	Cardiac disorders	Arteriospasm coronary	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2003		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1972	31DEC1972	N
		Investigations	Catheterisation cardiac	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2019		Y
			Gout	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Amnesia	01JAN2012		Y
			Neuropathy peripheral	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
			Cancer surgery	01JAN2014	31DEC2014	N
			Gastrectomy	19MAY2020	19MAY2020	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1082 10821029	Infections and infestations	Appendicitis	03MAR2020	03MAR2020	N
		Surgical and medical procedures	Appendectomy	03MAR2020	03MAR2020	N
	C4591001 1082 10821032	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	02MAR1988	02MAR1988	N
	C4591001 1082 10821033	Eye disorders	Cataract	04AUG2013	04AUG2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	04JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1991	31DEC1991	N
					31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	04AUG2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	04AUG2012		Y
			Tendonitis	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Cataract operation	04AUG2018	04AUG2018	N
			Meniscus removal	01JAN1991	31DEC1991	N
			Tenotomy	01JAN1999	31DEC1999	N
			Tonsillitis	01JAN1967	31DEC1967	N
	C4591001 1082 10821040	Infections and infestations				
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1082 10821042	Eye disorders	Eyelid ptosis	01JAN1962	31DEC1962	N
			Hypermetropia	01JAN1962		Y
			Myopia	01JAN1962		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	05AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Pregnancy, puerperium and perinatal conditions	Retained placenta or membranes	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Ptosis repair	01JAN1962	31DEC1962	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821048	Eye disorders	Presbyopia	01JAN1970		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Benign tumour excision	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1082 10821051	Eye disorders	Hypermetropia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Reproductive system and breast disorders	Prostatitis	15JUL2020	29JUL2020	N
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1082 10821052	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Eye disorders	Hypermetropia	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
			Caesarean section	11JUL1991	11JUL1991	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821055	Eye disorders	Hypermetropia	01JAN2010		Y
		Infections and infestations	Extradural abscess	01JAN2018	31DEC2018	N
			Tonsillitis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1993	31DEC1993	N
	C4591001 1082 10821057	Eye disorders	Myopia	01JAN1971		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Infections and infestations	Genital herpes	01JAN2007		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1967		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Foot operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1082 10821058	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1992		Y
		Infections and infestations	Adenoiditis	01JAN1952	31DEC1952	N
			Appendicitis	01JAN1954	31DEC1954	N
			Tonsillitis	01JAN1952	31DEC1952	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1952	31DEC1952	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Appendicectomy	01JAN1954	31DEC1954	N
			Rhinoplasty	01JAN1960	31DEC1960	N
			Tonsillectomy	01JAN1952	31DEC1952	N
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1082 10821059	Eye disorders	Myopia	01JAN1975		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	10SEP1981	10SEP1981	N
				24JUL1989	24JUL1989	N
				24SEP1984	24SEP1984	N
	C4591001 1082 10821061	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Eye disorders	Myopia	01JAN1960		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Nervous system disorders	Sciatica	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
			Thyroidectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1082 10821062	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Diverticulitis	01JAN2008	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Ligament disorder	01JAN2011	31DEC2012	N
				01JAN2016	31DEC2017	N
			Scoliosis	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1998	31DEC1999	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Colectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
	C4591001 1082 10821063	Eye disorders	Myopia	01JAN1971		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Hepatobiliary disorders	Cholestasis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1985	31DEC1985	N
		Investigations	Cardiac murmur	01JAN1969		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
			Depression	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Bone operation	01JAN1985	31DEC1985	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Uvulectomy	01JAN1993	31DEC1993	N
	C4591001 1082 10821068	Eye disorders	Hypermetropia	01JAN1992		Y
		Infections and infestations	Tonsillitis	01JAN1961	31DEC1961	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1984	31DEC1984	N
				01JAN1992	31DEC1992	N
				01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2005	31DEC2005	N
			Tenoplasty	01JAN1984	31DEC1984	N
				01JAN1992	31DEC1992	N
				01JAN2000	31DEC2000	N
		Vascular disorders	Tonsillectomy	01JAN1961	31DEC1961	N
			Hypertension	01JAN1992		Y
	C4591001 1082 10821074	Eye disorders	Glaucoma	01JAN1995		Y
			Myopia	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Bone operation	01JAN1983	31DEC1983	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1082 10821075	Injury, poisoning and procedural complications	Joint dislocation	01JAN1979	31DEC1979	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010	31DEC2010	N
			Muscle spasms	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Shoulder operation	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821076	Eye disorders	Vasectomy	01JAN2000	31DEC2000	N
			Hypermetropia	01JAN2005		Y
			Presbyopia	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004	31DEC2009	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
	C4591001 1082 10821079	Endocrine disorders	Prostatic operation	01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
			Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1962		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN1973		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Restless legs syndrome	01JAN1995		Y
	C4591001 1082 10821086	Surgical and medical procedures	Joint arthroplasty	01JAN2010	31DEC2010	N
			Muscle operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1990		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Nervous system disorders	Syncope	01JAN2002		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1999	31DEC1999	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1082 10821087	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	31DEC2019	N
			Arthropathy	01MAY2020	31MAY2020	N
			Exostosis	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Carpectomy	01JAN2019	31DEC2019	N
			Foot operation	01JAN2016	31DEC2016	N
			Knee arthroplasty	01MAY2020	31MAY2020	N
	C4591001 1082 10821093	Eye disorders	Myopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Ankle arthroplasty	01JAN1992	31DEC1992	N
			Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1082 10821094	Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005	31DEC2005	N
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
					31DEC2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Open reduction of fracture	01JAN1988	31DEC1988	N
	C4591001 1082 10821096	Eye disorders	Cataract	01FEB2020	29FEB2020	N
			Presbyopia	01FEB2020	29FEB2020	N
		Infections and infestations	Appendicitis	01MAY2017	31MAY2017	N
		Social circumstances	Postmenopause	01DEC2010		Y
		Surgical and medical procedures	Appendicectomy	01MAY2017	31MAY2017	N
			Cataract operation	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821097	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Cardiac disorders	Coronary artery occlusion	01JAN2015	31DEC2015	N
		Eye disorders	Hypermetropia	01JAN2008		Y
			Myopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821098	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821099	Ear and labyrinth disorders	Deafness unilateral	01JAN1960		Y
		Endocrine disorders	Hypogonadism	01JAN2018		Y
			Hypothyroidism	01JAN2012		Y
		Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2020	31DEC2020	N
		Infections and infestations	Sinusitis	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2020	31DEC2020	N
			Nasal septal operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821101	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1082 10821103	Surgical and medical procedures	Coronary artery bypass	01JAN2007	31DEC2007	N
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1996	31DEC1996	N
			Foot fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2008	31DEC2008	N
			Malignant melanoma	01JAN1980	31DEC1980	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1082 10821108	Eye disorders	Myopia	01JAN2003	31DEC2003	N
			Presbyopia	01JAN2013		Y
		Infections and infestations	Cat scratch disease	01JAN1984	31DEC1984	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Keratomileusis	01JAN2003	31DEC2003	N
			Lymphadenectomy	01JAN1984	31DEC1984	N
			Skin neoplasm excision	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821110	Cardiac disorders	Arrhythmia	01JAN2010	31DEC2010	N
		Congenital, familial and genetic disorders	Factor II mutation	(b) (6) 1964		Y
		Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Eye disorders	Myopia	01JAN1976		Y
		Immune system disorders	Allergy to animal	01JAN1967	31DEC1975	N
			Mycotic allergy	01JAN1967	31DEC1975	N
			Seasonal allergy	01JAN1967		Y
			Smoke sensitivity	01JAN1967	31DEC1975	N
		Injury, poisoning and procedural complications	Rib fracture	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1996	31DEC1996	N
			Malignant melanoma	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1982		Y
			Depression	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967	31DEC1975	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN1996	31DEC1996	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1082 10821112	Eye disorders	Presbyopia	01JAN2009	31DEC2009	N
		Hepatobiliary disorders	Cholecystitis	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2001	N
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Intraocular lens implant	01JAN2009	31DEC2009	N
			Mammoplasty	01JAN2003	31DEC2003	N
	C4591001 1082 10821114	Congenital, familial and genetic disorders	Congenital anomaly	01JAN1992	31DEC1992	N
		Eye disorders	Myopia	01JAN1976		Y
		Gastrointestinal disorders	Uvulitis	01JAN2000	31DEC2000	N
		Infections and infestations	Sinusitis	01JAN1989	31DEC1989	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Birth defect correction	01JAN1992	31DEC1992	N
			Sinus operation	01JAN1989	31DEC1989	N
			Uvulectomy	01JAN2000	31DEC2000	N
	C4591001 1082 10821117	Eye disorders	Myopia	01JAN1969		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Salpingo-oophorectomy bilateral	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1082 10821118	Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Reaction to food additive	01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN1996	31DEC1996	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1082 10821119	Blood and lymphatic system disorders	Lymphadenopathy	01JAN1956	31DEC1956	N
		Eye disorders	Presbyopia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
			Tonsillitis	01JAN1956	31DEC1956	N
		Investigations	Blood testosterone decreased	01JAN2016		Y
			Intraocular pressure decreased	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1950		Y
		Surgical and medical procedures	Lymphadenectomy	01JAN1956	31DEC1956	N
			Spinal fusion surgery	01MAY2017	31MAY2017	N
		Vascular disorders	Tonsillectomy	01JAN1956	31DEC1956	N
			Hypertension	01JAN2014		Y
	C4591001 1082 10821121	Eye disorders	Myopia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Radius fracture	01JAN2002	31DEC2002	N
		Pregnancy, puerperium and perinatal conditions	Foetal death	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Bone operation	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1966	31DEC1966	N
			Uterine dilation and curettage	01JAN1988	31DEC1988	N
	C4591001 1082 10821122	Eye disorders	Presbyopia	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Radical prostatectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1082 10821124	Endocrine disorders	Goitre	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypothyroidism	01JAN1990		Y
		Eye disorders	Presbyopia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Triple negative breast cancer	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1976	31DEC1976	N
			Knee arthroplasty	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
	C4591001 1082 10821125	Cardiac disorders	Coronary artery disease	01JAN2002		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2006		Y
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018	31DEC2018	N
			Chondropathy	01JAN2018	31DEC2018	N
			Scoliosis	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Coronary arterial stent insertion	01JAN2002	31DEC2002	N
			Knee arthroplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1082 10821126	Eye disorders	Hypermetropia	01JAN2019		Y
			Myopia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1995		Y
	C4591001 1082 10821131	Eye disorders	Hypermetropia	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Meniscus removal	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1082 10821132	Cardiac disorders	Supraventricular tachycardia	01JAN1970		Y
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Myopia	01JAN1970		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
				01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2013	31DEC2013	N
			Osteoarthritis	01JAN2015		Y
				01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1998		Y
		Surgical and medical procedures	Bursa removal	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Joint arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1082 10821133	Skin and subcutaneous tissue disorders	Alopecia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1082 10821134	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1998		Y
			Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2006		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01NOV1994	30NOV1994	N
		Surgical and medical procedures	Elbow operation	01JAN2007	31DEC2007	N
			Hysterectomy	01NOV1994	30NOV1994	N
			Oophorectomy bilateral	01NOV1994	30NOV1994	N
	C4591001 1082 10821135	Eye disorders	Glaucoma	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Presbyopia	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1082 10821137	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2016		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1982		Y
		Eye disorders	Cataract	01JAN2006	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1995		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2007		Y
			Spinal osteoarthritis	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2003		Y
			Uterine leiomyoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
			Open reduction of fracture	01JAN1971	31DEC1971	N
			Uterine dilation and curettage	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1082 10821138	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer stage III	01JAN2010	31DEC2010	N
		Nervous system disorders	Anosmia	01JAN1970		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1082 10821141	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Presbyopia	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2004	31DEC2004	N
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006	31DEC2006	N
			Sciatica	03AUG2020		Y
		Psychiatric disorders	Depression	01JAN2018	25JUL2020	N
		Surgical and medical procedures	Appendectomy	01JAN1981	31DEC1981	N
			Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Female sterilisation	01JAN1985	31DEC1985	N
			Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1082 10821142	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Iodine allergy	01JAN1956		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1957	31DEC1957	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Wrist surgery	01JAN1957	31DEC1957	N
	C4591001 1082 10821146	Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		General disorders and administration site conditions	Hernia	01JAN1987	31DEC1995	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	31AUG2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
			Tenoplasty	01JAN2018	31DEC2018	N
	C4591001 1082 10821147	Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821152	Eye disorders	Hypermetropia	01JAN2002		Y
			Myopia	01JAN2002		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Injury, poisoning and procedural complications	Splenic rupture	01JAN1973	31DEC1973	N
		Investigations	Arthroscopy	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
			Splenectomy	01JAN1973	31DEC1973	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821153	Endocrine disorders	Hypothyroidism	01JAN1989		Y
			Thyroid mass	01JAN1989	31DEC1989	N
		Eye disorders	Hypermetropia	01JAN2001		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1984	31DEC1984	N
		Immune system disorders	Contrast media allergy	01JAN2000		Y
			Drug hypersensitivity	01JAN1971		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Investigations	Precancerous cells present	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N
				01JAN2017	31DEC2017	N
			Osteoporosis	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1984	31DEC1984	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN1984	31DEC1984	N
			Shoulder arthroplasty	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1082 10821155	Blood and lymphatic system disorders	Anaemia	01AUG2020		Y
		Eye disorders	Cataract	23DEC2019	23DEC2019	N
			Presbyopia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	23DEC2019	23DEC2019	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Salpingectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1082 10821157	Eye disorders	Hypermetropia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1082 10821159	Cardiac disorders	Cardiomyopathy	01JAN2001	31DEC2005	N
		Ear and labyrinth disorders	Tinnitus	01JAN1981		Y
		Nervous system disorders	Trigeminal neuralgia	01JAN1987	31DEC1990	N
		Surgical and medical procedures	Radiculotomy	01JAN1987	31DEC1987	N
				01JAN1990	31DEC1990	N
	C4591001 1082 10821160	Eye disorders	Myopia	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2013	31DEC2019	N
		Surgical and medical procedures	Cancer surgery	01JAN2019	31DEC2019	N
			Meniscus removal	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Cataract	01JAN2015	31DEC2015	N
		Eye disorders	Presbyopia	01JAN1988		Y
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign renal neoplasm	03MAR2020	03MAR2020	N
		Surgical and medical procedures	Appendectomy	01JAN1960	31DEC1960	N
			Intraocular lens implant	01JAN2015	31DEC2015	N
			Limb operation	01JAN1988	31DEC1988	N
			Nephrectomy	14MAY2020	14MAY2020	N
		Eye disorders	Myopia	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
					31DEC2010	N
			Intervertebral disc protrusion	01JAN2018	31DEC2018	N
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821165	Cardiac disorders	Trapeziectomy	01JAN2010	31DEC2010	N
			Aortic valve incompetence	26NOV2012	26NOV2012	N
			Atrial flutter	01JAN2018	31DEC2018	N
			Atrioventricular block	06JUN2014	06JUN2014	N
			Myocardial infarction	01DEC2019	31DEC2019	N
		Ear and labyrinth disorders	Deafness	01JAN2013		Y
		Eye disorders	Vision blurred	16AUG2016	16AUG2016	N
				22AUG2016	22AUG2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Trigger finger	01JAN2019	31DEC2019	N
		Psychiatric disorders	Sleep disorder	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2013		Y
		Surgical and medical procedures	Aortic valve repair	26NOV2012	26NOV2012	N
	Cardiac ablation		01JAN2018	31DEC2018	N	
				06DEC2014	06DEC2014	N
	Cataract operation		16AUG2016	16AUG2016	N	
				22AUG2016	22AUG2016	N
	Tendon sheath incision		01JAN2019	31DEC2019	N	
	Vasectomy		01JAN1975		Y	
	Vascular disorders		Hypertension	01JAN2005		Y
	Cardiac disorders		Atrial fibrillation	03AUG2020		Y
	Endocrine disorders		Hypothyroidism	01JAN1999		Y
	Eye disorders	Myopia	01JAN1980	31DEC1996	N	
		Presbyopia	01JAN1997		Y	
	C4591001 1082 10821166					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN1999		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	03AUG2020	31AUG2020	N
			Keratomileusis	01JAN1996	31DEC1996	N
			Toe operation	01FEB2009	28FEB2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1082 10821167	Ear and labyrinth disorders	Deafness unilateral	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Eye disorders	Cataract	01JAN2010	31DEC2011	N
		Gastrointestinal disorders	Tooth loss	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
		Injury, poisoning and procedural complications	Acetabulum fracture	01JAN2014	31DEC2014	N
			Ankle fracture	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	01JAN2011	31DEC2011	N
			Fibroma	01JAN1968	31DEC1968	N
		Surgical and medical procedures	Ankle operation	01JAN2005	31DEC2005	N
			Appendicectomy	01JAN1960	31DEC1960	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast conserving surgery	01JAN2011	31DEC2011	N
			Cataract operation	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
			Hip arthroplasty	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1968	31DEC1968	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Shoulder arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1971		Y
	C4591001 1082 10821169	Eye disorders	Myopia	01JAN1993		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1996	31DEC1996	N
			Meniscus injury	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1985	31DEC1985	N
			Plantar fasciitis	01JAN2009	31DEC2009	N
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Trigger finger	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Arthrodesis	01JAN1985	31DEC1988	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Foot operation	01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
			Ligament operation	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN1998	31DEC1998	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Tendon sheath incision	01JAN2015	31DEC2015	N
	C4591001 1082 10821170	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Eye disorders	Myopia	01JAN1960		Y
		Gastrointestinal disorders	Tooth impacted	01JAN1960	31DEC1960	N
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Investigations	Angiocardiogram	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cataract operation	01JAN1991	31DEC1991	N
				01JAN1997	31DEC1997	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821173	Gastrointestinal disorders	Tooth impacted	01JAN1972	31DEC1972	N
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
		Renal and urinary disorders	Ureteric stenosis	01JAN2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1968	31DEC1968	N
			Wisdom teeth removal	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1082 10821174	Eye disorders	Presbyopia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Tooth impacted	01JAN1977	31DEC1977	N
		Immune system disorders	Allergy to arthropod sting	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
			Salpingectomy	01JAN1990	31DEC1990	N
			Synovial cyst removal	01JAN1998	31DEC1998	N
			Wisdom teeth removal	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1082 10821176	Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
			Tooth impacted	01JAN1955	31DEC1955	N
		Infections and infestations	Appendicitis	01JAN1953	31DEC1953	N
			Tonsillitis	01JAN1947	31DEC1947	N
		Surgical and medical procedures	Tonsillectomy	01JAN1947	31DEC1947	N
			Wisdom teeth removal	01JAN1955	31DEC1955	N
	C4591001 1082 10821177	Gastrointestinal disorders	Tooth impacted	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1985		Y
			Meniscus injury	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
			Ejection fraction decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bone operation	01JAN1985	31DEC1985	N
			Breast conserving surgery	01JAN2012	31DEC2012	N
			Wisdom teeth removal	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1082 10821179	Ear and labyrinth disorders	Deafness unilateral	01JAN2016		Y
		Gastrointestinal disorders	Tooth impacted	01JAN1973	31DEC1973	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Insulin-requiring type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1082 10821181	Gastrointestinal disorders	Inguinal hernia	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Hernia repair	01JAN1999	31DEC1999	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1082 10821182	Cardiac disorders	Arteriosclerosis coronary artery	15JAN2020		Y
		Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastritis	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2000	31DEC2002	N
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2005		Y
				01JAN2010		Y
			Seasonal allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Ligament sprain	09JUN2020	09JUN2020	N
		Investigations	Heart rate irregular	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01SEP2017	30SEP2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	31DEC2015	N
		Surgical and medical procedures	Ankle operation	09JUN2020	09JUN2020	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Hernia hiatus repair	01JAN2002	31DEC2002	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Therapeutic embolisation	01JAN2015	31DEC2015	N
			Tendon rupture	01JAN1977	31DEC1977	N
	C4591001 1082 10821184	Injury, poisoning and procedural complications				
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N
			Spondylitis	16JUN2020	16JUN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Prostatectomy	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2014	31DEC2014	N
			Spinal fusion surgery	16JUN2020	16JUN2020	N
			Tenoplasty	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1082 10821189	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Tooth impacted	01JAN1978	31DEC1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Surgical and medical procedures	Oesophagogastric fundoplasty	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1082 10821190	Investigations	Arthroscopy	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercalcaemia	01DEC2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1988	31DEC1988	N
			Hysterectomy	01JUN1990	30JUN1990	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1082 10821193	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Arthroscopy	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1978	31DEC1980	N
			Spinal stenosis	01JAN1978	31DEC1980	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Prostatic operation	01JUN2019	30JUN2019	N
			Spinal laminectomy	01JAN1978	31DEC1978	N
				01JAN1980	31DEC1980	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1082 10821205	Gastrointestinal disorders	Umbilical hernia	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1082 10821209	Eye disorders	Myopia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2011	N
		Surgical and medical procedures	Prostatectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1082 10821213	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Myopia	01JAN1961		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Bile duct stone	01JAN1995	31DEC1995	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
				01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2001	31DEC2002	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1956	31DEC1956	N
				01JAN1998	31DEC1998	N
	C4591001 1082 10821214	Eye disorders	Myopia	01JAN1963		Y
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2011	31DEC2011	N
			Spinal osteoarthritis	01JAN1992	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2011	31DEC2011	N
			Spinal fusion surgery	01JAN1992	31DEC1992	N
				01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1082 10821219	Eye disorders	Cataract	01JAN2010	31DEC2018	N
		Nervous system disorders	Trigeminal neuralgia	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
	C4591001 1082 10821223	Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Squamous cell carcinoma of skin	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Caesarean section	07JUL1972	07JUL1972	N
				10OCT1975	10OCT1975	N
			Female sterilisation	01JAN1975	31DEC1975	N
	C4591001 1083 10831003	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1083 10831008	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1083 10831012	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2015		Y
		Eye disorders	Cataract	01JAN2002		Y
		Gastrointestinal disorders	Rectal prolapse	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN1992		Y
				01JAN2000		Y
				01JAN2002		Y
				01JAN2004		Y
				01JAN2014		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Herpes simplex	01JAN2013		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Obesity	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN1989		Y
			Spinal osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1982	31DEC1982	N
		Nervous system disorders	Migraine	01JAN1967		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2014	31DEC2016	N
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			Cholecystectomy	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
			Rectal prolapse repair	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2010	31DEC2010	N
			Urinary bladder suspension	01JAN2016	31DEC2016	N
	C4591001 1083 10831014	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Oral herpes	01JAN1962		Y
		Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN1982		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1996		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric bypass	01JAN2007	31DEC2007	N
			Hip arthroplasty	01DEC2019	31DEC2019	N
				01JAN2008	31DEC2008	N
	C4591001 1083 10831016	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1083 10831019	Eye disorders	Cataract	01JAN2017		Y
		Hepatobiliary disorders	Hepatic steatosis	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01NOV2019		Y
		Nervous system disorders	Headache	01JAN2017		Y
			Migraine	01JAN2007		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Menopause	01JUN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Oophorectomy bilateral	01JUN2020		Y
		Vascular disorders	Hot flush	01JUN2020		Y
			Hypertension	01JAN2019		Y
	C4591001 1083 10831021	Cardiac disorders	Arrhythmia	01JAN2005		Y
		Immune system disorders	Allergy to plants	01JAN1992		Y
			Drug hypersensitivity	01JAN1958		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	20MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1083 10831022	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Nervous system disorders	Headache	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
	C4591001 1083 10831023	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2013		Y
		Vascular disorders	Hypertension	01DEC2005		Y
	C4591001 1083 10831024	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831027	Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Infections and infestations	Genital herpes	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1083 10831031	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2004		Y
			Muscle twitching	01JAN1995		Y
			Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Renal and urinary disorders	Urinary incontinence	01DEC2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
		Vascular disorders	Deep vein thrombosis	01JAN2015		Y
	C4591001 1083 10831036	Infections and infestations	Herpes simplex	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01APR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003		Y
	C4591001 1083 10831039	Gastrointestinal disorders	Dyspepsia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Type 1 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Turbinectomy	01JAN2018	31DEC2018	N
	C4591001 1083 10831041	Immune system disorders	Seasonal allergy	01JAN1988		Y
	C4591001 1083 10831042	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
	C4591001 1083 10831050	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2015		Y
		Eye disorders	Cataract	01JAN2000	31DEC2000	N
			Glaucoma	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1961		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	02AUG2020		Y
			Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2000	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN1965		Y
		Renal and urinary disorders	Bladder prolapse	01JAN1981	31DEC1981	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Gastric banding	01JAN2003	31DEC2003	N
			Knee arthroplasty	01JAN2001	31DEC2001	N
				01JAN2005		Y
			Urinary bladder suspension	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831051	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Social circumstances	Organ donor	01APR2014		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1083 10831053	Cardiac disorders	Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				24MAY1990		Y
			Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN1995		Y
			Osteoarthritis	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1083 10831056	Eye disorders	Glaucoma	01FEB2020		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
	C4591001 1083	Surgical and medical procedures	Hysterectomy	01JAN2003		Y
	10831059	Congenital, familial and genetic disorders	Arteriovenous malformation	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN1990		Y
		Nervous system disorders	Cerebrovascular accident	01OCT1987	31OCT1987	N
			Migraine	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	01JAN1990	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1083	Social circumstances	Postmenopause	01JAN2010		Y
	10831064					
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1083	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	10831066					
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004		Y
	C4591001 1083	Eye disorders	Cataract	11MAY2020		Y
	10831071					
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2017	31DEC2019	N
		Nervous system disorders	Headache	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1083 10831072	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Glaucoma	01JAN2010		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Fracture treatment	01NOV2018	30NOV2018	N
			Glaucoma surgery	01JAN2018	31DEC2018	N
			Intraocular lens implant	01JAN2018	31DEC2018	N
			Micrographic skin surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1083 10831073	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1083 10831075	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1083 10831076	Vascular disorders	Hypertension	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1968		Y
		Immune system disorders	Food allergy	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Herpes simplex	01JAN1990		Y
			Tonsillitis	01JAN1962	31DEC1963	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1990	31DEC1990	N
			Wrist fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1998	N
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1953	31DEC1999	N
			Rhinitis allergic	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Fracture treatment	01JAN1990	31DEC1990	N
				01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septal operation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1083 10831077	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1083 10831079	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Irritable bowel syndrome	01OCT2019		Y
		Infections and infestations	Ophthalmic herpes zoster	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Sciatica	01JAN2016	31DEC2016	N
				01JUN2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2008	31DEC2008	N
			Intraocular lens implant	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1083 10831080	Eye disorders	Cataract	01JAN2013	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Hepatobiliary disorders	Cholecystitis acute	01JAN2006		Y
		Immune system disorders	Food allergy	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Bronchitis	01MAR2020	30APR2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1083 10831085	Immune system disorders	Allergy to animal	01JAN1979		Y
			Allergy to vaccine	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Tendonitis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1083 10831089	Eye disorders	Cataract	01JAN2008	31DEC2008	N
		Infections and infestations	Hepatitis A	01JAN1977	31DEC1977	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Alcoholism	01JAN1972		Y
		Social circumstances	Tobacco user	01JAN1971	31DEC2012	N
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
	C4591001 1083 10831092	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Morton's neuralgia	01JAN2011	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Neurectomy	01DEC2019		Y
	C4591001 1083 10831095	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Hypoacusis	01JAN2013		Y
		Gastrointestinal disorders	Constipation	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
			Hypokalaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1083 10831096	Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Obesity	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Dyspnoea	01JAN2019	30NOV2019	N
			Rhinitis allergic	01JAN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Coronary arterial stent insertion	01NOV2019	30NOV2019	N
			Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hot flush	01JAN1998		Y
			Hypertension	01JAN2011		Y
	C4591001 1083 10831097	Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
	C4591001 1083 10831100	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2015	N
		Hepatobiliary disorders	Cholecystitis	01JAN1996	31DEC1996	N
		Infections and infestations	Diverticulitis	01JAN2012	31AUG2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Reproductive system and breast disorders	Cystocele	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN1990	31DEC2015	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831103	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017	31JAN2021	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1083 10831104	Investigations	Heart rate decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Trigeminal neuralgia	01JAN1990	31DEC1990	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01MAR2020		Y
		Surgical and medical procedures	Finger amputation	01JAN1966	31DEC1966	N
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1083 10831107	Cardiac disorders	Coronary artery disease	01JAN1996		Y
			Myocardial infarction	01JAN1996	31DEC1996	N
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Macular degeneration	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Intraocular lens implant	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1083 10831108	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Food allergy	01FEB2020		Y
			Rubber sensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Vitamin B complex deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1980	31DEC1980	N
	C4591001 1083 10831110	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	17AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2000	31DEC2000	N
	C4591001 1083 10831111	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	17AUG2020		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1083 10831114	Cardiac disorders	Arrhythmia	01JAN2015		Y
			Coronary artery disease	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1083 10831115	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1955		Y
		Infections and infestations	Herpes simplex	01JAN1969		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005	31DEC2011	N
		Surgical and medical procedures	Cancer surgery	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Gastrectomy	01JAN2011	31DEC2011	N
	C4591001 1083 10831116	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1083 10831117	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Skin neoplasm excision	01JAN2019	31DEC2019	N
		Vascular disorders	Hot flush	01JAN2001		Y
	C4591001 1083 10831120	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1083 10831121	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1083 10831125	Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN1980		Y
		Nervous system disorders	Epilepsy	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1083 10831129	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
			Squamous cell carcinoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1083 10831134	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraocular melanoma	01JAN2003	31DEC2003	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1972		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1083 10831137	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Hearing aid user	01JAN2005		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831138	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
			Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
			Glomerular filtration rate decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN1995		Y
	C4591001 1083 10831144	Eye disorders	Diabetic retinopathy	01JAN2016		Y
			Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Continuous glucose monitoring	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1976		Y
			Obesity	01JAN1973		Y
			Type 2 diabetes mellitus	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01MAR2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1966	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Peripheral nerve neurostimulation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				12NOV2019	12NOV2019	N
		Vascular disorders	Hypertension	01JAN1976		Y
	C4591001 1083 10831146	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1083 10831147	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
			Muscle spasms	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Pigmentation disorder	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1083 10831149	Gastrointestinal disorders	Dyspepsia	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Investigations	Blood triglycerides increased	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
			Back pain	01JAN2001		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Neuropathy peripheral	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977		Y
			Knee arthroplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831155	Endocrine disorders	Hypothyroidism	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Alcoholism	01JAN1995	31DEC1997	N
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2014		Y
			Drug dependence	01JAN1995	31DEC1997	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2017	31DEC2017	N
	C4591001 1083 10831156	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01MAR2019		Y
			Seasonal allergy	01JAN1991		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Obesity	01JAN1978		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1964	31DEC1989	N
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1992	31DEC2018	N
	C4591001 1083 10831158	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
	C4591001 1083 10831159	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN1951		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
		Social circumstances	Postmenopause	01JAN1994		Y
	C4591001 1083 10831165	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1977		Y
	C4591001 1083 10831167	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Knee operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1083 10831168	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Transurethral prostatectomy	01NOV2019	31DEC2019	N
	C4591001 1083 10831172	Eye disorders	Cataract	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	31DEC2011	N
			Inguinal hernia	01JAN2011	31DEC2011	N
		Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Throat cancer	01JAN1999	31DEC1999	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN2011	31DEC2011	N
			Radiation therapy to ear, nose, or throat	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831173	Endocrine disorders	Hypogonadism male	01JAN2009		Y
			Hypothyroidism	01JAN1972		Y
			Testicular failure	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1965		Y
		Investigations	Prostatic specific antigen increased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
			Erectile dysfunction	01JAN2011		Y
			Prostatic mass	01JAN2019		Y
	C4591001 1083 10831175	Gastrointestinal disorders	Umbilical hernia	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1083 10831176	Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2005		Y
		Investigations	C-reactive protein increased	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1083 10831182	Metabolism and nutrition disorders	Haemochromatosis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1083 10831184	Gastrointestinal disorders	Mouth ulceration	01JAN1968		Y
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018		Y
			Squamous cell carcinoma	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2018		Y
		Surgical and medical procedures	Cancer surgery	01JAN2017	31DEC2017	N
				01JAN2018		Y
				01JAN2019	31DEC2019	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005		Y
			Migraine	01JAN1970		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2010	31DEC2010	N
			Uterine prolapse	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
	C4591001 1083 10831190	Ear and labyrinth disorders	Meniere's disease	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Investigations	Computerised tomogram coronary artery	01JUN2020	30JUN2020	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
			Rotator cuff syndrome	01FEB2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31MAR2008	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Breast conserving surgery	01MAR2008	31MAR2008	N
			Cochlea implant	01MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1998		Y
					31DEC1998	N
			Radiotherapy	01MAR2008	31DEC2008	N
			Rotator cuff repair	01FEB2019	28FEB2019	N
		Vascular disorders	Arteriosclerosis	01FEB2020		Y
	C4591001 1083 10831192	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Infections and infestations	Appendicitis perforated	01DEC2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Appendectomy	01DEC2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1083 10831195	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831199	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2017		Y
		Reproductive system and breast disorders	Balanoposthitis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831200	Eye disorders	Eye pruritus	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Lactose intolerance	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
			Intervertebral disc protrusion	01JAN2009	31DEC2009	N
			Osteoporosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of eyelid	01JAN1997	31DEC1999	N
			Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
			Eyelid operation	01JAN1997	31DEC1999	N
			Intervertebral disc operation	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
	C4591001 1083 10831204	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831206	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
			Seasonal allergy	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01APR2018	30APR2018	N
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1083 10831208	Gastrointestinal disorders	Dyspepsia	01JAN1978		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Food allergy	01JAN1965		Y
			Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1992	N
				01JAN1996	31DEC1996	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1083 10831209	Immune system disorders	Seasonal allergy	01JAN1964		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN1970	31DEC1970	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1083 10831215	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Thyroid operation	01JAN2018	31JAN2018	N
	C4591001 1083 10831216	Endocrine disorders	Hypothyroidism	01JAN1965		Y
		Eye disorders	Cataract	01JAN2009	31DEC2009 31DEC2012	N N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017	31DEC2018	N
			Inguinal hernia	01JAN1998	31DEC1998	N
			Mouth ulceration	01JAN1949	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31JAN2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2003		Y
			Erectile dysfunction	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01JAN2019	31JAN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831217	Vascular disorders	Hypertension	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Vitamin D deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN1995		Y
			Transient global amnesia	01MAR2018	31MAR2018	N
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1083 10831218	Social circumstances	Postmenopause	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Seasonal allergy	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1994		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Cardiac disorders	Coronary artery disease	01JAN2016		Y
	C4591001 1083 10831220	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Abscess drainage	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831224	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Helicobacter infection	17JUL2020	31JUL2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JAN1999	31DEC1999	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1975		Y
	C4591001 1083 10831225	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
			Intervertebral disc protrusion	01JAN2011		Y
			Spinal stenosis	01JAN2013	31DEC2013	N
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Social circumstances	Organ donor	12JUL2002	12JUL2002	N
		Surgical and medical procedures	Nephrectomy	12JUL2002	12JUL2002	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
			Spinal nerve stimulator implantation	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1083 10831226	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Metabolism and nutrition disorders	Obesity	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2018		Y
		Psychiatric disorders	Depression	31MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1083 10831228	Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1987	31DEC1987	N
	C4591001 1083 10831229	Vascular disorders	Hypertension	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Rotator cuff syndrome	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN1971		Y
	C4591001 1083 10831230	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Dry mouth	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2020		Y
			Polymyalgia rheumatica	01JAN2015	31DEC2015	N
			Spinal osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Salivary gland neoplasm	01JAN2015	31DEC2015	N
		Psychiatric disorders	Bipolar I disorder	01JAN2019		Y
			Insomnia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1083 10831231	Cardiac disorders	Arrhythmia	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
	C4591001 1083 10831233	Gastrointestinal disorders	Dyspepsia	01MAY2020		Y
			Mouth ulceration	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1996	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1083 10831234	Cardiac disorders	Atrial fibrillation	01JAN2016	31DEC2016	N
		Congenital, familial and genetic disorders	Arnold-Chiari malformation	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01NOV2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831236	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Herpes zoster	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
		Nervous system disorders	Post herpetic neuralgia	01JAN2014		Y
	C4591001 1083 10831237	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Gastrectomy	01JAN2011	31DEC2011	N
	C4591001 1083 10831239	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1083 10831243	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN1997	31DEC2002	N
		Nervous system disorders	Neuropathy peripheral	01JAN2002		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Gastric bypass	01JAN2002		Y
			Hysterectomy	01JAN2008	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1083 10831248	Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1083 10831251	Immune system disorders	Drug hypersensitivity	01AUG2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01APR2019		Y
			Intervertebral disc protrusion	01AUG2019	31AUG2019	N
		Surgical and medical procedures	Rotator cuff repair	01DEC2019	31DEC2019	N
			Spinal fusion surgery	01AUG2019	31AUG2019	N
	C4591001 1083 10831257	Endocrine disorders	Goitre	01JAN2003		Y
		Gastrointestinal disorders	Constipation	23SEP2019		Y
			Dyspepsia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN1975		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2018	30APR2018	N
		Nervous system disorders	Migraine	01JAN1993		Y
		Psychiatric disorders	Insomnia	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN1993		Y
	C4591001 1083 10831261	Cardiac disorders	Atrial fibrillation	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
			Tobacco user	01JAN1964	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1083 10831263	Congenital, familial and genetic disorders	Stargardt's disease	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1083 10831269	Cardiac disorders	Arrhythmia	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tuberculosis	01JAN2005	31DEC2005	N
		Investigations	Blood potassium decreased	01MAR2020		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1083 10831274	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Dry eye	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypoglycaemia	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1967		Y
		Nervous system disorders	Migraine	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982		Y
		Vascular disorders	Hot flush	01JAN1983		Y
	C4591001 1083 10831275	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	16SEP2020		Y
		Nervous system disorders	Circadian rhythm sleep disorder	01APR2020		Y
	C4591001 1083 10831277	Immune system disorders	Food allergy	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1974	31DEC1974	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
			Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Skin neoplasm excision	01JAN1974	31DEC1974	N
	C4591001 1083 10831280	Cardiac disorders	Cardiac failure congestive	01JAN2011		Y
			Myocardial infarction	01JAN2011	31DEC2011	N
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1949		Y
			Chronic obstructive pulmonary disease	01JAN2012		Y
			Sleep apnoea syndrome	01JAN1998		Y
		Social circumstances	Cardiac assistance device user	01JAN2012		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Cataract operation	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
	C4591001 1083 10831283	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2010		Y
			Iodine allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841002	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Caesarean section	29OCT1992	29OCT1992	N
			Oophorectomy bilateral	01JAN2002	31DEC2002	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1084 10841005	Endocrine disorders	Hypothyroidism	01JAN1966		Y
		Eye disorders	Macular degeneration	01JAN2015		Y
			Myopia	01JAN1955		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Colitis ulcerative	01JAN1983		Y
		Immune system disorders	Allergy to plants	01JAN1986		Y
			Drug hypersensitivity	01JAN1950		Y
				01JAN1969		Y
				01JAN1983		Y
				01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
			Chronic sinusitis	01JAN1999	31DEC1999	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Reproductive system and breast disorders	Breast mass	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Appendectomy	01JAN1999	31DEC1999	N
			Breast conserving surgery	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Sinus operation	01JAN1999	31DEC1999	N
		Vascular disorders	Haemorrhage	01JAN1999	31DEC1999	N
			Hypertension	01JAN2005		Y
	C4591001 1084 10841006	Ear and labyrinth disorders	Deafness bilateral	01JAN1983		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN1970	31DEC1970	N
			Hand fracture	01JAN2013	31DEC2013	N
			Upper limb fracture	01JAN1976	31DEC1976	N
		Investigations	Blood cholesterol increased	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01FEB2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01DEC1998		Y
		Psychiatric disorders	Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2002	31DEC2002	N
			Fracture treatment	01JAN1976	31DEC1976	N
				01JAN2013	31DEC2013	N
	C4591001 1084 10841007	Immune system disorders	Allergy to plants	01JAN1980		Y
			Contrast media allergy	01JAN1998		Y
	C4591001 1084 10841010	Gastrointestinal disorders	Constipation	01JAN2010	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN2003		Y
		Infections and infestations	Staphylococcal infection	01JAN2015	31DEC2015	N
			Tonsillitis	01JAN1949	31DEC1949	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1966		Y
			Intervertebral disc protrusion	01JAN1966		Y
			Muscle spasms	01JAN2010		Y
			Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2004		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
			Prostatomegaly	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Rash	01MAR2020	25JUL2020	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
			Knee operation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1949	31DEC1949	N
			Vasectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Aortic aneurysm	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841011	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Immune system disorders	Allergy to plants	01JAN1980		Y
			Drug hypersensitivity	01JAN1965		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Surgical and medical procedures	Sphenoid sinus operation	01NOV2010	30NOV2010	N
	C4591001 1084 10841019	Eye disorders	Visual acuity reduced	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Gastrointestinal bacterial overgrowth	01JUL2019	01JUL2020	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2000	31OCT2000	N
		Psychiatric disorders	Depression	01FEB2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01MAY1992	31MAY1992	N
		Skin and subcutaneous tissue disorders	Rosacea	01MAY2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01OCT2000	31DEC2000	N
			Central venous catheter removal	01MAY2001	31MAY2001	N
			Central venous catheterisation	01OCT2000	31OCT2000	N
			Explorative laparotomy	01MAY1992	31MAY1992	N
		Vascular disorders	Hypertension	01JAN2018	31JUL2020	N
	C4591001 1084 10841020	Eye disorders	Vitreous detachment	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1957	31DEC1957	N
				01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1967	31DEC1967	N
			Inguinal hernia repair	01JAN1957	31DEC1957	N
				01JAN2000	31DEC2000	N
	C4591001 1084 10841021	Blood and lymphatic system disorders	Anaemia	01JAN1975		Y
		Eye disorders	Visual acuity reduced	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1960	31DEC1963	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961	31DEC1966	N
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1084 10841022	Eye disorders	Macular degeneration	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
			Hypercholesterolaemia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2019	31DEC2019	N
			Tendon disorder	01JUN2020	30JUN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N
			Squamous cell carcinoma of skin	01JAN2014	31DEC2017	N
		Surgical and medical procedures	Appendectomy	01JAN2002	31DEC2002	N
			Cancer surgery	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Skin neoplasm excision	01MAR2020	31MAR2020	N
			Tenoplasty	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841024	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
				01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2014	31MAY2015	N
		Reproductive system and breast disorders	Endometriosis	01JAN1992	28FEB1993	N
		Surgical and medical procedures	Bunion operation	01MAY2015	31MAY2015	N
			Caesarean section	11AUG1982	11AUG1982	N
				11NOV1988	11NOV1988	N
				28OCT1987	28OCT1987	N
			Hysterectomy	01FEB1993	28FEB1993	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1084 10841025	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1951	31DEC1951	N
		Infections and infestations	Osteomyelitis	01JAN2009	31DEC2009	N
			Pneumonia	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Eye injury	01JAN1956		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Osteoporosis	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
				01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
				Lung operation	01JAN1990	31DEC1990
			Toe amputation	01JAN2009	31DEC2009	N
	C4591001 1084 10841026	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1958	31DEC1960	N
		Nervous system disorders	Migraine	01JAN1970		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841027	Cardiac disorders	Supraventricular tachycardia	01JAN2018		Y
		Eye disorders	Visual acuity reduced	01JAN2015		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	17MAY2017		Y
			Haematochezia	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Investigations	Blood cholesterol increased	01JAN1996		Y
			Colonoscopy	01DEC2017	31DEC2017	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841028	Eye disorders	Visual acuity reduced	01JAN1962		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2008	31DEC2008	N
			Trigger finger	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN2008	31DEC2008	N
			Limb operation	01JAN2010	31DEC2010	N
			Meniscus operation	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841030	Eye disorders	Visual acuity reduced	01JAN1974		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1958		Y
			Seasonal allergy	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2018	31DEC2018	N
			Nerve injury	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990	31DEC2015	N
			Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2017	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1990	31DEC2015	N
			Muscle operation	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
			Wrist surgery	01JAN2014	31DEC2014	N
			Hiatus hernia	01JAN2015	31DEC2015	N
	C4591001 1084 10841032	Gastrointestinal disorders				
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Nervous system disorders	Headache	01JAN1980		Y
			Sciatica	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Caesarean section	01JAN1991	31DEC1991	N
				01JAN1993	31DEC1993	N
			Endometrial ablation	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841034		Hernia hiatus repair	01JAN2015	31DEC2015	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Visual acuity reduced	01JAN1974		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013		Y
	C4591001 1084 10841037	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011		Y
		Social circumstances	Postmenopause	01OCT2011		Y
		Eye disorders	Cataract	01JAN2019		Y
			Visual acuity reduced	01JAN1961		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Ankle fracture	18JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Rotator cuff syndrome	01JAN2002	31DEC2002	N	
	Psychiatric disorders	Insomnia	01FEB2020		Y	
	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y	
	Social circumstances	Postmenopause	01JAN1991		Y	
	Surgical and medical procedures	Fracture treatment	01JAN2003	31DEC2003	N	
		Rotator cuff repair	01JAN2002	31DEC2002	N	
	Vascular disorders	Hypertension	01JAN2017		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841039	Eye disorders	Glaucoma	01JAN2016		Y
			Visual acuity reduced	01JAN1966		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01OCT2013		Y
			Umbilical hernia	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001	31DEC2001	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2001	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Autism spectrum disorder	01JAN2005		Y
			Depression	01AUG2014		Y
			Post-traumatic stress disorder	01JAN1970	31DEC1970	N
		Reproductive system and breast disorders	Peyronie's disease	01JAN2000		Y
		Surgical and medical procedures	Angioplasty	01JAN2013	31DEC2013	N
			Hernia repair	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
			Knee arthroplasty	01JAN2001	31DEC2001	N
			Prostatectomy	01JAN2002	31DEC2002	N
			Stent placement	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Arterial occlusive disease	01JAN2013	31DEC2013	N
			Hypertension	01JAN2019		Y
	C4591001 1084 10841040	Endocrine disorders	Hypothyroidism	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Visual acuity reduced	01JAN1968		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004	N
			Uterine leiomyoma	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Breast mass	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
			Breast conserving surgery	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084 10841043	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Eye disorders	Cataract	01SEP2019	30SEP2019	N
			Diabetic retinopathy	01JAN2001		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Hepatic steatosis	15JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Investigations	Blood testosterone decreased	01FEB2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2007		Y
		Nervous system disorders	Diabetic neuropathy	01OCT2017		Y
			Transient ischaemic attack	01AUG2017		Y
		Psychiatric disorders	Anxiety	07SEP2017		Y
			Depression	07SEP2017		Y
		Surgical and medical procedures	Cataract operation	01SEP2019	30SEP2019	N
			Foot amputation	01NOV2018	30NOV2018	N
			Tonsillectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1084 10841045	Eye disorders	Cataract	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Visual acuity reduced	01JAN1963		Y
		Gastrointestinal disorders	Appendix disorder	01JAN1963	31DEC1963	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
			Cataract operation	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841046	Cardiac disorders	Arrhythmia	01JAN2014		Y
			Atrial fibrillation	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cardiac failure congestive	01JUN2020		Y
		Gastrointestinal disorders	Hiatus hernia	28APR2017	28APR2017	N
		Infections and infestations	Staphylococcal skin infection	01JAN2016		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN1987	31DEC1987	N
		Investigations	Biopsy lung	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1994	31DEC1994	N
				01JAN2009	31DEC2009	N
		Nervous system disorders	Headache	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
			Oropharyngeal pain	01JAN2017		Y
		Surgical and medical procedures	Bone operation	01JAN1987	31DEC1987	N
			Cancer surgery	01JAN1994	31DEC1994	N
				01JAN2009	31DEC2009	N
			Cardiac ablation	01JAN2014	31DEC2014	N
			Cardioversion	01SEP2014	30SEP2017	N
			Hernia repair	28APR2017	28APR2017	N
			Rotator cuff repair	03DEC2019	03DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841048	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
			Diverticulitis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Cataract operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841049	Blood and lymphatic system disorders	Anaemia	01JAN1995		Y
		Eye disorders	Visual acuity reduced	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1993	31DEC1998	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1989		Y
	C4591001 1084 10841050	Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN2007		Y
		Eye disorders	Cataract	01JAN2016	31DEC2018	N
		Gastrointestinal disorders	Umbilical hernia	18OCT1974	18OCT1974	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2018	N
			Foot deformity	01JAN2002	31DEC2002	N
			Rotator cuff syndrome	01JAN1999	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Breast mass	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Rash	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01SEP2004		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
			Bunion operation	01JAN2002	31DEC2002	N
			Hip arthroplasty	01AUG2018	31AUG2018	N
				01JUN2017	30JUN2017	N
			Rotator cuff repair	01MAY2018	31MAY2018	N
			Umbilical hernia repair	01JAN1976	31DEC1976	N
				18OCT1974	18OCT1974	N
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1084 10841051	Ear and labyrinth disorders	Deafness bilateral	01JAN1988		Y
		Eye disorders	Visual acuity reduced	01JAN1966		Y
		Gastrointestinal disorders	Umbilical hernia	09SEP2018	09SEP2018	N
		Hepatobiliary disorders	Cholecystitis	01JAN1990	31DEC1990	N
		Infections and infestations	Pneumonia	15DEC2012	20DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	24MAY2012	24MAY2012	N
		Renal and urinary disorders	Bladder prolapse	01JAN2018		Y
				01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Endometriosis	01JAN1966	31DEC1988	N
			Infertility	01JAN1988		Y
		Surgical and medical procedures	Abdominoplasty	31JAN2008	31JAN2008	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Gastric bypass	23MAY2002	23MAY2002	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Tendon sheath incision	21FEB2020	21FEB2020	N
				28AUG2007	28AUG2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Umbilical hernia repair	09SEP2018	09SEP2018	N
			Varicose vein operation	04JUN2018	04JUN2018	N
			Vascular graft	14OCT2014	14OCT2014	N
				21FEB2017	21FEB2017	N
	C4591001 1084 10841052	Cardiac disorders	Tachycardia	01JAN2004		Y
		Eye disorders	Visual acuity reduced	01JAN1964		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
			Inguinal hernia	01JAN1980	31DEC1980	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Foot deformity	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2004		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2012		Y
			Inguinal hernia repair	01JAN1980	31DEC1980	N
			Mammoplasty	01JAN1992	31DEC1992	N
			Otoplasty	01JAN1974	31DEC1974	N
			Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1084 10841053	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Low density lipoprotein increased	01JAN2015		Y
	C4591001 1084 10841063	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Eye disorders	Visual acuity reduced	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Infections and infestations	Sinusitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1984	31DEC1986	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	04APR1990	04APR1990	N
				26MAY1986	26MAY1986	N
			Female sterilisation	04APR1990	04APR1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841065	Eye disorders	Visual acuity reduced	01JAN1970		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
	C4591001 1084 10841067	Eye disorders	Cataract	01JUN2019		Y
			Visual acuity reduced	01JAN2005		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Immune system disorders	Iodine allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2019	31JUL2019	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC1980	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01JUL2019	31JUL2019	N
			Transurethral prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841070	Eye disorders	Visual acuity reduced	01JAN1970		Y
		General disorders and administration site conditions	Cyst	01JAN2006	31DEC2006	N
				01OCT2019	31OCT2019	N
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1989		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Neck surgery	01JAN2006	31DEC2006	N
			Wound closure	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084 10841074	Eye disorders	Cataract	01JAN2019		Y
			Visual acuity reduced	01JAN1959		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
		Infections and infestations	Herpes simplex	01JAN2003		Y
					31DEC2003	N
		Investigations	Precancerous cells present	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Decreased appetite	01JAN1997	31DEC1997	N
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Incontinence	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2000		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2016	31DEC2016	N
			Cervicectomy	01JAN2010	31DEC2010	N
			Mammoplasty	01JAN2006	31DEC2006	N
			Urinary bladder suspension	01JAN2003	31DEC2003	N
			Uterine dilation and curettage	01JAN1980	31DEC1980	N
		Eye disorders	Cataract	01JAN2017		Y
			Visual acuity reduced	01JAN2015		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1998		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841075	Eye disorders	Visual acuity reduced	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841078	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Tinnitus	01JAN1976		Y
			Vertigo	01JAN1976		Y
		Eye disorders	Visual acuity reduced	01JAN1990		Y
		Gastrointestinal disorders	Gastrointestinal ulcer	01JAN1990	31DEC1995	N
			Gastrooesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841080	Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Visual impairment	01JAN1984		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN1999		Y
		Renal and urinary disorders	Urge incontinence	01NOV2019		Y
		Reproductive system and breast disorders	Infertility	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841088	Ear and labyrinth disorders	Deafness bilateral	01JAN1998		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Visual acuity reduced	01JAN1994		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN1993		Y
			Infected bite	01JAN2014	31DEC2014	N
			Septic shock	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN1993		Y
			Trigger finger	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
		Nervous system disorders	Carotid artery disease	01JAN2019		Y
			Transient ischaemic attack	01JUN2019	30JUN2019	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2016	31DEC2016	N
			Cataract operation	01JAN2018	31DEC2018	N
			Ligament operation	01JAN1959	31DEC1959	N
			Prostatectomy	01JAN2005	31DEC2005	N
			Spinal laminectomy	01JAN1993	31DEC1993	N
			Tendon sheath incision	01JAN2015	31DEC2015	N
	C4591001 1084 10841093	Endocrine disorders	Hypothyroidism	01JAN2018	31DEC2018	N
			Thyroid disorder	01JAN2018	31DEC2018	N
		Eye disorders	Visual acuity reduced	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Genital herpes	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1980		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Renal stone removal	01JAN2018	31DEC2018	N
			Thyroidectomy	01JAN2018	31DEC2018	N
	C4591001 1084 10841096	Eye disorders	Visual acuity reduced	01JAN1971		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1084 10841103	Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Eye disorders	Visual acuity reduced	01JAN1985		Y
		Infections and infestations	Diverticulitis	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1084 10841106	Cardiac disorders	Bradycardia	01JAN1964		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Visual acuity reduced	01JAN1995		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
	C4591001 1084 10841108	Infections and infestations	Urinary tract infection	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1971	31DEC1971	N
			Foot fracture	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01SEP2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841109	Eye disorders	Visual acuity reduced	01JAN1978		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1983		Y
		Injury, poisoning and procedural complications	Ankle fracture	17APR1999	17APR1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1978	31DEC1978	N
			Asthma	01JAN1969		Y
			Rhinitis allergic	01JAN1964		Y
	C4591001 1084 10841110	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1985	31DEC1985	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Infections and infestations	Sepsis	24FEB2015	24FEB2015	N
		Investigations	Biopsy prostate	23FEB2015	23FEB2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001	31DEC2002	N
		Nervous system disorders	Parkinson's disease	01SEP2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01SEP2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN1985	31DEC1985	N
			Spinal operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1084 10841112	Endocrine disorders	Goitre	01JAN1993		Y
			Hypothyroidism	01JAN1993		Y
		Eye disorders	Visual acuity reduced	01JAN1982		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
		Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1084 10841116	Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Corneal transplant	01JAN2005	31DEC2005	N
	C4591001 1084 10841125	Cardiac disorders	Myocardial infarction	01JAN2007	31DEC2007	N
		Eye disorders	Visual acuity reduced	01JAN2017		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1988	31DEC1988	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb injury	01JAN2006	31DEC2006	N
			Rib fracture	01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2008		Y
		Renal and urinary disorders	Nephropathy	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Haemorrhoid operation	01JAN1988	31DEC1988	N
			Knee operation	01JAN2014	31DEC2014	N
			Shoulder operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1084 10841127	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Eye disorders	Visual acuity reduced	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Pancreatitis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Intervertebral disc protrusion	01JAN1980	31DEC1980	N
			Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1995	N
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N
			Gastrectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2014	31DEC2014	N
			Spinal laminectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841128	Eye disorders	Cataract	01JAN2002	31DEC2002	N
				01JAN2004	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016	31DEC2017	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Allergy to animal	01JAN1995		Y
			Allergy to chemicals	01JAN1962		Y
			Drug hypersensitivity	01JAN1979		Y
				01JAN1982		Y
			Food allergy	01JAN1981		Y
			Seasonal allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2005	31DEC2019	N
			Chronic kidney disease	01JAN2018		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1994	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1962		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rosacea	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2002	31DEC2002	N
				01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN1985	31DEC1985	N
			Hernia repair	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Urinary bladder suspension	01JUN2019	30JUN2019	N
	C4591001 1084 10841130	Eye disorders	Visual acuity reduced	01JAN1966	31DEC2010	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2009		Y
		General disorders and administration site conditions	Hernia	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1991		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1966		Y
			Depression	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841131	Eye disorders	Corneal disorder	01JAN2010	31DEC2020	N
		Immune system disorders	Hypersensitivity	01JAN2014		Y
		Infections and infestations	Bronchitis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Spinal operation	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841132	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
			Vertigo positional	01JAN1970		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Infections and infestations	Bronchitis	01JAN2012	31DEC2012	N
			Pneumonia	01JAN1968	31DEC1968	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1982		Y
			Spinal osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1982	31DEC1982	N
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Gastric banding	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Knee arthroplasty	01APR2017	30APR2017	N
			Oophorectomy	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1084 10841133	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Dehydration	01JAN2017	31DEC2017	N
			Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841134	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spondylolisthesis	01JAN1986		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Varicocele	01JAN1985		Y
		Surgical and medical procedures	Cancer surgery	01JAN1997	31DEC1997	N
			Gastric bypass	01JAN2011	31DEC2011	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Knee operation	01JAN1980	31DEC2016	N
			Shoulder arthroplasty	01JAN1995	31DEC1995	N
			Spinal fusion surgery	01JAN1999	31DEC1999	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1084 10841135	Eye disorders	Visual acuity reduced	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Infections and infestations	Appendicitis	01FEB1984	29FEB1984	N
		Injury, poisoning and procedural complications	Animal bite	01OCT2019	31OCT2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JUN1999	30JUN1999	N
		Reproductive system and breast disorders	Prostatitis	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01FEB1984	29FEB1984	N
			Pneumonectomy	01JUN1999	30JUN1999	N
			Rabies immunisation	01OCT2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1084 10841139	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2013	31DEC2013	N
		Investigations	Colonoscopy	09AUG2018	09AUG2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Hernia repair	01JAN2013	31DEC2013	N
	C4591001 1084 10841140	Cardiac disorders	Cardiac disorder	01SEP2014	01SEP2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Spinal stenosis	01JAN2009		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2009	31DEC2009	N
			Stent placement	01SEP2014	01SEP2014	N
		Vascular disorders	Hypertension	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841142	Injury, poisoning and procedural complications	Ankle fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Surgical and medical procedures	Cancer surgery	01JAN2011	31DEC2011	N
			Fracture treatment	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841144	Endocrine disorders	Thyroid mass	01JAN2008	31DEC2008	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1973	31DEC1973	N
		Nervous system disorders	Headache	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1973	31DEC1973	N
			Thyroidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1948	31DEC1948	N
			Wrist surgery	01JAN2015	31DEC2015	N
	C4591001 1084 10841145	Ear and labyrinth disorders	Ear pain	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	19MAY1992	19MAY1992	N
		Surgical and medical procedures	Appendectomy	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1992	31DEC1992	N
			Hysterectomy	19MAY1992	19MAY1992	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1084 10841147	Blood and lymphatic system disorders	Anaemia	01JAN1970		Y
		Cardiac disorders	Sinus node dysfunction	01JAN2015	31DEC2015	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Age-related macular degeneration	01JAN2015		Y
			Dry eye	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Irritable bowel syndrome	01JAN2015		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2005		Y
		Immune system disorders	Sarcoidosis	01JAN1994	31DEC1994	N
		Infections and infestations	Urinary tract infection	01JAN1960		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2003		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1999	31DEC1999	N
			Neuralgia	01JAN1999		Y
			Sciatica	01JAN1989		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1998		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1977	31DEC1977	N
			Fibrocystic breast disease	01JAN1970		Y
			Ovarian cyst	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1979	31DEC1979	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1957		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Actinic keratosis	01JAN2008		Y
		Surgical and medical procedures	Cancer surgery	01JAN2017	31DEC2017	N
			Cardiac pacemaker insertion	01JAN2015	31DEC2015	N
			Carpal tunnel decompression	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN1977	31DEC1977	N
			Knee arthroplasty	01JAN1998	31DEC1998	N
				01JAN2005	31JAN2005	N
				01SEP2005	30SEP2005	N
			Oophorectomy	01JAN1986	31DEC1986	N
			Rhinoplasty	01JAN1979	31DEC1979	N
			Shoulder arthroplasty	01JAN1989	31DEC1989	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1084 10841149	Blood and lymphatic system disorders	Anaemia	01JAN1960		Y
		Cardiac disorders	Coronary artery disease	01JAN2007		Y
			Myocardial infarction	15JAN2007	15JAN2007	N
		Eye disorders	Cataract	01JAN2001	31DEC2015	N
			Diabetic retinopathy	01JAN2007		Y
			Visual acuity reduced	01JAN1955		Y
		Infections and infestations	Bronchitis	01JAN1969	31DEC2009	N
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Back pain	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2007		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1955	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Coronary artery bypass	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Vitrectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1084 10841150	Ear and labyrinth disorders	Deafness unilateral	01JAN1998		Y
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Visual acuity reduced	01JAN1956		Y
		Gastrointestinal disorders	Appendix disorder	01JAN1958	31DEC1958	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013	31DEC2013	N
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2007	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1958	31DEC1958	N
			Colectomy	01JAN2008	31DEC2008	N
			Explorative laparotomy	01JAN1978	31DEC1978	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N
			Temporomandibular joint surgery	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841151	Cardiac disorders	Palpitations	01JAN2019		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Keratomileusis	01JAN2013	31DEC2013	N
			Nerve block	01FEB2020	29FEB2020	N
			Vasectomy	01JAN1978	31DEC1978	N
	C4591001 1084 10841152	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Bunion operation	01JAN1996	31DEC1996	N
			Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Sinus operation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841157	Hepatobiliary disorders	Hepatic steatosis	01JAN2015	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985	31DEC2017	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841158	Eye disorders	Myopia	01JAN2002	31DEC2002	N
			Visual acuity reduced	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Photorefractive keratectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841160	Eye disorders	Visual acuity reduced	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Varicocele	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Spinal laminectomy	01JAN2000	31DEC2000	N
			Surgery	01JAN1978	31DEC1978	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1084 10841161	Eye disorders	Visual acuity reduced	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1979	31DEC1979	N
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	30SEP2019	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Surgical and medical procedures	Circumcision	01JAN2009	31DEC2009	N
			Debridement	01JAN1968	31DEC1968	N
			Hernia repair	01JAN1999	31DEC1999	N
			Polypectomy	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1084 10841162	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841165	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN1975		Y
			Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2011	N
			Spinal osteoarthritis	01JAN1955	31DEC2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1975	31DEC1975	N
			Prostate cancer	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Exeresis	01JAN2013	31DEC2013	N
			Hip arthroplasty	01FEB2011	28FEB2011	N
				01JUL2010	31JUL2010	N
			Skin neoplasm excision	01JAN1975	31DEC1975	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
			Stent placement	01APR2017	30APR2017	N
	C4591001 1084 10841166	Eye disorders	Cataract	01JAN2013		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Muscle injury	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
			Scoliosis	01JAN1981		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1988	31DEC1988	N
		Social circumstances	Postmenopause	01JAN1988		Y
		Surgical and medical procedures	Appendectomy	01JAN1954	31DEC1954	N
	C4591001 1084 10841167	Eye disorders	Cataract	01JAN2008	31DEC2010	N
			Visual acuity reduced	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01APR2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2007	31DEC2012	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1990		Y
		Surgical and medical procedures	Cancer surgery	01JAN2010	31DEC2010	N
			Cataract operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Mastectomy	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
	C4591001 1084 10841168	Investigations	Biopsy breast	01JAN1970	31DEC1970	N
			Colonoscopy	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1084 10841169	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Eye disorders	Visual acuity reduced	01JAN1952		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
			Trigger finger	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN1951	31DEC1951	N
			Cataract operation	01NOV2008	30NOV2008	N
				01SEP2008	30SEP2008	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
			Stent placement	01JAN2010	31DEC2010	N
			Tendon sheath incision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1949	31DEC1949	N
			Vasectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841171	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841172	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1947	31DEC1947	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Finger amputation	01JAN1985	31DEC1985	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1947	31DEC1947	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841173	Cardiac disorders	Palpitations	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Cataract	01JAN2012		Y
			Visual acuity reduced	01JAN1980		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1969		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1975		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Microsurgery to hand	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841174	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	27NOV2007	27NOV2007	N
		Surgical and medical procedures	Hysterectomy	27NOV2007	27NOV2007	N
	C4591001 1084 10841175	Ear and labyrinth disorders	Tinnitus	01JAN2004		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2003	31DEC2012	N
		Surgical and medical procedures	Meniscus operation	01JAN2006	31DEC2006	N
			Skin lesion removal	01JAN2018	31DEC2018	N
	C4591001 1084 10841176	Gastrointestinal disorders	Umbilical hernia	01JAN1990	31DEC1999	N
				01JAN2012	31DEC2012	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Nasal operation	01JAN1985		Y
			Umbilical hernia repair	01JAN1991	31DEC1999	N
				01JAN2012	31DEC2012	N
	C4591001 1084 10841177	Endocrine disorders	Hyperthyroidism	01JAN2013		Y
		Eye disorders	Visual acuity reduced	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1084 10841178	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN1965		Y
		Eye disorders	Visual acuity reduced	01JAN1961		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1974	31DEC1974	N
					31DEC1975	N
		Psychiatric disorders	Depression	01JAN1996	31DEC1997	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1979	31DEC1983	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1974	31DEC1974	N
				01JAN1975	31DEC1975	N
			Ovarian cystectomy	01JAN1979	31DEC1979	N
				01JAN1983	31DEC1983	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1084 10841180	Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Diabetic retinopathy	01JAN2010		Y
			Glaucoma	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2012		Y
					31DEC2012	N
			Coronary artery bypass	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841183	Surgical and medical procedures	Stent placement	01JAN2017	31DEC2017	N
		Vascular disorders	Arterial occlusive disease	01JAN2017		Y
	C4591001 1084 10841184	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Eye disorders	Cataract	01JAN2019		Y
					29FEB2020	N
			Visual acuity reduced	01JAN1967		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2017	31DEC2017	N
		General disorders and administration site conditions	Facial pain	01JAN2016		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
			Vitamin B12 deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Myasthenia gravis	01JAN1980		Y
		Surgical and medical procedures	Cataract operation	01FEB2020	29FEB2020	N
			Cholecystectomy	01JAN1982	31DEC1982	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1084 10841190	Eye disorders	Cataract	01JAN2013	31DEC2015	N
			Visual acuity reduced	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2002	31DEC2018	N
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	19DEC2020	N
			Osteoarthritis	01JAN1983		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Nervous system disorders	Diabetic neuropathy	01JAN2004		Y
			Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2018	31DEC2018	N
			Knee arthroplasty	01OCT2019	31OCT2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JUN2019	30JUN2019	N
			Ventriculo-peritoneal shunt	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841191	Cardiac disorders	Angina pectoris	01AUG1994		Y
			Coronary artery disease	01JAN1994		Y
		Eye disorders	Cataract	01NOV2015	30NOV2015	N
				01OCT2015	31OCT2015	N
		General disorders and administration site conditions	Chest pain	01AUG1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1974		Y
			Type 2 diabetes mellitus	01JAN1974		Y
			Vitamin B complex deficiency	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Arthritis	01SEP1996		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2008	31OCT2008	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2012		Y
			Keratosis pilaris	01AUG2012		Y
		Surgical and medical procedures	Cataract operation	01NOV2015	30NOV2015	N
				01OCT2015	31OCT2015	N
			Coronary artery bypass	01JAN1994	31DEC1994	N
			Knee operation	01JAN1962	31DEC1962	N
			Renal stone removal	01OCT2008	31OCT2008	N
			Skin cryotherapy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1084 10841192	Eye disorders	Visual acuity reduced	01JAN1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841193	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000	31DEC2015	N
			Osteoarthritis	01JAN1988		Y
			Synovial cyst	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1961	31DEC1996	N
			Pulmonary embolism	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Cholecystectomy	01APR2018	30APR2018	N
			Knee arthroplasty	01NOV2018	31DEC2018	N
			Nasal septal operation	01JAN1996	31DEC1996	N
			Shoulder operation	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
			Spinal operation	01JAN2015	31DEC2015	N
			Synovial cyst removal	01JAN2002	31DEC2002	N
			Tenoplasty	01JAN2000	31DEC2000	N
		Vascular disorders	Angiopathy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Deep vein thrombosis	01JAN1982	31DEC1982	N
			Hypertension	01JAN2005		Y
	C4591001 1084 10841194	Eye disorders	Visual acuity reduced	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2004	31DEC2004	N
	C4591001 1084 10841195	Ear and labyrinth disorders	Deafness bilateral	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	22MAY2020	22MAY2020	N
			Intervertebral disc protrusion	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Bunion operation	22MAY2020	22MAY2020	N
			Intervertebral disc operation	01JAN2009	31DEC2009	N
			Skin neoplasm excision	01JAN2009	31DEC2009	N
	C4591001 1084 10841196	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Eye disorders	Visual acuity reduced	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1995	31DEC1996	N
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Bladder prolapse	01JAN2016	31DEC2018	N
		Surgical and medical procedures	Appendectomy	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast conserving surgery	01JAN1995	31DEC1995	N
			Caesarean section	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Urinary bladder suspension	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
	C4591001 1084 10841198	Eye disorders	Visual acuity reduced	01JAN1963		Y
		Infections and infestations	Pneumonia	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1966	31DEC1974	N
		Surgical and medical procedures	Metacarpal excision	22NOV2013	22NOV2013	N
			Umbilical hernia repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841202	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Spinal pain	01JAN1997	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Intervertebral disc operation	01JAN1998	31DEC1998	N
			Limb operation	17FEB2020	17FEB2020	N
			Spinal fusion surgery	01JAN1998	31DEC1998	N
	C4591001 1084 10841203	Eye disorders	Visual acuity reduced	01JAN1974		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Injury, poisoning and procedural complications	Ligament rupture	01DEC2019	24DEC2019	N
			Meniscus injury	01DEC2019	24DEC2019	N
		Investigations	Blood calcium increased	01SEP2019		Y
			Catheterisation cardiac	01SEP2019	30SEP2019	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1980	08JUN2020	N
			Rotator cuff syndrome	01JAN1976	31DEC1976	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2018	10AUG2020	N
			Sleep apnoea syndrome	01SEP2019		Y
		Surgical and medical procedures	Arthrodesis	08JUN2020	08JUN2020	N
			Gastrectomy	01JAN2010	31DEC2010	N
			Keratomileusis	01JAN2003	31DEC2003	N
			Knee operation	24DEC2019	24DEC2019	N
			Nasal septal operation	10AUG2020	10AUG2020	N
			Tonsillectomy	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841204	Eye disorders	Cataract	01JAN2017		Y
			Visual acuity reduced	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Gallbladder rupture	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
				01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1990	31DEC1990	N
				01JAN2020	31JAN2020	N
			Squamous cell carcinoma	01APR2020	30APR2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Hip arthroplasty	01JAN2004	31DEC2004	N
				01JAN2011	31DEC2011	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
			Limb operation	01APR2020	30APR2020	N
				01JAN2020	31JAN2020	N
			Skin operation	01JAN1990	31DEC1990	N
			Spinal operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841205	Eye disorders	Cataract	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Visual acuity reduced	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
			Uterine leiomyoma	01JAN1991	31DEC1991	N
		Renal and urinary disorders	Hypertonic bladder	01JAN1985	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
			Spinal fusion surgery	17AUG2017	17AUG2017	N
	C4591001 1084 10841206	Congenital, familial and genetic disorders	Atrial septal defect	01JAN2013	31DEC2013	N
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Visual acuity reduced	01JAN1955		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2013	31DEC2013	N
			Cataract operation	01JAN2018	31DEC2018	N
	C4591001 1084 10841207	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Visual acuity reduced	01JAN2017		Y
		Surgical and medical procedures	Cancer surgery	01JAN1995	31DEC1995	N
			Cataract operation	01JAN2017	31DEC2017	N
			Keratomileusis	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841210	Cardiac disorders	Atrial fibrillation	01JAN1998	30SEP2016	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Cardiac ablation	01SEP2016	30SEP2016	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1084 10841211	Eye disorders	Blepharitis	01JAN2017	31DEC2017	N
			Cataract	01JAN2010	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1997	31DEC2003	N
			Trigger finger	01JAN1995	31DEC2003	N
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2017	31DEC2017	N
			Eye operation	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Shoulder operation	01JAN2003	31DEC2003	N
				01NOV1997	30NOV1997	N
			Tendon sheath incision	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1084 10841212	Cardiac disorders	Coronary artery disease	01JAN1989	31DEC1989	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1972		Y
		Eye disorders	Visual acuity reduced	01JAN1990	31DEC1990	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Immune system disorders	Allergy to plants	01JAN1985		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841213	Eye disorders	Visual acuity reduced	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercalcaemia	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basosquamous carcinoma	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1972	31DEC1982	N
			Sleep apnoea syndrome	01APR2020		Y
			Tonsillar hypertrophy	01JAN1958	31DEC1958	N
		Surgical and medical procedures	Parathyroidectomy	01JAN2014	31DEC2014	N
			Sinus operation	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1958	31DEC1958	N
			Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1084 10841216	Cardiac disorders	Tachycardia	01JAN2011	31DEC2011	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Visual acuity reduced	01JAN1959		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1998		Y
		Investigations	Biopsy breast	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Breast mass	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2011	31DEC2011	N
			Eye operation	01JAN1967	31DEC1967	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1084 10841217	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteoma	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Bilateral orchidectomy	01JUN2020	30JUN2020	N
		Vascular disorders	Thrombosis	01JAN1996	31DEC1996	N
	C4591001 1084 10841218	Surgical and medical procedures	Bone marrow donation	01JAN2002	31DEC2002	N
	C4591001 1084 10841219	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Eye disorders	Visual acuity reduced	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Limb mass	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bone neoplasm	01JAN2004	31DEC2004	N
			Haemangioma of liver	01JAN2009	31DEC2009	N
			Oral neoplasm	01JAN2010	31DEC2010	N
		Nervous system disorders	Headache	01JAN1983		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01MAY2020		Y
		Renal and urinary disorders	Bladder prolapse	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Foot operation	01JAN2010	31DEC2010	N
			Haemangioma removal	01JAN2009	31DEC2009	N
			Oral cavity neoplasm surgery	01JAN2010	31DEC2010	N
			Spinal operation	01JAN2004	31DEC2004	N
	C4591001 1084 10841221	Eye disorders	Cataract	01JAN2018		Y
			Retinal detachment	01JAN1959	31DEC1959	N
			Visual acuity reduced	01JAN1959		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1994		Y
			Osteopenia	01JAN2010		Y
			Osteoporosis	01JAN2010		Y
		Renal and urinary disorders	Incontinence	01JAN2010		Y
			Nephropathy	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Ankle operation	01JAN2018	31DEC2018	N
			Eye operation	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1084 10841225	Eye disorders	Visual acuity reduced	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1084 10841226	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN1988		Y
		Eye disorders	Amblyopia	01JAN1999		Y
			Astigmatism	01JAN1999		Y
			Cataract	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1978	31DEC1978	N
			Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1978	31DEC1978	N
			Ureterolithotomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841227	Eye disorders	Visual acuity reduced	01JAN2000	31DEC2013	N
		Gastrointestinal disorders	Umbilical hernia	01JAN1974	31DEC1980	N
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fibromyalgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Post-traumatic stress disorder	06AUG2019		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN1985	31DEC2015	N
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN1995		Y
			Urticaria papular	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Baker's cyst excision	01JAN1982	31DEC1982	N
			Female sterilisation	01JAN1977	31DEC1977	N
			Keratomileusis	01JAN2013	31DEC2013	N
			Umbilical hernia repair	01JAN1974	31DEC1974	N
				01JAN1977	31DEC1977	N
				01JAN1980	31DEC1980	N
	C4591001 1084 10841229	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Atrial septal defect repair	(b) (6) 1959	31DEC2007	N
			Caesarean section	01JAN1987	31DEC1987	N
			Cardiac operation	01JAN2007	31DEC2007	N
	C4591001 1084 10841230	Ear and labyrinth disorders	Tinnitus	01JAN1991		Y
		Eye disorders	Cataract	01JAN2010	31DEC2014	N
			Cogan's syndrome	01JAN1990		Y
			Retinal detachment	01JAN2011	31DEC2011	N
			Visual acuity reduced	01JAN1965		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1973	31DEC1973	N
			Foot fracture	01JAN1993	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Biopsy prostate	01FEB2020	29FEB2020	N
			Blood triglycerides increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2008	31DEC2009	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Arthrodesis	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
			Carpal tunnel decompression	01JAN2009	31DEC2009	N
			Cataract operation	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
			Retinopexy	01JAN2011	31DEC2011	N
			Rhinoplasty	01JAN1973	31DEC1973	N
			Sesamoidectomy	01JAN1997	31DEC1997	N
			Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1084 10841231	Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Strabismus	01JAN1962	31DEC1962	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
				01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Ankle operation	01JAN2020	31JAN2020	N
			Cataract operation	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N
		Eye disorders	Macular degeneration	01JAN2017		Y
	C4591001 1084 10841232	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN1995	31DEC2012	N
	C4591001 1084 10841233	Cardiac disorders	Atrial fibrillation	01JAN2012	31DEC2012	N
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Limb fracture	01JAN2011	31DEC2011	N
			Meniscus injury	01JAN2007	31DEC2007	N
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31AUG2019	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Adenoidectomy	01JAN1955	31DEC1955	N
			Cardiac ablation	01JAN2012	31DEC2012	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	01JAN2016	31DEC2016	N
			Meniscus operation	01JAN2007	31DEC2007	N
			Prostatectomy	01AUG2019	31AUG2019	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1084 10841235	Eye disorders	Cataract	01MAY2020		Y
			Myopia	01JAN1996		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1084 10841236	Eye disorders	Cataract	01JAN2015	31DEC2017	N
			Visual acuity reduced	01JAN1943		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1990		Y
		Investigations	Biopsy breast	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
			Scoliosis	01JAN1951		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2008	31DEC2008	N
			Menorrhagia	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Eyelid operation	01JAN1999	31DEC1999	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1084 10841238	Cardiac disorders	Atrial fibrillation	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2019	31DEC2020	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
				01JAN2020	31DEC2020	N
			Gastrectomy	01JAN2012	31DEC2012	N
			Shoulder operation	01JAN1965	31DEC1965	N
				01JAN1973	31DEC1973	N
			Vasectomy	01JAN1974	31DEC1974	N
	C4591001 1084 10841239	Blood and lymphatic system disorders	Anaemia	01JAN1960		Y
		Eye disorders	Visual acuity reduced	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
				01JAN1971		Y
		Injury, poisoning and procedural complications	Intervertebral disc injury	01JAN2016	31DEC2016	N
			Meniscus injury	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN1980	31DEC1980	N
			Spinal operation	01JAN2016	31DEC2016	N
			Uterine dilation and curettage	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841240	Ear and labyrinth disorders	Presbycusis	01JAN2005		Y
		Eye disorders	Visual acuity reduced	01JAN1965		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Urinary incontinence	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Prostatectomy	01JAN2009	31DEC2009	N
			Tenoplasty	01JAN2014	31DEC2014	N
	C4591001 1084 10841242	Ear and labyrinth disorders	Presbycusis	01JAN2014		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Uveitis	01JAN2018	31DEC2018	N
			Visual acuity reduced	01JAN1982		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1967		Y
			Large intestine polyp	01JUL2020		Y
			Oesophageal stenosis	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	01JUL2020	31JUL2020	N
			Oesophagogastroduodenoscopy	01JUL2020	31JUL2020	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1961		Y
		Surgical and medical procedures	Intraocular lens implant	01JAN2016	31DEC2016	N
			Rhinoplasty	01JAN1976	31DEC1976	N
			Vitrectomy	01JAN2018	31DEC2018	N
	C4591001 1084 10841243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2006	31DEC2006	N
			Oophorectomy bilateral	01JAN2007	31DEC2007	N
	C4591001 1084 10841244	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31AUG2019	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1989	31DEC1989	N
		Psychiatric disorders	Libido decreased	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6)1961	31DEC1966	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Salpingectomy	01JAN1989	31DEC1989	N
			Skin neoplasm excision	01AUG2019	31AUG2019	N
			Spinal operation	01JAN1983	31DEC1983	N
	C4591001 1084 10841245	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood oestrogen decreased	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841246	Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N
			Umbilical hernia	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Limb injury	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2012	31DEC2012	N
			Leg amputation	01JAN1995	31DEC1995	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841247	Eye disorders	Cataract	01JAN1999	31DEC1999	N
			Vitreous disorder	01MAY2018	31MAY2018	N
		Infections and infestations	Onychomycosis	24JUN2020		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1985	31DEC1985	N
			Osteopenia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Bunion operation	01JAN1985	31DEC1985	N
			Cataract operation	01JAN1999	31DEC1999	N
			Vitrectomy	01MAY2018	31MAY2018	N
	C4591001 1084 10841248	Hepatobiliary disorders	Cholelithiasis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2016		Y
		Surgical and medical procedures	Cholelithotomy	01JAN1981	31DEC1981	N
			Inguinal hernia repair	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841250	Eye disorders	Visual acuity reduced	01JAN2015		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Palatal operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841252	Eye disorders	Visual acuity reduced	01JAN1967		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Arterial repair	01JAN1967	31DEC1967	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Mammoplasty	01JAN2009	31DEC2009	N
	C4591001 1084 10841253	Eye disorders	Myopia	01JAN2005		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Female sterilisation	29OCT1990	29OCT1990	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841256	Cardiac disorders	Myocardial infarction	17SEP2019	17SEP2019	N
		Eye disorders	Visual acuity reduced	01JAN1957		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertriglyceridaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Stent placement	01SEP2019	30SEP2019	N
			Tonsillectomy	01JAN1955	31DEC1955	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841258	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Visual acuity reduced	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Excessive skin	01MAY2020	31MAY2020	N
		Surgical and medical procedures	Eyelid operation	01MAY2020	31MAY2020	N
			Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1084 10841260	Ear and labyrinth disorders	Vertigo	01JAN1982		Y
		Eye disorders	Myopia	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Aspiration	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841261	Blood and lymphatic system disorders	Thrombocytopenia	01JAN1957	31DEC1957	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Visual acuity reduced	01JAN1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Hernia repair	01JAN1994	31DEC1994	N
			Skin neoplasm excision	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1948	31DEC1948	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841264	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Limb injury	01MAY1988	31MAY1988	N
			Tendon rupture	01APR2018	30APR2018	N
		Musculoskeletal and connective tissue disorders	Fistula	01NOV2018	30NOV2018	N
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01AUG2018	31AUG2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2016		Y
		Surgical and medical procedures	Arterial graft	01MAY1988	31MAY1988	N
			Cancer surgery	01JAN2018	31DEC2018	N
			Carpal tunnel decompression	01AUG2018	31AUG2018	N
			Fistula repair	01NOV2018	30NOV2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2013	31DEC2013	N
			Micrographic skin surgery	01JAN2018	31DEC2018	N
			Tenoplasty	01APR2018	30APR2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1084 10841265	Gastrointestinal disorders	Gastrointestinal inflammation	01JAN2008	31DEC2008	N
			Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1950	31DEC1950	N
		Investigations	Prostatic specific antigen increased	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Cough	01JAN2018		Y
		Surgical and medical procedures	Jejunal operation	01JAN2008	31DEC2008	N
			Limb operation	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841266	Cardiac disorders	Cardiac failure congestive	01JAN2005		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Ocular hypertension	01JUN2020		Y
		General disorders and administration site conditions	Atrophy	22AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01JAN1975		Y
		Infections and infestations	Gangrene	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2020	N
				01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1985		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Coronary artery bypass	01JAN2005	31DEC2005	N
			Toe amputation	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841271	Eye disorders	Visual acuity reduced	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2018		Y
			Hypercholesterolaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	28FEB2014	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Mastectomy	01FEB2014	28FEB2014	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1084 10841276	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN2014		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma	01JAN1987	31DEC1987	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01APR2020		Y
			Depression	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Thoracotomy	01JAN1987	31DEC1987	N
	C4591001 1084 10841278	Eye disorders	Visual acuity reduced	01JAN1981		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2001	31DEC2001	N
		Investigations	Bacterial test positive	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
			Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Arthroscopic surgery	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841282	Ear and labyrinth disorders	Deafness	01JAN2004		Y
			Tinnitus	01JAN2004		Y
		Eye disorders	Visual acuity reduced	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2012	31DEC2012	N
		Investigations	Colonoscopy	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Musculoskeletal and connective tissue disorders	Osteoporosis	01SEP2019		Y	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y	
		Surgical and medical procedures	Cholecystectomy	01FEB2012	29FEB2012	N	
			Meniscus removal	01DEC1970	31DEC1970	N	
			Spinal operation	01JAN2007	31DEC2007	N	
			Vasectomy	01JAN1987	31DEC1987	N	
			Vertebroplasty	20MAR2018	20MAR2018	N	
			Vascular disorders	Hypertension	01JAN2001		Y
			Endocrine disorders	Hypothyroidism	01JAN1969		Y
	C4591001 1084 10841284	Eye disorders	Visual acuity reduced	01JAN2010		Y	
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N	
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y	
				01JAN2000		Y	
				01JAN2015		Y	
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N	
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y	
			Osteoporosis	01JAN2020		Y	
		Psychiatric disorders	Depression	01JAN1969		Y	
		Reproductive system and breast disorders	Oligomenorrhoea	01JAN1988	31DEC1988	N	
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N	
			Cholecystectomy	01JAN2006	31DEC2006	N	
			Gastric bypass	01JAN2008	31DEC2008	N	
			Hysterectomy	01JAN1988	31DEC1988	N	
			Oophorectomy bilateral	01JAN1988	31DEC1988	N	

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salpingectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1084 10841289	Gastrointestinal disorders	Diverticulum	01JAN2018		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1976	31DEC1976	N
			Hepatic steatosis	01APR2020		Y
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1976	31DEC1976	N
			Caesarean section	01JAN1975	31DEC1975	N
				01JAN1976	31DEC1976	N
				01JAN1982	31DEC1982	N
			Cholecystectomy	01JAN1976	31DEC1976	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Salpingectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1084 10841293	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1084 10841295	Eye disorders	Visual acuity reduced	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
			Latent tuberculosis	01JAN1995		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	12AUG2020	N
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1966		Y
		Surgical and medical procedures	Appendectomy	01JAN1976		Y
			Skin neoplasm excision	01JAN2019	12AUG2020	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1084 10841296	Immune system disorders	Allergy to animal	01JAN2017		Y
			Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Sepsis	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1992	31DEC1992	N
			Foot operation	01JAN2007	31DEC2007	N
			Spinal operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1084 10841297	Eye disorders	Cataract	01JAN2010		Y
			Glaucoma	01JAN1990		Y
			Retinal tear	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
			Erectile dysfunction	01JAN2005		Y
		Surgical and medical procedures	Retinal operation	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1084 10841298	Eye disorders	Visual acuity reduced	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1990		Y
		Infections and infestations	Herpes zoster	01JAN2011		Y
			Tonsillitis	01JAN1961	31DEC1961	N
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
			Nasal septal operation	01JAN1960	31DEC1960	N
				01JAN1974	31DEC1974	N
				01JAN1986	31DEC1986	N
			Rhinoplasty	01JAN1960	31DEC1960	N
				01JAN1974	31DEC1974	N
				01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1961	31DEC1961	N
	C4591001 1084 10841299	Eye disorders	Visual acuity reduced	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
	C4591001 1084 10841300	Cardiac disorders	Atrial fibrillation	01SEP2016		Y
		Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Squamous cell carcinoma	01JAN2014	31DEC2014	N
			Cardioversion	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1084 10841302	Eye disorders	Visual acuity reduced	01JAN2008		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2008		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1980	31DEC1980	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
	C4591001 1084 10841304	Eye disorders	Visual acuity reduced	01JAN2012		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
			Hepatic steatosis	01JAN2017	31DEC2020	N
		Injury, poisoning and procedural complications	Humerus fracture	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01AUG2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1988	31DEC1988	N
			Urinary bladder suspension	01JUN2017	30JUN2017	N
	C4591001 1084 10841305	Immune system disorders	Hypersensitivity	01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1084 10841310	Eye disorders	Visual acuity reduced	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2000	31DEC2000	N
	C4591001 1084 10841313	Eye disorders	Dry eye	01JAN2000		Y
			Visual acuity reduced	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Infections and infestations	Chronic tonsillitis	01JAN1974	31DEC1994	N
		Metabolism and nutrition disorders	Diabetes mellitus	01DEC2019		Y
			Hypolipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1980	31DEC1980	N
			Renal cancer	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Nephrectomy	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841314	Eye disorders	Visual acuity reduced	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2012	31DEC2012	N
			Mastectomy	01JAN2011	31DEC2011	N
			Hypothyroidism	01JAN1998		Y
	C4591001 1084 10841319	Endocrine disorders				
		Eye disorders	Cataract	01APR2019	31AUG2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
			Irritable bowel syndrome	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal stenosis	01JAN1985		Y
			Carpal tunnel syndrome	01JAN1998	31DEC1999	N
		Nervous system disorders	Migraine	01JAN1981		Y
			Anxiety	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
			Surgical and medical procedures	Arthroscopic surgery	01JAN2000	31DEC2000
				01JAN2001	31DEC2001	N
				Caesarean section	01JAN1993	01JAN1993

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				02FEB1987	02FEB1987	N
				21OCT1992	21OCT1992	N
			Carpal tunnel decompression	01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
			Cataract operation	01APR2019	30APR2019	N
				01AUG2019	31AUG2019	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Neuroprosthesis implantation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
	C4591001 1084 10841320	Eye disorders	Visual acuity reduced	01JAN1957	31DEC1957	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Infections and infestations	Bronchitis	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2004	31DEC2004	N
				01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2006		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1953		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN2004	31DEC2004	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1084 10841323	Eye disorders	Myopia	01JAN1977		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Facial operation	01JAN1981	31DEC1981	N
	C4591001 1084 10841325	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Visual acuity reduced	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Carpal tunnel decompression	01FEB2020	29FEB2020	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1084 10841326	Eye disorders	Blepharitis	01OCT2019	29FEB2020	N
			Visual acuity reduced	01JAN1971		Y
		Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
		Reproductive system and breast disorders	Fallopian tube cyst	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
			Blepharoplasty	01FEB2020	29FEB2020	N
			Cardiac pacemaker insertion	07DEC2012	07DEC2012	N
			Cyst removal	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841329	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1084 10841331	Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N
			Tenoplasty	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841332	Ear and labyrinth disorders	Deafness unilateral	01JAN1965		Y
		Eye disorders	Visual acuity reduced	01JAN1977		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Rhinitis	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Nervous system disorders	Headache	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
			Nasal septum deviation	01JAN1995	31DEC1995	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
			Eczema	01JAN1968		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
			Uvulectomy	01JAN1995	31DEC1995	N
	C4591001 1084 10841335	Eye disorders	Visual acuity reduced	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	19OCT2019		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2004	N
	C4591001 1084 10841336	Cardiac disorders	Myocardial infarction	01JAN2002	31DEC2002	N
		Eye disorders	Visual acuity reduced	01JAN1963		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2000	31DEC2000	N
			Myalgia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC1995	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2002	31DEC2002	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1084 10841337	Congenital, familial and genetic disorders	Cryptorchism	01JAN1960	28FEB2011	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN2013		Y
			Tinnitus	01JAN1995		Y
			Vertigo	01JAN1990		Y
		General disorders and administration site conditions	Inflammation	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018	31DEC2018	N
			Rheumatoid arthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2010	31DEC2010	N
		Nervous system disorders	Epilepsy	01JAN1972		Y
			Neuropathy peripheral	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Ligament operation	01JAN1978	31DEC1978	N
				01JAN1979	31DEC1979	N
			Rotator cuff repair	01JAN2002	31DEC2002	N
			Testicular operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841340	Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2009		Y
			Milk allergy	01JAN2009		Y
			Seasonal allergy	01JAN2009		Y
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Nervous system disorders	Headache	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Keratotomy	01JAN1989	31DEC1989	N
	C4591001 1084 10841341	Eye disorders	Cataract	01OCT2011	22NOV2011	N
			Visual acuity reduced	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2007	31DEC2007	N
				01JAN2012	31DEC2012	N
		Investigations	Laparoscopy	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01SEP2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC1998	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01OCT2011	22NOV2011	N
					27DEC2011	N
			Open reduction of fracture	01JAN2007	31DEC2007	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2012	31DEC2012	N
			Thrombectomy	01JAN1975	05JUL2011	N
					28JAN2011	N
		Vascular disorders	Varicose vein	28JAN1975	31DEC2011	N
	C4591001 1084 10841343	Eye disorders	Visual acuity reduced	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
	C4591001 1084 10841345	Eye disorders	Myopia	01JAN1969		Y
		Investigations	Colonoscopy	01JAN2019	31JAN2019	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1084 10841347	Eye disorders	Visual acuity reduced	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1972		Y
		Infections and infestations	Diverticulitis	01JAN2008		Y
			Tonsillitis	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982	31DEC1982	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rosacea	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Colectomy	01JAN2008	31DEC2008	N
			Laser therapy	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1084 10841349	Eye disorders	Glaucoma	01JAN2005		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01MAY2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1988	31DEC1988	N
			Renal tumour excision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841357	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2019		Y
			Visual acuity reduced	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Investigations	Hysteroscopy	01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2010		Y
		Social circumstances	Postmenopause	01APR2010		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1084 10841361	Eye disorders	Visual acuity reduced	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Arthroscopic surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1084 10841362	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Eye disorders	Strabismus	01JAN2005		Y
			Visual acuity reduced	01JAN2010		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Coronary artery bypass	01DEC2016	31DEC2016	N
			Hernia repair	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1084 10841363	Endocrine disorders	Hypothyroidism	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012	31DEC2012	N
			Hiatus hernia	01JAN2013	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Lung abscess	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Mammoplasty	01JUL2020	31JUL2020	N
			Oesophagogastric fundoplasty	01JAN2014	31DEC2014	N
			Thoracotomy	01JAN2012	31DEC2012	N
	C4591001 1084 10841364	Endocrine disorders	Autoimmune thyroiditis	01JAN1978		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Oophorectomy	01JAN1982	31DEC1982	N
	C4591001 1084 10841366	Gastrointestinal disorders	Inguinal hernia	01JAN2015		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Wrist surgery	01JAN1996	31DEC1996	N
	C4591001 1084 10841367	Cardiac disorders	Coronary artery disease	01JAN2016		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		Ear and labyrinth disorders	Hypoacusis	01JAN2012		Y
		Eye disorders	Cataract	01JAN2018		Y
			Glaucoma	01JAN2014		Y
			Visual acuity reduced	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Xerosis	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01FEB2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Angiopathic neuropathy	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1084 10841368	Cardiac disorders	Atrial fibrillation	01APR2019	30JUN2019	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01JUN2019	30JUN2019	N
			Sinuplasty	01JAN2018	31DEC2018	N
	C4591001 1084 10841369	Eye disorders	Visual acuity reduced	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
				01JAN1996	31DEC1996	N
	C4591001 1084 10841370	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
			Inguinal hernia	01JAN1976	31DEC1976	N
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Onychomycosis	01MAR2020		Y
		Investigations	Blood testosterone decreased	01JAN1998		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01MAY2020		Y
			Type 2 diabetes mellitus	23JUL2013		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
			Inguinal hernia repair	01JAN1976	31DEC1976	N
	C4591001 1084 10841377	Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Abdominal hernia	05JUN2020	05JUN2020	N
			Constipation	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Chronic sinusitis	01JAN1980		Y
		Investigations	Catheterisation cardiac	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2014	31DEC2014	N
			Prostate cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Cerebrovascular accident	01JAN2011	31JUL2011	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1995		Y
			Rash	01JAN2000		Y
		Surgical and medical procedures	Aortic aneurysm repair	01JAN2012	31DEC2012	N
			Carotid endarterectomy	01JAN2011	31DEC2011	N
			Cryotherapy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia repair	05JUN2020	05JUN2020	N
			Radical cystectomy	01JAN2014	31DEC2014	N
			Sinuplasty	01MAR2017	31MAR2017	N
		Vascular disorders	Aortic aneurysm	01JAN2012	31DEC2012	N
			Arteriosclerosis	01JAN2011	31DEC2011	N
			Hypertension	01JAN2012		Y
	C4591001 1084 10841379	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Visual acuity reduced	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1990	31DEC1991	N
		Metabolism and nutrition disorders	Gout	01JAN1997		Y
			Hypercholesterolaemia	01MAY2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
			Back pain	01JAN2017		Y
			Pain in extremity	01JAN2020		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Colectomy	01JAN2012	31DEC2012	N
			Gastric bypass	01JAN2009	31DEC2009	N
			Knee operation	01JAN1991	31DEC1991	N
			Limb operation	01AUG2020	31AUG2020	N
			Shoulder operation	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
			Spinal operation	01MAR2017	31DEC2017	N
			Urinary bladder suspension	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1976	31DEC1976	N
	C4591001 1084 10841380	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Rhinitis	01JAN2016		Y
		Injury, poisoning and procedural complications	Cartilage injury	01MAR2020	25AUG2020	N
			Ligament rupture	01MAR2020	25AUG2020	N
		Investigations	Colonoscopy	01AUG2020	31AUG2020	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN1983	31DEC1983	N
	C4591001 1084 10841383	Eye disorders	Glaucoma	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Intervertebral disc protrusion	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
				01JAN1994	31DEC1994	N
		Skin and subcutaneous tissue disorders	Granuloma annulare	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Glaucoma surgery	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN1975	31DEC1975	N
	C4591001 1084 10841387	Ear and labyrinth disorders	Deafness unilateral	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Visual acuity reduced	01JAN1963		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN1994	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteopenia	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1084 10841389	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Obsessive-compulsive disorder	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Myomectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841392	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Visual acuity reduced	01JAN2005		Y
			Vitreous detachment	01FEB2016	29FEB2016	N
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y
		Hepatobiliary disorders	Hepatic steatosis	19OCT2012	31OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Infections and infestations	Appendicitis	24OCT2017	24OCT2017	N
		Investigations	Biopsy breast	01JAN2000	31DEC2000	N
			Laparoscopy	01JAN1983	31DEC1983	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2001	31DEC2011	N
			Osteoarthritis	31AUG2017		Y
			Rotator cuff syndrome	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Surgical and medical procedures	Appendectomy	24OCT2017	24OCT2017	N
			Bunion operation	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Rotator cuff repair	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
	C4591001 1084 10841395	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Eye disorders	Optic ischaemic neuropathy	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2010	N
		Renal and urinary disorders	Urinary incontinence	01JAN1994		Y
		Reproductive system and breast disorders	Endometrial thickening	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Bladder operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2018	31DEC2018	N
			Mastectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841397	Ear and labyrinth disorders	Deafness	01DEC2015		Y
		Eye disorders	Myopia	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2015	31AUG2015	N
		Nervous system disorders	Amnesia	01JAN2013		Y
			Headache	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Lipoma excision	01AUG2015	31AUG2015	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1084 10841398	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	01JAN2014	31DEC2014	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Coronary artery bypass	01JAN2016	31DEC2016	N
			Plastic surgery to the face	01JAN1971	31DEC1971	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1084 10841399	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Myopia	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Osteopenia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Embolism arterial	01JAN2004	31DEC2004	N
	C4591001 1084 10841400	Eye disorders	Cataract	01JAN2019		Y
			Visual acuity reduced	01JAN1990		Y
		Gastrointestinal disorders	Constipation	01JAN1998		Y
			Diverticulum	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Sinusitis	01JAN1996		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1970	31DEC1999	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Colectomy	01JAN1999	31DEC1999	N
			Face lift	01JAN1994	31DEC1994	N
		Vascular disorders	Hot flush	01JAN1960		Y
	C4591001 1084 10841401	Eye disorders	Visual acuity reduced	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2020	29FEB2020	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Caesarean section	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endometrial ablation	01JAN1990	31DEC1990	N
	C4591001 1084 10841403	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1991		Y
	C4591001 1084 10841406	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Hypermetropia	01JAN1945		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal stenosis	01JAN2002		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1988	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01NOV2000		Y
			Cataract operation	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
			Lithotripsy	01JAN1988	31DEC1988	N
				01JAN1992	31DEC1992	N
				01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1084 10841408	Gastrointestinal disorders	Inguinal hernia	01JAN1970	31DEC1970	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Investigations	Cardiac murmur	16SEP2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31DEC1970	N
			Caesarean section	01JAN1989	31DEC1989	N
			Inguinal hernia repair	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1084 10841411	Cardiac disorders	Palpitations	01JAN2005		Y
		Ear and labyrinth disorders	Vertigo	01JUN2020		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Visual acuity reduced	01JAN2008		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1989	31DEC1989	N
		General disorders and administration site conditions	Hernia	01JAN1989	31DEC1989	N
		Infections and infestations	Urinary tract infection	01JUN2020	31DEC2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011	30JUN2020	N
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016	31DEC2017	N
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
			Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1084 10841414	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2015		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2013	31DEC2013	N
		Infections and infestations	Oral herpes	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N
			Bone neoplasm	01JAN2013	31DEC2013	N
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Hernia repair	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01MAR2020	31MAR2020	N
			Tenoplasty	01JAN2014	31DEC2014	N
			Tumour excision	01JAN2013	31DEC2013	N
	C4591001 1084 10841415	Eye disorders	Visual acuity reduced	01JAN1974		Y
		Hepatobiliary disorders	Bile duct stone	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
			Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1084 10841419	Immune system disorders	Seasonal allergy	01JAN1951		Y
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1951	N
		Investigations	Blood testosterone decreased	01JAN2002		Y
			Colonoscopy	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
			Osteoporosis	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Sciatica	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995		Y
		Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1951	31DEC1951	N
	C4591001 1084 10841421	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841424	Eye disorders	Myopia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	13DEC1983	13DEC1983	N
	C4591001 1084 10841427	Eye disorders	Myopia	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1978	31DEC1978	N
			Pelvic fracture	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Bunion operation	01JAN2012	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841430	Cardiac disorders	Arrhythmia	01JAN2006		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2013		Y
		Eye disorders	Cataract	01JAN2006	07MAY2019	N
			Visual acuity reduced	01JAN2000		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2012	13JUN2012	N
				01JAN2017	10MAR2017	N
			Large intestine polyp	11MAY2018	11MAY2018	N
		Hepatobiliary disorders	Cholecystitis	01JAN2010	01MAR2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Syncope	11MAY2020	12MAY2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	07MAY2019	07MAY2019	N
			Cholecystectomy	01MAR2015	01MAR2015	N
			Inguinal hernia repair	10MAR2017	10MAR2017	N
				13JUN2012	13JUN2012	N
			Large intestinal polypectomy	11MAY2018	11MAY2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1084 10841440	Ear and labyrinth disorders	Meniere's disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2009		Y
			Seasonal allergy	01JAN1969		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN1976	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1994		Y
		Psychiatric disorders	Alcoholism	01JAN1976	31DEC2017	N
			Attention deficit hyperactivity disorder	01JAN2003		Y
			Depression	01JAN1983		Y
		Social circumstances	Postmenopause	01JUN2018		Y
		Surgical and medical procedures	Gastric bypass	01JAN2001	31DEC2001	N
			Knee operation	01JAN2013	31DEC2013	N
	C4591001 1084 10841443	Cardiac disorders	Mitral valve prolapse	01JAN2008		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2003		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2002		Y
				01JAN2018		Y
			Rubber sensitivity	01JAN2015		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1969	31DEC1969	N
		Investigations	Cardiac murmur	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB2002	31JUL2002	N
				01JAN2002	31AUG2002	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1965	31DEC1965	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2006	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Mastectomy	01AUG2002	31AUG2002	N
			Radiotherapy	01OCT2002	31DEC2002	N
			Salpingectomy	01JAN1965	31DEC1965	N
			Spinal operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841444	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1987		Y
		Immune system disorders	Allergy to animal	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Adenoidectomy	01JAN2006	31DEC2006	N
			Cyst removal	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN2006	31DEC2006	N
			Uvulectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1084 10841445	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Visual acuity reduced	01JAN1984	31DEC1984	N
		Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Skin and subcutaneous tissue disorders	Dry skin	01JAN1995		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1084 10841446	Ear and labyrinth disorders	Hypoacusis	01JAN1976		Y
		Eye disorders	Diabetic retinopathy	01JAN2017		Y
			Visual acuity reduced	01JAN1980		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1959	31DEC1959	N
		Infections and infestations	Tonsillitis	01JAN1997	31DEC1997	N
		Injury, poisoning and procedural complications	Injury corneal	01JAN2017	31DEC2017	N
			Limb injury	01JAN1972		Y
		Investigations	Blood testosterone decreased	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991	31DEC1991	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1995	31DEC1996	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1999		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1997	31DEC1997	N
			Carpal tunnel decompression	01JAN1995	31DEC1995	N
			Hernia repair	01JAN1959	31DEC1959	N
			Spinal operation	01JAN1991	31DEC1991	N
	C4591001 1084 10841447	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Mycotic allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1084 10841451	Eye disorders	Visual acuity reduced	01JAN1978		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JUN2020		Y
	C4591001 1084 10841453	Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Eye disorders	Cataract	01JAN2009	31DEC2013	N
		Gastrointestinal disorders	Constipation	01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985	31DEC2018	N
		Psychiatric disorders	Depression	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1952	(b) (6) 1952	N
			Sleep apnoea syndrome	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1994		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841455	Eye disorders	Dry eye	01JAN2005		Y
			Visual acuity reduced	01JAN1973	31JUL2019	N
		Gastrointestinal disorders	Gingival blister	01JAN2015		Y
			Oral mucosal blistering	01JAN2015		Y
		Immune system disorders	Rubber sensitivity	01JAN1968		Y
			Seasonal allergy	01JAN1985		Y
		Infections and infestations	Pneumonia	01JAN2013	31DEC2013	N
			Tonsillitis	01JAN1975	31DEC1975	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991	31DEC1991	N
			Intervertebral disc protrusion	01JAN2018	31DEC2018	N
			Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2011	31DEC2013	N
		Skin and subcutaneous tissue disorders	Blister	01JAN2015		Y
			Eczema	01JAN2008		Y
			Skin irritation	01FEB2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Intraocular lens implant	01JUL2019	31DEC2019	N
			Keratomileusis	01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
			Spinal operation	01JAN1991		Y
			Tonsillectomy	01JAN1975		Y
	C4591001 1084 10841459	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Eye disorders	Cataract	01JAN2013	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Intraocular lens implant	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
			Stent placement	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1084 10841460	Endocrine disorders	Hyperthyroidism	01JAN2013		Y
		Eye disorders	Visual acuity reduced	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2003		Y
		Surgical and medical procedures	Kidney ablation	01JAN2003	31DEC2003	N
			Thyroidectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841463	Immune system disorders	Seasonal allergy	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1084 10841467	Hepatobiliary disorders	Hepatic steatosis	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2006		Y
			Vitamin D deficiency	01JAN2015		Y
		Surgical and medical procedures	Gastric banding	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1084 10841470	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841471	Ear and labyrinth disorders	Deafness bilateral	01JAN1992		Y
		Eye disorders	Visual acuity reduced	01JAN1960		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1992	31DEC1997	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Urinary bladder suspension	01JAN1997	31DEC1997	N
	C4591001 1084 10841472	Eye disorders	Visual acuity reduced	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN1991		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sciatica	01APR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841473	Ear and labyrinth disorders	Deafness bilateral	01JAN2007		Y
		Eye disorders	Cataract	01JAN1998		Y
			Myopia	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN1980		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Infections and infestations	Appendicitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1084 10841475	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Dermatochalasis	01MAR2020	31MAR2020	N
			Visual acuity reduced	01JAN1970	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Surgical and medical procedures	Blepharoplasty	01MAR2020	31MAR2020	N
			Caesarean section	01JAN1982	31DEC1982	N
				01JAN1985	31DEC1985	N
				01JAN1991	31DEC1991	N
				01JAN1993	31DEC1993	N
			Cholecystectomy	01AUG2012	31AUG2012	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Keratomileusis	01JAN2005	31DEC2005	N
			Food allergy	01JAN1973		Y
	C4591001 1084 10841476	Immune system disorders				
		Investigations	Colonoscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1084 10841477	Ear and labyrinth disorders	Tinnitus	01JAN1960		Y
		Eye disorders	Dry eye	01JAN2015		Y
			Visual acuity reduced	01JAN2010		Y
		Immune system disorders	Allergy to plants	01JAN1999		Y
			Mycotic allergy	01JAN1999		Y
		Investigations	Laparoscopy	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841478	Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2018	N
		Cardiac disorders	Bradycardia	01JAN2018	31DEC2018	N
		Eye disorders	Glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1988	31DEC1988	N
			Limb injury	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Ankle operation	01JAN1988	31DEC1988	N
			Cardiac pacemaker insertion	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1975	31DEC1975	N
			Polypectomy	01JAN2012	31DEC2012	N
			Shoulder operation	01JAN1990	31DEC1990	N
			Vascular disorders	Hot flush	01JAN2015	
	C4591001 1084 10841482	Endocrine disorders	Hypertension	01JAN2015		Y
			Hypothyroidism	01JAN2008		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Foot deformity	20AUG2020	20AUG2020	N
			Osteoarthritis	01MAR2020	31MAR2020	N
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01DEC2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bunion operation	20AUG2020	20AUG2020	N
			Caesarean section	01JAN1981	31DEC1981	N
			Cholecystectomy	01JAN2019	31DEC2019	N
			Knee arthroplasty	01MAR2020	31MAR2020	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1963	31DEC2019	N
			Tonsillitis	01JAN1960	31DEC1960	N
	C4591001 1084 10841483	Infections and infestations				
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1973	31DEC1973	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01JAN1973	31DEC1973	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
	C4591001 1084 10841485	Eye disorders	Cataract	01JAN2017	17AUG2020	N
			Dacryostenosis acquired	01JAN2010	31DEC2010	N
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Food allergy	01JAN2005		Y
			Rubber sensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Sensitive skin	01JAN1961		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
			Cataract operation	17AUG2020	17AUG2020	N
			Dacryocystorhinostomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1084 10841490	Eye disorders	Cataract	01JAN2013	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2001		Y
				01JAN2010		Y
			Food allergy	01JAN1965		Y
			Seasonal allergy	01JAN1993		Y
		Infections and infestations	Osteomyelitis	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	31DEC2000	N
			Osteoarthritis	01JAN1996		Y
			Rotator cuff syndrome	01JAN1982	31DEC1982	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2019	30SEP2019	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Cataract operation	01JAN2014	31DEC2014	N
			Rotator cuff repair	01JAN1982	31DEC1982	N
			Skin neoplasm excision	01SEP2019	30SEP2019	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
				01JAN2016	31DEC2016	N
	C4591001 1084 10841491	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Cardiac disorders	Mitral valve incompetence	01JAN2005		Y
		Eye disorders	Cataract	01JAN2009	31DEC2019	N
			Visual acuity reduced	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Nervous system disorders	Seizure	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Cataract operation	01JAN2019	31DEC2019	N
	C4591001 1084 10841497	Cardiac disorders	Ventricular extrasystoles	01FEB2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01APR2010	30APR2010	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
	C4591001 1084 10841498	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
			Umbilical hernia	01JAN2017	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003	31DEC2003	N
				01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	31DEC1990	N
			Shoulder operation	01JAN2003	31DEC2003	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1084 10841501	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Pharyngitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1084 10841504	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Eye disorders	Myopia	01JAN1998		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
			Constipation	01JAN2010		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN1991	31DEC1991	N
		Investigations	Colonoscopy	01JAN2013	31DEC2013	N
			Endoscopy	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2010	N
			Osteopenia	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Limb operation	01JAN1991	31DEC1991	N
	C4591001 1084 10841505	Cardiac disorders	Atrial fibrillation	01JAN1953	31DEC2015	N
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Myopia	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-small cell lung cancer	01FEB2009	30SEP2009	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950	31DEC1960	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Lung lobectomy	01JAN2009	31DEC2009	N
			Uterine prolapse repair	01JAN2018	31DEC2018	N
	C4591001 1084 10841507	Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2017		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Gonorrhoea	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007	31DEC2015	N
			Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1084 10841508	Congenital, familial and genetic disorders	Keratosis follicular	01JAN2005		Y
		Eye disorders	Myopia	01JAN1957		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1950	31DEC1954	N
				01JAN1988	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1972	31DEC1972	N
		Surgical and medical procedures	Hernia repair	01JAN1954	31DEC1954	N
				01JAN1990	31DEC1990	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lung operation	01JAN1972	31DEC1972	N
			Vasectomy	01JAN1975	31DEC1975	N
	C4591001 1084 10841510	Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Retinal tear	01JAN2019	31DEC2019	N
			Visual acuity reduced	01JAN2019		Y
		Injury, poisoning and procedural complications	Back injury	01JAN1977		Y
			Foot fracture	01JAN1995	31DEC1995	N
			Muscle rupture	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
			Upper limb fracture	01JAN2018	31DEC2018	N
			Wound	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1977		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Bone operation	01JAN2019	31DEC2019	N
			Brain tumour operation	01JAN1997	31DEC1997	N
			Cataract operation	01JAN2018	31DEC2018	N
			Foot operation	01JAN1995	31DEC1995	N
			Fracture treatment	01JAN1995	31DEC1995	N
			Intervertebral disc operation	01JAN1978	31DEC1978	N
			Knee operation	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
			Removal of foreign body	01JAN1985	31DEC1985	N
			Retinal operation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1084 10841515		Spinal fusion surgery	01JAN1977	31DEC1977	N
		Eye disorders	Visual acuity reduced	01JAN2014		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
			Hepatitis C	01JAN2001		Y
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Intervertebral disc protrusion	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1974	31DEC1974	N
		Nervous system disorders	Neuropathy peripheral	01JAN2011		Y
		Pregnancy, puerperium and perinatal conditions	Abortion	01JAN1975	31DEC1975	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2008		Y
		C4591001 1084 10841516	Cardiac disorders	Atrial fibrillation	01JAN2006	
			Coronary artery disease	01JAN2006		Y
	Eye disorders		Visual acuity reduced	01JAN1963		Y
	Gastrointestinal disorders		Dyspepsia	01JAN2015		Y
	General disorders and administration site conditions		Hernia	01JAN2012	31DEC2012	N
	Immune system disorders		Seasonal allergy	01JAN1992		Y
	Metabolism and nutrition disorders		Gout	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertriglyceridaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2006		Y
		Surgical and medical procedures	Cardiac ablation	02JUN2020	02JUN2020	N
			Coronary artery bypass	12OCT2006	12OCT2006	N
			Hernia repair	01JAN2012	31DEC2012	N
			Knee operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1084 10841523	Cardiac disorders	Mitral valve prolapse	01JAN1979		Y
		Eye disorders	Cataract	01JAN2016	31AUG2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
			Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
			Osteoporosis	01JAN2011		Y
		Reproductive system and breast disorders	Adnexal torsion	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Cataract operation	01AUG2019	31AUG2019	N
			Oophorectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	31JUL2020		Y
	C4591001 1084 10841524	Cardiac disorders	Cardiomyopathy	01JAN2002	31DEC2003	N
		Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Eye disorders	Visual acuity reduced	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Hiatus hernia	01JAN2010		Y
			Umbilical hernia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2014		Y
			Catheterisation cardiac	01JAN2006	31DEC2006	N
			Cystoscopy	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Renal and urinary disorders	Renal cyst	01JUN2020	30JUN2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Shoulder arthroplasty	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1948	31DEC1948	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1084 10841525	Eye disorders	Glaucoma	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1960		Y
			Depression	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
			Uvulectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1084 10841527	Cardiac disorders	Myocardial infarction	01JAN2005	31DEC2005	N
		Eye disorders	Visual acuity reduced	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Ligament operation	01JAN1990	31DEC1990	N
			Stent placement	01JAN2005	31DEC2005	N
				01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1084 10841528	Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Retinal detachment	01JAN2016	31DEC2016	N
			Visual acuity reduced	01JAN1966		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Thoracic vertebral fracture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1986	31DEC1986	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1996	31DEC1996	N
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1996	31DEC1996	N
			Cataract operation	01JAN2015	31DEC2015	N
			Chondrectomy	01JAN2008	31DEC2008	N
			Nasal septal operation	01JAN1971	31DEC1971	N
			Oral surgery	01JAN1986	31DEC1986	N
			Retinal operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1084 10841529	Injury, poisoning and procedural complications	Hip fracture	15SEP1970	15SEP1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hip arthroplasty	15SEP1970	15SEP1970	N
	C4591001 1084 10841531	Eye disorders	Cataract	19NOV2019	19NOV2019	N
			Retinal tear	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1953		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	19NOV2019	19NOV2019	N
			Retinal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1085 10851001	Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851005	Psychiatric disorders	Depression	01NOV2014		Y
			Insomnia	01MAY2019		Y
		Social circumstances	Postmenopause	01FEB2018		Y
	C4591001 1085 10851006	Immune system disorders	Seasonal allergy	01SEP1987		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2016		Y
		Social circumstances	Postmenopause	01SEP2013		Y
	C4591001 1085 10851007	Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1085 10851008	Endocrine disorders	Hypogonadism male	01JAN2007		Y
	C4591001 1085 10851009	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851010	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851011	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1085 10851012	Cardiac disorders	Angina pectoris	01JAN2016		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Vascular disorders	Hypertension	01SEP2015		Y
	C4591001 1085 10851021	Gastrointestinal disorders	Constipation	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1085 10851024	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851025	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1970		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pruritus allergic	01JAN1970		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2012	31DEC2012	N
			Umbilical hernia repair	01AUG2016	31AUG2016	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1085 10851028	Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Herpes zoster	18SEP2019	25SEP2019	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Vitamin D decreased	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1988		Y
		Surgical and medical procedures	Hernia repair	01DEC2012	31DEC2012	N
			Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1085 10851031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
	C4591001 1085 10851036	Cardiac disorders	Atrioventricular block complete	03OCT2019	05OCT2019	N
		Immune system disorders	Seasonal allergy	01MAR1955		Y
		Injury, poisoning and procedural complications	Arthropod sting	04AUG2020	04AUG2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	05OCT2019	05OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851038	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1085 10851040	Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2016		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2016	31DEC2016	N
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1946		Y
			Intervertebral disc protrusion	01JAN1978	31DEC1978	N
			Osteoarthritis	01JAN1980	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982	31DEC1982	N
			Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
			Cataract operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Chondroplasty	01JAN1972	31DEC1978	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Nasal septal operation	01JAN1982	31DEC1982	N
			Spinal laminectomy	01JAN1978	31DEC1978	N
			Synovial cyst removal	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851042	Cardiac disorders	Myocardial infarction	01JAN2020	31JAN2020	N
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1986	31DEC1986	N
	C4591001 1085 10851043	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
	C4591001 1085 10851044	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1085 10851045	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Meniscus injury	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1085 10851046	Ear and labyrinth disorders	Conductive deafness	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1986	31DEC1986	N
				01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1989	31DEC1989	N
	C4591001 1085 10851053	Social circumstances	Postmenopause	01JAN2000		Y
		Endocrine disorders	Hyperthyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851054	Reproductive system and breast disorders	Dyspareunia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1085 10851055	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1085 10851056	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851057	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1085 10851059	Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2017		Y
	C4591001 1085 10851060	Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851061	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851065	Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2015	N
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851066	General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
				01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JUL2000	31JUL2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JUL2000	31JUL2000	N
			Ligament operation	01JAN1995	31DEC1995	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851071	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JUN2020	30JUN2020	N
			Knee operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851072	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Nervous system disorders	Tremor	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2008	31DEC2008	N
	C4591001 1085 10851073	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
	C4591001 1085 10851074	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1085 10851076	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1085 10851077	Social circumstances	Ex-tobacco user	01SEP2019	30SEP2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851078	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1085 10851080	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1085 10851082	Cardiac disorders	Mitral valve incompetence	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851083	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1085 10851084	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	29JUN2020	29JUN2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1085 10851085	Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1085 10851086	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Surgical and medical procedures	Spinal fusion surgery	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851087	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1085 10851088	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
	C4591001 1085 10851089	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	13JUN2020	13JUN2020	N
	C4591001 1085 10851091	Endocrine disorders	Hypothyroidism	01JAN1996		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1085 10851092	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851093	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1085 10851094	Eye disorders	Glaucoma	01JAN2000		Y
	C4591001 1085 10851095	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851096	Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851097	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851100	Cardiac disorders	Aortic valve stenosis	01JAN1953		Y
			Atrial fibrillation	01JAN1997		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851101	Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2016		Y
	C4591001 1085 10851102	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
	C4591001 1085 10851103	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Insomnia	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851105	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN2000		Y
			Umbilical hernia	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851107	Endocrine disorders	Hypothyroidism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1085 10851111	Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1085 10851113	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
	C4591001 1085 10851115	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2016		Y
			Intervertebral disc protrusion	01JAN1999	31DEC1999	N
		Nervous system disorders	Headache	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1965		Y
		Social circumstances	Postmenopause	01MAY2018		Y
	C4591001 1085 10851116	Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Surgical and medical procedures	Aortic valve repair	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851117	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851118	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
	C4591001 1085 10851119	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851120	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1997	N
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1085 10851121	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1085 10851122	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
	C4591001 1085 10851123	Metabolism and nutrition disorders	Hypercholesterolaemia	26DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	26DEC2019		Y
	C4591001 1085 10851126	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851130	Eye disorders	Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Oesophageal spasm	01JAN2005		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
			Psoriasis	01JAN2019		Y
		Vascular disorders	Arteriosclerosis	01JAN1990		Y
	C4591001 1085 10851131	Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851133	Gastrointestinal disorders	Umbilical hernia	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee operation	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Deep vein thrombosis	01JAN2008	31DEC2008	N
			Hypertension	01JAN2014		Y
	C4591001 1085 10851134	Congenital, familial and genetic disorders	Thalassaemia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Folliculitis	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851135	Immune system disorders	Seasonal allergy	01JAN2017		Y
	C4591001 1085 10851138	Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1085 10851139	Cardiac disorders	Mitral valve prolapse	01MAR1998	31MAR1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2002		Y
		Surgical and medical procedures	Mitral valve repair	01MAR1998	31MAR1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851144	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
	C4591001 1085 10851145	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Nervous system disorders	Myoclonic epilepsy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851146	Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1085 10851147	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1085 10851148	Gastrointestinal disorders	Colitis ulcerative	01JAN1978		Y
			Gastroesophageal reflux disease	01JAN1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851149	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
	C4591001 1085 10851150	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851151	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01MAR1970	31MAR1970	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851152	Endocrine disorders	Hyperthyroidism	01JAN1975		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1976		Y
	C4591001 1085 10851156	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2014		Y
		Vascular disorders	Hypertension	01MAY2009		Y
	C4591001 1085 10851160	Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2012	31DEC2012	N
	C4591001 1085 10851161	Cardiac disorders	Atrial flutter	01JAN2017		Y
		Gastrointestinal disorders	Small intestinal obstruction	01JAN2005	31DEC2005	N
		Investigations	Laparoscopy	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
	C4591001 1085 10851162	Endocrine disorders	Hyperthyroidism	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851166	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01OCT2014	31OCT2014	N
	C4591001 1085 10851167	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01FEB2020		Y
		Surgical and medical procedures	Hip arthroplasty	05JUL2020	05JUL2020	N
	C4591001 1085 10851168	Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
	C4591001 1085 10851169	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851171	Metabolism and nutrition disorders	Gout	01JAN1990		Y
	C4591001 1085 10851172	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1085 10851173	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01APR2020	30APR2020	N
				01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1085 10851174	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1085 10851176	Investigations	Blood testosterone decreased	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1085 10851177	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1085 10851181	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1085 10851182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1085 10851183	Psychiatric disorders	Anxiety	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851184	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1085 10851185	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
	C4591001 1085 10851186	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1085 10851187	Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1085 10851190	Endocrine disorders	Hypothyroidism	01NOV2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2017		Y
		Psychiatric disorders	Anxiety	01MAY2018		Y
			Depression	01MAY2015		Y
		Social circumstances	Postmenopause	01JUL2004		Y
		Vascular disorders	Hypertension	01FEB2010		Y
	C4591001 1085 10851194	Immune system disorders	Seasonal allergy	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851197	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851198	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1085 10851199	Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1085 10851201	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851205	Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Transient ischaemic attack	01JAN1999	31DEC1999	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2017	31JAN2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1085 10851207	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1085 10851208	Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851209	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1085 10851213	Infections and infestations	Onychomycosis	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1085 10851214	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851215	Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1085 10851216	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851218	Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1085 10851220	General disorders and administration site conditions	Inflammation	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
	C4591001 1085 10851222	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851223	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1085 10851224	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
			Type 2 diabetes mellitus	01DEC2019		Y
		Nervous system disorders	Cerebrovascular accident	29OCT2019	29OCT2019	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1085 10851226	Cardiac disorders	Atrial fibrillation	01SEP2005		Y
		Endocrine disorders	Hypothyroidism	01OCT1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Osteoporosis	01SEP2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP1990		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1085 10851227	Endocrine disorders	Hypothyroidism	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
	C4591001 1085 10851228	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851230	Cardiac disorders	Atrial fibrillation	01JAN2014	31MAY2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851232	Cardiac disorders	Sinus arrhythmia	01JAN1990		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1085 10851233	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1978		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
			Erectile dysfunction	01AUG2020		Y
	C4591001 1085 10851234	Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01DEC2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1085 10851235	General disorders and administration site conditions	Necrosis	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1085 10851241	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1085 10851247	Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1085 10851251	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1976	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851254	Cardiac disorders	Arrhythmia	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851255	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851257	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Anticoagulant therapy	01JAN2019		Y
			Heart valve replacement	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1085 10851258	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
	C4591001 1085 10851260	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1085 10851262	Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Appendix cancer	01JAN2017	31DEC2019	N
			Basal cell carcinoma	01JUL2020	20AUG2020	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Micrographic skin surgery	20AUG2020	20AUG2020	N
		Vascular disorders	Hypertension	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851263	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851266	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1085 10851267	Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851268	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1085 10851271	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1971		Y
	C4591001 1085 10851272	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Bruxism	01JAN2014		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1085 10851273	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2005	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851274	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851275	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1085 10851278	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1085 10851279	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1085 10851282	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1992		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN1995	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1085 10851288	Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Female sterilisation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1973		Y
	C4591001 1085 10851289	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Hormone level abnormal	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1085 10851292	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1085 10851293	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1085 10851297	Cardiac disorders	Atrial fibrillation	01JAN1988		Y
			Mitral valve prolapse	01JAN1988		Y
		Endocrine disorders	Hyperthyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 1 diabetes mellitus	01JAN1966		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1085 10851303	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01OCT2019	31MAR2020	N
	C4591001 1085 10851306	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1085 10851313	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2016	31JAN2016	N
		Vascular disorders	Aortic aneurysm	01JAN2016	31JAN2016	N
			Hypertension	01JAN2013		Y
	C4591001 1085 10851315	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851317	Hepatobiliary disorders	Cholangitis sclerosing	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1085 10851318	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1085 10851319	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1085 10851322	Infections and infestations	Onychomycosis	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
			Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1085 10851324	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC2018	30APR2019	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Mastectomy	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1085 10851326	Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1085 10851329	Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2001	31DEC2001	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1085 10851331	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1085 10851333	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1085 10851334	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Hepatobiliary disorders	Hepatic cirrhosis	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2006		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1085 10851335	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2017		Y
		Surgical and medical procedures	Splenectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1085 10851340	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1085 10851347	Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1973	31DEC1973	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Chronic obstructive pulmonary disease	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1973	31DEC1973	N
			Inguinal hernia repair	01JAN1973	31DEC1973	N
			Prophylaxis	01JAN2018		Y
	C4591001 1085 10851348	Eye disorders	Glaucoma	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1085 10851353	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1085 10851360	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871001	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Dry eye	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN1979		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871002	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1087 10871003	Infections and infestations	Chronic tonsillitis	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Hypercalcaemia	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2004	N
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1998	31DEC1998	N
	C4591001 1087 10871004	Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Contrast media allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
	C4591001 1087 10871005	Vascular disorders	Hypertension	01JAN2005		Y
		Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871006	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Spinal osteoarthritis	01JAN2012		Y
	C4591001 1087 10871008	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1087 10871009	Eye disorders	Cataract	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Hypokalaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871011	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Vascular disorders	Deep vein thrombosis	01JAN2015		Y
			Hypertension	01JAN1977		Y
	C4591001 1087 10871012	Endocrine disorders	Hypothyroidism	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1087 10871013	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871014	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
			Coronary artery disease	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN1946		Y
				01JAN1956		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
			Sinusitis	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871015	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1965		Y
		Surgical and medical procedures	Female sterilisation	01JAN1975	31DEC1975	N
	C4591001 1087 10871016	Immune system disorders	Seasonal allergy	01JAN1950		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Nervous system disorders	Headache	01JAN1968		Y
			Restless legs syndrome	01JAN1950		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1087 10871017	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871018	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Iris disorder	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
	C4591001 1087 10871019	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2015		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	30MAY2017		Y
			Hypercholesterolaemia	09AUG2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
			Osteoporosis	01JUN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JUN2004	30JUN2004	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871022	Eye disorders	Glaucoma	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lactose intolerance	01JAN1960		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1981		Y
	C4591001 1087 10871023	Metabolism and nutrition disorders	Lactose intolerance	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1087 10871024	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
		Endocrine disorders	Hyperthyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1087 10871025	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN2012		Y
			Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1087 10871026	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871027	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871029	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Cardiac disorders	Cardiac failure congestive	01JAN1995		Y
			Coronary artery disease	01JAN1995		Y
			Mitral valve disease	01JAN1998		Y
		Ear and labyrinth disorders	Auditory disorder	01JAN1990		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN1980		Y
			Nausea	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Food allergy	01JAN1980		Y
				01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hyperlipidaemia	01JAN1992		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2000		Y
		Nervous system disorders	Amnesia	01JAN2018		Y
			Diabetic neuropathy	01JAN2010		Y
			Migraine	01JAN1980		Y
			Tremor	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1995		Y
			Dyspnoea	01JAN1995		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1087 10871030	Cardiac disorders	Coronary artery disease	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN1955		Y
		Psychiatric disorders	Depression	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1087 10871031	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
					31DEC2012	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN2013		Y
	C4591001 1087 10871032	Eye disorders	Cataract	01JUL2020		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Rotator cuff syndrome	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871033	Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871034	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1087 10871036	Eye disorders	Glaucoma	01JAN2005		Y
		Immune system disorders	Allergy to vaccine	01JAN1970		Y
		Infections and infestations	Rhinitis	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
	C4591001 1087 10871037	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1087 10871038	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
			Varicose vein	01JAN1998		Y
	C4591001 1087 10871039	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN1992		Y
	C4591001 1087 10871040	Eye disorders	Presbyopia	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871043	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Investigations	Heart rate irregular	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01DEC2018		Y
	C4591001 1087 10871044	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
	C4591001 1087 10871047	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1940		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1087 10871048	Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1960		Y
			Myalgia	01JAN2015		Y
			Osteopenia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871049	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871050	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN1983		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
	C4591001 1087 10871051	Immune system disorders	Drug hypersensitivity	01JAN1976		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871054	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1087 10871055	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871056	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2008		Y
	C4591001 1087 10871057	Gastrointestinal disorders	Inguinal hernia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hernia repair	01JAN2016	31DEC2016	N
	C4591001 1087 10871058	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2013		Y
			Osteoarthritis	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871063	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2005		Y
		Eye disorders	Conjunctivitis allergic	01JAN2018		Y
			Dry eye	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN1989		Y
		Nervous system disorders	Migraine	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN2015	31DEC2017	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
			Restless legs syndrome	01JAN2015		Y
	C4591001 1087 10871070	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Eye disorders	Glaucoma	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1087 10871071	Metabolism and nutrition disorders	Fluid retention	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871072	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871073	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1087 10871075	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	03AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871077	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1087 10871079	Surgical and medical procedures	Arthrodesis	01JAN2008	31DEC2008	N
		Eye disorders	Ulcerative keratitis	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1087 10871080	Immune system disorders	Allergy to arthropod sting	01JAN1955		Y
			Seasonal allergy	01JAN2009		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871081	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871082	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Nausea	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1087 10871090	Metabolism and nutrition disorders	Hypoglycaemia	01JAN1980		Y
	C4591001 1087 10871091	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871093	Surgical and medical procedures	Vasectomy	01JAN1981	31DEC1981	N
	C4591001 1087 10871098	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871100	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871101	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Diverticulum	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1087 10871105	Eye disorders	Myopia	01JAN1961		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Rubber sensitivity	01JAN1950		Y
		Infections and infestations	Genital herpes	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1986	31DEC1986	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1975		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871106	Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Food allergy	01JAN1948		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1087 10871112	Gastrointestinal disorders	Constipation	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Iron deficiency	01MAY2020		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1087 10871115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871116	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871117	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1087 10871121	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
			Oesophageal ulcer	01JAN2019		Y
			Varices oesophageal	01JAN2019		Y
		Hepatobiliary disorders	Cirrhosis alcoholic	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
	C4591001 1087 10871122	Gastrointestinal disorders	Anal incontinence	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Metabolism and nutrition disorders	Vitamin B complex deficiency	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871124	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acrochordon	01JAN2010		Y
			Glomus tumour	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871125	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Eye disorders	Retinal tear	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2002		Y
			Hyperlipidaemia	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1087 10871126	Cardiac disorders	Cardiac failure	01JAN2012		Y
		Nervous system disorders	Epilepsy	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
	C4591001 1087 10871128	Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y
	C4591001 1087 10871129	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1087 10871130	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1957		Y
			Sleep apnoea syndrome	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871131	Cardiac disorders	Coronary artery disease	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019		Y
	C4591001 1087 10871132	Vascular disorders	Hypertension	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1087 10871133	Vascular disorders	Hypertension	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Dyspepsia	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN2011		Y
		Infections and infestations	Candida infection	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Inclusion body myositis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995		Y
	C4591001 1087 10871134	Vascular disorders	Hypertension	01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
	C4591001 1087 10871136	Skin and subcutaneous tissue disorders	Dermatitis	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1087 10871137	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
	C4591001 1087 10871139	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	30SEP2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2019	31JUL2019	N
	C4591001 1087 10871140	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01APR2018		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2010		Y
	C4591001 1087 10871141	Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1087 10871142	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
	C4591001 1087 10871143	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1087 10871144	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2007		Y
		Vascular disorders	Aortic aneurysm	01JAN2017		Y
	C4591001 1087 10871145	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871147	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal disorder	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871150	Cardiac disorders	Atrial fibrillation	06JUN2017		Y
			Coronary artery disease	06JUN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Vascular disorders	Deep vein thrombosis	01JAN1994		Y
			Hypertension	01JAN2018		Y
	C4591001 1087 10871154	Gastrointestinal disorders	Colitis ischaemic	01NOV2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1987	N
		Social circumstances	Postmenopause	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1087 10871155	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Hypermetropia	01JAN1955		Y
			Myopia	01JAN1955		Y
		Immune system disorders	Drug hypersensitivity	01MAY2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Hyperlipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871156	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Umbilical hernia	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypokalaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Neuralgia	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871157	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Injury, poisoning and procedural complications	Burns third degree	01JAN2000	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
		Psychiatric disorders	Depression	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Mastectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1087 10871158	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871159	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Dry eye	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2015		Y
				01JAN2019		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1087 10871161	Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
	C4591001 1087 10871162	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Oophorectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871164	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871165	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1087 10871167	Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1087 10871168	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN2005		Y
			Rubber sensitivity	01JAN2015		Y
		Investigations	Intraocular pressure increased	01NOV2016		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1087 10871169	Injury, poisoning and procedural complications	Spinal column injury	01JAN1993		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Spinal stenosis	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871170	Congenital, familial and genetic disorders	Alpha-1 antitrypsin deficiency	01FEB2020		Y
		Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Iodine allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Polycythaemia vera	01JAN2010		Y
		Nervous system disorders	Monoplegia	01JAN1973		Y
	C4591001 1087 10871173	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
				01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	24AUG1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871174	Ear and labyrinth disorders	Auditory disorder	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Macular degeneration	01JAN1990		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JUN2019		Y
			Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
			Osteoporosis	01FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1987		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871175	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Inguinal hernia	01JAN1996	31DEC1996	N
			Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871176	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
			Rubber sensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Rhinitis allergic	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871177	Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1087 10871178	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperamylasaemia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1087 10871183	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871184	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1087 10871185	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Food allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
		Psychiatric disorders	Libido decreased	01JAN2015		Y
	C4591001 1087 10871187	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
			Restless legs syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871188	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Dry eye	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
			Perennial allergy	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Osteoarthritis	01JAN1993		Y
		Nervous system disorders	Migraine	01JAN1990		Y
			Neuropathy peripheral	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1087 10871190	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2000		Y
	C4591001 1087 10871193	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871197	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009		Y
	C4591001 1087 10871198	Cardiac disorders	Angina pectoris	01JAN2010		Y
			Atrial fibrillation	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871199	Endocrine disorders	Hypothyroidism	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Back pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01NOV1998	30NOV1998	N
	C4591001 1087 10871200	General disorders and administration site conditions	Oedema peripheral	01JUN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1975		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871202	Ear and labyrinth disorders	Motion sickness	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2015		Y
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871203	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
			Parkinson's disease	01JAN2015		Y
			Sinus headache	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2005		Y
	C4591001 1087 10871204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
	C4591001 1087 10871206	Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871207	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1087 10871208	Cardiac disorders	Cardiac failure congestive	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Glaucoma	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN1981		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871210	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1087 10871211	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871216	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1087 10871217	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871218	Metabolism and nutrition disorders	Gout	01JAN2012		Y
			Hypercholesterolaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871219	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1087 10871220	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
	C4591001 1087 10871221	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1087 10871222	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871223	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871224	Infections and infestations	Urinary tract infection	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hot flush	01JAN2008		Y
	C4591001 1087 10871226	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871227	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1087 10871228	Cardiac disorders	Cardiac failure congestive	01FEB2020		Y
			Coronary artery disease	01FEB2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
		Surgical and medical procedures	Coronary artery bypass	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871229	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871232	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Macular degeneration	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871233	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
	C4591001 1087 10871234	Blood and lymphatic system disorders	Anaemia	01FEB2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2019		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871236	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1087 10871237	Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1087 10871238	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1087 10871240	Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Blindness unilateral	01AUG2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1949		Y
			Perennial allergy	01JAN1970		Y
	C4591001 1087 10871242	Social circumstances	Postmenopause	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871245	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN2004		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Iron deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1087 10871246	Cardiac disorders	Angina pectoris	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Arteriosclerosis	01JUN2020		Y
			Hypertension	01JAN2019		Y
	C4591001 1087 10871249	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Aortic disorder	01JAN2018		Y
	C4591001 1087 10871250	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Dry eye	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN1995		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1945		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1087 10871251	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871253	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1087 10871254	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1087 10871255	Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1087 10871256	Metabolism and nutrition disorders	Gout	01JAN1980		Y
			Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Carotid artery disease	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871257	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871258	Immune system disorders	Allergy to chemicals	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1087 10871259	Eye disorders	Dry eye	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Infections and infestations	Herpes simplex	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871260	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1087 10871261	Eye disorders	Glaucoma	01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871263	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871264	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Investigations	Blood testosterone decreased	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Muscle spasms	01JAN1998		Y
		Nervous system disorders	Narcolepsy	01JAN2018		Y
			Neuropathy peripheral	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1087 10871266	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1087 10871268	Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Vascular disorders	Deep vein thrombosis	01JAN2013		Y
			Hypertension	01JAN1990		Y
	C4591001 1087 10871269	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871270	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871271	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Social circumstances	Postmenopause	01DEC2006		Y
	C4591001 1087 10871272	Eye disorders	Eyelid ptosis	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
				01JAN1988		Y
				01JAN2018		Y
			Food allergy	01JAN2018		Y
		Infections and infestations	Rhinitis	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871273	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1087 10871274	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871275	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
	C4591001 1087 10871277	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1087 10871278	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1087 10871280	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1087 10871281	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1087 10871283	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871284	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871286	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871287	Immune system disorders	Contrast media allergy	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871289	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN1989	31DEC1990	N
		General disorders and administration site conditions	Ulcer haemorrhage	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
				01JAN2020		Y
		Infections and infestations	Arthritis infective	01AUG2018	31AUG2018	N
				01JAN2019	31DEC2019	N
				01JUL2018	31JUL2018	N
				01NOV2018	30NOV2018	N
			Device related infection	01JUN2018		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
			Hyponatraemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Haemarthrosis	01JAN2020	31JAN2020	N
			Myalgia	01JAN2018		Y
			Osteoarthritis	01JAN1986		Y
		Nervous system disorders	Tremor	01JAN2005		Y
		Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013	31DEC2013	N
			Testicular cyst	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2018		Y
		Surgical and medical procedures	Arthrodesis	01JAN2014	31DEC2014	N
			Exeresis	01JAN2013	31DEC2013	N
			Hernia repair	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01NOV2019	30NOV2019	N
			Orchidectomy	01MAR2018	31MAR2018	N
			Shoulder arthroplasty	16JUN2020	16JUN2020	N
			Synovectomy	01JUN2020	30JUN2020	N
	C4591001 1087 10871290	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1087 10871291	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871292	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871294	Immune system disorders	Seasonal allergy	01JAN2011		Y
		Nervous system disorders	Headache	01JAN1982		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Oophorectomy	01JAN2010	31DEC2010	N
	C4591001 1087 10871295	Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1087 10871298	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
	C4591001 1087 10871300	Social circumstances	Postmenopause	01JAN2008		Y
		Cardiac disorders	Angina pectoris	01JAN2018		Y
			Coronary artery disease	01JUN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2000		Y
			Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871302	Immune system disorders	Rubber sensitivity	01JAN2012		Y
	C4591001 1087 10871303	Psychiatric disorders	Anxiety	01JAN2008		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1087 10871304	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1962		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
			Seasonal allergy	01JAN1946		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871305	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1087 10871306	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871307	Reproductive system and breast disorders	Ovarian cyst	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
			Oophorectomy bilateral	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1087 10871309	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Iodine allergy	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2020		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1087 10871311	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Cardiac disorders	Tachycardia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1949		Y
			Drug hypersensitivity	01JAN1990		Y
				01JAN2005		Y
				01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1985		Y
			Narcolepsy	01JAN1995		Y
			Restless legs syndrome	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1997		Y
	C4591001 1087 10871312	Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
				01JAN1960		Y
				01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1087 10871313	Eye disorders	Blindness unilateral	01JAN1967		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Umbilical hernia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871315	Cardiac disorders	Atrial flutter	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Perennial allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871317	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
	C4591001 1087 10871318	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871319	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN1960		Y
				01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871320	Ear and labyrinth disorders	Meniere's disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1087 10871322	Cardiac disorders	Atrial fibrillation	01MAR2019		Y
		Gastrointestinal disorders	Diverticulum	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Neuralgia	01MAR2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1087 10871324	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2019		Y
			Spinal stenosis	01JAN2019		Y
		Nervous system disorders	Tension headache	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1087 10871326	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871327	Cardiac disorders	Atrial fibrillation	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
	C4591001 1087 10871328	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871329	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2016		Y
			Osteoarthritis	01JAN2018		Y
				01JAN2020		Y
			Tendonitis	01NOV2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1087 10871331	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1985		Y
	C4591001 1087 10871334	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Fibromyalgia	01JAN2016		Y
			Osteoporosis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1087 10871335	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871337	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015		Y
	C4591001 1087 10871339	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871340	Gastrointestinal disorders	Dyspepsia	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1993		Y
			Spinal osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1087 10871341	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871344	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871345	General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
	C4591001 1087 10871346	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871347	Cardiac disorders	Coronary artery disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary artery occlusion	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Stent placement	01JAN2010	31DEC2010	N
	C4591001 1087 10871350	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2020	08JAN2021	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1087 10871351	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1998		Y
			Hypercholesterolaemia	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Renal and urinary disorders	Nocturia	01JAN2016		Y
	C4591001 1087 10871352	Eye disorders	Eyelid ptosis	01JAN1963		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Sinusitis	01JAN1990		Y
		Injury, poisoning and procedural complications	Scar	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN1998		Y
	C4591001 1087 10871353	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871358	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Rubber sensitivity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1087 10871362	Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1087 10871364	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1087 10871365	Immune system disorders	Seasonal allergy	01JAN1958		Y
		Nervous system disorders	Migraine	01JAN1962		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871366	Cardiac disorders	Palpitations	01JAN2015		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2011		Y
				01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1087 10871367	Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871368	Cardiac disorders	Coronary artery disease	01JAN2003		Y
		Eye disorders	Cataract	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2019		Y
			Hypercholesterolaemia	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1087 10871369	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1087 10871370	Endocrine disorders	Hypothyroidism	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1978	31DEC1978	N
		Nervous system disorders	Essential tremor	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1087 10871371	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871373	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1087 10871374	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1087 10871375	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1087 10871376	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1087 10871379	Vascular disorders	Hypertension	01JAN1994		Y
		Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Investigations	Electrocardiogram T wave inversion	01JAN1946		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2019		Y
	C4591001 1087 10871380	Vascular disorders	Hypertension	01JAN2012		Y
		Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1087 10871381	Vascular disorders	Hypertension	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1087 10871382	Vascular disorders	Hypertension	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871383	Cardiac disorders	Cardiac failure congestive	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Gastrointestinal disorders	Diverticulum	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN1999		Y
				01JAN2011		Y
			Rubber sensitivity	01JAN1999		Y
			Seasonal allergy	01JAN1961		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Muscle spasms	01JAN2014		Y
			Osteoarthritis	01JAN2006		Y
			Spinal osteoarthritis	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1087 10871384	Cardiac disorders	Angina pectoris	01JAN1998		Y
			Coronary artery disease	01JAN1996		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Diverticulitis	01JUN2019		Y
			Herpes simplex	01JUN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN1999		Y
			Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1087 10871385	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1993		Y
		Immune system disorders	Food allergy	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
			Rhinitis perennial	01JAN1960		Y
			Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1087 10871386	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
			Cardiac failure congestive	01JAN2012		Y
			Coronary artery disease	01JAN2001		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Type 1 diabetes mellitus	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1087 10871388	Endocrine disorders	Hyperthyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1087 10871390	Cardiac disorders	Tachycardia	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
			Dyspepsia	01JAN2010		Y
			Gastritis	01JAN2017		Y
			Hiatus hernia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
		Infections and infestations	Diverticulitis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871392	Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871396	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871397	Hepatobiliary disorders	Cholelithiasis	01JAN1978	31DEC1978	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871400	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871402	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1087 10871403	Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Dementia Alzheimer's type	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN1979		Y
			Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871405	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
			Toothache	01SEP2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871406	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes zoster	01JAN1970		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
	C4591001 1087 10871407	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1087 10871408	Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Varicose vein	01JAN1998		Y
	C4591001 1087 10871409	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
			Seasonal allergy	01MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1087 10871410	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871411	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
			Sinus node dysfunction	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871416	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1087 10871417	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871418	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1087 10871419	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Nervous system disorders	Tension headache	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871421	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2018		Y
	C4591001 1087 10871422	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1087 10871423	Immune system disorders	Seasonal allergy	01MAR2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871424	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871425	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1087 10871428	General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Salpingectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Deep vein thrombosis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871429	Cardiac disorders	Coronary artery disease	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1087 10871430	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871431	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2019	N
	C4591001 1087 10871432	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1087 10871433	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2015		Y
			Tremor	01JAN2015		Y
	C4591001 1087 10871434	Immune system disorders	Drug hypersensitivity	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1087 10871437	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN1985		Y
	C4591001 1087 10871438	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871439	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871440	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871441	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Investigations	Cardiac murmur	01JAN1946		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1994		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1087 10871442	Eye disorders	Dry eye	01JAN2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871444	Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871445	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871446	Immune system disorders	Drug hypersensitivity	01MAY2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Deep vein thrombosis	01MAY2020		Y
			Hypertension	01JAN2010		Y
	C4591001 1087 10871447	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Oophorectomy	01JAN1985	31DEC1985	N
			Salpingectomy	01JAN1985	31DEC1985	N
	C4591001 1087 10871448	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1087 10871449	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1988		Y
	C4591001 1087 10871450	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
	C4591001 1087 10871452	Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01FEB2019	28FEB2019	N
		Surgical and medical procedures	Hysterectomy	01FEB2019	28FEB2019	N
	C4591001 1087 10871453	General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1087 10871455	Cardiac disorders	Bundle branch block right	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Rubber sensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	01JAN2012		Y
			Uterine leiomyoma	01JAN1979	31DEC1979	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
	C4591001 1087 10871456	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871458	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871459	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1087 10871460	Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Allergy to metals	01JAN1955		Y
			Drug hypersensitivity	01JAN1956		Y
				01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN2008		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
			Rosacea	01JAN2017		Y
		Surgical and medical procedures	Breast operation	01JUN2008	30JUN2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871461	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871462	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JUL2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2019		Y
			Osteoarthritis	01JAN2018	31JUL2019	N
			Spinal osteoarthritis	01SEP2019		Y
		Psychiatric disorders	Bipolar disorder	01JAN2007		Y
			Depression	01JAN2007		Y
			Insomnia	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1986	31DEC1986	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Oophorectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1087 10871463	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Dyspepsia	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1087 10871464	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian germ cell teratoma	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Oophorectomy	01JAN2017	31DEC2017	N
	C4591001 1087 10871465	Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1087 10871466	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871467	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Back injury	09SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2018		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Insomnia	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871470	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1087 10871472	Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871475	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1087 10871476	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Bipolar disorder	01JAN2005		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	03FEB1985	03FEB1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871477	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1087 10871478	Cardiac disorders	Atrial flutter	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Depression	01JUL2020		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871479	Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1087 10871481	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Pancreatitis	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2003		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871482	Social circumstances	Postmenopause	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871483	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871485	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1977		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Psychiatric disorders	Insomnia	01JAN1983		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1087 10871489	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1087 10871492	Vascular disorders	Hypertension	01JAN2005		Y
		Cardiac disorders	Coronary artery disease	01JAN1999		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1945		Y
				01JAN2004		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Hypercholesterolaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Nervous system disorders	Amnesia	01JUL2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1087 10871495	Vascular disorders	Hypertension	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1087 10871496	Immune system disorders	Allergy to chemicals	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871498	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871500	Eye disorders	Dry eye	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1954		Y
				01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Tension headache	01JAN1991		Y
		Renal and urinary disorders	Hypertonic bladder	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871501	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1087 10871502	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1087 10871503	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1087 10871505	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1087 10871507	Immune system disorders	Rubber sensitivity	01JAN2005		Y
		Social circumstances	Postmenopause	01JUL2019		Y
		Surgical and medical procedures	Female sterilisation	01JUN2002	30JUN2002	N
	C4591001 1087 10871509	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1087 10871514	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1986		Y
			Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871515	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Perennial allergy	01JAN1960		Y
		Psychiatric disorders	Anxiety	04NOV2016		Y
			Depression	04NOV2016		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1087 10871516	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1087 10871517	Eye disorders	Hypermetropia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1087 10871518	Eye disorders	Glaucoma	01JAN2019	01JAN2010	Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871519	Cardiac disorders	Atrial fibrillation	01JAN2010	01JAN2005	Y
			Coronary artery disease	01JAN2008		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	06MAY2020		Y
			Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Aortic stenosis	01JAN2008		Y
			Hypertension	01JAN2000		Y
	C4591001 1087 10871521	Eye disorders	Macular degeneration	01JAN2018		Y
		Immune system disorders	Perennial allergy	01JAN1958		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Seizure	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1087 10871522	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1087 10871523	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1087 10871524	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
	C4591001 1087 10871526	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1087 10871528	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871532	Eye disorders	Macular degeneration	01JAN2004		Y
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1971		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1087 10871534	Endocrine disorders	Hypothyroidism	01DEC2019		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871536	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN1977		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1087 10871537	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1087 10871538	Infections and infestations	Staphylococcal skin infection	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1087 10871539	Cardiac disorders	Myocardial infarction	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Constipation	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypovitaminosis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2019		Y
	C4591001 1087 10871540	Endocrine disorders	Hypothyroidism	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01APR2019	30APR2019	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	11APR2019	11APR2019	N
			Female sterilisation	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1087 10871542	Metabolism and nutrition disorders	Gout	01JAN2004		Y
			Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN1987	31DEC1987	N
			Prostate cancer	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2020		Y
		Surgical and medical procedures	Cancer surgery	01JAN1987	31DEC1987	N
			Radiotherapy to prostate	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1087 10871547	Endocrine disorders	Hypothyroidism	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1087 10871549	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Fungal skin infection	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Alcoholism	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2013		Y
			Depression	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2015		Y
	C4591001 1087 10871559	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Dry eye	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1942		Y
				01JAN1990		Y
				01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuralgia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Rhinitis perennial	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1087 10871560	Metabolism and nutrition disorders	Gout	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1087 10871561	Gastrointestinal disorders	Constipation	01JAN2019		Y
			Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2018		Y
	C4591001 1087 10871566	Vascular disorders	Hypertension	01JAN2019		Y
		Cardiac disorders	Angina pectoris	01AUG2017		Y
			Myocardial infarction	01AUG2017	31AUG2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Perennial allergy	01JAN1953		Y
			Rubber sensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN1980	31DEC1980	N
	C4591001 1087 10871567	Immune system disorders	Allergy to metals	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995	31DEC1995	N
	C4591001 1087 10871569	Vascular disorders	Hypertension	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871570	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1087 10871574	Cardiac disorders	Mitral valve incompetence	01JAN2008	31DEC2008	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Hepatitis A	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2019	31DEC2019	N
			Mitral valve repair	01JAN2008	31DEC2008	N
			Prostatectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Arteriosclerosis	01JAN2019	31DEC2019	N
			Hypertension	01JAN1995		Y
	C4591001 1087 10871575	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2003		Y
				01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign renal neoplasm	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN2003		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Nephrectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871577	Eye disorders	Macular degeneration	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2008		Y
			Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Renal and urinary disorders	Renal disorder	01JAN2014		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1999	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1951		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871578	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1087 10871580	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2008	31DEC2010	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871585	Cardiac disorders	Supraventricular tachycardia	01JAN2004		Y
		Endocrine disorders	Goitre	01JAN1975		Y
		Immune system disorders	Contrast media allergy	01JAN1980		Y
			Drug hypersensitivity	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Investigations	Blood oestrogen decreased	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of the vulva	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Bladder prolapse	01JAN2010	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cancer surgery	01JAN2012	31DEC2012	N
			Rectocele repair	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1087 10871587	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1998		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
					31DEC2017	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Deep vein thrombosis	01JAN1995		Y
			Hypertension	01JAN1998		Y
	C4591001 1087 10871589	Cardiac disorders	Coronary artery disease	01JAN2006		Y
			Myocardial infarction	01JAN2006	31DEC2006	N
		Congenital, familial and genetic disorders	Gallbladder anomaly congenital	(b) (6) 1952	31DEC1982	N
		Endocrine disorders	Testicular failure	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
			Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
			Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
			Trigeminal neuralgia	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1982	31DEC1982	N
			Coronary arterial stent insertion	01JAN2006	31DEC2006	N
			Knee operation	01JAN1992	31DEC1992	N
	C4591001 1087 10871590	Immune system disorders	Drug hypersensitivity	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2001	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Gastric bypass	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1087 10871591	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Diabetic retinopathy	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	20MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Iron deficiency	01JAN1990		Y
			Obesity	01JAN2000	27OCT2020	N
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20MAR2020		Y
					31DEC2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1087 10871592	Endocrine disorders	Parathyroid disorder	01JAN1993	31DEC1993	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Gallbladder operation	01JAN1999	31DEC1999	N
			Parathyroidectomy	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1087 10871600	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1088 10881001	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1088 10881002	Ear and labyrinth disorders	Vertigo	01JAN1980		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
			Irritable bowel syndrome	01JAN2010		Y
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881003	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Thyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881004	Gastrointestinal disorders	Abdominal distension	01JAN2005		Y
			Haemorrhoids	01JAN2019		Y
			Nausea	01JAN2005		Y
		Infections and infestations	Oral herpes	01JAN1985		Y
		Investigations	Hepatic enzyme increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2006		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2005		Y
			Major depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1984		Y
	C4591001 1088 10881006	Infections and infestations	Urinary tract infection	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1088 10881007	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01MAR2018	31MAR2018	N
		Vascular disorders	Hot flush	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881008	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	02OCT2018	28MAR2019	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Mastectomy	28MAR2019	28MAR2019	N
	C4591001 1088 10881013	Infections and infestations	Oral herpes	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881014	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1088 10881015	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1088 10881018	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1088 10881020	Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881022	Blood and lymphatic system disorders	Anaemia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1963		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN1944		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Stenosis	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis perennial	01JAN1990		Y
	C4591001 1088 10881023	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JUN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881026	Infections and infestations	Herpes zoster	01JAN1991	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
	C4591001 1088 10881027	Gastrointestinal disorders	Inguinal hernia	01APR2020		Y
	C4591001 1088 10881028	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2019		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881029	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Social anxiety disorder	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hot flush	01JAN2002		Y
			Hypertension	01JAN2005		Y
				01JAN2010		Y
	C4591001 1088 10881031	Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881032	Cardiac disorders	Coronary artery disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Investigations	Blood cholesterol increased	01JAN1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Coronary artery bypass	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1088 10881034	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881035	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Perennial allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Stress fracture	09AUG2020		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
			Vitamin D deficiency	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1088 10881041	Cardiac disorders	Atrial fibrillation	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Glaucoma	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Blood triglycerides increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Hearing aid user	01JAN1950		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1088 10881042	Cardiac disorders	Atrial fibrillation	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1088 10881043	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1088 10881046	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1088 10881047	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
	C4591001 1088 10881049	Investigations	Blood triglycerides increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Multiple allergies	01JAN1953		Y
	C4591001 1088 10881052	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881055	Cardiac disorders	Coronary artery disease	01JAN1997		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2013		Y
			Sleep apnoea syndrome	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1968		Y
	C4591001 1088 10881056	Cardiac disorders	Cardiovascular disorder	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1980		Y
			Sleep apnoea syndrome	01DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1088 10881057	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2014		Y
	C4591001 1088 10881058	Surgical and medical procedures	Vasectomy	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1088 10881061	Skin and subcutaneous tissue disorders	Rosacea	01JAN2012		Y
		Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
	C4591001 1088 10881062	Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Herpes virus infection	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	01JAN2003		Y
			Sensitive skin	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881063	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
			Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Renal and urinary disorders	Urethral disorder	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Prophylaxis	01JAN1995		Y
	C4591001 1088 10881066	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881068	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1088 10881069	Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1088 10881070	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Hepatobiliary disorders	Biliary tract disorder	01JAN2018		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01FEB2020		Y
	C4591001 1088 10881071	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881072	Congenital, familial and genetic disorders	Tourette's disorder	01JAN1961		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN1954		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881075	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	21AUG2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1088 10881076	General disorders and administration site conditions	Peripheral swelling	01JAN2010		Y
	C4591001 1088 10881078	Vascular disorders	Deep vein thrombosis	01JAN2015		Y
	C4591001 1088 10881083	Gastrointestinal disorders	Constipation	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Angiopathy	01JAN2015		Y
	C4591001 1088 10881085	Cardiac disorders	Cardiac failure congestive	01JAN2014		Y
			Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1088 10881086	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Sinus headache	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN1975		Y
			Depression	01JAN1975		Y
			Insomnia	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1968		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1088 10881088	Gastrointestinal disorders	Dyspepsia	01JAN2009		Y
		Infections and infestations	Oral herpes	01JAN1960		Y
			Staphylococcal infection	20JUL2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	24AUG2009		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1088 10881089	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1088 10881090	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1088 10881091	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1999		Y
		Infections and infestations	Chronic sinusitis	01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Pain in extremity	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN1998		Y
	C4591001 1088 10881092	Endocrine disorders	Gonadotrophin deficiency	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1088 10881093	General disorders and administration site conditions	Oedema	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1948		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1995		Y
			Osteoporosis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1948		Y
			Cough	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881096	Investigations	Cardiac murmur	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1088 10881097	Investigations	Heart rate irregular	01DEC2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881099	Cardiac disorders	Atrial fibrillation	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2008		Y
		Nervous system disorders	Headache	01JAN2013		Y
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 1088 10881104	Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1088 10881105	Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1957		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1088 10881106	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881108	Gastrointestinal disorders	Diverticulum	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2015		Y
	C4591001 1088 10881110	Vascular disorders	Hypertension	01JAN2002		Y
		Cardiac disorders	Coronary artery disease	01JAN2004		Y
	C4591001 1088 10881113	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Cardiac disorders	Angina pectoris	01JAN1997		Y
		Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Eye disorders	Macular degeneration	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1088 10881115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hypercholesterolaemia	01JUL2020		Y
			Vitamin D deficiency	01JAN2010		Y
		Psychiatric disorders	Depression	01JUN2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881118	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1088 10881119	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881120	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1088 10881121	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hot flush	01JAN2002		Y
			Hypertension	01JAN2000		Y
	C4591001 1088 10881122	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
	C4591001 1088 10881124	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1958		Y
			Rosacea	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881126	Cardiac disorders	Coronary artery disease	01JAN1983		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881127	Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2020		Y
	C4591001 1088 10881129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1088 10881131	Infections and infestations	Onychomycosis	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1088 10881132	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Osteoporosis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
			Emphysema	01JAN2017		Y
	C4591001 1088 10881133	Gastrointestinal disorders	Oesophageal stenosis	01JAN2012		Y
		Investigations	Blood testosterone decreased	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pollakiuria	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1088 10881135	Skin and subcutaneous tissue disorders	Dermatitis	01JAN2012		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1980		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1088 10881136	Vascular disorders	Hypertension	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	01JUL2020		Y
	C4591001 1088 10881138	Social circumstances	Postmenopause	01JAN2020		Y
		Endocrine disorders	Basedow's disease	01JAN2010		Y
			Hyperthyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1088 10881139	Social circumstances	Rhinitis perennial	01JAN2010		Y
		Cardiac disorders	Postmenopause	01JAN1995		Y
			Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1088 10881140	Investigations	Sleep apnoea syndrome	01JAN2015		Y
		Metabolism and nutrition disorders	Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Vitamin D deficiency	01JAN2015		Y
			Arthralgia	01JAN2017		Y
			Back pain	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
	C4591001 1088 10881141	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881142	Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1088 10881145	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Perennial allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Insomnia	01JAN2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Micturition urgency	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
			Wheezing	01JAN1969		Y
	C4591001 1088 10881146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1088 10881147	Gastrointestinal disorders	Large intestine polyp	01JAN2012		Y
		Investigations	Hepatic enzyme increased	01FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881149	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Multiple allergies	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
	C4591001 1088 10881150	Immune system disorders	Multiple allergies	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881154	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1088 10881155	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1088 10881156	Cardiac disorders	Coronary artery disease	01JAN2003		Y
		Endocrine disorders	Hyperthyroidism	01JAN2003		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Multiple allergies	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Depression	01JAN1988		Y
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2008		Y
			Hypertension	01JAN2015		Y
	C4591001 1088 10881157	Cardiac disorders	Supraventricular extrasystoles	01JAN2015		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JUL2020		Y
			Gastroesophageal reflux disease	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Multiple allergies	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1088 10881163	Cardiac disorders	Atrial fibrillation	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
	C4591001 1088 10881164	Infections and infestations	Sinusitis	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1982		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1088 10881165	Surgical and medical procedures	Oophorectomy	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Rhinitis perennial	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881167	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2019		Y
	C4591001 1088 10881168	Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1088 10881170	Immune system disorders	Perennial allergy	01JAN2001		Y
		Infections and infestations	Rocky mountain spotted fever	11AUG2020	18AUG2020	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
	C4591001 1088 10881172	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1962		Y
	C4591001 1088 10881173	Gastrointestinal disorders	Colitis ulcerative	01JAN1990		Y
			Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2018		Y
	C4591001 1088 10881174	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1088 10881178	Investigations	Androgens abnormal	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881179	Cardiac disorders	Tachycardia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2000		Y
	C4591001 1088 10881181	Eye disorders	Pigmentary glaucoma	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01FEB2020		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1088 10881182	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1088 10881184	Infections and infestations	Diverticulitis	01JAN1994		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881186	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2017		Y
			Hyperlipidaemia	01JAN2010		Y
			Iron deficiency	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin D deficiency	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Prostatitis	01JAN2014	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881188	Vascular disorders	Hypertension	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Retinal artery occlusion	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1982		Y
		Investigations	Cardiac murmur	01JAN1952		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2010		Y
			Intracranial aneurysm	01JAN2002		Y
			Migraine	01JAN1983		Y
	C4591001 1088 10881190	Vascular disorders	Hypertension	01JAN2010		Y
			Peripheral artery aneurysm	01AUG2020		Y
		Eye disorders	Dry eye	01JAN2012		Y
			Glaucoma	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Oedema	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Hypokalaemia	01JAN2012		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1961		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	Vascular disorders	Hypertension	01JAN2000		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881191	Gastrointestinal disorders	Eructation	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2009	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1088 10881195	Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
		Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1088 10881198	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1088 10881199	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1088 10881202	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1088 10881203	Cardiac disorders	Atrial fibrillation	01MAR2019		Y
			Coronary artery disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1088 10881204	Cardiac disorders	Atrial fibrillation	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1088 10881205	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2018		Y
			Nausea	01JAN2018		Y
		General disorders and administration site conditions	Oedema	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2015		Y
			Fibromyalgia	01JAN2018		Y
			Muscle spasms	01JAN2018		Y
			Osteoporosis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1971		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1088 10881206	Cardiac disorders	Atrial fibrillation	01JAN2011		Y
			Myocardial infarction	01JAN2010	31DEC2011	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1088 10881207	Gastrointestinal disorders	Diverticulum	01JAN2018		Y
			Large intestine polyp	01JAN2018		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
			Obesity	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1088 10881208	Gastrointestinal disorders	Dry mouth	01JAN1983		Y
			Dyspepsia	01JAN2015		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1088 10881210	Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1088 10881211	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881212	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1088 10881215	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1088 10881216	Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
			Ventricular tachycardia	01DEC2016		Y
		Gastrointestinal disorders	Constipation	01MAR2016		Y
		Immune system disorders	Multiple allergies	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
			Muscle spasms	01JAN2016		Y
			Osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01APR2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1088 10881223	Eye disorders	Glaucoma	01JAN2018		Y
		Infections and infestations	Urinary tract infection	01JAN1962		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1962		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1088 10881226	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1088 10881228	Nervous system disorders	Migraine	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1088 10881229	Psychiatric disorders	Bipolar disorder	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1088 10881230	Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1088 10881231	Cardiac disorders	Atrial fibrillation	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1088 10881234	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Insomnia	01JAN1990		Y
	C4591001 1088 10881236	Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Nausea	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Back pain	01JAN2009		Y
			Neck pain	01JAN2009		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Bipolar I disorder	01JAN1994		Y
			Insomnia	01JAN1958		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1088 10881237	Cardiac disorders	Cardiac failure congestive	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881241	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1088 10881242	Gastrointestinal disorders	Constipation	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Renal and urinary disorders	Haematuria	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Aortic aneurysm	01JAN2016		Y
			Hypertension	01JAN1975		Y
	C4591001 1088 10881243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
	C4591001 1088 10881244	Metabolism and nutrition disorders	Fluid retention	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Nervous system disorders	Essential tremor	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
	C4591001 1088 10881247	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1088 10881249	Investigations	Blood testosterone decreased	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
	C4591001 1088 10881250	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881252	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1976		Y
		Nervous system disorders	Migraine	01JAN1965		Y
			Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1088 10881253	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1088 10881257	Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1088 10881260	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1088 10881262	Gastrointestinal disorders	Diarrhoea	01JAN1977		Y
		Metabolism and nutrition disorders	Gout	01JAN2008		Y
			Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Mobility decreased	13OCT2020		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
			Endometrial cancer	01JAN1982	31DEC1982	N
		Nervous system disorders	Restless legs syndrome	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lymphoedema	01JAN2005		Y
	C4591001 1088 10881263	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891001	General disorders and administration site conditions	Oedema	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
				01JAN2014		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Ankle operation	01JAN1992	31DEC1992	N
			Appendectomy	01JAN1965	31DEC1965	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JAN2000	31DEC2000	N
			Splenectomy	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1950	31DEC1950	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Arterial occlusive disease	01JAN2005	31DEC2005	N
			Hypertension	01JAN2014		Y
	C4591001 1089 10891002	Infections and infestations	Appendicitis	01JAN1979	31DEC1979	N
			Tonsillitis	01JAN1966	31DEC1966	N
		Psychiatric disorders	Depression	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1089 10891003	Hepatobiliary disorders	Gallbladder disorder	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2019		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2001	31DEC2001	N
			Skeletal injury	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Magnesium deficiency	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Muscle spasms	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Bone operation	01JAN1966	31DEC1966	N
			Cholecystectomy	01JAN2002	31DEC2002	N
			Shoulder operation	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1089 10891004	Vascular disorders	Hypertension	01JAN2010		Y	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y	
		Immune system disorders		Nausea	01JAN2010		Y
				Drug hypersensitivity	01JAN1968		Y
					01JAN2000		Y
					01JAN2010		Y
					01JAN2016		Y
		Musculoskeletal and connective tissue disorders		Seasonal allergy	01JAN2000		Y
				Back pain	01JAN2010		Y
				Osteoarthritis	01JAN2010		Y
		Psychiatric disorders		Bipolar disorder	01JAN2012		Y
		Reproductive system and breast disorders		Colpocele	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders		Bronchitis chronic	01JAN2010		Y
		Surgical and medical procedures		Hysterectomy	01JAN1990	31DEC1990	N
	Mammoplasty			01JAN1985	31DEC1985	N	
	Rectocele repair			01JAN2010	31DEC2010	N	
	C4591001 1089 10891005	Cardiac disorders	Coronary artery occlusion	01JAN2013	31DEC2013	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y	
		Immune system disorders	Seasonal allergy	01JAN2010		Y	
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N	
		Investigations	Blood cholesterol increased	01JAN2013		Y	
	Metabolism and nutrition disorders		Gout	01JAN2011		Y	
			Type 2 diabetes mellitus	01JAN2013		Y	
	Musculoskeletal and connective tissue disorders		Osteoarthritis	01JAN2013		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carotid artery occlusion	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2013		Y
		Surgical and medical procedures	Arterial repair	01JAN2008	31DEC2008	N
			Coronary artery bypass	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1089 10891006	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
			Sinusitis	01JAN1995	31DEC1995	N
			Staphylococcal infection	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1984	31DEC1984	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2019	31DEC2019	N
			Temporomandibular joint surgery	01JAN1984	31DEC1984	N
	C4591001 1089 10891007	Cardiac disorders	Myocardial infarction	04MAY2015	04MAY2015	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
				01JAN1996		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Investigations	Blood cholesterol increased	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Blood triglycerides increased	01JAN1993		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Vascular graft	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1089 10891008	Cardiac disorders	Angina pectoris	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		General disorders and administration site conditions	Oedema	01JAN2006		Y
		Immune system disorders	Food allergy	01JAN2019		Y
			Seasonal allergy	01JAN2006		Y
		Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2006		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1990	31DEC1990	N
				01JAN1993	31DEC1993	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1089 10891009	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Investigations	Biopsy breast	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1089 10891012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01SEP2019		Y
			Intervertebral disc degeneration	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Colonoscopy	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891016	Cardiac disorders	Atrial fibrillation	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1995	31DEC1995	N
		Investigations	Heart rate irregular	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Fracture treatment	01JAN1995	31DEC1995	N
			Nasal septal operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1089 10891017	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1089 10891018	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Nausea	01JAN2019		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1983	31DEC1983	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
				01JAN2002		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1089 10891019	Cardiac disorders	Myocardial infarction	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN1992		Y
				01JAN1993		Y
			Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Coronary arterial stent insertion	01JAN2001	31DEC2001	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891021	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1089 10891023	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1089 10891024	General disorders and administration site conditions	Oedema	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1089 10891026	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
	C4591001 1089 10891028	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
			Tonsillitis	01JAN1962	31DEC1962	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Back pain	01DEC2012		Y
			Osteoarthritis	01NOV2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
			Spinal operation	01NOV2012	30NOV2012	N
			Toe operation	01NOV2018	30NOV2018	N
			Tonsillectomy	01JAN1962	31DEC1962	N
			Vasectomy	01JAN1970		Y
	C4591001 1089 10891030	Immune system disorders	Drug hypersensitivity	01JAN1960		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Female sterilisation	01JAN1965	31DEC1965	N
			Knee arthroplasty	01JAN1972	31DEC1972	N
				01JAN1986	31DEC1986	N
			Shoulder operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1089 10891031	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y
		Investigations	Heart rate irregular	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891032	Cardiac disorders	Coronary artery disease	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Aortic aneurysm repair	01JAN2014	31DEC2014	N
			Cataract operation	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JAN2008	31DEC2008	N
		Vascular disorders	Aortic aneurysm	01JAN2014	31DEC2014	N
			Hypertension	01JAN2008		Y
	C4591001 1089 10891033	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Rubber sensitivity	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Obesity	01JAN1999	31DEC1999	N
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Abdominoplasty	01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN1985	31DEC1985	N
			Shoulder operation	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1089 10891034	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891035	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891037	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891038	Eye disorders	Dry eye	01JAN2013		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2007		Y
				01JAN2008		Y
			Seasonal allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN1998	31DEC1998	N
			Limb injury	01JAN1987	31DEC1987	N
				01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Hypokalaemia	01JAN2008		Y
			Obesity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2008		Y
			Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Knee operation	01JAN1998	31DEC1998	N
			Limb operation	01JAN1987	31DEC1987	N
				01JAN1990	31DEC1990	N
			Wrist surgery	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1089 10891039	Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Infections and infestations	Adenoiditis	01JAN1959	31DEC1959	N
			Tonsillitis	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Obesity	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1959	31DEC1959	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Gastric bypass	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Limb operation	01OCT2019	31OCT2019	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891042	Eye disorders	Dry eye	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2011	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1089 10891043	Cardiac disorders	Angina pectoris	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
			Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Vascular graft	01JAN2004	31DEC2004	N
		Vascular disorders	Arterial occlusive disease	01JAN2004	31DEC2004	N
			Hypertension	01JAN2014		Y
	C4591001 1089 10891044	Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
			Tonsillitis	01JAN1979	31DEC1979	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1978	31DEC1978	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Appendectomy	01JAN1956	31DEC1956	N
			Bunion operation	01JAN1978	31DEC1978	N
			Cholecystectomy	01JAN1985	31DEC1985	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891045	Injury, poisoning and procedural complications	Chest injury	01JAN1972	31DEC1972	N
			Hand fracture	01JAN1972	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Surgical and medical procedures	Bone operation	01JAN1972	31DEC1972	N
			Knee arthroplasty	01JAN1973	31DEC1973	N
				01JAN2014	31DEC2014	N
			Limb operation	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01JAN2008	31DEC2008	N
			Tenoplasty	01JAN2008	31DEC2008	N
	C4591001 1089 10891046	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
			Tonsillitis	01JAN1975	31DEC1975	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1989	31DEC1989	N
			Caesarean section	01JAN1984	31DEC1984	N
				01JAN1987	31DEC1987	N
				01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891047	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN1955	31DEC1955	N
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1089 10891048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1089 10891051	Endocrine disorders	Hypothyroidism	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
			Oestradiol decreased	01JAN1991		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Presyncope	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
			Rosacea	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1089 10891052	Eye disorders	Dry eye	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1990		Y
		Investigations	Cardiac murmur	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2006	31DEC2006	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Penile prosthesis insertion	01JAN2013	31DEC2013	N
			Prostatectomy	01JAN2006	31DEC2006	N
			Sinus operation	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1089 10891053	Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN1997	31DEC1997	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ossicular operation	01JAN2011	31DEC2011	N
			Paranasal sinus polypectomy	01JAN1997	31DEC1997	N
	C4591001 1089 10891060	Cardiac disorders	Coronary artery stenosis	01JAN2006	31DEC2006	N
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2001	31DEC2007	N
		Immune system disorders	Allergy to arthropod sting	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
				01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2019	30SEP2019	N
			Coronary artery bypass	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2001	31DEC2001	N
				01JAN2007	31DEC2007	N
			Knee operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1089 10891063	Cardiac disorders	Arrhythmia	01JAN2004		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2005		Y
		Nervous system disorders	Tremor	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1089 10891066	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Nervous system disorders	Transient ischaemic attack	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1089 10891068	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1966	31DEC1966	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2008	31DEC2008	N
			Knee operation	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1089 10891069	Gastrointestinal disorders	Intestinal obstruction	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1089 10891071	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1990		Y
			Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2016		Y
		Nervous system disorders	Essential tremor	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2009	31DEC2009	N
			Spinal fusion surgery	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891073	Cardiac disorders	Myocardial infarction	01JAN2003	31DEC2003	N
				01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1983		Y
			Irritable bowel syndrome	01JAN2011		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
				01JAN1991		Y
				01JAN2018		Y
				01SEP2008		Y
			Seasonal allergy	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1991	31DEC1991	N
		Nervous system disorders	Diabetic neuropathy	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1999		Y
		Surgical and medical procedures	Ankle operation	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Spinal operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1089 10891075	Eye disorders	Cataract	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1089 10891081	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013	31DEC2013	N
			Vitamin B complex deficiency	01JAN2013		Y
			Vitamin D deficiency	01APR2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Gastric bypass	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1089 10891083	Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	31DEC1990	N
			Ossicular operation	01JAN2000	31DEC2000	N
			Prostatectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1089 10891086	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1089 10891087	General disorders and administration site conditions	Oedema peripheral	01MAR2020		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Gout	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891088	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN1970		Y
			Nausea	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
			Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Dementia Alzheimer's type	01NOV2019		Y
			Neuropathy peripheral	01JAN2018		Y
			Tremor	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
			Spinal operation	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089	Psychiatric disorders	Anxiety	01JAN2008	31DEC2008	N
	10891089			01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1089	Endocrine disorders	Hypothyroidism	01JAN2017		Y
	10891090					
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	01JAN1982	31DEC1982	N
			Knee operation	01DEC2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
	10891092					
		Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Gallbladder hypofunction	01JAN1992	31DEC1992	N
		Infections and infestations	Diverticulitis	01JAN2019		Y
		Injury, poisoning and procedural complications	Ulnar nerve injury	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01JUN2019	30JUN2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JUN2019	30JUN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1990	31DEC1990	N
			Elbow operation	01JUN2019	30JUN2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891093	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Sinusitis	01JAN1988	31DEC2004	N
			Tonsillitis	01JAN1959	31DEC1959	N
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Pain in jaw	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Foot operation	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Sinus operation	01JAN1988	31DEC1988	N
				01JAN1990	31DEC1990	N
				01JAN1992	31DEC1992	N
				01JAN1994	31DEC1994	N
				01JAN1997	31DEC1997	N
				01JAN2000	31DEC2000	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1089 10891094	Investigations	Blood cholesterol increased	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Spinal stenosis	01JAN2010		Y
		Surgical and medical procedures	Spinal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891095	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Renal and urinary disorders	Renal cyst	01JAN1983	31DEC1983	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Lithotripsy	01JAN2018	31DEC2018	N
			Renal cyst excision	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891096	Gastrointestinal disorders	Diarrhoea	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN1980		Y
			Irritable bowel syndrome	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2000		Y
				01JAN2015		Y
			Food allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
				01JAN1996	31DEC1996	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Female sterilisation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1089 10891098	Cardiac disorders	Angina pectoris	01JAN2000	31DEC2001	N
		Ear and labyrinth disorders	Vertigo	01JAN1980		Y
		Eye disorders	Glaucoma	01JAN2009		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2003	31DEC2003	N
			Gastroesophageal reflux disease	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000	31DEC2000	N
			Seasonal allergy	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1089 10891099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Lymphadenectomy	01JAN1979	31DEC1979	N
			Tonsillectomy	01JAN1960	31DEC1960	N
			Urethral operation	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891102	General disorders and administration site conditions	Fatigue	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN1985	31DEC1985	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Acoustic neuroma removal	01JAN1985	31DEC1985	N
			Appendicectomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1089 10891104	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN1950	31DEC1950	N
			Ligament operation	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1089 10891108	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1984		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891109	Gastrointestinal disorders	Constipation	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Infections and infestations	Genital herpes	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Exeresis	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891110	Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
	C4591001 1089 10891117	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	13AUG2007	31DEC2007	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
			Vasectomy	01JAN1978	31DEC1978	N
	C4591001 1089 10891118	Metabolism and nutrition disorders	Obesity	01JAN1965	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
			Gastric banding	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891122	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
			Large intestinal ulcer	01JAN2011	31DEC2011	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1994		Y
			Insomnia	01JAN1990		Y
			Post-traumatic stress disorder	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1089 10891124	Immune system disorders	Contrast media allergy	01JAN1984		Y
			Drug hypersensitivity	01JAN2006		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2006	31DEC2006	N
			Mastectomy	01JAN2012	31DEC2012	N
	C4591001 1089 10891125	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Colectomy	01JAN1970	31DEC1970	N
			Coronary arterial stent insertion	01JUL2020	31DEC2020	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Spinal operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891126	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Bladder operation	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Thyroid operation	01JAN2018	31DEC2018	N
	C4591001 1089 10891127	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
			Meniscus injury	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Foot operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Knee operation	01JAN2012	31DEC2012	N
			Shoulder operation	01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N
			Wrist surgery	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1089 10891128	Immune system disorders	Seasonal allergy	01JAN1950		Y
		Infections and infestations	Tonsillitis	01JAN1949	31DEC1949	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1949		Y
	C4591001 1089 10891129	Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1089 10891133	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Heart valve replacement	01JAN2010	31DEC2010	N
			Shoulder operation	01JAN2011	31DEC2011	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891137	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Malocclusion	01JAN1992	31DEC1992	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Jaw operation	01JAN1992	31DEC1992	N
	C4591001 1089 10891142	Cardiac disorders	Angina pectoris	01JAN2017	31DEC2017	N
			Arrhythmia	01JAN2011		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891143	Endocrine disorders	Hypothyroidism	01MAR2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Brain operation	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2019	31DEC2019	N
				31OCT2016	31OCT2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1089 10891144	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2006		Y
			Insomnia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			Female sterilisation	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Spinal operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1089 10891145	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2014		Y
			Rubber sensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN1999	31DEC1999	N
	C4591001 1089 10891148	Cardiac disorders	Arrhythmia	01JAN2010		Y
			Mitral valve prolapse	01JAN1977		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2004	N
			Ovarian cyst	01JAN1979	31DEC1979	N
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN1967	31DEC1967	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1967	31DEC1967	N
			Caesarean section	01JAN1981	31DEC1981	N
				01JAN1983	31DEC1983	N
			Endometrial ablation	01JAN2004	31DEC2004	N
			Explorative laparotomy	01JAN1979	31DEC1979	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1089 10891150	Gastrointestinal disorders	Impaired gastric emptying	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Investigations	Arthroscopy	01JAN1991	31DEC1991	N
				01JAN2001	31DEC2001	N
				01JAN2015	31DEC2015	N
			Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1991		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
			Dizziness	01JAN2000		Y
		Surgical and medical procedures	Atrial appendage closure	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891154	Gastrointestinal disorders	Abdominal hernia	01JAN2015	31DEC2015	N
			Diarrhoea	01JAN2009		Y
			Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2015		Y
			Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1973		Y
			Type 2 diabetes mellitus	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2003	31DEC2003	N
		Nervous system disorders	Cerebrovascular accident	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2015	31DEC2015	N
			Knee operation	01JAN2013	31DEC2013	N
			Shoulder operation	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891157	Cardiac disorders	Supraventricular tachycardia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood potassium decreased	01JAN1995		Y
			Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2016	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
			Gastric banding	01JAN2016	31DEC2016	N
			Tenoplasty	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1089 10891159	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2015	31DEC2015	N
	C4591001 1089 10891160	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2011	31DEC2011	N
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Foot operation	01JAN2011	31DEC2011	N
			Rotator cuff repair	01JAN2009	31DEC2009	N
	C4591001 1089 10891161	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Neck injury	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Rotator cuff syndrome	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Prostatectomy	01JAN2012	31DEC2012	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
			Spinal corpectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891163	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Investigations	Blood testosterone decreased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
			Osteoporosis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016	31DEC2016	N
			Tenoplasty	01JAN2020	31JAN2020	N
	C4591001 1089 10891164	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1089 10891167	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891169	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Infections and infestations	Diverticulitis	01MAR2015	31MAR2015	N
			Herpes zoster	01JAN1987	31DEC1987	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01MAR2015	31MAR2015	N
			Urge incontinence	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1089 10891170	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2013		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1089 10891171	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
				01JAN2018		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
			Myalgia	01JAN2015		Y
			Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Spinal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1089 10891172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1981	31DEC1981	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980		Y
			Migraine	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1976		Y
			Depression	01JAN1976		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1982		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN1981	31DEC1981	N
			Female sterilisation	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
				01JAN2018	31DEC2018	N
	C4591001 1089 10891174	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1089 10891175	Ear and labyrinth disorders	Deafness unilateral	01JAN2006	31DEC2006	N
		Investigations	Blood oestrogen decreased	01JAN2008		Y
			Progesterone decreased	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Ear operation	01JAN2006	31DEC2006	N
	C4591001 1089 10891177	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2000	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Blepharoplasty	01MAR2020	31MAR2020	N
			Cataract operation	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Limb operation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Cholelithiasis	01JAN1990	31DEC1990	N
	C4591001 1089 10891178	Hepatobiliary disorders				
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01APR2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1996	31DEC1996	N
			Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1996		Y
			Obsessive-compulsive disorder	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1996	31DEC1996	N
			Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1089 10891184	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1984	31DEC1984	N
		Investigations	Blood cholesterol increased	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Elbow operation	01JAN1986	31DEC1986	N
			Shoulder operation	01JAN1984	31DEC1984	N
			Spinal fusion surgery	01JAN2020	31JAN2020	N
			Spinal operation	05DEC2019	05DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891187	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Intervertebral disc degeneration	01JAN2014		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN2010	31DEC2010	N
	C4591001 1089 10891188	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000	31DEC2000	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN1998	31DEC1998	N
			Neck surgery	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1960	31DEC1960	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891189	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Umbilical hernia	01JAN1955	31DEC1955	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1975		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
			Knee operation	01JAN1976	31DEC1976	N
			Sinus operation	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN2005	31DEC2005	N
			Umbilical hernia repair	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891190	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Haemochromatosis	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Surgical and medical procedures	Knee arthroplasty	01JUN2013	30JUN2013	N
			Vasectomy	01AUG1996	31AUG1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891191	Injury, poisoning and procedural complications	Jaw fracture	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Internal fixation of fracture	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1089 10891195	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
	C4591001 1089 10891202	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2005		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
	C4591001 1089 10891203	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1975	31DEC1975	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2018		Y
			Seasonal allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1957		Y
		Surgical and medical procedures	Ankle operation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1975	31DEC1975	N
			Hysterectomy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1089 10891208	General disorders and administration site conditions	Oedema	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1967		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2012	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2011	31DEC2011	N
		Nervous system disorders	Diabetic neuropathy	01JAN2000		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Surgical and medical procedures	Ankle operation	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891210	General disorders and administration site conditions	Oedema peripheral	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Surgical and medical procedures	Knee operation	01JAN2010	31DEC2010	N
	C4591001 1089 10891211	Immune system disorders	Drug hypersensitivity	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Hip fracture	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Hip surgery	01JAN1979	31DEC1979	N
	C4591001 1089 10891214	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Gastrectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891216	Injury, poisoning and procedural complications	Tibia fracture	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Bone operation	01JAN1987	31DEC1987	N
			Nasal operation	01JAN1980	31DEC1980	N
			Vasectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891217	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Mammoplasty	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891218	Cardiac disorders	Atrial fibrillation	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1089 10891219	Cardiac disorders	Arrhythmia	01JAN2014		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Scoliosis	01JAN1977		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Adenoidal hypertrophy	01JAN1977	31DEC1977	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1977	31DEC1977	N
			Female sterilisation	01JAN2009	31DEC2009	N
			Spinal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1089 10891222	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
	C4591001 1089 10891223	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Peroneal nerve palsy	01JAN1986		Y
		Psychiatric disorders	Insomnia	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Hip surgery	01JAN1985	31DEC1985	N
			Knee operation	01JAN1985	31DEC1985	N
	C4591001 1089 10891224	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2019	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891229	Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1089 10891236	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Genital herpes	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1089 10891237	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891240	Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
	C4591001 1089 10891242	Cardiac disorders	Arrhythmia	01JAN2019	31DEC2019	N
			Coronary artery occlusion	01JAN2010	31DEC2010	N
		Infections and infestations	Sinusitis	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2019	31DEC2019	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Sinus operation	01JAN2005	31DEC2005	N
			Spinal operation	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891243	Endocrine disorders	Empty sella syndrome	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Infections and infestations	Tinea pedis	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01JAN2005		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1996	31DEC1996	N
			Osteomalacia	01JAN2005		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1981		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Bunion operation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891244	Cardiac disorders	Coronary artery occlusion	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891245	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1089 10891247	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1954		Y
		Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
			Tonsillitis	01JAN1945	31DEC1945	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1957	31DEC1957	N
			Lymphadenectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1945	31DEC1945	N
	C4591001 1089 10891248	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Pelvic laparoscopy	01JAN1986	31DEC1986	N
				01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2002	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Depression	01JAN1983		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1970	31DEC2010	N
			Pelvic cyst	01JAN1976	31DEC1979	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Laparotomy	01JAN1978	31DEC1978	N
			Shoulder operation	01JAN2004	31DEC2004	N
	C4591001 1089 10891249	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1089 10891250	Ear and labyrinth disorders	Deafness bilateral	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1089 10891251	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1977		Y
				01JAN1990		Y
			Rubber sensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Investigations	Biopsy breast normal	01JAN1989	31DEC1989	N
			Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1977	31DEC1977	N
	C4591001 1089 10891252	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891254	Gastrointestinal disorders	Constipation	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Parkinson's disease	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1089 10891256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2013		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2009		Y
				01JAN2011		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1089 10891258	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2018	31DEC2018	N
			Limb operation	01JAN1986	31DEC1986	N
			Nasal septal operation	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1089 10891260	Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2019	31DEC2019	N
			Uterine leiomyoma	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Appendicectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast conserving surgery	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1089 10891262	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Foot operation	01JAN2012	31DEC2012	N
	C4591001 1089 10891263	Cardiac disorders	Angina pectoris	01MAR2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Immune system disorders	Contrast media allergy	01JAN2000		Y
			Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Heart rate irregular	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1990	31DEC1990	N
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Foot operation	01JAN2011	31DEC2011	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
				01JAN2020	31JAN2020	N
			Spinal operation	01JAN2017	31DEC2017	N
			Tumour excision	01JAN1990	31DEC1990	N
	C4591001 1089 10891264	Cardiac disorders	Angina pectoris	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891265	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1089 10891266	Injury, poisoning and procedural complications	Hand fracture	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Keratomileusis	01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
			Limb operation	01JAN2016	31DEC2016	N
			Prostatectomy	01JAN2008	31DEC2008	N
			Shoulder operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891267	Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN2002	31DEC2002	N
				01JAN2004	31DEC2004	N
	C4591001 1089 10891269	Eye disorders	Glaucoma	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
	C4591001 1089 10891270	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Laparoscopy	01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Varicose vein	01JAN1996	31DEC1996	N
	C4591001 1089 10891274	Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2018	31DEC2018	N
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1089 10891276	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1969	31DEC1969	N
				01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN1969		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2010	31DEC2010	N
			Shoulder arthroplasty	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1089 10891281	Cardiac disorders	Myocardial infarction	01JAN1996	31DEC1996	N
	C4591001 1089 10891282	Endocrine disorders	Pituitary enlargement	24JAN2014	24JAN2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Facial paralysis	24JAN2014		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hypophysectomy	17DEC2019	17DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891284	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Surgical and medical procedures	Tendon graft	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1089 10891286	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC2016	N
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01APR2020	31AUG2020	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Vasectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891290	Injury, poisoning and procedural complications	Femur fracture	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Surgical and medical procedures	Cancer surgery	01JAN2002	31DEC2002	N
			Neck surgery	14NOV2019	14NOV2019	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1089 10891292	Gastrointestinal disorders	Hiatus hernia	01JAN2016	31DEC2016	N
		Investigations	Cardiac murmur	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891295	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1089 10891297	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1980	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1089 10891298	General disorders and administration site conditions	Oedema	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Heart rate irregular	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1089 10891300	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891301	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891302	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
		General disorders and administration site conditions	Oedema	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	01JAN1997	N
		Nervous system disorders	Restless legs syndrome	01JAN2011		Y
			Transient ischaemic attack	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1996		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Bladder operation	01JAN2010	01JAN2010	N
				01JAN2013	01JAN2013	N
			Breast conserving surgery	01JAN1997	01JAN1997	N
			Bunion operation	01JAN2003	31DEC2003	N
				01JAN2007	31DEC2007	N
			Hysterectomy	01MAR1974	31DEC1974	N
			Knee arthroplasty	03JAN2014	03JAN2014	N
				25AUG2014	25AUG2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
			Peripheral vascular disorder	01MAR2013		Y
	C4591001 1089 10891303	Investigations	Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1089 10891304	Gastrointestinal disorders	Haemorrhoids	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018	31DEC2018	N
			Pain in extremity	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Arthrodesis	01JAN2016	31DEC2016	N
			Knee operation	01JAN2000	31DEC2000	N
	C4591001 1089 10891305	Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Cardiac murmur	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1089 10891307	Nervous system disorders	Migraine	01JAN1962		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1089 10891308	Injury, poisoning and procedural complications	Ligament rupture	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Fracture treatment	01JAN2010	31DEC2010	N
			Shoulder arthroplasty	01JAN2019	31DEC2019	N
			Shoulder operation	01JAN2012	31DEC2012	N
	C4591001 1089 10891312	Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Cholecystectomy	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Mammoplasty	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1951	31DEC1951	N
	C4591001 1089 10891314	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1089 10891316	Musculoskeletal and connective tissue disorders	Back pain	01JAN1972		Y
			Neck pain	01JAN2015		Y
			Osteoarthritis	01JAN1976		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31DEC2017	N
	C4591001 1089 10891319	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1976		Y
			Rotator cuff syndrome	01JUN2018	30JUN2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1995	31DEC1995	N
			Tonsillar neoplasm benign	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891320	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1089 10891321	Cardiac disorders	Arrhythmia	01JAN2011		Y
			Atrioventricular block	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1961	31DEC1961	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1089 10891322	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Retinal detachment	01JAN1973	31DEC1973	N
	C4591001 1089 10891324	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
				01JAN2008		Y
			Perennial allergy	01JAN2013		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Bunion operation	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1089 10891325	Immune system disorders	Perennial allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1089 10891326	Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2018		Y
			Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Ankle operation	01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Thyroidectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891327	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1962	31DEC1962	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC1980	N
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Limb operation	01JAN1962	31DEC1962	N
			Tonsillectomy	01JAN1954		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891328	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1089 10891329	Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1089 10891331	Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1986		Y
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
			Blood cholesterol increased	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Knee operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1089 10891333	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891341	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1991	31DEC1991	N
			Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2014	N
			Migraine	01JAN2017		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN1985	31DEC1985	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Intervertebral disc operation	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee operation	01JAN1998	31DEC1998	N
			Shoulder operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1089 10891344	Injury, poisoning and procedural complications	Limb injury	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Limb operation	01JAN1990	31DEC1990	N
	C4591001 1089 10891345	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Spinal operation	01JAN2015	31DEC2015	N
	C4591001 1090 10901003	Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
	C4591001 1090 10901004	Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01DEC1953		Y
		Infections and infestations	Oral herpes	01JAN1983		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1090 10901010	Eye disorders	Glaucoma	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01NOV2006	31DEC2006	N
	C4591001 1090 10901011	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01NOV2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1970		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01DEC2017		Y
	C4591001 1090 10901013	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Urinary tract infection	01JAN1982		Y
		Psychiatric disorders	Anxiety disorder	01SEP2017	31MAR2020	N
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1090 10901017	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01MAR2020		Y
			Spinal osteoarthritis	01JAN1995		Y
		Nervous system disorders	Syncope	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1963		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
	C4591001 1090 10901018	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01NOV2015	31DEC2015	N
	C4591001 1090 10901019	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN1964		Y
		Investigations	Epinephrine	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1991		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1963	31DEC1963	N
			Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1090 10901026	Cardiac disorders	Atrial flutter	01JAN2008	31DEC2008	N
		Infections and infestations	Onychomycosis	01FEB2020		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Eye operation	01JAN1996	31DEC1996	N
			Patellectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901027	Gastrointestinal disorders	Inguinal hernia	01DEC2014	31JAN2015	N
		Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Bronchitis	01JAN2013	31DEC2013	N
				01JAN2017		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01MAY2019	30SEP2019	N
		Investigations	Heart rate irregular	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of testis	01JAN1975	31DEC2006	N
			Paraganglion neoplasm benign	01JAN2019	31JUL2020	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2015		Y
			Testicular pain	01JAN1975	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Pharyngeal disorder	01JUN2020	18JUN2020	N
			Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31JAN2015	N
			Nasopharyngeal surgery	18JUN2020	18JUN2020	N
			Orchidectomy	01JAN1994	31DEC1994	N
				01JAN2006	31DEC2006	N
			Spinal nerve stimulator implantation	01MAR2013	31MAR2013	N
			Transurethral prostatectomy	01AUG2018	31AUG2018	N
	C4591001 1090 10901030	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		General disorders and administration site conditions	Oedema peripheral	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Injury, poisoning and procedural complications	Back injury	01JAN1998		Y
		Investigations	Blood testosterone decreased	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypokalaemia	01AUG2020		Y
			Type 2 diabetes mellitus	01SEP2016		Y
		Nervous system disorders	Migraine	01JAN1973	31DEC1973	N
			Neuropathy peripheral	01JAN1984		Y
				01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1966		Y
		Surgical and medical procedures	Cataract operation	01APR2018	30APR2018	N
			Intervertebral disc operation	01JAN1998	31DEC1998	N
				01OCT2018	31OCT2018	N
			Spinal laminectomy	01FEB2019	28FEB2019	N
			Spinal operation	01JAN2020	31JAN2020	N
		Vascular disorders	Vasculitis	01MAY2020	31DEC2020	N
	C4591001 109010901032	Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N
	C4591001 109010901033	Blood and lymphatic system disorders	Anaemia vitamin B12 deficiency	01JAN2016		Y
		Congenital, familial and genetic disorders	Porphyria	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 109010901036	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Menopause	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901042	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN1970		Y
			Neuropathy peripheral	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2005	31DEC2005	N
	C4591001 1090 10901048	Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN1969		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2002	31DEC2002	N
		Nervous system disorders	Essential tremor	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Colectomy	01JAN2002	31DEC2002	N
			Parathyroid gland operation	01JAN2015	31DEC2015	N
			Parathyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901056	Endocrine disorders	Autoimmune thyroiditis	01JAN1979		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
	C4591001 1090 10901057	Ear and labyrinth disorders	Meniere's disease	01JAN1982	31DEC2000	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder neoplasm	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nocturia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2006	31DEC2006	N
				01JAN2015	31DEC2015	N
			Prostate ablation	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1090 10901059	Endocrine disorders	Thyroid mass	01JAN2011		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Surgical and medical procedures	Blood donation	01JAN1970		Y
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Aortic aneurysm	01JAN2007		Y
			Hypertension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901060	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01FEB2019	31DEC2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2000		Y
		Surgical and medical procedures	Gastric bypass	01JAN2013	31DEC2013	N
			Nephrectomy	01FEB2019	28FEB2019	N
			Prostatic urethral lift procedure	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1090 10901062	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Inguinal hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2013	31DEC2013	N
		Psychiatric disorders	Bipolar disorder	01JAN1977	31DEC2000	N
			Depression	01JAN1975	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1975	31DEC2018	N
		Social circumstances	Blood donor	01JAN2016	31DEC2019	N
		Surgical and medical procedures	Joint arthroplasty	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Vasectomy	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901063	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Urinary tract infection	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Psychiatric disorders	Anxiety disorder	01JAN2009		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2013		Y
			Urinary incontinence	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N
			Meniscus operation	01JAN2008	31DEC2008	N
	C4591001 1090 10901064	Cardiac disorders	Bundle branch block left	01JAN2018		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2019	02JUN2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	01MAR2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Hernia repair	01JAN1998	31DEC1998	N
			Knee arthroplasty	01MAR2018	01MAR2018	N
			Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901066	Endocrine disorders	Hypothyroidism	01JAN1978		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2020	31JAN2020	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Salivary gland cancer	01JAN1968	31DEC1968	N
		Surgical and medical procedures	Bone operation	01JAN2020	31JAN2020	N
			Salivary gland operation	01JAN1968	31DEC1968	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
			Thyroidectomy	01JAN1978	31DEC1978	N
			Vasectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1090 10901069	Immune system disorders	Allergy to animal	01JAN2000		Y
		Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1962	31MAR1988	N
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Metabolism and nutrition disorders	Gout	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Neuropathy peripheral	01JAN1973		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Coronary artery bypass	01DEC2001	31DEC2001	N
			Hip surgery	01JAN2019	31DEC2019	N
			Knee operation	01DEC2018	31DEC2018	N
			Spinal fusion surgery	01JAN1988	31DEC1988	N
			Splenectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901071	Ear and labyrinth disorders	Hypoacusis	01JAN2016		Y
		Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1945		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Skin hypopigmentation	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1090 10901075	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Renal failure	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Haemorrhoid operation	01JAN2005	31DEC2005	N
			Intervertebral disc operation	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2016		Y
			Thrombosis	01JAN2016		Y
	C4591001 1090 10901077	Eye disorders	Dry eye	01JAN2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2013		Y
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign gastrointestinal neoplasm	01JAN1995	31DEC1995	N
		Nervous system disorders	Sciatica	01JAN2014		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
			Bunion operation	01JAN1992	31DEC1992	N
			Cancer surgery	01FEB2020	31DEC2020	N
			Foot operation	01JAN2007	31DEC2007	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Knee operation	01JAN1994	31DEC1994	N
				01JAN2005	31DEC2005	N
			Medical device implantation	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
	C4591001 1090 10901078	Immune system disorders	Mycotic allergy	01JAN1962		Y
		Investigations	Blood cholesterol increased	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Joint stiffness	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1962		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hernia repair	01JAN1990	31DEC1990	N
			Lenticular operation	01JAN2018	31JAN2018	N
			Spinal operation	01JAN2000	31DEC2000	N
			Splenectomy	01JAN1978	31DEC1978	N
			Tonsillectomy	01JAN1949	31DEC1949	N
	C4591001 1090 10901080	Gastrointestinal disorders	Gastric ulcer	01JAN1998	31DEC1998	N
		Infections and infestations	Pneumonia viral	01JAN2005	31DEC2019	N
		Metabolism and nutrition disorders	Gout	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1992		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901082	Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1955		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901083	Psychiatric disorders	Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01DEC2010		Y
		Surgical and medical procedures	Blepharoplasty	15FEB2020	15FEB2020	N
			Nasal septal operation	07JUN2020	07JUN2020	N
	C4591001 1090 10901087	Immune system disorders	Allergy to animal	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mite allergy	01JAN2018		Y
			Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC1995	N
		Psychiatric disorders	Depression	01JAN2007	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN1995	31DEC1995	N
	C4591001 1090 10901089	Gastrointestinal disorders	Abdominal hernia	01JAN2019	31OCT2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Bronchitis chronic	01JAN1976		Y
			Rhinitis allergic	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hernia repair	01OCT2019	31OCT2019	N
	C4591001 1090 10901091	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Gastric bypass	01JAN2012	31DEC2012	N
			Splenectomy	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901092	Gastrointestinal disorders	Inguinal hernia	01JAN1983	31DEC1983	N
				01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1999	31DEC1999	N
			Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Cancer surgery	01JAN2018	31DEC2018	N
			Cataract operation	01AUG2016	31AUG2016	N
				01JUL2016	31JUL2016	N
			Prostatic operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1090 10901098	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteoporosis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1960		Y
		Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Hysteropexy	01JAN1975	31DEC1975	N
			Knee arthroplasty	01OCT2019	31OCT2019	N
			Oophorectomy	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1995	31DEC1995	N
			Radiotherapy to thyroid	01JAN2009	31DEC2009	N
			Urinary bladder suspension	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1090 10901100	Injury, poisoning and procedural complications	Upper limb fracture	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2019	N
			Lymphoma	01JAN1999	31DEC2000	N
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1090 10901102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01MAR2007		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JUL1976	31DEC1976	N
		Surgical and medical procedures	Hysterectomy	21JAN2002	21JAN2002	N
			Knee arthroplasty	01JAN2015	31JAN2015	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1090 10901110	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Fracture treatment	01APR2000	30APR2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1962		Y
		Reproductive system and breast disorders	Pelvic prolapse	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1090 10901117	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN1996		Y
		Surgical and medical procedures	Appendectomy	01JAN1959	31DEC1959	N
			Cataract operation	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1090 10901118	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Hiatus hernia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Bone loss	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1990	31DEC1990	N
			Parathyroid tumour benign	01JAN1990	31DEC1990	N
		Nervous system disorders	Anosmia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01MAR1990		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2004	31DEC2004	N
			Joint surgery	01JAN2017	31DEC2017	N
			Mastectomy	01JAN1990	31DEC1990	N
			Meniscus removal	01JAN2006	31DEC2006	N
			Parathyroid gland operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
			Lymphoedema	01JAN1991		Y
	C4591001 1090 10901119	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1966		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901121	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
			Squamous cell carcinoma	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Blepharoplasty	01JAN2020	31JAN2020	N
			Cataract operation	01JUL2020	31DEC2020	N
			Female sterilisation	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hot flush	01JAN2012		Y
	C4591001 1090 10901122	Cardiac disorders	Coronary artery disease	01JAN2017	31DEC2017	N
			Tachycardia	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN2004		Y
			Gastrooesophageal reflux disease	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1992		Y
			Panic disorder	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1997		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
	C4591001 1090 10901123	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Renal and urinary disorders	Haematuria	01JAN2015		Y
			Hypertonic bladder	01JAN2017		Y
			Urinary incontinence	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
				01SEP2019	30SEP2019	N
	C4591001 1090 10901124	Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2020	31JAN2020	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1090 10901126	Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
	C4591001 1090 10901127	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		General disorders and administration site conditions	Fatigue	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	01JAN2005	31DEC2006	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1989		Y
			Bipolar disorder	01JAN1971		Y
			Depression	01JAN1971		Y
				01JAN1980	31DEC1980	N
				01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
			Urinary incontinence	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
			Psoriasis	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
	C4591001 1090 10901129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1090 10901130	Eye disorders	Glaucoma	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1951		Y
			Seasonal allergy	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
			Uterine leiomyoma	01JAN1994	31DEC1998	N
		Nervous system disorders	Tension headache	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901134	Eye disorders	Cataract	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Food allergy	01JAN1968		Y
		Nervous system disorders	Migraine	01JAN1974		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN1970		Y
	C4591001 1090 10901137	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
				01JAN2009	31DEC2009	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1090 10901138	Immune system disorders	Allergy to chemicals	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Visual field defect	01JUN2020	31JUL2020	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000	31DEC2005	N
		Surgical and medical procedures	Blepharoplasty	01JUL2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JUN2020	31DEC2020	N
			Calcific deposits removal	01JAN2019	31DEC2019	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1090 10901141	Cardiac disorders	Congestive cardiomyopathy	01JAN2007		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2011		Y
	C4591001 1090 10901142	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1997	31DEC1997	N
		Nervous system disorders	Syncope	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Allergic bronchitis	01JAN2010		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
			Skin lesion removal	01JAN2019	31JAN2019	N
		Vascular disorders	Hot flush	01JAN2007		Y
			Hypertension	01JAN2010		Y
	C4591001 1090 10901143	Investigations	Low density lipoprotein increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1950		Y
			Drug eruption	01JAN2010		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901144	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Knee operation	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
	C4591001 1090 10901145	Nervous system disorders	Transient ischaemic attack	01OCT1997	31OCT1997	N
		Surgical and medical procedures	Bunion operation	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN2015	31DEC2018	N
			Toe operation	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1090 10901146	Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
	C4591001 1090 10901148	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Meniscus operation	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901149	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2018		Y
	C4591001 1090 10901150	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1996		Y
		Immune system disorders	Rubber sensitivity	01JAN1997		Y
		Investigations	Blood cholesterol increased	01JAN1987		Y
		Psychiatric disorders	Anxiety disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2014		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1090 10901151	Eye disorders	Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC2000	N
		Infections and infestations	Herpes simplex	01JAN2005		Y
			Poliomyelitis	01JAN1954	31DEC1954	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2000	31DEC2000	N
			Surgery	01JAN1960	31DEC1960	N
			Synovial cyst removal	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901152	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN1965		Y
			Drug hypersensitivity	01JAN1995		Y
			Dust allergy	01JAN1965		Y
			Seasonal allergy	01JAN1965		Y
			Smoke sensitivity	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1992		Y
			Osteoporosis	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Surgical and medical procedures	Lithotripsy	01JAN1989	31DEC1989	N
	C4591001 1090 10901153	Gastrointestinal disorders	Gastric disorder	01JAN2015		Y
		Investigations	Cardiac murmur	(b) (6) 1963		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
	C4591001 1090 10901155	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Appendicitis	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN1990	31DEC1990	N
				01JAN1995	31DEC1995	N
			Appendectomy	01JAN2004	31DEC2004	N
			Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1090 10901158	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
				01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016		Y
			Rubber sensitivity	01JAN1956		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Skin neoplasm excision	01JUN2015	30JUN2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901159	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2016	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01MAR2017	30APR2017	N
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019	31DEC2019	N
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN1989		Y
			Inguinal hernia repair	01OCT2017	31OCT2017	N
			Knee arthroplasty	01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1090 10901162	Ear and labyrinth disorders	Vertigo positional	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Retinal operation	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
			Retinopexy	01JAN1963	31DEC1963	N
	C4591001 1090 10901164	Gastrointestinal disorders	Dyspepsia	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1963	31DEC1963	N
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2018	N
			Squamous cell carcinoma of skin	01JAN2000	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901165	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Infections and infestations	Appendicitis	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
			Cholecystectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901166	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970	31DEC1970	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1976	31DEC1976	N
			Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1090 10901168	Infections and infestations	Appendicitis	01JAN1949	31DEC1949	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1949	31DEC1949	N
			Cataract operation	01JAN2019	31DEC2019	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1090 10901170	Cardiac disorders	Myocardial infarction	01JAN2007	31DEC2007	N
		Eye disorders	Glaucoma	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
			Malignant melanoma	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2007	31DEC2007	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Spinal laminectomy	01JAN1971	31DEC1971	N
			Stent placement	01JAN2007	31DEC2007	N
	C4591001 1090 10901171	Gastrointestinal disorders	Inguinal hernia	01NOV2008	31DEC2008	N
		Infections and infestations	Tonsillitis	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019	02APR2020	N
		Nervous system disorders	Peroneal nerve palsy	30DEC2019		Y
		Psychiatric disorders	Affective disorder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hernia repair	01JAN2008	31DEC2008	N
			Intervertebral disc operation	02APR2020	02APR2020	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1090 10901173	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
	C4591001 1090 10901175	Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
		Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980	31DEC2016	N
			Inguinal hernia	01JAN1956	31DEC1957	N
		General disorders and administration site conditions	Cyst	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2017		Y
			Iodine allergy	01JAN1989		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1994		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1977	31DEC1977	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Peripheral vascular disorder	01JAN2006		Y
	C4591001 1090 10901176	Cardiac disorders	Atrial fibrillation	01JUL2020	31JUL2020	N
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Nervous system disorders	Cerebrovascular accident	01SEP2019	30SEP2019	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
			Nephrolithiasis	01JAN1980	31DEC2017	N
			Urge incontinence	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Bronchitis chronic	01JAN2016		Y
			Rhinitis allergic	01JAN1987		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
			Implantable cardiac monitor insertion	01JUL2020	31JUL2020	N
			Knee operation	01JAN2005	31DEC2005	N
			Sinus operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901179	Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2016		Y
			Scoliosis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
				18OCT2018	18OCT2018	N
		Vascular disorders	Hot flush	01JAN2005		Y
	C4591001 1090 10901180	Cardiac disorders	Myocardial infarction	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Bronchitis chronic	01JAN1980		Y
			Dyspnoea	01JAN1980		Y
			Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Angioplasty	01JAN2000	31DEC2000	N
			Spinal operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1090 10901181	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01AUG2019		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1090 10901182	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901183	Eye disorders	Dry eye	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2002	31DEC2003	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
		Surgical and medical procedures	Toe operation	01JAN2002	31DEC2002	N
				01JAN2003	31DEC2003	N
	C4591001 1090 10901184	Immune system disorders	Drug hypersensitivity	01JAN1990	31DEC1990	N
		Infections and infestations	Gastroenteritis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2018	N
		Psychiatric disorders	Depression	01JUL2000		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Hysterectomy	19JUN2019	19JUN2019	N
			Knee arthroplasty	19JUN2018	19JUN2018	N
	C4591001 1090 10901186	Eye disorders	Cataract	01JAN2017		Y
		General disorders and administration site conditions	Hernia	01JAN1950	31DEC1950	N
				01JAN1986	31DEC1986	N
				01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01APR1983	30APR1983	N
				01JAN1988		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1959		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901188	Gastrointestinal disorders	Colitis ulcerative	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950	31DEC1980	N
			Rhinitis allergic	01JAN1950		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1090 10901189	Immune system disorders	Seasonal allergy	01DEC1962		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1090 10901190	Eye disorders	Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1971	31DEC1971	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Blood triglycerides increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Trigeminal neuralgia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2010	N
			Intraocular lens implant	01JAN1950	31DEC1950	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1978		Y
			Raynaud's phenomenon	01JAN2010		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2018	31DEC2018	N
	C4591001 1090 10901191	Gastrointestinal disorders	Constipation	01JAN2010		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
			Herpes simplex	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01JAN2008	31DEC2009	N
			Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2001		Y
			Insomnia	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Colectomy	01JAN2015	31DEC2015	N
			Craniotomy	01JAN2009	31DEC2009	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Fracture treatment	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2013	31DEC2013	N
			Shoulder operation	01JAN2007	31DEC2007	N
	C4591001 1090 10901192	Ear and labyrinth disorders	Tinnitus	01JAN1985		Y
		Immune system disorders	Food allergy	01JAN1958		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1090 10901194	Investigations	Blood cholesterol increased	01NOV2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2001		Y
		Surgical and medical procedures	Coronary artery bypass	01NOV2019	30NOV2019	N
			Vascular stent insertion	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01NOV2019		Y
			Peripheral vascular disorder	01JAN2013		Y
	C4591001 1090 10901195	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Hernia	01JAN1988	31DEC1988	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2019	31AUG2019	N
		Surgical and medical procedures	Hernia repair	01JAN1988	31DEC1988	N
	C4591001 1090 10901196	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Irritable bowel syndrome	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to chemicals	01JUL2020		Y
			Allergy to metals	01JUL2020		Y
			Food allergy	01JAN1982		Y
			Seasonal allergy	01JAN2003		Y
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1975		Y
			Eczema	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1090 10901198	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Investigations	Lipids increased	23JUN2020		Y
		Psychiatric disorders	Depression	01NOV2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
	C4591001 1090 10901202	Investigations	Blood testosterone decreased	01JAN2016		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1971	31JAN1971	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901203	Ear and labyrinth disorders	Vertigo	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01NOV2018	30NOV2018	N
			Skin lesion removal	23JUN2020	23JUN2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1090 10901205	Cardiac disorders	Atrial fibrillation	01JAN2007	31DEC2011	N
		Gastrointestinal disorders	Constipation	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2003	31DEC2003	N
				01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990		Y
		Nervous system disorders	Parkinson's disease	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2007	31DEC2011	N
			Meniscus removal	01JAN2003	31DEC2003	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1973	31DEC1973	N
			Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1090 10901207	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1980	31DEC1980	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1956		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Vascular disorders	Hot flush	01JAN2003		Y
			Hypertension	01JAN1990		Y
	C4591001 1090 10901208	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901209	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1992		Y
		Surgical and medical procedures	Renal stone removal	01JAN2017	31DEC2017	N
	C4591001 1090 10901213	Immune system disorders	Drug hypersensitivity	01JAN2019	31JAN2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAY2018	30NOV2018	N
		Nervous system disorders	Cluster headache	01JAN2000		Y
		Renal and urinary disorders	Ureteric obstruction	01JAN2019	30APR2019	N
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN2020		Y
		Surgical and medical procedures	Prostatectomy	01NOV2018	30NOV2018	N
			Ureteric repair	01APR2019	30APR2019	N
	C4591001 1090 10901214	Immune system disorders	Drug hypersensitivity	01JAN1953		Y
				01JAN2003		Y
		Infections and infestations	Pneumonia	01APR2017	30APR2017	N
		Renal and urinary disorders	Urinary incontinence	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01MAY2020	31MAY2020	N
			Female sterilisation	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1090 10901215	Infections and infestations	Appendicitis	01JAN1951	31DEC1951	N
		Investigations	Blood cholesterol increased	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1989		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1955		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
			Rosacea	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN1951	31DEC1951	N
			Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Lithotripsy	01JAN2001	31DEC2001	N
			Spinal laminectomy	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1945	31DEC1945	N
	C4591001 1090 10901217	Immune system disorders	Mycotic allergy	01JAN1993	31DEC1993	N
			Psychiatric disorders	Depression	01JAN2013	31DEC2017
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Rosacea	01NOV2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypotension	01JAN1982		Y
	C4591001 1090 10901218	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1998	31DEC2000	N
			Osteopenia	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
			Urinary incontinence	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1090 10901219	Immune system disorders	Allergy to arthropod sting	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Surgical and medical procedures	Sinus operation	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
			Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1090 10901223	Ear and labyrinth disorders	Deafness	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Spinal laminectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hot flush	01JAN2016		Y
	C4591001 1090 10901227	Immune system disorders	Food allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901228	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
	C4591001 1090 10901229	Gastrointestinal disorders	Gastric ulcer	01JAN1998	31DEC1998	N
		Immune system disorders	Food allergy	01JAN1974		Y
			Iodine allergy	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31JAN2018	N
	C4591001 1090 10901230	Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG1970		Y
	C4591001 1090 10901231	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1090 10901232	Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2019		Y
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Breast conserving surgery	01MAR1999	31MAR1999	N
	C4591001 1090 10901233	Ear and labyrinth disorders	Vertigo positional	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2011	31DEC2013	N
				01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal cancer	01JAN1984	31DEC1984	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1992	31DEC1992	N
		Reproductive system and breast disorders	Vaginal stricture	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Colectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Surgery	01JAN1992	31DEC1992	N
		Vascular disorders	Hot flush	01JAN1990		Y
			Hypertension	01JAN2005		Y
	C4591001 1090 10901234	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2009		Y
		Infections and infestations	Herpes simplex	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1968	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
			Tracheostomy	01JAN1955	31DEC1955	N
	C4591001 1090 10901235	Investigations	Blood cholesterol increased	01JAN2010		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2008	31DEC2012	N
	C4591001 1090 10901236	Eye disorders	Dry eye	10SEP2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1946		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997	31DEC2016	N
					31JUL2000	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hip arthroplasty	01JUL2000	31JUL2000	N
				01JUN2005	30JUN2005	N
			Pyloroplasty	01JAN1946	31JAN1946	N
			Shoulder arthroplasty	01OCT2015	29FEB2016	N
	C4591001 1090 10901237	Cardiac disorders	Myocardial infarction	06JUL2018	06JUL2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01AUG2018		Y
				01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2004		Y
		Nervous system disorders	Migraine	01JAN1960		Y
		Renal and urinary disorders	Renal impairment	01AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1963		Y
			Psoriasis	01JAN2005		Y
		Surgical and medical procedures	Coronary artery bypass	06JUL2018	06JUL2018	N
			Tenoplasty	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901240	Ear and labyrinth disorders	Hypoacusis	01JAN2008		Y
		Immune system disorders	Food allergy	01JAN1983		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Renal and urinary disorders	Haematuria	01JAN1996	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1950		Y
		Surgical and medical procedures	Sinus operation	01JAN2005	31DEC2005	N
			Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901241	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01MAY2019	31MAY2019	N
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1090 10901242	Cardiac disorders	Ventricular extrasystoles	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Infections and infestations	Fungal skin infection	01AUG2018		Y
			Scarlet fever	01JAN1958	31DEC1958	N
		Nervous system disorders	Migraine	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01MAY2019	29FEB2020	N
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1090 10901243	Investigations	Blood cholesterol increased	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2017		Y
	C4591001 1090 10901247	Ear and labyrinth disorders	Deafness	01JAN2011		Y
			Vertigo	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2015	31DEC2015	N
			Spinal column injury	14JUN2020		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Surgical and medical procedures	Parathyroid gland operation	01JAN2014	31DEC2014	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901252	Investigations	Lipids increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2015		Y
		Renal and urinary disorders	Incontinence	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2017	N
			Limb operation	01JAN1990	31DEC1990	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1090 10901254	Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2016		Y
	C4591001 1090 10901255	Gastrointestinal disorders	Umbilical hernia	01JUL2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1090 10901257	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN1990		Y
			Food allergy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1984		Y
		Social circumstances	Menopause	01JUN2018		Y
	C4591001 1090 10901258	Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1090 10901259	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colorectal cancer	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Non-Hodgkin's lymphoma	01JAN2004	31DEC2005	N
		Nervous system disorders	Essential tremor	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Colectomy	01JAN2005	31DEC2005	N
			Wrist surgery	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901261	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2000		Y
			Rhinitis allergic	01JAN1964		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2014	31DEC2014	N
			Knee operation	01JAN1993	31DEC1993	N
			Prostatic operation	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1090 10901263	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Transient ischaemic attack	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Hernia repair	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1090 10901265	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN2002		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
			Lipids increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Pelvic pain	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Foot operation	01JAN1994	31DEC1994	N
				01JAN1997	31DEC1997	N
	C4591001 1090 10901272	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1090 10901273	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012	31DEC2015	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
			Rosacea	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Transurethral prostatectomy	01JAN2015	31DEC2015	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1090 10901274	Congenital, familial and genetic disorders	Dolichocolon	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2004	31DEC2004	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Breast cancer	01JAN1984	31DEC2003	N
				01JAN2002	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Mastectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1090 10901275	Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2014	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Hip arthroplasty	01DEC2017	31DEC2017	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901279	Infections and infestations	Hepatitis A	01JAN1972	31DEC1972	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2010		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Aortic dilatation	01JAN2014		Y
			Hypertension	01JAN2010		Y
	C4591001 1090 10901280	Ear and labyrinth disorders	Hypoacusis	01JAN2013		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2014		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Surgical and medical procedures	Hernia repair	01MAR2014	31MAR2014	N
	C4591001 1090 10901282	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1974		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1090 10901284	Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901285	Immune system disorders	Drug hypersensitivity	01JAN1985		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN1971	31DEC1981	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1981	31DEC1981	N
	C4591001 1090 10901286	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1090 10901287	Immune system disorders	Allergy to animal	(b) (6) 1959		Y
			Allergy to arthropod sting	(b) (6) 1959		Y
			Dust allergy	(b) (6) 1959		Y
			Mycotic allergy	(b) (6) 1959		Y
			Seasonal allergy	(b) (6) 1959		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Rhinitis allergic	(b) (6) 1959		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1090 10901292	Gastrointestinal disorders	Dyspepsia	01JAN1944		Y
			Gastric ulcer	01JAN1961	31DEC1966	N
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1944		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2001	31DEC2001	N
		Renal and urinary disorders	Urinary incontinence	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1949		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2015	31DEC2015	N
				01JAN2020	31DEC2020	N
			Tonsillectomy	01JAN1947	31DEC1947	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1090 10901293	Ear and labyrinth disorders	Deafness	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2020		Y
		Surgical and medical procedures	Colectomy	01JAN2009	31DEC2009	N
			Metabolic surgery	15MAY2020	15MAY2020	N
	C4591001 1090 10901296	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteoporosis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01OCT2019	31OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901298	Cardiac disorders	Myocardial infarction	01AUG2016	31AUG2016	N
			Sinus bradycardia	02SEP2019		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Dupuytren's contracture operation	01JAN2015	31DEC2016	N
			Lithotripsy	01JAN2017	31DEC2017	N
			Stent placement	01AUG2016	31AUG2016	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1090 10901299	Eye disorders	Uveitis	01JAN2005	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2000	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901300	Investigations	Lipids increased	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic myeloid leukaemia	01JAN1991		Y
			Prostate cancer	01JAN1988	31DEC1988	N
		Renal and urinary disorders	Chronic kidney disease	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901301	Eye disorders	Glaucoma	01JAN2002		Y
			Pupils unequal	01JAN1958	31DEC1958	N
	C4591001 1090 10901302	Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Investigations	Blood cholesterol increased	01DEC2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC1995	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
			Urinary incontinence	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1090 10901303	Cardiac disorders	Atrial flutter	21JUN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
			Squamous cell carcinoma	14OCT2016	18APR2019	N
				19DEC2014	14OCT2016	N
		Surgical and medical procedures	Vasectomy	30MAY1996	30MAY1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901305	Immune system disorders	Drug hypersensitivity	01DEC1978		Y
		Infections and infestations	Sinusitis	01JAN1981		Y
			Tuberculosis	01JUL1978	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Spinal fusion surgery	01NOV2018	30NOV2018	N
			Tonsillectomy	01JAN1975	31DEC1975	N
	C4591001 1090 10901306	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1986		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
			Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1090 10901307	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Blood calcium decreased	01JAN2018		Y
			Blood cholesterol increased	10FEB2018		Y
			Vitamin D decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2002		Y
			Sinus headache	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1090 10901308	Cardiac disorders	Congestive cardiomyopathy	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Renal and urinary disorders	Hypertonic bladder	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1964		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901309	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Psychiatric disorders	Anxiety disorder	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901310	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Post herpetic neuralgia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Pilonidal sinus repair	01JAN2008	31DEC2008	N
	C4591001 1090 10901311	Eye disorders	Dry eye	01JAN2007		Y
		Gastrointestinal disorders	Diverticulum	01JAN1992		Y
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Anxiety disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JUL2015		Y
			Rosacea	01JUN2019		Y
			Seborrhoeic dermatitis	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Fasciotomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1090 10901313	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN2008		Y
			Depression	01JAN1995	31DEC2000	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Thyroglossal cyst excision	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2012	31DEC2012	N
			Vocal cord operation	01JUN2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1090 10901317	Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901322	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
					02MAR2021	N
				01MAR2012	31MAR2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	01JAN1980	31DEC2007	N
		Surgical and medical procedures	Hip arthroplasty	01MAR2013	31MAR2013	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1090 10901327	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1090 10901331	Endocrine disorders	Hypogonadism	01JAN2019		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1953		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Surgical and medical procedures	Coronary artery surgery	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2016	31JAN2016	N
				01SEP2015	30SEP2015	N
			Knee operation	01FEB2011	28FEB2011	N
			Spinal fusion surgery	01NOV2010	30NOV2010	N
	C4591001 1090 10901332	Eye disorders	Cataract	01JAN2015	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2007		Y
		Infections and infestations	Appendicitis	01JAN1950	31DEC1950	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC1995		Y
		Surgical and medical procedures	Female sterilisation	01JAN1973	31DEC1973	N
			Spinal laminectomy	01JAN1966		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1090 10901337	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1977	31DEC1977	N
	C4591001 1090 10901340	Hepatobiliary disorders	Hepatic steatosis	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Lipids increased	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2012	31DEC2012	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1090 10901342	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Contrast media allergy	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN1965		Y
				01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	01JAN2016		Y
	C4591001 1090 10901344	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901345	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1090 10901351	Cardiac disorders	Supraventricular tachycardia	01JAN2018		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
			Scoliosis	01JAN2019		Y
			Spinal osteoarthritis	01JAN1985		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
			Restless legs syndrome	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Blepharoplasty	01JUN2020	30JUN2020	N
			Bunion operation	01JAN2004	31DEC2004	N
			Cataract operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1090 10901352	Eye disorders	Cataract	01JAN2016	31DEC2018	N
			Macular fibrosis	01JAN2005		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1991	31DEC1991	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Helicobacter infection	01JAN2010	28FEB2010	N
		Injury, poisoning and procedural complications	Concussion	01JAN2017	31DEC2017	N
			Subdural haemorrhage	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	28FEB2015	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	Transient global amnesia	01JAN2012	31JAN2012	N
		Skin and subcutaneous tissue disorders	Stress urinary incontinence	01JAN1982		Y
		Social circumstances	Purpura	01JAN2015		Y
		Surgical and medical procedures	Postmenopause	01JAN2001		Y
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1991	31DEC1991	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Meniere's disease	20JAN1998		Y
	C4591001 1090 10901354	Ear and labyrinth disorders				
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Inguinal hernia	01JAN2004	31JAN2005	N
		Investigations	Blood cholesterol increased	01JAN1996		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20JUN1968		Y
		Surgical and medical procedures	Hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JUL2014		Y
	C4591001 1090 10901359	Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Knee operation	01JAN1980	31DEC1980	N
			Shoulder operation	01JAN2016	31DEC2016	N
	C4591001 1090 10901361	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1090 10901364	Gastrointestinal disorders	Hiatus hernia	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1090 10901368	Injury, poisoning and procedural complications	Ankle fracture	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2018	28FEB2018	N
				01JAN2017	31DEC2018	N
			Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Intraocular lens implant	01JAN2017		Y
			Prostatectomy	01JAN2018	31DEC2018	N
			Urinary bladder suspension	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901376	Gastrointestinal disorders	Barrett's oesophagus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2018		Y
			Periarthritis	01MAR2019		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1966		Y
	C4591001 1090 10901381	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Blood donor	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hot flush	01JAN1994		Y
	C4591001 1090 10901385	Cardiac disorders	Palpitations	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01APR2020	30APR2020	N
		Vascular disorders	Hot flush	01JAN2012		Y
	C4591001 1090 10901388	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2019	18DEC2019	N
			Periarthritis	01JAN2012	31DEC2013	N
		Nervous system disorders	Headache	01JAN1968		Y
			Migraine	01JAN1968		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01OCT2019		Y
		Social circumstances	Menopause	01AUG2010		Y
		Surgical and medical procedures	Knee arthroplasty	18DEC2019		Y
			Shoulder operation	01JAN2013		Y
		Vascular disorders	Raynaud's phenomenon	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901389	Cardiac disorders	Atrial fibrillation	01JAN2020		Y
		Infections and infestations	Herpes simplex	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
			Spinal osteoarthritis	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Nervous system disorders	Transient ischaemic attack	01JAN2012	31DEC2012	N
				15SEP2019	31DEC2019	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1999		Y
			Jaw operation	01JAN1983		Y
			Skin neoplasm excision	01MAR2019		Y
	C4591001 1090 10901390	Blood and lymphatic system disorders	Anaemia	01DEC2019	31DEC2020	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018	31DEC2020	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2008	31DEC2009	N
		Surgical and medical procedures	Hysterectomy	01JAN2004		Y
			Uterine tumour excision	01JAN2008	31DEC2008	N
		Vascular disorders	Lymphoedema	01JAN2016		Y
	C4591001 1090 10901396	Blood and lymphatic system disorders	Anaemia	01JAN1975		Y
		Endocrine disorders	Hyperprolactinaemia	01JAN1984	31DEC1998	N
			Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Herpes simplex	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1090 10901403	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2004		Y
			Gastric ulcer	01JAN2010	31DEC2015	N
			Gastrooesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Sinusitis	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Osteoarthritis	01JAN1990		Y
			Osteoporosis	01JAN1998		Y
			Spinal osteoarthritis	01JAN1990		Y
		Nervous system disorders	Facial paralysis	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2005	N
			Urinary incontinence	01DEC2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1948		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1990	31DEC2000	N
		Social circumstances	Menopause	01JAN1985		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1948		Y
			Cholecystectomy	01JAN2005	31DEC2005	N
			Cryotherapy	01JAN1990	31DEC1990	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01JAN1991	31DEC1995	N
			Hypertension	01JAN1991		Y
	C4591001 1090 10901404	Ear and labyrinth disorders	Meniere's disease	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1962		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987		Y
			Cholecystectomy	01DEC2019	31DEC2019	N
			Endometrial ablation	01JAN2009	31DEC2009	N
			Gastrectomy	01JAN2014	31DEC2014	N
	C4591001 1090 10901405	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Nephrectomy	01JAN1997	31DEC1997	N
	C4591001 1090 10901406	Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Inguinal hernia	01JAN1993	31DEC1993	N
			Umbilical hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Oral herpes	01JAN2000		Y
			Osteomyelitis	01NOV1992	31DEC1992	N
		Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1993	31DEC1993	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901409	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Infections and infestations	Sinusitis	01JAN1980		Y
		Investigations	Cardiac murmur	01JAN1988		Y
		Psychiatric disorders	Anxiety disorder	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01OCT2009	31OCT2009	N
			Sinus operation	01NOV2018	30NOV2018	N
			Thyroidectomy	01DEC2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN2009		Y
	C4591001 1090 10901411	Nervous system disorders	Migraine	01JAN2005		Y
			Petit mal epilepsy	01JAN1978	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1958	31DEC1970	N
			Rhinitis allergic	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
			Rosacea	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Sinus operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901412	Investigations	Blood cholesterol increased	01JAN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2019	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
			Stress urinary incontinence	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01MAR2020		Y
			Sleep apnoea syndrome	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1090 10901414	Gastrointestinal disorders	Umbilical hernia	01JUN1990	31AUG1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1999	N
				01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Malignant melanoma	01JAN2017	31DEC2017	N
	C4591001 1090 10901415	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1973		Y
			Food allergy	01JAN1973		Y
			Seasonal allergy	01JAN1973		Y
		Infections and infestations	Urinary tract infection	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteopenia	01JAN1996		Y
			Spinal osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1090 10901420	Eye disorders	Cataract	01JAN2015		Y
			Dry eye	01JAN2019		Y
			Macular degeneration	01JAN2015		Y
		Immune system disorders	Allergy to plants	01JAN1990		Y
			Drug hypersensitivity	01JAN1990		Y
			Dust allergy	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes zoster	01JUN2005	31AUG2005	N
			Tonsillitis	01JAN1957	31DEC1957	N
		Injury, poisoning and procedural complications	Limb injury	01DEC2010	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
			Synovial cyst	01JAN1990	31DEC1990	N
		Nervous system disorders	Migraine	01JAN1959		Y
		Psychiatric disorders	Depression	08NOV2016		Y
		Renal and urinary disorders	Nocturia	01JAN2017		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1982	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Limb operation	01JAN1990	31DEC1990	N
				01JAN2011	31DEC2011	N
			Oophorectomy	01JAN2002	31DEC2002	N
			Pulmonary resection	01JAN1983	31DEC1983	N
			Tonsillectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Deep vein thrombosis	01JAN2001	31DEC2001	N
			Hypertension	01JAN2015		Y
	C4591001 1090 10901425	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1090 10901428	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Lipids increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901430	Nervous system disorders	Trigeminal neuralgia	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cranial operation	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Shoulder arthroplasty	01JUN2020	31DEC2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901433	Gastrointestinal disorders	Colitis ulcerative	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Clostridium difficile infection	01JAN1991	31DEC1991	N
			Herpes simplex	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1991	31DEC1991	N
				01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901434	Endocrine disorders	Hypothyroidism	01JAN2008	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Investigations	Blood cholesterol increased	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1963	31DEC1987	N
		Surgical and medical procedures	Appendectomy	01JAN1983	31DEC1983	N
	C4591001 1090 10901436	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
	C4591001 1090 10901438	Gastrointestinal disorders	Gastric ulcer	01JAN1997	31DEC1997	N
			Inguinal hernia	01JAN2010	31DEC2015	N
			Pancreatic cyst	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2009		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1090 10901439	Ear and labyrinth disorders	Deafness bilateral	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis obstructive	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01MAR2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
			Vitamin D deficiency	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1090 10901442	Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
			Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1090 10901445	Gastrointestinal disorders	Crohn's disease	01JAN2007		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Allergy to animal	01JAN1947		Y
			Dust allergy	01JAN1950		Y
			Seasonal allergy	01JAN1950		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN1974	31DEC1974	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
			Peripheral nerve operation	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
			Strabismus correction	01JAN1949	31DEC1949	N
				01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1090 10901446	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2005	31DEC2005	N
			Shoulder operation	01JAN2013	31DEC2013	N
	C4591001 1090 10901449	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
			Meniere's disease	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2003	31DEC2003	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
	C4591001 1090 10901450	Investigations	Blood cholesterol increased	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
	C4591001 1090 10901455	Cardiac disorders	Angina pectoris	01JAN2017		Y
			Cardiac failure congestive	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1970	31DEC1970	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN1970		Y
		Surgical and medical procedures	Appendectomy	01JAN1965	31DEC1965	N
			Hysterectomy	01JAN1970	31DEC1970	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
				01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1090 10901456	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Injury, poisoning and procedural complications	Hip fracture	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
				01JAN1996	31DEC1996	N
				01JAN2016	31DEC2016	N
				01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1090 10901458	Endocrine disorders	Goitre	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1090 10901459	Investigations	Blood cholesterol increased	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1961		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1090 10901460	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01MAY2019	31MAY2019	N
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1090 10901462	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Stent placement	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1090 10901466	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1090 10901467	Gastrointestinal disorders	Diarrhoea	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Female sterilisation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901468	Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Surgical and medical procedures	Nerve block	01JAN2015		Y
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1090 10901469	Eye disorders	Retinal detachment	11AUG2006	11AUG2006	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2018		Y
		Immune system disorders	Contrast media allergy	01JAN1972		Y
		Infections and infestations	Herpes simplex	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Surgical and medical procedures	Tendon sheath incision	01NOV2018	30NOV2018	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1090 10901471	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN2003		Y
				01JAN2016		Y
			Seasonal allergy	01JAN1963		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2003	N
		Psychiatric disorders	Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1090 10901472	Cardiac disorders	Ventricular extrasystoles	22SEP2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Eye operation	01JAN1961	31DEC1961	N
			Hip arthroplasty	01JAN2011	31DEC2011	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
	C4591001 1090 10901475	Gastrointestinal disorders	Abdominal hernia	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
			Squamous cell carcinoma	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1090 10901478	Cardiac disorders	Tachycardia	01JAN2005	31DEC2007	N
		Endocrine disorders	Hypothyroidism	01DEC2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2006	31DEC2006	N
			Muscle rupture	20OCT2013	20OCT2013	N
			Tendon rupture	01MAY2001	31MAY2001	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Rotator cuff syndrome	20OCT2013	20OCT2013	N
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y
			Depression	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2007	31DEC2007	N
	C4591001 1090 10901483	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1090 10901485	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1090 10901486	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Nervous system disorders	Tension headache	01JAN1990	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Bone operation	01JUN2017	30JUN2017	N
	C4591001 1090 10901487	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2019		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
			Squamous cell carcinoma	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety disorder	01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1963		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Haemorrhoid operation	01JAN2008	31DEC2008	N
			Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1090 10901488	Immune system disorders	Rubber sensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1090 10901490	Cardiac disorders	Ventricular extrasystoles	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Injury, poisoning and procedural complications	Burns third degree	01JAN1996	31DEC1996	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Skin graft	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1090 10901492	Gastrointestinal disorders	Gastrooesophageal reflux disease	01OCT2019		Y
			Intestinal polyp	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
				01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1090 10901493	Gastrointestinal disorders	Constipation	01JAN1974		Y
			Diarrhoea	01JAN1974		Y
		Immune system disorders	Allergy to animal	01JAN1965		Y
			Drug hypersensitivity	01JAN1983		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1968	N
			Urinary tract infection	01JAN1978	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lentigo maligna	01NOV2019	08JAN2020	N
			Uterine leiomyoma	01JAN2004	31DEC2006	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
			Urge incontinence	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965	31DEC2005	N
			Bronchitis chronic	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN2006		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Endometrial ablation	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1090 10901494	Immune system disorders	Contrast media allergy	01JAN2000		Y
			Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JUL2020		Y
		Nervous system disorders	Subarachnoid haemorrhage	01JAN2000	31DEC2000	N
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hot flush	01JAN1995		Y
	C4591001 1090 10901495	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Rubber sensitivity	01JAN1985		Y
		Infections and infestations	Diverticulitis	01JAN2018	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Osteoporosis	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Colectomy	01JAN2019		Y
			Hysterectomy	01JAN1974	31DEC1974	N
	C4591001 1090 10901499	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Dyspepsia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2010	N
			Open reduction of fracture	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901500	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
					31DEC2018	N
			Osteoporosis	01JAN2005		Y
			Spinal osteoarthritis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Female sterilisation	01JAN1976		Y
			Knee arthroplasty	01JAN2018	31OCT2018	N
	C4591001 1090 10901501	Eye disorders	Cataract	01JAN2018	31AUG2019	N
			Macular degeneration	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010	31DEC2017	N
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980	31MAR2020	N
			Vertebral osteophyte	01JAN2012	31AUG2019	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31AUG2019	N
			Knee arthroplasty	01JUN2019	30JUN2019	N
				01MAR2020	31DEC2020	N
			Spinal operation	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901504	Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901505	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1090 10901506	Endocrine disorders	Hypogonadism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
				01JAN2017		Y
		Infections and infestations	Sinusitis	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN2005		Y
			Depression	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	11FEB2018	11FEB2018	N
	C4591001 1090 10901511	Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
			Hepatic cyst	01JAN2014		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y
			Depression	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
			Stress urinary incontinence	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Bone operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hot flush	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901514	Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1090 10901519	Gastrointestinal disorders	Impaired gastric emptying	01JAN2015		Y
		Investigations	Inguinal hernia	01JAN2003	31JAN2015	N
		Musculoskeletal and connective tissue disorders	Blood cholesterol increased	01JAN2000		Y
			Rheumatoid arthritis	01JAN2004		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1090 10901521	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Umbilical hernia	01JAN1998	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01SEP2000		Y
		Infections and infestations	Hepatitis C	01JAN1970	31DEC2004	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2000	31DEC2002	N
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1989		Y
			Insomnia	01JAN1989		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Incisional hernia repair	01JAN2002	31DEC2002	N
			Oophorectomy	01JAN1988	31DEC1988	N
			Umbilical hernia repair	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901523	Renal and urinary disorders	Stress urinary incontinence	01JAN2016		Y
		Social circumstances	Blood donor	01SEP2019	31JUL2020	N
			Postmenopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
			Urinary bladder suspension	01JAN2016	31DEC2016	N
	C4591001 1090 10901525	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Nervous system disorders	Neuropathy peripheral	14SEP2017		Y
		Psychiatric disorders	Insomnia	01JAN1957		Y
		Surgical and medical procedures	Jaw operation	01JAN1992	31DEC1992	N
			Rotator cuff repair	01NOV2017	30NOV2017	N
	C4591001 1090 10901531	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Nervous system disorders	Cerebrovascular accident	18OCT2016	31DEC2016	N
			Restless legs syndrome	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1997	31DEC2014	N
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1090 10901532	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUL1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1090 10901533	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
			Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01APR2014	31DEC2014	N
			Wrist fracture	01JUN2000	31DEC2000	N
		Investigations	Cardiac murmur	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN2000	31DEC2001	N
				01JAN2014	31DEC2014	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1090 10901534	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2006	N
			Uterine cancer	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2002	31DEC2002	N
				01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901541	Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Urge incontinence	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Cardiac operation	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2012	31DEC2012	N
		Vascular disorders	Arteriosclerosis	01JAN2016		Y
	C4591001 1090 10901542	Cardiac disorders	Mitral valve prolapse	01JAN1992		Y
		Eye disorders	Dry eye	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Infections and infestations	Herpes virus infection	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1090 10901545	Ear and labyrinth disorders	Eustachian tube dysfunction	01JAN1980		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Investigations	Lipids increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Breast conserving surgery	04SEP2009	31DEC2009	N
			Tympanoplasty	04SEP2020	04SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901549	Metabolism and nutrition disorders	Gout	01AUG2010	31AUG2010	N
			Hypercholesterolaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JUL2015	31JUL2015	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Social circumstances	Blood donor	01JAN1979		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1090 10901552	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN1995		Y
			Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1971		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
		Social circumstances	Blood donor	01MAY2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1090 10901553	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2018	31JAN2019	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendectomy	01JAN1960	31JAN1960	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	01AUG1995	31AUG1995	N
				01JUL1990	31JUL1990	N
			Lymphoid tissue operation	01OCT2018	31OCT2018	N
	C4591001 1090 10901554	Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
					31DEC1999	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN1999	31DEC1999	N
			Shoulder arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1090 10901555	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1956		Y
		Infections and infestations	Hepatitis B	01JAN1997	31DEC2009	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1956		Y
	C4591001 1090 10901556	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1090 10901560	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901562	Immune system disorders	Allergy to arthropod sting	01JAN1976		Y
			Drug hypersensitivity	01JAN1985		Y
		Investigations	Biopsy breast	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Blood donor	01JAN1980		Y
			Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
			Gastric bypass	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2014	31DEC2014	N
			Plastic surgery	01JAN2015	31DEC2015	N
			Skin cosmetic procedure	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1090 10901563	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2019	N
			Malignant melanoma	01JAN2003	31DEC2003	N
			Squamous cell carcinoma of skin	01JAN2010	31DEC2019	N
				01SEP2019	30SEP2020	N
		Social circumstances	Blood donor	01JAN1982		Y
		Surgical and medical procedures	Cancer surgery	01SEP2019	30SEP2019	N
					31DEC2019	N
			Skin neoplasm excision	01JAN2003	31DEC2003	N
				01SEP2019	30SEP2020	N
			Vasectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1090 10901564	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
			Urinary incontinence	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2008	31DEC2008	N
				01JAN2017	31DEC2017	N
			Gallbladder operation	01JAN1990	31DEC1990	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1090 10901568	Gastrointestinal disorders	Constipation	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1090 10901569	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
			Rhinitis allergic	01JAN1956		Y
			Sleep apnoea syndrome	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN1995	31DEC1995	N
		Eye disorders	Glaucoma	01JAN2010		Y
			Retinal detachment	01OCT2010	31MAR2011	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Retinopexy	01DEC2010	31DEC2010	N
				01JAN2011	31JAN2011	N
				01MAR2011	31MAR2011	N
				01OCT2010	31OCT2010	N
		Vascular disorders	Angiopathy	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Adnexal torsion	01MAR1996	31MAR1996	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
			Oophorectomy	01MAR1996	31MAR1996	N
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
			Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911004	Endocrine disorders	Hypothyroidism	01SEP1986		Y
		Eye disorders	Glaucoma	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01NOV2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1091 10911007	General disorders and administration site conditions	Pain	01JAN2008		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911010	General disorders and administration site conditions	Hernia	01JAN2012	31DEC2012	N
		Infections and infestations	Labyrinthitis	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01JAN1990	31DEC1990	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911012	Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2006	31DEC2006	N
	C4591001 1091 10911016	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1091 10911018	Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hypercholesterolaemia	01JAN2005		Y
	C4591001 1091 10911021	Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
				01JAN2017		Y
			Back pain	01JAN1985		Y
			Joint instability	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911023	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1091 10911024	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
	C4591001 1091 10911026	Injury, poisoning and procedural complications	Tendon injury	01JAN2002	31DEC2002	N
	C4591001 1091 10911028	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Lipoma excision	01JAN2000	31DEC2000	N
	C4591001 1091 10911029	Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1091 10911030	Musculoskeletal and connective tissue disorders	Joint swelling	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Knee operation	01JAN1980	31DEC1980	N
	C4591001 1091 10911031	Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911034	Eye disorders	Macular degeneration	01JAN2016		Y
		Immune system disorders	Allergy to animal	01JAN1988		Y
			Seasonal allergy	01JAN1988		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Spinal laminectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1091 10911035	General disorders and administration site conditions	Pain	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1091 10911036	Injury, poisoning and procedural complications	Ankle fracture	01JAN1999	31DEC1999	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2001	31DEC2001	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000		Y
		Social circumstances	Postmenopause	17FEB2017		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2001	31DEC2001	N
			Open reduction of fracture	01JAN1999	31DEC1999	N
	C4591001 1091 10911040	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN1951		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
				01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1971		Y
	C4591001 1091 10911041	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008		Y
			Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2020	31JAN2020	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1091 10911044	Cardiac disorders	Mitral valve prolapse	01JAN1996		Y
		Eye disorders	Cataract	01DEC2018		Y
				01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Oesophageal ulcer	01JAN1988	31DEC1988	N
			Rectal haemorrhage	01OCT2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Spinal column injury	01MAY2019	31MAY2019	N
		Investigations	Biopsy colon normal	01OCT2018	31OCT2018	N
			Colonoscopy	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2019		Y
			Osteopenia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1963	31DEC1991	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
				01JAN2019		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
				24SEP2019	24SEP2019	N
			Cataract operation	01DEC2018	31DEC2018	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Oesophagogastric fundoplasty	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1091 10911045	Blood and lymphatic system disorders	Thrombocytopenia	01JAN2019		Y
		Cardiac disorders	Sinus node dysfunction	01JAN2016		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	30NOV2001	N
			Hepatic cyst	01OCT2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Beta haemolytic streptococcal infection	01MAY2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Post procedural diarrhoea	01NOV2001		Y
			Snake bite	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
				01JAN2001	05APR2018	N
				01JAN2018		Y
			Rheumatic fever	01JAN1959	31DEC1959	N
		Nervous system disorders	Sciatica	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2001	30NOV2001	N
			Hip arthroplasty	05APR2018	05APR2018	N
		Vascular disorders	Aortic arteriosclerosis	01OCT2017		Y
			Aortic dilatation	01OCT2017		Y
			Hypertension	01JAN2015		Y
	C4591001 1091 10911048	Gastrointestinal disorders	Large intestine polyp	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2009	31DEC2009	N
	C4591001 1091 10911049	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2003		Y
		Nervous system disorders	Headache	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1091 10911050	Injury, poisoning and procedural complications	Meniscus injury	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
			Headache	01JAN2000		Y
			Neuropathy peripheral	01JAN2010		Y
			Sciatica	01JAN2004		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
			Meniscus operation	01JAN1963	31DEC1963	N
	C4591001 1091 10911055	Eye disorders	Cataract	01JAN2000	31DEC2000	N
					31JAN2001	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cataract operation	01DEC2000	31DEC2000	N
				01JAN2001	31JAN2001	N
			Female sterilisation	01JAN1976	31DEC1976	N
	C4591001 1091 10911059	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Back injury	01JAN2019	31MAY2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019	31MAY2019	N
			Osteoarthritis	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1091 10911060	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1091 10911063	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN2020	24JAN2020	N
			Uterine leiomyoma	01JAN1990	31DEC1996	N
		Surgical and medical procedures	Benign breast lump removal	24JAN2020	24JAN2020	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1091 10911064	Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Nervous system disorders	Migraine	01JAN1966	31DEC2015	N
		Psychiatric disorders	Depression	01JAN1985		Y
			Insomnia	01JAN1985		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN1994	31DEC1995	N
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1091 10911068	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1970		Y
	C4591001 1091 10911071	Gastrointestinal disorders	Constipation	01FEB2019		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Tension headache	01DEC2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911073	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Injury, poisoning and procedural complications	Muscle injury	01DEC2018	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN1974	31DEC1974	N
			Muscle reattachment	01DEC2018	31DEC2018	N
	C4591001 1091 10911074	Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1091 10911076	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1091 10911080	Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Chronic sinusitis	01JAN2010		Y
			Oral herpes	01JAN2000		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2019		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
			Rectocele	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Rectocele repair	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinus operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1091 10911081	Cardiac disorders	Arrhythmia	01JAN2015	31DEC2015	N
		Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
			Otitis media	01JAN2000		Y
			Pneumonia	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
			Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1091 10911084	Immune system disorders	Drug hypersensitivity	01JAN1952		Y
				01JAN1978		Y
				01JAN2005		Y
				01SEP2019		Y
		Infections and infestations	Urinary tract infection	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1091 10911092	Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01NOV2019	30NOV2019	N
			Pneumonia	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01NOV2019	30NOV2019	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Meniscus operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911094	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1967	31DEC1967	N
				01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Shoulder operation	01JAN1967	31DEC1967	N
				01JAN1970	31DEC1970	N
	C4591001 1091 10911097	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Haemorrhoids	01JAN1997	31DEC1997	N
		Immune system disorders	Food allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2008	31DEC2008	N
			Haemorrhoid operation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1091 10911100	Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2019		Y
			Spinal osteoarthritis	01SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
				01MAY2019	31MAY2019	N
			Uterine leiomyoma	01JAN1987	31DEC1990	N
		Surgical and medical procedures	Cataract operation	01DEC2019	31DEC2019	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Oophorectomy bilateral	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
				01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1091 10911101	Eye disorders	Cataract	01JAN2010	31DEC2012	N
			Glaucoma	01JAN1972		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1946		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ankle operation	01JAN2015	31DEC2015	N
			Cataract operation	01JAN2012	31DEC2012	N
				01NOV2012	30NOV2012	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1091 10911102	Endocrine disorders	Hyperthyroidism	01JAN2000	31DEC2000	N
			Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2000	31DEC2000	N
	C4591001 1091 10911105	Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2006		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
			Intervertebral disc degeneration	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
			Libido decreased	01JAN2014		Y
		Renal and urinary disorders	Renal cyst	01JAN2020	31JAN2020	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Intervertebral disc operation	01JAN2008	31DEC2008	N
			Renal cyst excision	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1091 10911109	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Surgical and medical procedures	Turbinectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1091 10911110	Gastrointestinal disorders	Appendiceal mucocoele	01JAN1993	31DEC1993	N
			Gastrooesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019		Y
			Seborrhoeic keratosis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
		Surgical and medical procedures	Colectomy	01JAN1993	31DEC1993	N
	C4591001 1091 10911112	Cardiac disorders	Myocardial infarction	01JAN1997	31DEC1997	N
		Hepatobiliary disorders	Gallbladder rupture	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1992		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN1992	31DEC1992	N
			Nerve injury	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2017	31DEC2017	N
	C4591001 1091 10911114	Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1091 10911117	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1985		Y
	C4591001 1091 10911126	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1966		Y
			Irritable bowel syndrome	01JAN1966		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01MAR2012		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Carpal tunnel decompression	08AUG2020	31AUG2020	N
			Skin neoplasm excision	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911127	Immune system disorders	Seasonal allergy	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
	C4591001 1091 10911128	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
	C4591001 1091 10911129	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Sinusitis	01JAN1979		Y
			Tonsillitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Ligament sprain	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Ligament operation	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Turbinectomy	01DEC2017	31DEC2017	N
	C4591001 1091 10911131	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN1984		Y
			Depression	01JAN1984		Y
	C4591001 1091 10911147	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal obstruction	01JAN2000	31DEC2000	N
			Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Nasal operation	01JAN2000	31DEC2000	N
	C4591001 1091 10911148	Cardiac disorders	Postural orthostatic tachycardia syndrome	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Polymorphic light eruption	01OCT2019		Y
		Surgical and medical procedures	Precancerous lesion excision	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1091 10911153	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2001	31DEC2001	N
		Hepatobiliary disorders	Gallbladder cholesterolosis	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Biopsy lymph gland normal	01JAN2001	31DEC2001	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
	C4591001 1091 10911154	Cardiac disorders	Bundle branch block	01JAN2010		Y
		Gastrointestinal disorders	Pancreatitis acute	01DEC2017	31DEC2017	N
				01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1960		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01DEC2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1995		Y
			Osteoarthritis	01JAN1985		Y
				01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01APR2018		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
			Essential tremor	01FEB2020		Y
			Migraine	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012	01JUL2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Urinary control neurostimulator implantation	01JUL2020	01JUL2020	N
		Vascular disorders	Hypertension	01DEC2017		Y
			Peripheral vascular disorder	01JAN2015		Y
	C4591001 1091 10911155	Gastrointestinal disorders	Dyspepsia	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911159	Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Vasectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1091 10911161	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2020	31JAN2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2020		Y
		Surgical and medical procedures	Cancer surgery	01JAN2020	31JAN2020	N
	C4591001 1091 10911163	General disorders and administration site conditions	Pain	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1091 10911167	Gastrointestinal disorders	Large intestine polyp	09NOV2016	09NOV2016	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01AUG2017	28FEB2018	N
		Nervous system disorders	Migraine	01JAN1973		Y
		Renal and urinary disorders	Atonic urinary bladder	01JAN2001		Y
		Surgical and medical procedures	Large intestinal polypectomy	09NOV2016	09NOV2016	N
	C4591001 1091 10911168	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01FEB2019		Y
		Social circumstances	Postmenopause	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911170	Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Iodine allergy	01JAN1990		Y
			Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Tibia fracture	28DEC2019	28DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
				01JAN2018		Y
	C4591001 1091 10911171	Psychiatric disorders	Anxiety	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Meniscus operation	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Nervous system disorders	Myoclonus	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1990	31DEC1990	N
	C4591001 1091 10911173	Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Salpingectomy	01JAN1990	31DEC1990	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911178	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911180	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1091 10911181	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911184	Psychiatric disorders	Anxiety	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Spleen operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1091 10911187	Eye disorders	Amblyopia	(b) (6) 1963		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Hiatus hernia	01JAN2011		Y
		Immune system disorders	Iodine allergy	01JAN1980		Y
			Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	(b) (6) 1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1995		Y
			Synovial cyst	01JAN2000		Y
					31DEC2009	N
		Social circumstances	Postmenopause	01JUN2013		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN2009	31DEC2009	N
	C4591001 1091 10911190	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Injury, poisoning and procedural complications	Ligament sprain	06AUG2020		Y
		Investigations	Colonoscopy normal	01AUG2020	31AUG2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1091 10911191	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1091 10911193	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2000		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004	N
				01JAN2016	31DEC2016	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
				01JAN2016	31DEC2016	N
			Cataract operation	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1091 10911194	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1091 10911195	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAY2020		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1091 10911199	Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
			Scoliosis	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Spinal nerve stimulator implantation	27DEC2019		Y
	C4591001 1091 10911201	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01DEC2019		Y
			Osteopenia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1091 10911205	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2017		Y
				01JAN2018		Y
		Investigations	Cardiac murmur	01JAN1951		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
			Dizziness	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1956		Y
	C4591001 1091 10911209	Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Infections and infestations	Appendicitis	01NOV2019	30NOV2019	N
			Pneumonia	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Sleep apnoea syndrome	01JUL2019		Y
		Surgical and medical procedures	Appendectomy	01NOV2019	30NOV2019	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Meniscus operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911211	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911213	Ear and labyrinth disorders	Vertigo	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013	30NOV2019	N
			Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Brain injury	01JAN2006		Y
			Migraine	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2006		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Shoulder arthroplasty	01NOV2019	30NOV2019	N
	C4591001 1091 10911214	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Colectomy	01JAN1997	31DEC1997	N
			Colostomy	01JAN1997		Y
	C4591001 1091 10911217	Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Ovarian cystectomy	01JAN1980	31DEC1980	N
	C4591001 1091 10911222	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carotid artery occlusion	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2013		Y
	C4591001 1091 10911224	Surgical and medical procedures	Arterial therapeutic procedure	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	04DEC2019	04DEC2019	N
	C4591001 1091 10911225	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1091 10911228	Skin and subcutaneous tissue disorders	Rash	01FEB2020		Y
	C4591001 1091 10911230	Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1091 10911231	Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Metabolic surgery	01JAN2017	31DEC2017	N
	C4591001 1091 10911234	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Injury, poisoning and procedural complications	Muscle injury	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1091 10911235	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1091 10911242	Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1091 10911243	Ear and labyrinth disorders	Deafness	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1091 10911244	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal pain	01JAN2008	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of spinal cord	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911247	Cardiac disorders	Arrhythmia	01JAN2015	31DEC2015	N
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Parkinson's disease	01AUG2019		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Cataract operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1091 10911248	Immune system disorders	Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911249	Cardiac disorders	Ventricular tachycardia	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2001	31DEC2001	N
	C4591001 1091 10911251	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2012		Y
	C4591001 1091 10911253	Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Neurological symptom	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
				01OCT2019	31OCT2019	N
	C4591001 1091 10911254	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Mammoplasty	01JAN1993	31DEC1993	N
	C4591001 1091 10911258	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Otitis media	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1980	31DEC1980	N
				01JAN1984	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Knee arthroplasty	12AUG2012	12AUG2012	N
			Ligament operation	01JAN1980	31DEC1980	N
				01JAN1984	31DEC1984	N
			Spinal fusion surgery	30OCT2019	30OCT2019	N
			Spinal laminectomy	30OCT2019	30OCT2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1091 10911259	Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1091 10911262	Cardiac disorders	Coronary artery occlusion	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	12AUG2020	12AUG2020	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2013	20JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	12AUG2020	12AUG2020	N
			Spinal nerve stimulator implantation	20JUL2020	20JUL2020	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1091 10911263	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911264	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2005	31DEC2005	N
	C4591001 1091 10911266	Metabolism and nutrition disorders	Vitamin D deficiency	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1091 10911267	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2012		Y
				01JAN2015		Y
				01JAN2019		Y
		Investigations	Thyroid function test normal	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911268	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1970		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Oophorectomy bilateral	01JAN2015	31DEC2015	N
	C4591001 1091 10911269	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign mediastinal neoplasm	01JAN1990	31DEC1990	N
			Uterine leiomyoma	01JAN2006	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Mediastinal operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1091 10911272	Endocrine disorders	Basedow's disease	01JAN1985	31DEC1985	N
			Hypothyroidism	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1994		Y
		Surgical and medical procedures	Radioactive iodine therapy	01JAN1985	31DEC1985	N
	C4591001 1091 10911273	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1091 10911274	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
	C4591001 1091 10911275	Congenital, familial and genetic disorders	Developmental hip dysplasia	(b) (6) 1960		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2020		Y
			Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01MAY2020		Y
		Vascular disorders	Hot flush	01JAN2005		Y
	C4591001 1091 10911280	Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1091 10911285	Infections and infestations	Diverticulitis	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01MAR2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Cervical polyp	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911287	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1990		Y
				01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Insomnia	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1091 10911292	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1091 10911294	Cardiac disorders	Palpitations	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
	C4591001 1091 10911295	Hepatobiliary disorders	Cholelithiasis	01APR2019	30APR2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01APR2019	30APR2019	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Knee operation	01JAN1977	31DEC1977	N
			Metabolic surgery	01DEC2014	31DEC2014	N
	C4591001 1091 10911296	Endocrine disorders	Hyperthyroidism	01JAN2003	31DEC2004	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2004		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2017		Y
			Vaginal prolapse	01JAN2012	31DEC2012	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1091 10911299	Gastrointestinal disorders	Gastric ulcer	01JAN2018	31JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Iron deficiency	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1091 10911305	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Reaction to colouring	01JAN1990		Y
			Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1991		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1965		Y
				01JAN2015	31DEC2017	N
			Spondylitis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN1999	31DEC1999	N
				01JAN2006	31DEC2006	N
			Limb operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1091 10911307	Cardiac disorders	Mitral valve prolapse	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1091 10911308	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1091 10911312	Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1091 10911316	Injury, poisoning and procedural complications	Joint injury	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1091 10911318	Cardiac disorders	Atrial flutter	01JAN1996		Y
		Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1996		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1982	31DEC1982	N
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1996		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1982	31DEC1982	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010	31DEC2010	N
		Vascular disorders	Deep vein thrombosis	01JAN1996		Y
			Hypertension	01JAN2013		Y
	C4591001 1091 10911323	Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2014		Y
	C4591001 1091 10911326	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Infections and infestations	Appendicitis	01JAN2006		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Surgical and medical procedures	Ankle operation	01JAN2002		Y
			Appendicectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911330	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1091 10911332	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Nervous system disorders	Headache	01JAN2017		Y
	C4591001 1091 10911335	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Tooth extraction	05JUN2020	05JUN2020	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1091 10911337	Endocrine disorders	Hypogonadism male	01JAN2000		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1981	31DEC1981	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Nervous system disorders	Essential tremor	01JAN2018		Y
			Pineal gland cyst	11FEB2002		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1981	31DEC1981	N
			Tonsillectomy	01JAN1963	31DEC1963	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1091 10911345	Gastrointestinal disorders	Dental caries	01JAN2018	31DEC2019	N
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1961		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2020		Y
		Social circumstances	Edentulous	01JAN2019	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1091 10911346	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1091 10911347	Eye disorders	Glaucoma	01JAN2000		Y
		Immune system disorders	Food allergy	01DEC1975		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1091 10911349	Surgical and medical procedures	Female sterilisation	01APR1981	30APR1981	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2011	N
		Nervous system disorders	Headache	01JAN1980		Y
	C4591001 1091 10911354	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1091 10911359	Gastrointestinal disorders	Inguinal hernia	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1979	31DEC1979	N
	C4591001 1091 10911364	Gastrointestinal disorders	Aphthous ulcer	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Food allergy	01JAN1981		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN1985		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1963		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinuplasty	01JAN1990	31DEC1990	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1091 10911365	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Eye disorders	Eye inflammation	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
				01JAN1969		Y
				01JAN2012		Y
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2015		Y
			Lactose intolerance	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
			Knee arthroplasty	01FEB2013	28FEB2013	N
				01OCT2012	31OCT2012	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1091 10911367	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1091 10911369	Eye disorders	Cataract	01JAN2014	31DEC2016	N
			Dry eye	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
			Cataract operation	01JAN2016	31DEC2016	N
	C4591001 1091 10911370	Immune system disorders	Allergy to arthropod sting	01JAN1976		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Meniscus operation	01JAN2005	31DEC2005	N
	C4591001 1091 10911374	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1091 10911377	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Glaucoma	01JAN2018	31DEC2019	N
		Gastrointestinal disorders	Diarrhoea	01JAN2016		Y
			Hiatus hernia	01JAN2017	31DEC2017	N
			Pancreatitis acute	01JAN2003	31DEC2003	N
		Infections and infestations	Chronic sinusitis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Carcinoid tumour pulmonary	01JAN2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Eye operation	01JAN2019	31DEC2019	N
			Hernia hiatus repair	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1993		Y
			Lung lobectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921004	Eye disorders	Myopia	01JAN1997		Y
			Presbyopia	01JAN1997		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	17FEB2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Onychomycosis	01FEB2020		Y
			Oral herpes	01JAN2009		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2015	31DEC2015	N
			Hip fracture	18FEB2015	18FEB2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	23SEP2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	17FEB2017	17FEB2017	N
	C4591001 1092	Vascular disorders	Hypertension	01JAN2007		Y
	10921005	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
	C4591001 1092	Vascular disorders	Hypertension	01JAN2015		Y
	10921006	Eye disorders	Myopia	01JAN1980		Y
			Presbyopia	01JAN1980		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1959	31DEC1959	N
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
			Tonsillitis	01JAN1963	31DEC1963	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
			Tendon rupture	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Rotator cuff syndrome	03FEB2020	03FEB2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	14JUL2020	14JUL2020	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Inguinal hernia repair	01JAN1959	31DEC1959	N
			Meniscus operation	01JAN2012	31DEC2012	N
			Rotator cuff repair	03FEB2020	03FEB2020	N
			Skin neoplasm excision	14JUL2020	14JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tenoplasty	01JAN1981	31DEC1981	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1092 10921007	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921009	Cardiac disorders	Angina pectoris	01JAN2017		Y
		Ear and labyrinth disorders	Deafness	01JAN2008		Y
		Eye disorders	Cataract	01JAN2011		Y
			Dry eye	01JAN2013		Y
			Glaucoma	01JAN2012		Y
			Myopia	01JAN2008		Y
			Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
			Haemorrhoids	01JAN1983	31DEC1983	N
			Hiatus hernia	01JAN1999		Y
			Large intestine polyp	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Osteoarthritis	01JAN1993	31DEC1993	N
				01MAY2007	31MAY2007	N
			Spinal osteoarthritis	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Cerebrovascular accident	07FEB2020	07FEB2020	N
		Renal and urinary disorders	Bladder prolapse	01MAY2002	31MAY2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Incontinence	01JAN2006		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Bladder repair	01MAY2002	31MAY2002	N
			Haemorrhoid operation	01JAN1983	31DEC1983	N
			Hip arthroplasty	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Knee arthroplasty	01MAY2007	31MAY2007	N
			Polypectomy	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1092 10921010	Cardiac disorders	Angina pectoris	01JAN1994	31DEC1994	N
			Arrhythmia	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
			Myopia	01JAN2019		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN2017		Y
			Gastroesophageal reflux disease	01AUG2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Urinary tract infection	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01MAR2008		Y
			Hypercalcaemia	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1997	31DEC1997	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2016		Y
			Cataract operation	01MAR2016	31MAR2016	N
			Coronary angioplasty	01JAN1994	31DEC1994	N
			Coronary artery bypass	01MAR2008	01MAR2008	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01JAN2004	31DEC2004	N
			Parathyroidectomy	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1092 10921011	Eye disorders	Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN1974		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
			Tonsillitis	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
			Osteopenia	01JAN2017		Y
			Plantar fasciitis	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2005		Y
			Uterine leiomyoma	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1972		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Oophorectomy	01JAN1971	31DEC1971	N
			Tonsillectomy	01JAN1971	31DEC1971	N
	C4591001 1092 10921012	Cardiac disorders	Angina pectoris	01JAN2010	31DEC2010	N
			Coronary artery disease	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc protrusion	01JAN2005		Y
			Spinal stenosis	01JAN2005		Y
		Nervous system disorders	Tremor	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2015		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921013	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921014	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Myopia	01JAN2009		Y
			Presbyopia	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
				01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
			Herpes zoster	01JAN2015	31DEC2015	N
			Herpes zoster oticus	01JAN2015	31DEC2015	N
			Tonsillitis	01JAN1951	31DEC1951	N
		Injury, poisoning and procedural complications	Joint dislocation	30OCT2019	30OCT2019	N
			Upper limb fracture	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
				20AUG2010	20AUG2010	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Facial paralysis	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1965	31DEC1965	N
			Cancer surgery	01JAN2008	31DEC2008	N
			Cataract operation	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Coronary arterial stent insertion	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN1965	31DEC1965	N
			Tonsillectomy	01JAN1951	31DEC1951	N
			Vascular stent insertion	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Arteriosclerosis	01JAN2013		Y
			Hypertension	01JAN2013		Y
			Peripheral vascular disorder	01JAN2013		Y
	C4591001 1092 10921015	Eye disorders	Myopia	01JUN1962		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2019		Y
			Inguinal hernia	01JAN2011	31DEC2011	N
			Umbilical hernia	01JAN1955	31DEC1955	N
		Immune system disorders	Hypersensitivity	01JAN1952		Y
			Seasonal allergy	01JAN1952		Y
		Infections and infestations	Appendicitis	01JUN1968	31DEC1968	N
			Tonsillitis	01JUN1962	31DEC1962	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN1988		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JUN2017	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2018	31AUG2018	N
				01JAN2012	31DEC2012	N
				01JUN2020	31DEC2020	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JUN2013		Y
		Vascular disorders	Hypertension	01JUN1988		Y
	C4591001 1092 10921016	Cardiac disorders	Bifascicular block	01OCT2016		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Myopia	01JAN1950		Y
			Presbyopia	01JAN1950		Y
		Gastrointestinal disorders	Inguinal hernia	28MAY2019	28MAY2019	N
			Large intestine polyp	01JAN2008	31DEC2008	N
		Infections and infestations	Tonsillitis	01APR2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
			Gout	01OCT2013	31OCT2013	N
		Nervous system disorders	Migraine	01SEP2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01OCT1990		Y
		Surgical and medical procedures	Intraocular lens implant	01JAN2018	31DEC2018	N
	C4591001 1092 10921017	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000	31DEC2019	N
			Tooth impacted	01JAN1970	31DEC1970	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Rhinitis	01JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1992	31DEC1992	N
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01JAN1992	31DEC1992	N
			Uterine polypectomy	01JAN2005	31DEC2005	N
			Wisdom teeth removal	01JAN1970	31DEC1970	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1092 10921019	Psychiatric disorders	Insomnia	01JAN2013		Y
	C4591001 1092 10921021	Endocrine disorders	Goitre	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01AUG2008		Y
	C4591001 1092 10921022	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1092 10921023	Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921025	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Myopia	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921028	Eye disorders	Myopia	01JAN2015		Y
			Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
			Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Nervous system disorders	Cerebrovascular accident	01JAN1998	31DEC1998	N
			Intracranial aneurysm	01JAN1998	31DEC1998	N
			Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Mammoplasty	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1092 10921030	Eye disorders	Cataract	01JAN2000	31DEC2000	N
			Presbyopia	01JAN1995		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1994		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2001		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
			Alopecia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1092 10921031	Eye disorders	Myopia	01JAN1966		Y
			Presbyopia	01JAN1966		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2019		Y
		Surgical and medical procedures	Polypectomy	01JAN2019	31DEC2019	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1092 10921032	Eye disorders	Myopia	01JAN1965		Y
			Presbyopia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign vascular neoplasm	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Vascular operation	01JAN2001	31DEC2001	N
	C4591001 1092 10921034	Cardiac disorders	Atrial fibrillation	01OCT2014		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Congenital, familial and genetic disorders	Thalassaemia	01JAN2010		Y
		Eye disorders	Myopia	01JAN2009		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1092 10921037	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Keratomileusis	01JAN2002	31DEC2002	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1092 10921038	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Endocrine disorders	Goitre	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2010	01JAN2010	N
			Hand fracture	01FEB2020	01FEB2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2008	01JAN2008	N
			Osteoarthritis	01JAN2010		Y
					01OCT2019	N
			Rotator cuff syndrome	01JAN1989	01JAN1989	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2002	01JAN2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN2008	01JAN2008	N
			Foot operation	01JAN2010	01JAN2010	N
			Hysterectomy	01JAN2019	01JAN2019	N
			Knee arthroplasty	01OCT2019	01OCT2019	N
			Rotator cuff repair	01JAN1989	01JAN1989	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Peripheral vascular disorder	01JAN1975	01JAN1975	N
	C4591001 1092 10921039	Cardiac disorders	Angina pectoris	09NOV2017		Y
			Coronary artery disease	09NOV2017		Y
		Eye disorders	Myopia	01JAN1962		Y
			Presbyopia	01JAN2004		Y
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2003	31DEC2003	N
			Gastroesophageal reflux disease	01JAN2001		Y
			Large intestine polyp	01JAN2001	31DEC2001	N
		General disorders and administration site conditions	Drug intolerance	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2003		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1991		Y
			Type 2 diabetes mellitus	01MAY2003		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Intervertebral disc protrusion	01JAN1998	31DEC1998	N
			Osteoarthritis	01JAN2007		Y
			Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2003	31DEC2003	N
			Uterine leiomyoma	01JAN1991	31DEC1991	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980	31DEC1980	N
			Migraine	01JAN1996		Y
			Neuropathy peripheral	01JAN1999		Y
		Renal and urinary disorders	Hypertonic bladder	31AUG2014		Y
			Proteinuria	05MAR2014		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Intervertebral disc operation	01JAN1998	31DEC1998	N
			Oophorectomy	01JAN1991	31DEC1991	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
			Skin lesion removal	01JAN2003	31DEC2003	N
	C4591001 1092 10921040	Eye disorders	Myopia	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2007		Y
		Infections and infestations	Impetigo	01JAN2011	31DEC2011	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Back pain	28FEB2019		Y
			Intervertebral disc degeneration	28FEB2019		Y
			Osteoarthritis	01JAN2009		Y
				01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	30JAN2020	30JAN2020	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Psychiatric disorders	Seasonal affective disorder	01JAN2007		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1993	31DEC1993	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cancer surgery	30JAN2020	30JAN2020	N
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Cryotherapy	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1092 10921041	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2009		Y
		Eye disorders	Myopia	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Inguinal hernia	01JAN1988	31DEC1988	N
			Large intestine polyp	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2008		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N
			Headache	01JAN2011		Y
		Psychiatric disorders	Bipolar disorder	01JAN1966		Y
			Depression	01JAN1969		Y
			Insomnia	01JAN1987		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JUN2014		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Coronary angioplasty	01JAN2008	31DEC2008	N
			Polypectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Aortic aneurysm	01JAN2016		Y
			Hypertension	01JAN1985		Y
			Intermittent claudication	01JAN2005		Y
			Peripheral vascular disorder	01JAN2008		Y
	C4591001 1092 10921043	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2003		Y
	C4591001 1092 10921044	Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1092 10921046	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921047	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1092 10921048	Cardiac disorders	Angina pectoris	01JAN2009		Y
			Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
			Obesity	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1092 10921049	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1971		Y
		Social circumstances	Postmenopause	01AUG2014		Y
	C4591001 1092 10921050	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Spinal osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1092 10921052	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Metabolism and nutrition disorders	Dyslipidaemia	19JUN2014		Y
	C4591001 1092 10921054	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1975		Y
	C4591001 1092 10921057	Social circumstances	Postmenopause	20JUN2000		Y
	C4591001 1092 10921058	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921059	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1092 10921060	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1092 10921061	Cardiac disorders	Bradycardia	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2014	31DEC2014	N
	C4591001 1092 10921062	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1092 10921063	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921067	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1092 10921068	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
	C4591001 1092 10921069	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1994		Y
	C4591001 1092 10921070	Cardiac disorders	Cardiac failure congestive	01JAN1993		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Hepatobiliary disorders	Hepatic cirrhosis	01JAN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1993		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921071	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1092 10921072	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1952		Y
	C4591001 1092 10921073	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921074	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1092 10921077	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2006		Y
		Surgical and medical procedures	Prostatectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921078	Cardiac disorders	Coronary artery disease	01JAN1988		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1989		Y
			Gout	01JAN2002		Y
			Type 2 diabetes mellitus	01SEP2009		Y
		Surgical and medical procedures	Endarterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921079	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1092 10921086	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1092 10921087	Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1092 10921088	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
	C4591001 1092 10921089	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1092 10921092	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
			Obesity	01JAN2008		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1092 10921093	Immune system disorders	Seasonal allergy	01JAN1963		Y
		Psychiatric disorders	Anxiety	01AUG2008		Y
			Bipolar disorder	01AUG2000		Y
			Depression	01AUG2000		Y
	C4591001 1092 10921094	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN1978		Y
				01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1092 10921095	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Spinal osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN1993		Y
	C4591001 1092 10921096	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
			Obesity	01JAN2009		Y
		Vascular disorders	Hypertension	04SEP2013		Y
	C4591001 1092 10921100	Nervous system disorders	Migraine	01JAN1960		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
	C4591001 1092 10921103	Metabolism and nutrition disorders	Dyslipidaemia	01MAY2010		Y
			Type 2 diabetes mellitus	11MAY2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921105	Cardiac disorders	Coronary artery disease	01MAY2002		Y
			Myocardial infarction	01MAY2002	01MAY2002	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
	C4591001 1092 10921107	Infections and infestations	Urinary tract infection	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1092 10921108	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				07AUG2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1092 10921110	Cardiac disorders	Atrial fibrillation	01SEP2019		Y
			Coronary artery disease	01JAN1981		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2019	30SEP2019	N
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1092 10921111	Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
			Obesity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921114	Cardiac disorders	Atrial fibrillation	01JAN2013		Y
			Coronary artery disease	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01SEP2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUN2018		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN1990	31DEC1990	N
	C4591001 1092 10921115	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2010		Y
		Nervous system disorders	Radiculopathy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1092 10921116	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Ocular vascular disorder	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1092 10921117	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1092 10921119	Eye disorders	Presbyopia	01JAN1973		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1092 10921120	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2008		Y
	C4591001 1092 10921121	Ear and labyrinth disorders	Deafness	01JAN2008		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Diverticulum	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Intervertebral disc degeneration	01JAN2000		Y
			Intervertebral disc protrusion	01JAN2012		Y
			Osteoarthritis	01JAN2011		Y
			Osteopenia	01JAN2017		Y
			Spinal osteoarthritis	01JAN2011		Y
			Tendonitis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2003	31DEC2003	N
		Nervous system disorders	Sinus headache	01JAN1964		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921123	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Gastric banding	01JAN2012		Y
			Gastric bypass	01JAN2007		Y
			Hernia repair	26JUN2020	26JUN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921124	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Ear and labyrinth disorders	Meniere's disease	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2010		Y
	C4591001 1092 10921126	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Iodine allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	03SEP2002		Y
			Spinal osteoarthritis	01JAN2007		Y
			Spinal stenosis	01JAN2007		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921129	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2012		Y
	C4591001 1092 10921134	Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Osteoarthritis	01JAN2007		Y
			Spinal osteoarthritis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01APR2009		Y
	C4591001 1092 10921135	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1092 10921136	General disorders and administration site conditions	Peripheral swelling	01MAR1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1977		Y
		Vascular disorders	Deep vein thrombosis	01MAR1989	31MAR1989	N
	C4591001 1092 10921137	Metabolism and nutrition disorders	Dyslipidaemia	25MAR2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary angioplasty	25APR2015	25APR2015	N
	C4591001 1092 10921138	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1092 10921140	Cardiac disorders	Angina pectoris	01JAN2012		Y
			Coronary artery disease	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1092 10921141	Ear and labyrinth disorders	Deafness	01JAN2012		Y
			Tinnitus	01JAN2012		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2015		Y
			Intestinal polyp	01MAR2019		Y
			Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Nervous system disorders	Sciatica	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2009		Y
			Insomnia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921145	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
	C4591001 1092 10921148	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
	C4591001 1092 10921149	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921150	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2010		Y
			Type 2 diabetes mellitus	01SEP2005		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921151	Gastrointestinal disorders	Diverticulum	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1985		Y
	C4591001 1092 10921152	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN1960		Y
				01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1092 10921154	Endocrine disorders	Hyperthyroidism	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
	C4591001 1092 10921155	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1092 10921156	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1092 10921159	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1092 10921163	Eye disorders	Myopia	01JAN1991		Y
			Presbyopia	01JAN1991		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2001	31DEC2001	N
		Nervous system disorders	Headache	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1092 10921164	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Vascular disorders	Hypertension	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921165	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1092 10921166	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1092 10921167	Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1092 10921169	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1954		Y
			Seasonal allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Obesity	01JAN1961		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Intervertebral disc protrusion	01SEP2009		Y
			Osteoarthritis	01JAN1995		Y
			Spinal stenosis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Renal and urinary disorders	Incontinence	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1092 10921170	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1092 10921171	Eye disorders	Glaucoma	01JAN1999		Y
		Immune system disorders	Hypersensitivity	01JAN1976		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1092 10921172	Endocrine disorders	Hyperthyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 1092 10921173	Metabolism and nutrition disorders	Dyslipidaemia	01MAY2008		Y
			Type 2 diabetes mellitus	01MAR2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Coronary angioplasty	01MAY2008	31MAY2008	N
			Coronary artery bypass	01JUL2008	31JUL2008	N
			Mastectomy	01DEC2010	31DEC2010	N
		Vascular disorders	Hypertension	01MAY2008		Y
	C4591001 1092 10921174	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921176	Immune system disorders	Hypersensitivity	01JAN1957		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1092 10921178	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921180	Cardiac disorders	Atrial fibrillation	01JUL2017		Y
			Cardiac failure congestive	01JAN2003		Y
			Coronary artery disease	01JUL2017		Y
			Myocardial infarction	01JAN2017	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JUL2003		Y
		Immune system disorders	Hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUL2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUL2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
			Fibroma	01JAN1992	31DEC1992	N
			Malignant melanoma	01JAN1979	31DEC1979	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Surgical and medical procedures	Coronary angioplasty	20DEC2018	20DEC2018	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Mastectomy	01JAN2007	31DEC2007	N
			Thyroidectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1092 10921182	Cardiac disorders	Myocardial infarction	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1092 10921185	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01APR2019		Y
	C4591001 1092 10921187	Cardiac disorders	Atrial fibrillation	06JUL2020		Y
			Coronary artery disease	10JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01MAY2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Nervous system disorders	Transient ischaemic attack	06DEC2013	06DEC2013	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Coronary artery bypass	10JAN2020	10JAN2020	N
			Implantable defibrillator insertion	06JUL2020	06JUL2020	N
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 1092 10921191	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1092 10921193	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921194	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1092 10921195	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1991	N
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921196	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1092 10921199	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01SEP2015		Y
		Vascular disorders	Hypertension	01SEP2015		Y
	C4591001 1092 10921202	Cardiac disorders	Myocardial infarction	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1092 10921207	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1092 10921212	Eye disorders	Glaucoma	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	08JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	02JAN2011		Y
			Obesity	01JAN1958		Y
			Type 2 diabetes mellitus	02JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoporosis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
		Nervous system disorders	Diabetic neuropathy	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cancer surgery	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	12JAN2010		Y
	C4591001 1092 10921213	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN2014		Y
		Vascular disorders	Hypertension	01OCT2014		Y
	C4591001 1092 10921214	Infections and infestations	Pneumonia	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
		Investigations	Heart rate irregular	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2019	31DEC2019	N
	C4591001 1092 10921215	Injury, poisoning and procedural complications	Head injury	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Seizure	01JAN1977		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
	C4591001 1092 10921216	Musculoskeletal and connective tissue disorders	Gouty arthritis	01JAN2018		Y
	C4591001 1092 10921220	Gastrointestinal disorders	Gastroesophageal reflux disease	20SEP2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	20SEP2015		Y
			Type 2 diabetes mellitus	20SEP2019		Y
		Psychiatric disorders	Anxiety	09OCT2003		Y
		Vascular disorders	Hypertension	27SEP2017		Y
	C4591001 1092 10921221	Endocrine disorders	Hypothyroidism	01AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984		Y
	C4591001 1092 10921222	Gastrointestinal disorders	Gastroesophageal reflux disease	10OCT2016		Y
		Immune system disorders	Food allergy	01JAN1967		Y
		Infections and infestations	Genital herpes	01JAN1978		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Throat cancer	01JAN2016	31DEC2016	N
	C4591001 1092 10921224	Endocrine disorders	Hypogonadism	01OCT2017		Y
	C4591001 1092 10921226	Cardiac disorders	Cardiac failure congestive	01JAN2020		Y
		Endocrine disorders	Hypothyroidism	01JAN1972		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1972		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood parathyroid hormone increased	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Obesity	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin B12 deficiency	01JAN2003		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Fibromyalgia	01JAN1992		Y
			Osteoporosis	01JAN2010		Y
			Spinal osteoarthritis	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN1987		Y
			Depression	01JAN1969		Y
			Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JAN2017		Y
			Sleep apnoea syndrome	01JAN1992		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Oophorectomy	01JAN2010	31DEC2010	N
	C4591001 1092 10921230	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1092 10921231	Blood and lymphatic system disorders	Anaemia	01JAN1992		Y
		Cardiac disorders	Cardiac failure congestive	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Irritable bowel syndrome	01JAN2010		Y
		General disorders and administration site conditions	Pain	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1993		Y
			Intervertebral disc degeneration	01JAN1980		Y
			Osteoarthritis	01JAN1980		Y
			Spinal osteoarthritis	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Spinal nerve stimulator implantation	01JAN2019		Y
		Vascular disorders	Raynaud's phenomenon	01JAN1992		Y
	C4591001 1092 10921232	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1092 10921233	Infections and infestations	Fungal infection	01JAN2011		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	27SEP2010		Y
	C4591001 1092 10921234	Endocrine disorders	Hypothyroidism	09JUN2020		Y
		Psychiatric disorders	Depression	09JAN2014		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1092 10921235	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Myopia	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Intestinal polyp	09JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1092 10921238	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
	C4591001 1092 10921240	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
	C4591001 1092 10921241	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1974		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1092 10921242	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1092 10921243	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921244	Nervous system disorders	Restless legs syndrome	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1092 10921250	Nervous system disorders	Migraine	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1092 10921251	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1092 10921252	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2018		Y
			Sleep apnoea syndrome	23DEC2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1092 10921253	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Congenital, familial and genetic disorders	Thalassaemia	(b) (6) 1953		Y
		Infections and infestations	Rhinitis	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921254	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1092 10921255	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1092 10921256	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1092 10921257	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2002		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
			Obesity	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1092 10921258	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
			Spinal osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1092 10921259	Cardiac disorders	Atrial fibrillation	18SEP2020		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Cataract	01JAN1944		Y
		Psychiatric disorders	Insomnia	15SEP2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1944		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01NOV2019		Y
	C4591001 1092 10921261	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01OCT2015		Y
			Type 2 diabetes mellitus	01OCT2010		Y
		Vascular disorders	Hypertension	01OCT2015		Y
	C4591001 1092 10921262	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Hepatitis B	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Plantar fasciitis	02OCT2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1092 10921263	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1092 10921264	Immune system disorders	Hypersensitivity	01JAN2000		Y
		Infections and infestations	Hepatitis C	24AUG2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1092 10921265†	General disorders and administration site conditions	Pain	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Investigations	HIV test positive	01JAN1987		Y
	C4591001 1092 10921266	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1092 10921267	Vascular disorders	Hypertension	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Psychiatric disorders	Depression	27SEP2016		Y
	C4591001 1092 10921268		Insomnia	01OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1092 10921269	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
	C4591001 1092 10921270	Social circumstances	Postmenopause	01JAN2005		Y
		Cardiac disorders	Coronary artery disease	01JAN1999		Y
		Eye disorders	Presbyopia	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1979		Y
			Obesity	01JAN1984		Y
			Type 2 diabetes mellitus	01APR2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01APR2009		Y
			Osteoarthritis	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JUN2008		Y
		Surgical and medical procedures	Female sterilisation	01OCT1989	31OCT1989	N
		Vascular disorders	Hypertension	01JAN1979		Y
			Peripheral vascular disorder	21OCT2019		Y
	C4591001 1092 10921273	Cardiac disorders	Coronary artery disease	01JAN2001		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01OCT1980		Y
		Nervous system disorders	Essential tremor	01JAN2009		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2007		Y
			Erectile dysfunction	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
			Dermatitis	01JAN2010		Y
			Eczema	01JAN2010		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2013		Y
			Coronary artery bypass	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1092 10921275	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1092 10921277	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1092 10921278	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2014		Y
	C4591001 1093 10931005	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1093 10931010	Eye disorders	Glaucoma	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Back pain	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01FEB2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
	C4591001 1093 10931012	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931016	Gastrointestinal disorders	Abdominal hernia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1093 10931021	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Diverticulum	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2012		Y
			Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Allergy to surgical sutures	01JAN2009		Y
			Iodine allergy	01JAN2004		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Clostridium difficile infection	01OCT2015	31OCT2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Intervertebral disc degeneration	01JAN2013		Y
			Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1993	31DEC1993	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2014	N
			Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Reproductive system and breast disorders	Pelvic prolapse	01JAN2008	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	01JAN2016		Y
			Dermatitis contact	01JAN1993		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Pelvic floor repair	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1093 10931023	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2016		Y
		Immune system disorders	Allergy to animal	01JAN2014		Y
			Drug hypersensitivity	01JAN1970		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC1995	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1093 10931024	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2001		Y
			Vitamin D deficiency	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931025	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931026	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01APR2017	30APR2017	N
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01APR2017	30APR2017	N
		Vascular disorders	Raynaud's phenomenon	01JAN1975		Y
	C4591001 1093 10931029	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931034	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1093 10931035	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Post-traumatic stress disorder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931036	Cardiac disorders	Myocardial infarction	15MAY2018	15MAY2018	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	15MAY2018	15MAY2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931037	Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1093 10931038	Gastrointestinal disorders	Constipation	24JUN2020		Y
			Hiatus hernia	24JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Magnesium deficiency	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	17NOV2018		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1093 10931044	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1093 10931045	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931046	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1093 10931047	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1093 10931048	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1093 10931050	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1093 10931051	Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1093 10931054	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Micturition urgency	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1093 10931059	Vascular disorders	Hypertension	10APR2020		Y
	C4591001 1093 10931060	Cardiac disorders	Arrhythmia	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy bilateral	01JAN2009	31DEC2009	N
	C4591001 1093 10931062	Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
	C4591001 1093 10931064	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1093 10931069	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931075	Cardiac disorders	Palpitations	01JAN2015		Y
	C4591001 1093 10931076	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Prostatectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1093 10931077	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Hyperlipidaemia	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014		Y
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1093 10931080	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN1960		Y
			Mycotic allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1093 10931081	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Pain in extremity	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931083	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1093 10931086	Cardiac disorders	Ventricular tachycardia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Calcium deficiency	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1093 10931092	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931097	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1093 10931102	Eye disorders	Macular degeneration	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1093 10931106	Immune system disorders	Rubber sensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Bile duct stone	01JAN2018	31DEC2018	N
			Jaundice	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Gastric bypass	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1093 10931110	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1093 10931112	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1093 10931114	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009	31OCT2019	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Knee arthroplasty	01OCT2019	31OCT2019	N
	C4591001 1093 10931116	Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Arterial occlusive disease	01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931119	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1093 10931120	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01NOV2008	31DEC2010	N
		Social circumstances	Menopause	01JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1093 10931122	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1093 10931125	Eye disorders	Glaucoma	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1952		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2001	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1093 10931128	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Septal myectomy	12JUL2019	12JUL2019	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1093 10931130	Endocrine disorders	Goitre	01JAN1981	31DEC1981	N
			Hypothyroidism	01JAN1981		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01NOV1995		Y
		Infections and infestations	Cystitis	14SEP2020	18SEP2020	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1977		Y
			Migraine	01JAN1986		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1981	31DEC1984	N
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
			Thyroidectomy	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931140	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1093 10931141	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1994	31DEC1996	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1968	31DEC2001	N
			Uterine cyst	01JAN1975	31DEC1977	N
		Surgical and medical procedures	Female sterilisation	01JAN1977	31DEC1977	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Spinal fusion surgery	01JAN1996	31DEC1996	N
	C4591001 1093 10931143	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1093 10931151	Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1093 10931156	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1093 10931159	Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1093 10931160	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1093 10931162	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1093 10931163	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1093 10931181	Endocrine disorders	Hypothyroidism	01DEC2019		Y
		Psychiatric disorders	Depression	01JUN2020		Y
	C4591001 1093 10931184	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2013		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1093 10931189	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1093 10931190	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Chronic sinusitis	01JUN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01JAN2016		Y
			Thyroid cancer	01JAN2018	31DEC2018	N
		Nervous system disorders	Partial seizures	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2018	31DEC2018	N
	C4591001 1093 10931191	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1093 10931192	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1093 10931193	Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1093 10931198	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Coronary angioplasty	01DEC2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1093 10931212	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1093 10931227	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
			Vitamin B12 deficiency	01JAN2019		Y
			Vitamin D deficiency	01JAN2015		Y
		Renal and urinary disorders	Hydronephrosis	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nephrectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1094 10941001	Infections and infestations	Helicobacter infection	01SEP2019	31OCT2019	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
			Prostatic specific antigen increased	01NOV2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Insomnia	26NOV2018		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2018		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1094 10941002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
			SARS-CoV-2 antibody test positive	12MAY2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2018		Y
			Osteopenia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1991	N
		Nervous system disorders	Diabetic neuropathy	01MAY2018		Y
		Psychiatric disorders	Depression	23MAY2019	27MAR2020	N
	C4591001 1094 10941003	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Haematochezia	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Vitamin D deficiency	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Abdominal operation	01JAN2012	31DEC2012	N
			Hip arthroplasty	09JUN2020	09JUN2020	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1094 10941005	Blood and lymphatic system disorders	Anaemia	25SEP2018		Y
		Cardiac disorders	Coronary artery disease	27MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Onychomycosis	06DEC2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Renal and urinary disorders	Nephropathy	27MAY2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	25SEP2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01NOV1995	30NOV1995	N
			Coronary artery bypass	01MAR2015	31MAR2015	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1094 10941006	Cardiac disorders	Cardiac failure	01JAN2020		Y
		Eye disorders	Cataract	01SEP2017	30SEP2017	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2009	31DEC2009	N
			Diverticulum	01APR2019		Y
			Gastroesophageal reflux disease	01JAN2018		Y
			Haemorrhoids	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Gout	01JAN1995		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01AUG2019		Y
			Osteoarthritis	01APR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2005	31DEC2005	N
		Nervous system disorders	Carotid artery stenosis	01JAN2020		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01DEC2019		Y
		Surgical and medical procedures	Colectomy	01JAN2005	31DEC2005	N
			Haemorrhoid operation	01JAN1984	31DEC1984	N
			Shoulder operation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941007	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	30AUG2019		Y
			Haemorrhoids	30AUG2019		Y
			Hiatus hernia	02JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Vitamin B12 deficiency	01AUG2019		Y
			Vitamin D deficiency	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteoporosis	01MAR2019		Y
		Nervous system disorders	Transient ischaemic attack	01JAN1995	31DEC1995	N
		Psychiatric disorders	Depression	01MAR2019		Y
		Renal and urinary disorders	Chronic kidney disease	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Knee arthroplasty	01JUL2017	31JUL2017	N
			Metabolic surgery	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1094 10941008	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Vitamin D deficiency	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
			Psoriasis	01JAN2010		Y
			Rosacea	01JAN1982		Y
	C4591001 1094 10941009	Endocrine disorders	Hypothyroidism	01JAN1967		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Hiatus hernia	01NOV2018	31JAN2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1984	31DEC1984	N
		Immune system disorders	Seasonal allergy	01JAN1952		Y
		Infections and infestations	Liver abscess	01JAN2017	31DEC2017	N
			Urinary tract infection	24JUL2020	28JUL2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
				01JUN2020		Y
			Back pain	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1991		Y
			Insomnia	01JAN1967		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2020		Y
			Nephrolithiasis	01AUG2017	31OCT2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN1984	31DEC1984	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Gastric banding	01JAN1985	31DEC1985	N
			Gastric bypass	01JAN2017	31DEC2017	N
			Hernia hiatus repair	01JAN2019	31JAN2019	N
			Hysterectomy	01JAN2001	31DEC2001	N
			Renal surgery	01OCT2017	31OCT2017	N
			Rhinoplasty	01JAN1963	31DEC1963	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1094 10941011	Cardiac disorders	Atrial fibrillation	01JAN2003		Y
		Endocrine disorders	Hypogonadism	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	30APR2017	N
			Neuropathy peripheral	01MAR2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemospermia	01FEB2020		Y
		Surgical and medical procedures	Carpal tunnel decompression	01APR2017	30APR2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1094 10941012	Blood and lymphatic system disorders	Anaemia	01DEC2016		Y
		Eye disorders	Diabetic retinopathy	26MAR2020		Y
		Infections and infestations	Herpes zoster	01JUN2014	30JUN2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01DEC2016		Y
				01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Renal and urinary disorders	Microalbuminuria	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Leg amputation	01JAN2013	31DEC2013	N
		Vascular disorders	Hot flush	01JAN1997		Y
	C4591001 1094 10941013	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Vitamin D deficiency	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941014	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Infections and infestations	Helicobacter infection	01MAR2019	31MAR2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Nervous system disorders	Sciatica	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
			Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Skin ulcer	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Skin graft	01JAN1986	31DEC1986	N
		Vascular disorders	Deep vein thrombosis	01JAN1980		Y
	C4591001 1094 10941015	Cardiac disorders	Atrial fibrillation	01JAN2014	30APR2020	N
		Endocrine disorders	Hypothyroidism	24JAN2020		Y
		Gastrointestinal disorders	Constipation	01MAY2018		Y
		Infections and infestations	Osteomyelitis	01JUL2018	30APR2020	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1977	31DEC1978	N
				01JUL2018	31JUL2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JUL2019		Y
			Vitamin D deficiency	01JUL2018		Y
		Nervous system disorders	Haemorrhagic stroke	01JUN2014	30JUN2014	N
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Bone operation	01JAN1978	31JAN1978	N
			Fracture treatment	01JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941018	Ear and labyrinth disorders	Deafness unilateral	01JAN2016		Y
		Gastrointestinal disorders	Abdominal pain	01SEP2019		Y
			Gastroesophageal reflux disease	01JUL2017		Y
			Haemorrhoids	01JAN1988	31DEC1988	N
			Large intestine polyp	01MAR2019	31MAR2019	N
		Immune system disorders	Drug hypersensitivity	01JUL2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2017		Y
			Lactose intolerance	(b) (6) 1953		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01NOV2017		Y
			Osteoporosis	01OCT2018		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2017	31DEC2017	N
			Ovarian cyst	01JAN1972	31DEC1972	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2003	31DEC2003	N
			Appendicectomy	01JAN1972	31DEC1972	N
			Breast cyst excision	01JAN2017	31DEC2017	N
			Caesarean section	01JAN1978	31DEC1978	N
				01JAN1981	31DEC1981	N
				01JAN1982	31DEC1982	N
				01JAN1988	31DEC1988	N
			Keratomileusis	01JAN2003	31DEC2003	N
			Oophorectomy	01JAN1972	31DEC1972	N
			Sinus operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JUL2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941019	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2012		Y
			Vitamin D deficiency	01NOV2012		Y
		Vascular disorders	Hypertension	01NOV2012		Y
	C4591001 1094 10941021	Blood and lymphatic system disorders	Thrombocytopenia	01DEC2018		Y
		Cardiac disorders	Arrhythmia	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01OCT2019		Y
			Gastroesophageal reflux disease	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01MAR2019		Y
		Metabolism and nutrition disorders	Decreased appetite	01MAY2020		Y
			Hyperlipidaemia	01DEC2018		Y
			Type 2 diabetes mellitus	01JAN2016		Y
			Vitamin D deficiency	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2020		Y
			Osteoporosis	01DEC2018		Y
		Nervous system disorders	Dementia	01DEC2018		Y
			Neuropathy peripheral	01DEC2018		Y
			Parkinson's disease	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01APR2020		Y
			Microalbuminuria	01MAR2019		Y
			Urinary incontinence	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2019		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1094 10941022	Vascular disorders	Hypertension	18DEC2018		Y	
		Gastrointestinal disorders	Diverticulum	01APR2015		Y	
			Gastroesophageal reflux disease		01JUN2016		Y
		Immune system disorders	Seasonal allergy		01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia		01JAN2016		Y
			Type 2 diabetes mellitus		01JAN2012		Y
			Vitamin D deficiency		01DEC2015		Y
		Musculoskeletal and connective tissue disorders	Back pain		01JAN2018		Y
			Osteopenia		01JUN2016		Y
		Nervous system disorders	Migraine		01SEP2014		Y
			Sciatica		27MAY2020		Y
		Psychiatric disorders	Depression		01JAN2017		Y
			Insomnia		01SEP2014		Y
		Renal and urinary disorders	Chronic kidney disease		08JAN2020		Y
		Microalbuminuria		01JAN2020		Y	
	Surgical and medical procedures	Female sterilisation		01JAN1973	31DEC1973	N	
	Vascular disorders	Aortic arteriosclerosis		01MAY2014		Y	
		Hypertension		01JAN1983		Y	
	C4591001 1094 10941023	Gastrointestinal disorders	Haemorrhoids	01OCT2016		Y	
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01JUN2016		Y	
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N	
	Metabolism and nutrition disorders	Hyperlipidaemia		01MAR2017		Y	
		Vitamin D deficiency		01APR2015		Y	
	Musculoskeletal and connective tissue disorders	Back pain		16MAY2020		Y	
	Nervous system disorders	Sciatica		16MAR2020		Y	



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01MAR2015		Y
	C4591001 1094 10941024	Surgical and medical procedures	Appendicectomy	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2000		Y
			Type 2 diabetes mellitus	01JUL2000		Y
		Renal and urinary disorders	Chronic kidney disease	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1094 10941026	Vascular disorders	Hypertension	01JUN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Ligament sprain	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2016		Y
			Type 2 diabetes mellitus	01DEC2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN1994		Y
		Nervous system disorders	Neuropathy peripheral	01FEB2020		Y
		Renal and urinary disorders	Hypertonic bladder	01AUG2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
			Foot operation	01JAN1994	31DEC1994	N
	C4591001 1094 10941027	Blood and lymphatic system disorders	Anaemia	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Injury, poisoning and procedural complications	Hip fracture	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Jaw fracture	01FEB2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Back pain	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01MAR2019		Y
		Psychiatric disorders	Insomnia	01OCT2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2018		Y
			Erectile dysfunction	01JAN2016		Y
	C4591001 1094 10941028	Gastrointestinal disorders	Haemorrhoids	01APR2014		Y
		Immune system disorders	Seasonal allergy	01APR2019		Y
		Infections and infestations	Onychomycosis	01FEB2015		Y
		Metabolism and nutrition disorders	Hyperhomocysteinaemia	01JUN2017		Y
			Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01OCT2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01APR2014		Y
		Psychiatric disorders	Insomnia	01AUG2016		Y
			Libido decreased	01DEC2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01DEC2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1094 10941029	Ear and labyrinth disorders	Meniere's disease	01OCT2019		Y
		Endocrine disorders	Hypothyroidism	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Blindness unilateral	01OCT2019		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2007		Y
			Vitamin B12 deficiency	01OCT2019		Y
			Vitamin D deficiency	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2019		Y
			Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01OCT2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2007		Y
		Surgical and medical procedures	Gastric banding	01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N
			Gastric bypass	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1970	31DEC1970	N
			Nephrectomy	01JAN2007	31DEC2007	N
			Rotator cuff repair	01JAN2004	31DEC2004	N
		Vascular disorders	Deep vein thrombosis	01JAN2007		Y
			Hypertension	01JAN2019		Y
	C4591001 1094 10941032	Ear and labyrinth disorders	Deafness	01AUG2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01AUG2018		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2003		Y
		Psychiatric disorders	Anxiety	01AUG2018		Y
		Renal and urinary disorders	Chronic kidney disease	01AUG2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2020		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1094 10941033	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Prostatic specific antigen increased	01FEB2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2016		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin B12 deficiency	01MAY2020		Y
			Vitamin D deficiency	01NOV2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAR2007	31DEC2007	N
		Nervous system disorders	Diabetic neuropathy	01NOV2015		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Renal and urinary disorders	Chronic kidney disease	01AUG2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Transurethral prostatectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1094 10941034	Blood and lymphatic system disorders	Anaemia	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
			Tonsillitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01APR2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2015	31DEC2015	N
			Uterine leiomyoma	01JAN1995	31DEC1995	N
		Nervous system disorders	Carotid artery occlusion	01FEB2018	01FEB2018	N
			Carpal tunnel syndrome	01JAN2017		Y
			Cerebrovascular accident	01JAN2017	31DEC2017	N
			Diabetic neuropathy	01JUN2020		Y
			Sciatica	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JUN2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
			Hypertonic bladder	01DEC2019		Y
			Stress urinary incontinence	01APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Rhinitis allergic	26OCT2018		Y
			Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Brain stent insertion	01FEB2018	28FEB2018	N
			Cholecystectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1996	31DEC1996	N
			Oophorectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1094 10941035	Metabolism and nutrition disorders	Vitamin D deficiency	28JUL2020		Y
		Renal and urinary disorders	Chronic kidney disease	14JUL2020		Y
		Reproductive system and breast disorders	Prostatitis	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	28JUL2020		Y
	C4591001 1094 10941036	Eye disorders	Glaucoma	01JAN2018		Y
		Gastrointestinal disorders	Diverticulum	01JUN2020		Y
			Dyspepsia	01JAN2019		Y
				01MAR2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1993	31DEC1993	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Vitamin D deficiency	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1993	31DEC1993	N
			Urinary bladder suspension	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1094 10941037	Blood and lymphatic system disorders	Anaemia	01DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Haemorrhoids	01DEC2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2020		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2017		Y
			Osteoarthritis	01DEC2014		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1094 10941039	Blood and lymphatic system disorders	Anaemia	01JAN1998		Y
		Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Hypokalaemia	28MAR2018		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin B12 deficiency	01JAN2017		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Osteoarthritis	01JAN1988		Y
			Osteopenia	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
			Syncope	01MAY2019		Y
		Renal and urinary disorders	Chronic kidney disease	01OCT2015		Y
			Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941041	Eye disorders	Cataract	01JAN2010	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN2010		Y
				01JAN2015		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1983		Y
			Type 2 diabetes mellitus	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	31DEC2009	N
				01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
		Nervous system disorders	Carotid artery stenosis	01JAN2014		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2003	31DEC2003	N
			Carotid artery stent insertion	01JAN2014	31DEC2014	N
			Cataract operation	01JAN2011	31DEC2011	N
			Hip arthroplasty	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1972	31DEC1972	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1094 10941042	Infections and infestations	Herpes zoster	01JAN1986		Y
		Investigations	Blood cholesterol increased	01JAN2017	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1989	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01SEP1990	31DEC1990	N
			Female sterilisation	01SEP1990	30SEP1990	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941044		Mammoplasty	01JAN2001	31DEC2001	N
		Cardiac disorders	Cardiac failure congestive	01APR2020		Y
		Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Infections and infestations	Tonsillitis	01JAN1948	31DEC1948	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01APR2020		Y
		Renal and urinary disorders	Chronic kidney disease	01APR2020		Y
			Urinary incontinence	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1948	31DEC1948	N
	C4591001 1094 10941045	Vascular disorders	Hypertension	01JAN2017		Y
		Cardiac disorders	Myocardial infarction	01JAN2020	31JAN2020	N
		Gastrointestinal disorders	Inguinal hernia	01JUL1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JUL2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2012	N
				09MAR2020	09MAR2020	N
			Syncope	31JUL2020		Y
		Psychiatric disorders	Nicotine dependence	01JAN1980		Y
	Reproductive system and breast disorders	Erectile dysfunction	01OCT2019		Y	
	Skin and subcutaneous tissue disorders	Dermatitis atopic	01APR2020		Y	
	Surgical and medical procedures	Coronary arterial stent insertion	15JAN2020	15JAN2020	N	
		Hernia repair	01JAN1990	31DEC1990	N	
	Vascular disorders	Hypertension	01JAN2010		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941046	Blood and lymphatic system disorders	Thrombocytopenia	01DEC2019		Y
		Cardiac disorders	Cardiomyopathy	01DEC2013		Y
			Chronic left ventricular failure	01JUL2017		Y
		Endocrine disorders	Thyroid mass	01FEB2020		Y
		Gastrointestinal disorders	Abdominal hernia	01JUN2019	30JUN2019	N
			Gastroesophageal reflux disease	01JUN2018		Y
		Immune system disorders	Drug hypersensitivity	01OCT2009		Y
			Seasonal allergy	01SEP2012		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Lumbar spinal stenosis	01APR2014	31DEC2014	N
			Spinal osteoarthritis	01FEB2010		Y
			Spondylitis	01FEB2010		Y
		Psychiatric disorders	Depression	01JUL2018	31MAR2019	N
			Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Abdominal hernia repair	01JUN2019	30JUN2019	N
			Spinal fusion surgery	01JUN2017	30JUN2017	N
				01MAY2016	31MAY2016	N
			Spinal laminectomy	01MAY2014	31MAY2014	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1094 10941047	Cardiac disorders	Coronary artery disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Haemorrhoids	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Hypovitaminosis	01NOV2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	04APR2020		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1094 10941050	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Immune system disorders	Seasonal allergy	01JAN1948		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2003	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
			Face lift	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Urinary bladder suspension	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1094 10941051	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Nasal septal operation	01JAN2008	31DEC2008	N
		Vascular disorders	Lymphoedema	01JAN2000		Y
	C4591001 1094 10941052	Hepatobiliary disorders	Cholelithiasis	01JAN1977	31DEC1977	N
			Non-alcoholic steatohepatitis	01JAN2011		Y
		Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Fall	01OCT2013	31OCT2013	N
			Road traffic accident	01JAN1974	31DEC1974	N
			Tibia fracture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Soft tissue sarcoma	01JAN2011	31DEC2011	N
		Pregnancy, puerperium and perinatal conditions	Complication of pregnancy	01JAN1989	31DEC1989	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Surgical and medical procedures	Appendectomy	01JAN2011	31DEC2011	N
			Fracture treatment	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Spinal operation	01OCT2013	31OCT2013	N
			Tonsillectomy	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941054	Vascular disorders	Hypertension	01JAN2006		Y
		Endocrine disorders	Hypothyroidism	01JAN2020		Y
		General disorders and administration site conditions	Peripheral swelling	01OCT2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin B12 deficiency	01OCT2015		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01FEB2019		Y
		Nervous system disorders	Diabetic neuropathy	01MAY2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
			Finger repair operation	01JAN2006	31DEC2006	N
		Inguinal hernia repair	01JAN1974	31DEC1974	N	
		Tonsillectomy	01JAN1964	31DEC1964	N	
	C4591001 1094 10941056	Vascular disorders	Hypertension	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
	C4591001 1094 10941057	Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2014		Y
		Endocrine disorders	Hypogonadism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
C4591001 1094 10941058		General disorders and administration site conditions	Hernia	01FEB2020		Y
			Pain	01FEB2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
			Type 2 diabetes mellitus	01FEB2020		Y
			Vitamin D deficiency	01FEB2020		Y
		Psychiatric disorders	Nicotine dependence	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01FEB2020		Y
		Surgical and medical procedures	Spinal operation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01FEB2020		Y
C4591001 1094 10941059		Gastrointestinal disorders	Abdominal pain	28JUL2020		Y
			Nausea	28JUL2020		Y
		General disorders and administration site conditions	Pain	01JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2001		Y
			Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2016	31DEC2016	N
			Diabetic neuropathy	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1974	31DEC1974	N
				01JAN1977	31DEC1977	N
				01JAN1979	31DEC1979	N
			Joint arthroplasty	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1094 10941060	Metabolism and nutrition disorders	Hypercholesterolaemia	14APR2015		Y
			Type 2 diabetes mellitus	14APR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Chronic kidney disease	07MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	25JUN2020		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31JAN2015	N
			Penile prosthesis insertion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	07MAR2018		Y
	C4591001 1094 10941061	Blood and lymphatic system disorders	Anaemia	01AUG2019		Y
		Eye disorders	Blindness unilateral	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Infections and infestations	Hepatitis C	01JAN2005	31MAR2020	N
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01MAY2020		Y
			Vitamin B12 deficiency	01AUG2019		Y
			Vitamin D deficiency	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Back pain	01JAN2010		Y
		Nervous system disorders	Myoclonus	01OCT2019		Y
		Psychiatric disorders	Depression	01SEP2019		Y
		Renal and urinary disorders	Chronic kidney disease	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2019		Y
			Sleep apnoea syndrome	01DEC2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1094 10941062	Cardiac disorders	Cardiac failure congestive	01FEB2016		Y
			Coronary artery disease	01JAN1999		Y
			Myocardial infarction	01JAN1999	31DEC1999	N
		Gastrointestinal disorders	Diverticulum	01MAY2019		Y
		Injury, poisoning and procedural complications	Fall	01JAN2014	31DEC2014	N
			Foot fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Vitamin D deficiency	01NOV2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01NOV2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1999	31DEC1999	N
			Foot operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1094 10941063	Injury, poisoning and procedural complications	Silicosis	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1989		Y
		Surgical and medical procedures	Eye operation	01JUN2016	30JUN2016	N
				01MAY2015	31MAY2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Peripheral vascular disorder	01JAN2019		Y
	C4591001 1094 10941064	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	31JUL2020		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertonic bladder	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Deep vein thrombosis	01SEP2011		Y
			Hypertension	01JAN2010		Y
	C4591001 1094 10941065	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
			Osteoporosis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1094 10941071	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
			Vitamin D deficiency	01AUG2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1998	31DEC1998	N
			Uterine cancer	01JAN1998	31DEC1998	N
		Nervous system disorders	Diabetic neuropathy	01MAY2017		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2017		Y
			Urinary incontinence	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Eye laser surgery	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Rotator cuff repair	01AUG2018	31AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01MAR2018	31MAR2018	N
		Vascular disorders	Hypertension	01MAY2017		Y
	C4591001 1094 10941072	Immune system disorders	Peripheral vascular disorder	01AUG2018		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Breast mass	07AUG2020		Y
	C4591001 1094 10941073	Vascular disorders	Hypertension	01JAN2015		Y
		Ear and labyrinth disorders	Deafness	01JAN2013		Y
		Endocrine disorders	Hypogonadism	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		General disorders and administration site conditions	Oedema peripheral	01AUG2018		Y
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01OCT2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01FEB2019		Y
			Microalbuminuria	01FEB2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2017		Y
		Vascular disorders	Aortic arteriosclerosis	01JUL2019		Y
			Hypertension	01JAN2013		Y
	C4591001 1094 10941074	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN1993	31DEC1993	N
	C4591001 1094 10941078	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1944	31DEC1944	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
			Vitamin D deficiency	20AUG2020		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1986	31DEC1986	N
		Nervous system disorders	Senile dementia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1094 10941079	General disorders and administration site conditions	Hernia	01JAN1989	31DEC1989	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Infections and infestations	Hepatitis C	01JAN1997	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1094 10941080	Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hypercholesterolaemia	01SEP2000		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2011		Y
		Nervous system disorders	Sciatica	01JAN2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941081	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Investigations	Blood testosterone increased	01JAN2016		Y
			Laparoscopy	01JAN1981	31DEC1981	N
				01JAN1982	31DEC1982	N
				01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2016		Y
			Vitamin D deficiency	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Renal and urinary disorders	Bladder prolapse	10AUG2020		Y
		Reproductive system and breast disorders	Infertility	01JAN1981	31DEC1984	N
			Uterine scar	01JAN1984	31DEC1984	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2004	31DEC2004	N
			Uterine operation	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941083	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Fasciotomy	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941085	Endocrine disorders	Hypogonadism	01NOV2015		Y
			Hypothyroidism	01NOV2015		Y
		Gastrointestinal disorders	Dyspepsia	01MAY2020		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hyperhomocysteinaemia	01NOV2017		Y
			Vitamin B12 deficiency	01NOV2017		Y
			Vitamin D deficiency	01NOV2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1983	31DEC1983	N
		Psychiatric disorders	Insomnia	01NOV2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
	C4591001 1094 10941086	Metabolism and nutrition disorders	Vitamin B complex deficiency	08MAY2000		Y
			Vitamin D deficiency	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Mastectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941088	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1972	31DEC1972	N
			Tumour excision	01JAN2016	31DEC2016	N
	C4591001 1094 10941089	Gastrointestinal disorders	Gastroesophageal reflux disease	09MAR2017		Y
		Infections and infestations	Diverticulitis	09MAR2017		Y
		Metabolism and nutrition disorders	Obesity	18MAY2020		Y
		Psychiatric disorders	Anxiety	09MAR2017		Y
			Depression	18MAY2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	01JAN2006	N
			Keratomileusis	01JAN2017	31DEC2017	N
			Mammoplasty	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1990	31DEC1990	N
	C4591001 1094 10941092	Eye disorders	Macular degeneration	01SEP2016		Y
		Gastrointestinal disorders	Diverticulum	01OCT2016		Y
			Dyspepsia	01JUL2019		Y
			Haemorrhoids	01MAR2020		Y
				01OCT2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
			Vitamin D deficiency	01SEP2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Osteopenia	01SEP2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN1992	31DEC1992	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1972	31DEC1972	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Knee arthroplasty	01MAY2017	31MAY2017	N
			Spinal operation	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941093	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Infections and infestations	Urinary tract infection	10JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y
	C4591001 1094 10941094	Psychiatric disorders	Depression	01JAN2019		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2018		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01NOV2015		Y
		Infections and infestations	Onychomycosis	01NOV2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Diabetic neuropathy	01MAY2017		Y
			Senile dementia	01MAY2017		Y
		Psychiatric disorders	Depression	01FEB2016		Y
		Renal and urinary disorders	Chronic kidney disease	01NOV2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertonic bladder	01NOV2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Erectile dysfunction	01MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01NOV2015		Y
		Surgical and medical procedures	Cataract operation	01JUL2017	31JUL2017	N
				01JUN2017	30JUN2017	N
			Spinal fusion surgery	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1094 10941096	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Bacterial vaginosis	09JUN2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	28APR2020		Y
		Surgical and medical procedures	Bunion operation	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Tonsillectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1094 10941097	Eye disorders	Glaucoma	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01MAR2020		Y
			Vitamin D deficiency	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteopenia	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01MAY2020		Y
			Senile dementia	01MAR2020		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1994		Y
			Sleep apnoea syndrome	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Oxygen therapy	01JAN2005		Y
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Intermittent claudication	01MAY2020		Y
	C4591001 1094 10941099	Gastrointestinal disorders	Gastrointestinal polyp	01SEP2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Vitamin D deficiency	11AUG2020		Y
		Nervous system disorders	Carotid artery stenosis	01JUL2019		Y
			Transient ischaemic attack	01JAN2012	31DEC2012	N
				01JUL2019	31JUL2019	N
		Reproductive system and breast disorders	Erectile dysfunction	11AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941101	Blood and lymphatic system disorders	Anaemia	10JUL2020		Y
		Cardiac disorders	Atrial fibrillation	01JAN2012		Y
			Cardiac failure congestive	01DEC2017		Y
			Coronary artery disease	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Cataract	01JAN2014		Y
			Glaucoma	01JAN2014		Y
		Gastrointestinal disorders	Flatulence	01JAN1975		Y
			Gastroesophageal reflux disease	01JAN1975		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Investigations	Catheterisation cardiac	01JAN2017	31JAN2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin B complex deficiency	01JUL2017		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
			Muscle spasms	04JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01APR2017		Y
			Coronary artery bypass	01JAN2012	31DEC2012	N
			Renal stone removal	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941102	Cardiac disorders	Atrial fibrillation	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		General disorders and administration site conditions	Oedema peripheral	01APR2016		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2016		Y
			Vitamin D deficiency	01DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Muscle spasms	04JUN2020		Y
			Osteoporosis	01JUL2015		Y
		Nervous system disorders	Sciatica	01SEP2015		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2015		Y
			Hypertonic bladder	01APR2017		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2007	31DEC2007	N
			Appendicectomy	01JAN2013	31DEC2013	N
			Cardiac pacemaker insertion	01JAN2007	31DEC2007	N
				01JAN2009	31DEC2009	N
			Female sterilisation	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1094 10941105	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1979	31DEC1979	N
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01FEB2020		Y
			Vitamin D deficiency	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Chronic kidney disease	01FEB2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941106	Endocrine disorders	Hypogonadism	01DEC2017		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2016	30SEP2016	N
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
			Vitamin D deficiency	01DEC2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2017		Y
		Surgical and medical procedures	Hernia repair	01SEP2016	30SEP2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1094 10941110	Endocrine disorders	Hypogonadism	01SEP2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin B12 deficiency	01JAN2019		Y
			Vitamin D deficiency	01OCT2015		Y
		Nervous system disorders	Carotid artery stenosis	01MAY2017		Y
			Diabetic neuropathy	01OCT2015		Y
		Renal and urinary disorders	Chronic kidney disease	01OCT2015		Y
			Nephrolithiasis	01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2015		Y
		Surgical and medical procedures	Renal stone removal	01JAN1990	31DEC1990	N
		Vascular disorders	Aortic arteriosclerosis	01OCT2015		Y
			Hypertension	01JAN1995		Y
			Peripheral vascular disorder	01OCT2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941111	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Infections and infestations	Uterine infection	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Upper limb fracture	01MAY2019	31MAY2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
				01JUN2011	30JUN2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN1958		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Breast conserving surgery	01SEP2005	30SEP2005	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Gastric bypass	01SEP2004	30SEP2004	N
			Hysterectomy	01JAN1976	31DEC1976	N
			Oophorectomy	01JAN1981	31DEC1981	N
			Shoulder arthroplasty	01JUN2011	30JUN2011	N
				01MAY2014	31MAY2014	N
		Vascular disorders	Hypotension	15FEB2020		Y
	C4591001 1094 10941112	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	26MAY2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Psychiatric disorders	Depression	26MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1094 10941114	Blood and lymphatic system disorders	Anaemia	01NOV2018		Y
		Eye disorders	Diabetic retinopathy	01AUG2019		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01NOV2018		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Chronic kidney disease	01JUL2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941115	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10JUL2018		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2019		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1991	31DEC1991	N
			Cholecystectomy	01JAN2004	31DEC2004	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1995	31DEC1995	N
	C4591001 1094 10941116	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2019	31DEC2019	N
			Dyspepsia	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01NOV2019		Y
		Immune system disorders	Seasonal allergy	01NOV2019		Y
		Infections and infestations	Helicobacter infection	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y
			Vitamin D deficiency	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01OCT2019		Y
			Insomnia	01MAY2020		Y
		Renal and urinary disorders	Microalbuminuria	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Wrist surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01AUG2019	30NOV2019	N
	C4591001 1094 10941118	Blood and lymphatic system disorders	Thrombocytopenia	01OCT2019		Y
		Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Endocrine disorders	Hypogonadism	01OCT2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
			Umbilical hernia	01JAN1990	31DEC1990	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
			Non-alcoholic steatohepatitis	01APR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1947	31DEC1947	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y
		Nervous system disorders	Restless legs syndrome	01JAN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01OCT2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2019		Y
			Erectile dysfunction	01OCT2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Umbilical hernia repair	01JAN1990	31DEC1990	N
		Vascular disorders	Hypotension	01OCT2019		Y
	C4591001 1094 10941119	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Dyspepsia	01OCT2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01DEC2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm malignant	01JAN1989	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JUN2019		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Brain tumour operation	01JAN1995	31DEC1995	N
			Caesarean section	01JAN1989	31DEC1989	N
				01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941120	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
			Coronary artery disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Sinusitis	18AUG2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Vitamin D deficiency	01JAN2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Pulmonary embolism	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1094 10941121	Cardiac disorders	Coronary artery disease	01JAN2006		Y
			Myocardial infarction	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Fall	01JAN2016	31DEC2016	N
			Hip fracture	01JAN2016	31DEC2017	N
			Road traffic accident	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2017		Y
			Vitamin D deficiency	01MAY2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1983		Y
		Renal and urinary disorders	Chronic kidney disease	01JUN2019		Y
			Microalbuminuria	01APR2020		Y
			Nephrolithiasis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2006	31DEC2006	N
			Cardiac pacemaker replacement	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip surgery	01JAN2017	31DEC2017	N
			Knee operation	01JAN1983	31DEC1983	N
			Nephrectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941122	Injury, poisoning and procedural complications	Spinal cord injury	01JUN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Surgical and medical procedures	Vertebroplasty	01JUN2015	31DEC2015	N
	C4591001 1094 10941123	Nervous system disorders	Carotid artery disease	08MAY2019		Y
	C4591001 1094 10941125	Endocrine disorders	Goitre	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2017		Y
			Obesity	01JAN2017		Y
			Vitamin D deficiency	01NOV2017		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN1968	31DEC1968	N
		Renal and urinary disorders	Chronic kidney disease	01DEC2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Limb operation	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941126	Ear and labyrinth disorders	Eustachian tube dysfunction	01DEC2018		Y
		Endocrine disorders	Hypothyroidism	01DEC2019		Y
		Immune system disorders	Seasonal allergy	01OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1094 10941128	Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Infections and infestations	Brain abscess	01JAN1980	31DEC1980	N
		Nervous system disorders	Epilepsy	01JAN2014	31DEC2014	N
				01MAR1980		Y
		Surgical and medical procedures	Ear operation	01JAN1980	31DEC1980	N
	C4591001 1094 10941130	Infections and infestations	Onychomycosis	10JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	14OCT2013	14OCT2013	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941133	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN2008	31DEC2008	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1094 10941134	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1094 10941135	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Rheumatoid arthritis	01JAN2019		Y
		Surgical and medical procedures	Limb operation	01JAN2012	31DEC2012	N
			Spinal operation	01JAN1996	31DEC1996	N
	C4591001 1094 10941136	Infections and infestations	Tonsillitis	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN2012	31DEC2012	N
	C4591001 1094 10941138	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin D deficiency	27AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005	31DEC2006	N
			Back pain	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Knee operation	01JAN2010	31DEC2010	N
			Spinal operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941139	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	T-cell lymphoma	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Cancer surgery	01JAN2001	01JAN2001	N
			Orthopaedic procedure	01JAN2005	31JAN2005	N
				01JAN2009	01JAN2009	N
			Tonsillectomy	01JAN2017	01JAN2017	N
	C4591001 1094 10941141	Blood and lymphatic system disorders	Anaemia	01AUG2018		Y
		Eye disorders	Glaucoma	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
			Vitamin D deficiency	01MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
				01MAY2017		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2017		Y
			Microalbuminuria	01MAR2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941142	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Cardiac disorders	Bundle branch block right	01JAN2019		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2020		Y
		Injury, poisoning and procedural complications	Splenic rupture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Alcohol use disorder	01JAN1980		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Diaphragmatic operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941145	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Umbilical hernia	01JAN1970	31DEC1970	N
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Injury, poisoning and procedural complications	Fall	01AUG2020	31AUG2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2020		Y
			Osteoporosis	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Skin burning sensation	01OCT2019		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1970	31DEC1970	N
	C4591001 1094 10941146	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1094 10941147	Gastrointestinal disorders	Umbilical hernia	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1094 10941148	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
			Peripheral vascular disorder	01JAN2017		Y
	C4591001 1094 10941149	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1094 10941151	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Vitamin D deficiency	01OCT2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01NOV2017		Y
			Osteoarthritis	01DEC2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JUN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1094 10941152	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1094 10941154	Gastrointestinal disorders	Enterovesical fistula	01SEP2019	31DEC2019	N
			Intestinal obstruction	01JUN2017	30JUN2017	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Onychomycosis	01AUG2017		Y
			Pneumonia	01JAN2015	31DEC2015	N
			Urinary tract infection	01JAN2019		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1968	31DEC1968	N
			Hip fracture	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2018		Y
			Vitamin B12 deficiency	01NOV2018		Y
			Vitamin D deficiency	01FEB2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2017		Y
			Intervertebral disc protrusion	01SEP2018		Y
		Nervous system disorders	Lumbar radiculopathy	01JUL2018		Y
		Psychiatric disorders	Anxiety	01SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01MAY2017		Y
		Renal and urinary disorders	Chronic kidney disease	01NOV2018		Y
			Cystitis interstitial	01JUL2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Intestinal fistula repair	01DEC2019	31DEC2019	N
	C4591001 1094 10941157	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Senile dementia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1094 10941158	Ear and labyrinth disorders	Meniere's disease	01JAN1990		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2019	03JAN2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Colectomy	01JUL2016	31JUL2016	N
			Hernia repair	01JAN2020	31JAN2020	N
			Spinal fusion surgery	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1094 10941159	Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
			Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN1973		Y
		Surgical and medical procedures	Caesarean section	01JAN1980	31DEC1980	N
				01JAN1989	31DEC1989	N
			Cholecystectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1094 10941160	Endocrine disorders	Hypothyroidism	01APR2017		Y
		Gastrointestinal disorders	Diarrhoea	31AUG2020	02SEP2020	N
			Vomiting	01SEP2020	03SEP2020	N
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Infections and infestations	Upper respiratory tract infection	01SEP2020	07SEP2020	N
			Urinary tract infection	01SEP2020	07SEP2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01APR2017		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1094 10941161	Endocrine disorders	Hypothyroidism	23MAR2020		Y
		Gastrointestinal disorders	Abdominal pain lower	23SEP2020		Y
			Dyspepsia	01JUN2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01APR2019		Y
		Nervous system disorders	Neuropathy peripheral	01MAR2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Limb operation	01JAN2010	31DEC2010	N
	C4591001 1094 10941162	Endocrine disorders	Hypogonadism	01OCT2015		Y
			Hypothyroidism	01MAR2017		Y
		Gastrointestinal disorders	Diverticulum	01OCT2013		Y
			Haemorrhoids	01OCT2013		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1991		Y
			Type 2 diabetes mellitus	01JAN2013		Y
			Vitamin D deficiency	01OCT2015		Y
		Nervous system disorders	Diabetic neuropathy	01JUN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1094 10941164	Cardiac disorders	Myocardial infarction	01AUG2009	31AUG2009	N
		Hepatobiliary disorders	Cholelithiasis	01DEC2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Infections and infestations	Joint abscess	01JUL1993	31JUL1993	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2009		Y
			Type 2 diabetes mellitus	01AUG2009		Y
			Vitamin B12 deficiency	01FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01DEC2009	31DEC2009	N
			Coronary angioplasty	01AUG2009	31AUG2009	N
				01FEB2010	28FEB2010	N
			Coronary arterial stent insertion	01SEP2009	30SEP2009	N
		Vascular disorders	Hypertension	01AUG2009		Y
	C4591001 1094 10941165	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2017		Y
			Vitamin D deficiency	01NOV2015		Y
		Psychiatric disorders	Insomnia	01NOV2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1094 10941168	Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Endocrine disorders	Testicular failure	01JAN2017		Y
		Gastrointestinal disorders	Diverticulum	01JUL2019		Y
			Gastroesophageal reflux disease	01AUG2016		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01JUN2016		Y
		Infections and infestations	Bronchitis	01AUG2019	30SEP2019	N
			Tonsillitis	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Gout	01AUG2016		Y
			Hypercholesterolaemia	01AUG2004		Y
			Hypertriglyceridaemia	01AUG2004		Y
			Type 2 diabetes mellitus	01AUG2004		Y
			Vitamin D deficiency	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2018		Y
			Back pain	01JAN2019		Y
			Intervertebral disc protrusion	01OCT1981	30APR2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myalgia	01MAY2020		Y
			Neck pain	01AUG2016		Y
		Nervous system disorders	Diabetic neuropathy	01AUG2004		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2016		Y
			Diabetic nephropathy	01MAY2016		Y
			Proteinuria	01AUG2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2017		Y
			Sleep apnoea syndrome	01JUN2018		Y
		Surgical and medical procedures	Intervertebral disc operation	01APR2010	30APR2010	N
			Tonsillectomy	01JAN2001	31DEC2001	N
			Turbinectomy	01JAN2001	31DEC2001	N
			Uvulopalatopharyngoplasty	01SEP2008	30SEP2008	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1094 10941170	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1094 10941171	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Knee operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1956	31DEC1956	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1094 10941172	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Type 2 diabetes mellitus	01JAN1996		Y
			Arthralgia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
	C4591001 1094 10941175	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1094 10941177	Ear and labyrinth disorders	Cerumen impaction	08OCT2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	13JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1965	31DEC1965	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JUN1985		Y
	C4591001 1094 10941178	Endocrine disorders	Hypothyroidism	01AUG2019		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1967	31DEC1967	N
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1979	31DEC1986	N
		Nervous system disorders	Seizure	01JAN1979		Y
		Psychiatric disorders	Bipolar disorder	01JAN1984		Y
			Depression	01JAN1984		Y
			Insomnia	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01AUG2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
			Hysterectomy	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1094 10941180	Cardiac disorders	Cardiac failure congestive	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2020		Y
			Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1094 10941183	Hepatobiliary disorders	Cholelithiasis	01NOV2019	31DEC2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Renal and urinary disorders	End stage renal disease	01MAR2019		Y
		Surgical and medical procedures	Dialysis	01JAN2019		Y
		Vascular disorders	Hypertension	01APR2018		Y
	C4591001 1094 10941184	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1094 10941187	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1094 10941191†	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Eye disorders	Glaucoma	01JUL2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2020		Y
		Investigations	HIV test positive	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin D deficiency	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Lumbar radiculopathy	01JAN2020		Y
			Neuropathy peripheral	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2020		Y
		Surgical and medical procedures	Spinal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Deep vein thrombosis	01JAN2020		Y
			Hypertension	01JAN2019		Y
	C4591001 1095 10951003	Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	01JAN2020		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1980		Y
			Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
	C4591001 1095 10951004	Gastrointestinal disorders	Umbilical hernia	01JAN2012	31DEC2012	N
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	01JAN2004	31DEC2004	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
	C4591001 1095 10951010	Investigations	Blood iron decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951012	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2020	02JUL2020	N
		Surgical and medical procedures	Rotator cuff repair	02JUL2020	02JUL2020	N
	C4591001 1095 10951013	Injury, poisoning and procedural complications	Humerus fracture	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1995		Y
		Surgical and medical procedures	Fracture treatment	01JAN1993	31DEC1993	N
			Knee arthroplasty	18DEC2014	18DEC2014	N
		Vascular disorders	Hot flush	01JAN1996		Y
	C4591001 1095 10951015	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2017		Y
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1095 10951016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1095 10951017	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1095 10951019	Ear and labyrinth disorders	Meniere's disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	22JUL2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	22JUL1990		Y
			Type 2 diabetes mellitus	22JUL1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
		Psychiatric disorders	Anxiety	22JUL2007		Y
			Bipolar disorder	22JUL2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Chronic obstructive pulmonary disease	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	22JUL1990		Y
	C4591001 1095 10951020	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1095 10951027	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951032	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Dry eye	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN1968		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1977	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JUL2000	31JUL2000	N
	C4591001 1095 10951035	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hypercholesterolaemia	01JAN2016		Y
	C4591001 1095 10951037	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Prostatectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1095 10951043	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1955		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31JAN2018	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951048	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1095 10951049	Cardiac disorders	Atrial fibrillation	15MAR2018		Y
		Immune system disorders	Seasonal allergy	10FEB2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	15JUL2004	15JUL2006	N
		Surgical and medical procedures	Prostatectomy	15JUL2006	15JUL2006	N
			Umbilical hernia repair	15JAN2008	15JAN2008	N
		Vascular disorders	Hypertension	14MAR2010		Y
	C4591001 1095 10951050	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01APR2000		Y
			Vitamin D deficiency	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Surgical and medical procedures	Hip arthroplasty	01JUL2007	31JUL2007	N
				01NOV2000	30NOV2000	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	13MAY2015	13MAY2015	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951051	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN2010		Y
		Endocrine disorders	Thyroid cyst	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1949		Y
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2012	31DEC2012	N
		Nervous system disorders	Sinus headache	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Appendectomy	01JAN1977	31DEC1977	N
			Knee operation	01JAN2012	31DEC2012	N
	C4591001 1095 10951052	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Hepatitis C	01JAN1999	31DEC2015	N
	C4591001 1095 10951053	Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2018		Y
	C4591001 1095 10951054	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Latent tuberculosis	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2014		Y
	C4591001 1095 10951065	Eye disorders	Myopia	01JAN1990	31DEC1995	N
		Gastrointestinal disorders	Hiatus hernia	01NOV2019	30NOV2019	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	01NOV2019	30NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Eye laser surgery	01JAN1995	31DEC1995	N
			Hernia hiatus repair	01NOV2019	30NOV2019	N
			Knee arthroplasty	01NOV2018	30NOV2018	N
			Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1095 10951067	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01DEC2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1973		Y
			Peripheral venous disease	01JAN2019		Y
	C4591001 1095 10951068	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Joint range of motion decreased	01JAN2013		Y
			Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Rotator cuff repair	01NOV2018	30NOV2018	N
			Toe operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1095 10951071	Immune system disorders	Seasonal allergy	01JAN1955		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1095 10951072	Eye disorders	Cataract	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1976	31DEC1976	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1975		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
			Renal stone removal	01JAN1976	31DEC1976	N
	C4591001 1095 10951075	Eye disorders	Vitreous detachment	01APR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y
	C4591001 1095 10951077	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1095 10951078	Cardiac disorders	Mitral valve prolapse	01JAN1978		Y
			Pericarditis	01JAN1968	31DEC1971	N
		Investigations	Heart rate irregular	01JUN1995		Y
		Metabolism and nutrition disorders	Dairy intolerance	01MAY2020		Y
			Gluten sensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Rheumatic fever	01JAN1968	31DEC1968	N
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951079	Ear and labyrinth disorders	Hypoacusis	(b) (6) 1959		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15JUN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1976	31DEC1976	N
	C4591001 1095 10951080	Injury, poisoning and procedural complications	Donor site complication	31DEC2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC2013	N
			Menopausal symptoms	01JAN2013		Y
		Surgical and medical procedures	Gingival graft	31DEC2019	31DEC2019	N
	C4591001 1095 10951081	Cardiac disorders	Tachyarrhythmia	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Surgical and medical procedures	Prostatectomy	01JAN2009	31DEC2009	N
	C4591001 1095 10951082	Infections and infestations	Tonsillitis	01JAN1951	31DEC1951	N
		Investigations	Blood testosterone decreased	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1949		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
			Prostatomegaly	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Prostatic operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1951	31DEC1951	N
		Vascular disorders	Hypertension	01MAY2018		Y
	C4591001 1095 10951086	General disorders and administration site conditions	Pain	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1982	31DEC1982	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Salpingectomy	01JAN1982	31DEC1982	N
	C4591001 1095 10951088	Immune system disorders	Food allergy	01JAN1995		Y
			Seasonal allergy	01JAN1960		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1970	31DEC2019	N
		Surgical and medical procedures	Skin neoplasm excision	01DEC2019	31DEC2019	N
			Varicose vein operation	01JAN2018	31DEC2018	N
		Vascular disorders	Varicose vein	01JAN1968	31DEC2018	N
	C4591001 1095 10951097	Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1095 10951098	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1095 10951099	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1095 10951100	Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Bipolar disorder	01JAN2003		Y
			Depression	01JAN2003		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31JUL2007	N
		Surgical and medical procedures	Caesarean section	04DEC1979	04DEC1979	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Hip arthroplasty	01OCT2015	31OCT2015	N
				13MAY2015	13MAY2015	N
			Hysterectomy	01JUL2007	01JUL2007	N
	C4591001 1095 10951101	Cardiac disorders	Mitral valve prolapse	01JAN2005		Y
		Congenital, familial and genetic disorders	Congenital jaw malformation	(b) (6) 1954	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Hepatitis B	01JAN1981	31DEC1981	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2011	31DEC2013	N
			Tendon rupture	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN1985		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2009		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
			Jaw operation	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1095 10951102	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1994	31DEC1998	N
			Upper limb fracture	01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N
		Investigations	Blood testosterone decreased	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	23NOV2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N
			Knee operation	01JAN1994	31DEC1994	N
				01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951103	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1095 10951104	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1095 10951105	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Hypersensitivity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1095 10951107	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Endocrine disorders	Hyperthyroidism	01JAN2009	31DEC2009	N
			Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Infections and infestations	Cellulitis	01MAR2020		Y
			Encephalitis eastern equine	01JAN2010		Y
			Hepatitis A	01JAN1965	31DEC1965	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Muscle strain	31JUL2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Psychiatric disorders	Insomnia	15JUL2020		Y
			Post-traumatic stress disorder	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	23DEC2019	23DEC2019	N
			Cardiac pacemaker removal	24JUL2020	24JUL2020	N
			Coronary arterial stent insertion	01JAN1995		Y
			Thyroidectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951108	Eye disorders	Cataract	01JAN2002	31DEC2002	N
		Infections and infestations	Herpes zoster	01FEB2020	29FEB2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2001	31DEC2002	N
		Psychiatric disorders	Anxiety	01APR2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2002	31DEC2002	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1948	31DEC1948	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951109	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2017	31AUG2017	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1975	31DEC1975	N
			Prostate ablation	01AUG2007	31AUG2007	N
	C4591001 1095 10951111	Infections and infestations	Hepatitis A	01JAN1962	01MAY1962	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951113	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2005	31DEC2005	N
			Lower limb fracture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2007		Y
		Nervous system disorders	Headache	01JAN2007		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Urinary incontinence	01NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1958	31MAY2020	N
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
			Nasal septal operation	01MAY2020	31MAY2020	N
			Neck surgery	01JAN2005	31JAN2005	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1095 10951117	Cardiac disorders	Coronary artery disease	01JUL2015		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Cancer surgery	01MAR2020	31MAR2020	N
			Cataract operation	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2018	31DEC2018	N
			Sinuplasty	01JAN2018	31DEC2018	N
			Stent placement	01JUL2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1095 10951118	General disorders and administration site conditions	Pain	01JAN2010	31DEC2015	N
		Immune system disorders	Hypersensitivity	01JAN1995		Y
		Infections and infestations	Herpes virus infection	01OCT1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01FEB2020	29FEB2020	N
				01JUN2020	30JUN2020	N
			Eye operation	01MAR2020	31MAR2020	N
			Knee arthroplasty	04AUG2015	04AUG2015	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1095 10951123	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Hiatus hernia	17AUG2017	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Restless legs syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1095 10951125	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2016		Y
			Type 2 diabetes mellitus	01NOV2014		Y
		Psychiatric disorders	Depression	01JUN2016		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2005	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Surgical and medical procedures	Urinary bladder suspension	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1095 10951126	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1095 10951127	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
				01MAY2020	31DEC2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2016	31DEC2016	N
				01MAY2020	31DEC2020	N
	C4591001 1095 10951130	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Bipolar disorder	01JAN2007		Y
			Insomnia	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1095 10951131	Immune system disorders	Anaphylactic reaction	01JAN1990		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951133	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1095 10951134	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1095 10951135	Cardiac disorders	Myocardial infarction	01JAN1977	31DEC1977	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Intervertebral disc degeneration	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Nasal polypectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951136	Surgical and medical procedures	Cardiac operation	15MAY2015	15MAY2015	N
		Vascular disorders	Aortic aneurysm	01JAN2015	31DEC2015	N
			Hypertension	01JAN2014		Y
	C4591001 1095 10951139	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1095 10951140	Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Appendectomy	01JAN1993	31DEC1993	N
	C4591001 1095 10951145	Hepatobiliary disorders	Cholelithiasis	01JUL2020		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	30APR2000	N
		Investigations	Arthroscopy	01APR2000	30APR2000	N
	C4591001 1095 10951151	Gastrointestinal disorders	Dyspepsia	01JAN1984		Y
		General disorders and administration site conditions	Cyst	07AUG2015	07AUG2015	N
		Infections and infestations	Gastrointestinal bacterial overgrowth	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
		Nervous system disorders	Headache	01JAN1984		Y
		Reproductive system and breast disorders	Cervical dysplasia	01MAR1994	30JUN1994	N
		Surgical and medical procedures	Hysterectomy	01JUN1994	30JUN1994	N
			Spinal fusion surgery	07AUG2015	07AUG2015	N
	C4591001 1095 10951157	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
				01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN2016		Y
		Surgical and medical procedures	Gastric bypass	01DEC2015	31DEC2015	N
			Hip arthroplasty	01SEP2016	30SEP2016	N
	C4591001 1095 10951158	Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1989		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951162	Eye disorders	Macular oedema	01JAN2014		Y
		Infections and infestations	Herpes simplex	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2018	N
			Back pain	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
	C4591001 1095 10951164	Eye disorders	Cataract	01JAN2015	30APR2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01APR2020	30APR2020	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1095 10951165	Cardiac disorders	Coronary artery disease	01JAN2017		Y
			Myocardial infarction	01JAN2017	31DEC2017	N
		Eye disorders	Dry eye	01AUG2019		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
	C4591001 1095 10951167	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
	C4591001 1095 10951179	Cardiac disorders	Coronary artery disease	01MAY2019		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
			Nasal polyps	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2019	31MAY2019	N
			Nasal polypectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1095 10951180	Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 1953		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2001	N
				01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2001	31DEC2001	N
			Vasectomy	01JAN1986	31DEC1986	N
	C4591001 1095 10951181	Metabolism and nutrition disorders	Hypercholesterolaemia	20JUN2008		Y
			Type 2 diabetes mellitus	01JUL2020		Y
			Vitamin D deficiency	01SEP2017		Y
		Psychiatric disorders	Depression	01MAR1975		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2000		Y
		Surgical and medical procedures	Transgender operation	01MAR2015		Y
		Vascular disorders	Hypertension	01JUN2008		Y
	C4591001 1095 10951190	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1095 10951192	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1095 10951195	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Epilepsy	01JAN1964		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951204	Cardiac disorders	Angina pectoris	01SEP2010		Y
			Coronary artery disease	01SEP2010		Y
			Myocardial infarction	01SEP2010	30SEP2010	N
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2011		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2010		Y
			Inguinal hernia repair	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1095 10951205	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1095 10951206	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Intervertebral disc degeneration	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
			Renal cyst	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1988		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
			Spinal nerve stimulator implantation	01JAN2009		Y
			Transurethral prostatectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1095 10951209	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
				01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1095 10951210	Endocrine disorders	Hypothyroidism	01MAY2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	25JUL2020		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1095 10951211	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1977		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1095 10951212	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2019		Y
				01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal stenosis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1095 10951213	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN1995		Y
		Injury, poisoning and procedural complications	Ligament rupture	01MAY2020	05JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2010		Y
		Psychiatric disorders	Bipolar disorder	01NOV1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Intervertebral disc operation	01DEC2005	31DEC2007	N
			Parathyroidectomy	01JUN2010	31MAY2012	N
	C4591001 1095 10951219	Psychiatric disorders	Depression	01OCT2019		Y
		Renal and urinary disorders	Urinary retention	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1095 10951220	Endocrine disorders	Hyperthyroidism	01JAN1998	01JAN2000	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	20JUN2016	01SEP2017	N
			Umbilical hernia	01JAN2013	01JAN2018	N
		General disorders and administration site conditions	Cyst	01JAN1998	01JAN1999	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	01JAN2015	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
			Arthritis	01JAN2012	01JAN2016	N
			Articular calcification	01JAN2010	01JAN2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2012		Y
				01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Osteonecrosis	01JAN2013	01JAN2018	N
		Surgical and medical procedures	Sleep apnoea syndrome	01JAN2016		Y
			Hernia hiatus repair	01JAN2018	01JAN2018	N
			Hip arthroplasty	01JAN2018	01JAN2018	N
			Knee operation	01JAN2013	01JAN2013	N
				01JAN2016	01JAN2016	N
			Meniscus operation	01JAN2015	01JAN2015	N
			Spinal fusion surgery	01JAN1999	01JAN1999	N
			Thyroidectomy	01JAN2000	01JAN2000	N
	C4591001 1095 10951221	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN2007		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2018	31JAN2018	N
				01JAN2020	31JAN2020	N
			Spinal fusion surgery	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1095 10951224	Congenital, familial and genetic disorders	Factor V Leiden mutation	(b) (6) 1959		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUN2020		Y
		Nervous system disorders	Migraine	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951226	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2018	31DEC2018	N
		Reproductive system and breast disorders	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Menorrhagia	01JAN2010	31DEC2010	N
			Breast conserving surgery	01JUN2018	30JUN2018	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Myomectomy	01JAN2005	31DEC2005	N
	C4591001 1095 10951227	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2008	N
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
	C4591001 1095 10951228	Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01OCT2017		Y
			Lichen planus	01JAN2009		Y
		Vascular disorders	Hypertension	01FEB2014		Y
	C4591001 1095 10951229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2001		Y
			Depression	01JAN1986		Y
			Insomnia	01MAR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Thrombosis	01JAN2010	31DEC2010	N
	C4591001 1095 10951230	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951232	Endocrine disorders	Hyperparathyroidism	01JAN1990	31DEC2010	N
		Eye disorders	Cataract	01JAN2019		Y
		Investigations	Cardiac murmur	25SEP2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1981		Y
			Seasonal affective disorder	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1095 10951238	Endocrine disorders	Hypothyroidism	20MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1977		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1095 10951239	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1095 10951242	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
				01JUN2020	01JUN2020	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1095 10951247	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Anaphylactic reaction	01JAN1995		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1977		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2010	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1095 10951249	Cardiac disorders	Myocardial infarction	01NOV2018	01NOV2018	N
				28FEB2007	28FEB2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1987		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01FEB2007		Y
				01NOV2018		Y
		Vascular disorders	Hypertension	28FEB2007		Y
	C4591001 1095 10951252	Immune system disorders	Hypersensitivity	01JAN1951		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1095 10951256	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31OCT2018	N
		Surgical and medical procedures	Lymphadenectomy	01OCT2018	31OCT2018	N
			Prostatectomy	01JAN2015	31DEC2015	N
	C4591001 1095 10951258	Cardiac disorders	Bradycardia	01JAN2011	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary artery disease	01JAN2007		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Pancreatitis	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2011	31DEC2014	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Coronary arterial stent insertion	01JAN2007	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951261	Gastrointestinal disorders	Diverticulum	01JAN2002		Y
		Immune system disorders	Hypersensitivity	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Cough variant asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1095 10951263	Gastrointestinal disorders	Inguinal hernia	01JAN1962	31DEC1962	N
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Gastric banding	01JAN2017		Y
			Inguinal hernia repair	01JAN1962	31DEC1962	N
			Orchidectomy	01JAN2016	31DEC2016	N
			Radiotherapy	01JAN2016	31DEC2017	N
			Food allergy	01JAN2018		Y
	C4591001 1095 10951264	Immune system disorders				
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Renal and urinary disorders	Proteinuria	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1095 10951265	Gastrointestinal disorders	Gastrointestinal perforation	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Fibula fracture	01JAN1985	31DEC1985	N
		Social circumstances	Tobacco user	01JAN1975		Y
		Surgical and medical procedures	Fracture treatment	01JAN1985	31DEC1985	N
			Gastrointestinal surgery	01JAN1987	31DEC1987	N
	C4591001 1095 10951272	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1095 10951276	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1095 10951279	Gastrointestinal disorders	Impaired gastric emptying	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Dehydration	01APR2020		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
	C4591001 1095 10951300	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Hepatitis B	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Surgical and medical procedures	Meniscus operation	01JAN2019	31DEC2019	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1096 10961001	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Surgical and medical procedures	Caesarean section	12JAN1988	12JAN1988	N
				12JAN1996	12JAN1996	N
				27JUN1989	27JUN1989	N
	C4591001 1096 10961002	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1096 10961003	Gastrointestinal disorders	Umbilical hernia	01JAN2017	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01MAY2020		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1996		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1976	31DEC1976	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1096 10961004	Endocrine disorders	Hypogonadism	01JAN2006		Y
		Gastrointestinal disorders	Hiatus hernia	01AUG2000	31AUG2000	N
				01AUG2006	31AUG2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Spinal fracture	01OCT2000	31OCT2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2006		Y
			Spondylitis	01OCT2000	31OCT2000	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1995	31JAN1995	N
		Surgical and medical procedures	Debridement	01JUL2012	31JUL2012	N
			Hernia hiatus repair	01AUG2006	31AUG2006	N
			Intervertebral disc operation	01OCT2000	31OCT2000	N
			Pleural operation	01JAN1995	31JAN1995	N
			Rotator cuff repair	01JUL2010	31JUL2010	N
			Spinal fusion surgery	01OCT2000	31OCT2000	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1096 10961005	Endocrine disorders	Hyperthyroidism	01JAN1957	31DEC1957	N
			Hypothyroidism	01JAN1957		Y
		Eye disorders	Macular degeneration	01JAN2016		Y
		Gastrointestinal disorders	Gingival recession	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2015		Y
			Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN2009	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Uterine scar	01JAN1963	31DEC1966	N
			Vaginal disorder	01JAN1966	31DEC1966	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Breast conserving surgery	01DEC2009	31DEC2009	N
			Hysterectomy	01JAN1966	31DEC1966	N
			Thyroidectomy	01JAN1957	31DEC1957	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1096 10961006	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2015		Y
				01JAN2019		Y
			Seasonal allergy	01JAN1957		Y
		Infections and infestations	Clostridium difficile infection	01FEB2014	31DEC2020	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2014	31DEC2014	N
		Investigations	Colonoscopy	01MAY2020	31MAY2020	N
		Nervous system disorders	Generalised tonic-clonic seizure	01JAN1985	31DEC1985	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2014	31DEC2014	N
			Salpingectomy	01JAN1981	31DEC1981	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1096 10961008	Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961014	Gastrointestinal disorders	Abdominal hernia	01JAN2000	31DEC2000	N
			Large intestine polyp	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Nervous system disorders	Post herpetic neuralgia	01JAN2016		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2005	31DEC2005	N
	C4591001 1096 10961015	Surgical and medical procedures	Vasectomy	01MAY1990	31DEC1990	N
	C4591001 1096 10961016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
			Limb injury	01JAN2002	31DEC2002	N
			Limb injury	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Ligament operation	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
			Toe operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961017	Gastrointestinal disorders	Gastrointestinal perforation	01JAN2003	31DEC2003	N
		General disorders and administration site conditions	Hernia	01JAN2008	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1975		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Fracture	01JAN2009	31DEC2009	N
			Meniscus injury	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Morton's neuralgia	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Hernia repair	01JAN2009	31DEC2009	N
			Knee operation	01JAN2015	31DEC2015	N
			Vascular operation	01JAN2003	31DEC2003	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1096 10961019	Hepatobiliary disorders	Gallbladder disorder	01JAN2000	31JAN2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31JAN2000	N
	C4591001 1096 10961020	Reproductive system and breast disorders	Colpocele	01JAN2008	31DEC2010	N
			Uterine prolapse	01JAN2000	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01DEC2010	31DEC2010	N
	C4591001 1096 10961021	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01NOV1999	30NOV1999	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN1995		Y
			Obesity	01JAN1992	31DEC2018	N
			Vitamin B12 deficiency	01JAN2015		Y
		Renal and urinary disorders	Bladder prolapse	01AUG2017		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Gastrectomy	01AUG2017	31AUG2017	N
			Hip arthroplasty	01NOV2017	30NOV2017	N
			Hysterectomy	01AUG1986	31AUG1986	N
			Spinal fusion surgery	01NOV1999	30NOV1999	N
	C4591001 1096 10961024	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01DEC2008		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01AUG1988	31AUG1988	N
	C4591001 1096 10961025	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN1986		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	14JAN2020	14JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				27AUG2019	27AUG2019	N
			Vasectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1096 10961028	Blood and lymphatic system disorders	Anaemia	01SEP2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
		Surgical and medical procedures	Transfusion	01SEP2019	30SEP2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1096 10961033	Psychiatric disorders	Bipolar disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2005		Y
	C4591001 1096 10961034	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1096 10961037	Immune system disorders	Drug hypersensitivity	01JAN1996		Y
				01JAN2019		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01NOV2019		Y
			Osteoarthritis	01NOV2019		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961039	Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	16NOV1990	16NOV1990	N
				19AUG1992	19AUG1992	N
				28NOV1988	28NOV1988	N
			Mammoplasty	01JAN2006	31DEC2006	N
	C4591001 1096 10961040	Nervous system disorders	Nerve compression	01JAN2014	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Spinal decompression	01JAN2015	31DEC2015	N
	C4591001 1096 10961041	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Prostatectomy	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961043	Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1096 10961044	Cardiac disorders	Cardiac failure congestive	04JUL2017		Y
			Coronary artery disease	04JUL2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2017		Y
			Drug abuse	01JAN2017	31DEC2017	N
			Insomnia	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1096 10961045	Endocrine disorders	Hyperthyroidism	01JAN1961	31DEC1963	N
			Hypothyroidism	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoarthritis	01JAN2015		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1981	31DEC1981	N
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1958		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1963	31DEC1963	N
	C4591001 1096 10961046	Gastrointestinal disorders	Abdominal discomfort	04AUG2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1970	31DEC1984	N
		Social circumstances	Postmenopause	01JAN1984		Y
		Surgical and medical procedures	Caesarean section	02FEB1983	02FEB1983	N
				27MAR1980	27MAR1980	N
			Hysterectomy	01JAN1984	31DEC1984	N
	C4591001 1096 10961048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1974	31DEC2017	N
			Irritable bowel syndrome	01JAN1974		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Oesophagogastric fundoplasty	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1985	31DEC1985	N
	C4591001 1096 10961050	Gastrointestinal disorders	Gastrointestinal disorder	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1940		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
	C4591001 1096 10961051	Congenital, familial and genetic disorders	Pyloric stenosis	01JAN1963	31DEC1963	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990		Y
	C4591001 1096 10961054	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Mastectomy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961055	Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Nervous system disorders	Tremor	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1958		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1096 10961056	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1096 10961058	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma benign	01NOV1998	01FEB1999	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Meningioma surgery	01FEB1999	01FEB1999	N
		Vascular disorders	Hot flush	01JAN2011		Y
			Hypertension	01JAN2015		Y
	C4591001 1096 10961065	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Hypertriglyceridaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	16AUG2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961066	Infections and infestations	Pilonidal cyst	01JUN1980	30JUN1980	N
		Injury, poisoning and procedural complications	Humerus fracture	01OCT2014	31OCT2014	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	17JUL2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Open reduction of fracture	01OCT2014	31OCT2014	N
			Pilonidal sinus repair	01JAN1980	31DEC1980	N
	C4591001 1096 10961068	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1096 10961069	Ear and labyrinth disorders	Deafness	01JAN1987		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Trigger finger	01MAY2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1096 10961070	Ear and labyrinth disorders	Meniere's disease	01JAN1965	31DEC1968	N
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000		Y
			Iodine allergy	01JAN2000		Y
			Seasonal allergy	01JAN1964		Y
		Injury, poisoning and procedural complications	Animal bite	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2000	31JUL2001	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Limb operation	01JAN2014	31DEC2014	N
			Mastectomy	01JUL2001	31JUL2001	N
	C4591001 1096 10961071	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1096 10961073	Ear and labyrinth disorders	Vertigo	01JAN1976		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1948		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1096 10961079	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1096 10961080	Psychiatric disorders	Depression	01JAN1988		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1096 10961086	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Staphylococcal infection	01JAN2017	31JAN2017	N
		Injury, poisoning and procedural complications	Facial bones fracture	01DEC1998	31DEC1998	N
			Scar	01DEC1998		Y
				01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Bipolar disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1096 10961091	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01DEC2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1096 10961092	Cardiac disorders	Mitral valve prolapse	01JAN1981		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Uterine prolapse	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1096 10961095	Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN1970	31DEC1970	N
	C4591001 1096 10961104	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01NOV2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Nervous system disorders	Headache	21AUG2020		Y
	C4591001 1096 10961118	Congenital, familial and genetic disorders	Type V hyperlipidaemia	09MAR2017		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2007		Y
			Prostate cancer	01MAY2017	26OCT2017	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	20APR2017		Y
		Surgical and medical procedures	Prostatectomy	26OCT2017	26OCT2017	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Essential hypertension	18OCT2017		Y
	C4591001 1096 10961119	Immune system disorders	Seasonal allergy	01JAN1963		Y
		Infections and infestations	Bronchitis	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2000	31DEC2010	N
				01JAN2012		Y
			Vitamin D deficiency	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Gastrectomy	01JAN2010	31DEC2010	N
			Uterine leiomyoma embolisation	01JAN2007	31DEC2007	N
	C4591001 1096 10961120	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1996	31DEC1996	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961121	Cardiac disorders	Sinus bradycardia	01JAN2000		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Obesity	01JAN2001		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961123	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Orchidopexy	01JAN1979	31DEC1979	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1096 10961126	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2011	N
			Lung neoplasm malignant	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Mastectomy	01JAN2011	31DEC2011	N
	C4591001 1096 10961127	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1096 10961128	Endocrine disorders	Hyperthyroidism	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1096 10961129	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Tendon injury	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2019	N
				01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JUN2019	30JUN2019	N
			Tendon operation	01JAN2017	31DEC2017	N
	C4591001 1096 10961131	Eye disorders	Cataract	01JAN2019	14AUG2020	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	10JUL2020	10JUL2020	N
				14AUG2020	31AUG2020	N
	C4591001 1096 10961132	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1096 10961133	Congenital, familial and genetic disorders	Congenital benign neoplasm	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	21JUL2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1975	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1096 10961134	Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JUL1983	31JUL1983	N
	C4591001 1096 10961135	Eye disorders	Cataract	01JAN2018	31DEC2019	N
			Macular degeneration	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Joint injury	01OCT2019	31OCT2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JUN2019	30JUN2019	N
			Knee operation	01OCT2019	31OCT2019	N
			Vasectomy	01JAN1978	31DEC1978	N
	C4591001 1096 10961143	Congenital, familial and genetic disorders	Dermoid cyst	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Epidermoid cyst excision	01JAN2000	31DEC2000	N
	C4591001 1096 10961144	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
			Urinary incontinence	01JAN2003	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Urinary bladder suspension	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1096 10961146	Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Rotator cuff repair	01JAN2007	31DEC2007	N
			Vasectomy	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961149	Eye disorders	Macular degeneration	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1096 10961155	Injury, poisoning and procedural complications	Ligament rupture	01JAN2003	31DEC2003	N
		Investigations	Cardiac murmur	01JAN2003		Y
			Electrocardiogram T wave inversion	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
		Surgical and medical procedures	Ligament operation	01JAN2003	31DEC2003	N
	C4591001 1096 10961156	Eye disorders	Cataract	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	12JUL2017	12JUL2017	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
			Retinal operation	01JAN2011	31DEC2011	N
			Shoulder arthroplasty	12JUL2017	12JUL2017	N
	C4591001 1096 10961157	Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN1988		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
			Metabolic surgery	01NOV2016	30NOV2016	N
			Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1096 10961160	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Vitamin D deficiency	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1096 10961161	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2002		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001		Y
		Nervous system disorders	Neuralgia	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	19AUG2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	16JUN1996	16JUN1996	N
			Myomectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1096 10961162	Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Eye disorders	Cataract	01JAN2003	31DEC2004	N
			Macular scar	01JAN2013	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
			Osteoporosis	01JAN2014		Y
		Social circumstances	Hearing aid user	01JAN2012		Y
			Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JAN2004	31DEC2004	N
			Vitrectomy	01JAN2014	31DEC2014	N
	C4591001 1096 10961163	Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961164	Gastrointestinal disorders	Hiatus hernia	01JAN2007	31DEC2007	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1096 10961165	Gastrointestinal disorders	Hiatus hernia	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	29FEB2008	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2008		Y
		Surgical and medical procedures	Prostatic operation	01FEB2008	29FEB2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1096 10961166	Cardiac disorders	Tachycardia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN2006	31DEC2006	N
		Injury, poisoning and procedural complications	Back injury	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Colectomy	01JAN2006	31DEC2006	N
			Hip surgery	01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
	C4591001 1096 10961167	Infections and infestations	Pilonidal cyst	01JAN1973	31DEC1973	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1973	31DEC1973	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1096 10961171	Immune system disorders	Rubber sensitivity	01JAN1954		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1096 10961174	Cardiac disorders	Supraventricular tachycardia	01JAN1995		Y
		Endocrine disorders	Diabetes insipidus	01JAN1994		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Skeletal injury	01DEC2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Female sterilisation	17JUN1994	17JUN1994	N
			Limb operation	01DEC2019		Y
	C4591001 1096 10961181	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Infections and infestations	Diverticulitis	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018	31DEC2019	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
			Prostatectomy	01JAN2019	31DEC2019	N
	C4591001 1096 10961182	Gastrointestinal disorders	Constipation	01JAN2018		Y
			Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine neoplasm	01JAN1996	31DEC1996	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1979	31DEC1992	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961183	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Haemorrhoids	01JAN2005		Y
			Irritable bowel syndrome	01JAN1996		Y
		Immune system disorders	Allergy to plants	01JAN1982		Y
			Drug hypersensitivity	01JAN1967		Y
				01JAN2002		Y
			Mycotic allergy	01JAN1982		Y
			Seasonal allergy	01JAN1982		Y
		Infections and infestations	Cystitis	01JAN1996	31DEC2005	N
			Kidney infection	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961184	Eye disorders	Cataract	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
			Prostatomegaly	01JAN2010		Y
	C4591001 1096 10961188	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
			Irritable bowel syndrome	01JAN1999		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1983		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1096 10961189	Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Knee operation	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1096 10961190	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
			Myocardial infarction	01JAN2009	31DEC2009	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Glaucoma	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Social circumstances	Hearing aid user	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961191	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Urinary tract infection	01AUG2020		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2012		Y
			Nasal injury	01JAN1976	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
			Shoulder operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1096 10961192	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	27OCT1999	27OCT1999	N
	C4591001 1096 10961193	Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2012		Y
			Hyperuricaemia	01JAN2012		Y
			Obesity	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31JAN2017	N
		Surgical and medical procedures	Polypectomy	01JAN2018	31DEC2018	N
			Prostatectomy	01JAN2017	31DEC2017	N
	C4591001 1096 10961194	Injury, poisoning and procedural complications	Limb injury	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Limb operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1096 10961198	Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961201	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
			Diverticulitis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
	C4591001 1096 10961202	Injury, poisoning and procedural complications	Ligament rupture	01JAN2003		Y
			Limb injury	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1096 10961204	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1981		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1096 10961221	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Infections and infestations	Skin infection	10AUG2020		Y
		Injury, poisoning and procedural complications	Nerve injury	13JUN2020	13JUN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2007	31DEC2007	N
			Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Spinal operation	01JAN2003	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1096 10961224	Infections and infestations	Paronychia	01APR2020		Y
		Injury, poisoning and procedural complications	Arthropod bite	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2010		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Reproductive system and breast disorders	Breast mass	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Abscess drainage	01JAN2018	31DEC2018	N
			Breast conserving surgery	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961232	Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1096 10961233	Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1096 10961234	Endocrine disorders	Hypothyroidism	01JAN2000		Y
			Thyroiditis	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
			Large intestine polyp	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
			Hepatitis A	01JAN1955	31DEC1955	N
			Pneumonia	01JAN2019	31DEC2019	N
			Poliomyelitis	01JAN1955	31DEC1955	N
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sweat gland tumour	01JAN2018	31DEC2018	N
		Nervous system disorders	Migraine	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN1996	31DEC1996	N
			Benign tumour excision	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Radioactive iodine therapy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961235	Blood and lymphatic system disorders	Anaemia	01JUL2020	31JUL2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteoarthritis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Knee arthroplasty	08JUL2020	08JUL2020	N
	C4591001 1096 10961237	Eye disorders	Cataract	01MAY2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Prostatomegaly	01FEB2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Spinal fusion surgery	01JUN2020	30JUN2020	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1096 10961241	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1096 10961247	Gastrointestinal disorders	Colitis	01JAN2008	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	04SEP2011	31DEC2013	N
		Nervous system disorders	Migraine	01JAN1986		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1096 10961248	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN2002		Y
		Infections and infestations	Pelvic inflammatory disease	01JAN2014	31DEC2014	N
			Tonsillitis	01JAN1973	31DEC1973	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1973	31DEC1973	N
			Transfusion	01JAN1973	31DEC1973	N
	C4591001 1096 10961250	Infections and infestations	Pneumonia	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1096 10961252	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2000	31DEC2000	N
			Upper limb fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1096 10961253	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959	31DEC1959	N
		Surgical and medical procedures	Spinal operation	01NOV2019	30NOV2019	N
	C4591001 1096 10961259	Cardiac disorders	Myocardial infarction	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Surgical and medical procedures	Cataract operation	01JAN2001	31DEC2001	N
			Hip arthroplasty	01JAN2007	31DEC2007	N
			Vasectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1096 10961260	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1096 10961269	Cardiac disorders	Angina pectoris	14FEB2020		Y
			Atrial fibrillation	01JAN2010		Y
			Coronary artery disease	01JAN2010		Y
			Myocardial infarction	14FEB2020	14FEB2020	N
		Eye disorders	Cataract	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Large intestinal obstruction	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01MAR2019		Y
			Vitamin B12 deficiency	01FEB2020		Y
		Nervous system disorders	Diabetic neuropathy	01MAR2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961270	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Nerve compression	01JAN1998		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1991	31DEC2007	N
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1096 10961272	Cardiac disorders	Atrial fibrillation	01DEC2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1096 10961273	Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1096 10961274	Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN1979		Y
			Benign neoplasm of thyroid gland	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N
			Gastrectomy	01JAN2018	31DEC2018	N
			Hysterectomy	31OCT2016	31OCT2016	N
			Ligament operation	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN1982	31DEC1982	N
			Thyroidectomy	01JAN2004	31DEC2004	N
	C4591001 1096 10961281	Injury, poisoning and procedural complications	Meniscus injury	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Meniscus operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1096 10961282	Cardiac disorders	Arrhythmia	01JAN2000		Y
		Nervous system disorders	Parkinson's disease	01JAN2017		Y
			Sciatica	01JAN2016		Y
		Reproductive system and breast disorders	Fallopian tube cyst	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1096 10961285	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2007	31MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961290	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament sprain	02SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1096 10961292	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Insomnia	01JAN1996		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
	C4591001 1096 10961294	Musculoskeletal and connective tissue disorders	Arthralgia	01DEC2019	01SEP2020	N
		Surgical and medical procedures	Ligament operation	01DEC2019	31DEC2019	N
			Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1096 10961295	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1096 10961297	Cardiac disorders	Aortic valve incompetence	01JUN2019	31DEC2019	N
			Arrhythmia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Hypertriglyceridaemia	01JAN1990		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2019	31DEC2019	N
	C4591001 1096 10961298	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1096 10961300	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1096 10961302	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1096 10961304	Endocrine disorders	Hypothyroidism	01JAN1968		Y
		Infections and infestations	Toxic shock syndrome	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1096 10961308	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Skin neoplasm excision	14AUG2020	14AUG2020	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1096 10961311	Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1999	31DEC1999	N
				01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1999	31DEC1999	N
			Cataract operation	01JAN2015	31DEC2015	N
			Hypertension	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961312	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Prostatectomy	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1096 10961314	Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Injury, poisoning and procedural complications	Back injury	01AUG2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01FEB2000	31DEC2019	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Manipulation	01AUG2019	31AUG2019	N
			Shoulder operation	01FEB2019	28FEB2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1096 10961315	Vascular disorders	Hypertension	01JAN2017		Y	
		Endocrine disorders	Hypothyroidism	01JAN2010		Y	
		Eye disorders	Cataract	01JAN2014	31DEC2014	N	
			Glaucoma	01JAN2010		Y	
		Immune system disorders	Seasonal allergy	01JAN2019		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y	
		Surgical and medical procedures	Cataract operation	01FEB2020	29FEB2020	N	
				01JAN2014	31DEC2014	N	
		C4591001 1096 10961316	Vascular disorders	Hypertension	01JAN2010		Y
			Metabolism and nutrition disorders	Obesity	01JUL2020		Y
	C4591001 1096 10961324	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N	
		Social circumstances	Postmenopause	01JAN2000		Y	
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N	
		Eye disorders	Iritis	01JAN1993		Y	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y	
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N	
			Joint dislocation	01JAN2000	31DEC2000	N	
		Musculoskeletal and connective tissue disorders	Ligament rupture	01JAN2000		Y	
	Arthralgia		01JAN2000		Y		
	C4591001 1096 10961325	Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y	
		Infections and infestations	Tooth abscess	01JAN2015	16OCT2020	N	



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1996	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2013	N
		Surgical and medical procedures	Prostatectomy	01JAN2013	31DEC2013	N
	C4591001 1096 10961326	Metabolism and nutrition disorders	Obesity	01JAN1996	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012	31DEC2014	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1971		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JUN2017	04SEP2020	N
	C4591001 1096 10961327	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1096 10961329	Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
			Limb operation	01JAN2012	31DEC2012	N
	C4591001 1096 10961332	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1958		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961333	Cardiac disorders	Sinus bradycardia	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1980		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1990	31DEC1990	N
	C4591001 1096 10961334	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
	C4591001 1096 10961337	Cardiac disorders	Myocardial infarction	01JAN2013	01JAN2013	N
		Injury, poisoning and procedural complications	Back injury	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Muscle spasms	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961338	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis	29APR2020		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1096 10961339	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2002		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1096 10961346	Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Nervous system disorders	Sinus headache	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Caesarean section	28JUN1983	28JUN1983	N
	C4591001 1096 10961347	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Obesity	01JAN1986		Y
			Vitamin D deficiency	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1999		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	03APR1986	03APR1986	N
				14APR1979	14APR1979	N
			Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1096 10961349	Eye disorders	Blindness	01JAN2015		Y
			Diabetic retinopathy	01JAN2014		Y
			Glaucoma	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Localised infection	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Surgical and medical procedures	Toe amputation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961352	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Myocardial infarction	01JAN1990	31DEC1990	N
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2013	31DEC2013	N
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Brain tumour operation	01JAN2013	31DEC2013	N
			Cardiac pacemaker insertion	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary artery bypass	01JAN2001	31DEC2001	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1096 10961353	Endocrine disorders	Goitre	01JAN1995	31DEC1995	N
			Hypothyroidism	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1978		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
			Thyroidectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1096 10961355	Injury, poisoning and procedural complications	Back injury	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	30MAY1980	30MAY1980	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Mammoplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961356	Endocrine disorders	Hypothyroidism	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Periodontal disease	01JAN2015		Y
		General disorders and administration site conditions	Polyp	01JAN1966	31DEC1966	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01FEB2020		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1966	31DEC1966	N
	C4591001 1096 10961361	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961363	Endocrine disorders	Thyroid mass	01JAN1985		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1990	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Thyroidectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1096 10961364	Immune system disorders	Seasonal allergy	01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1991	31DEC1991	N
			Meniscus injury	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Ligament operation	01JAN1991	31DEC1991	N
			Meniscus operation	01JAN2001	31DEC2001	N
	C4591001 1096 10961365	Injury, poisoning and procedural complications	Limb injury	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
	C4591001 1096 10961368	Congenital, familial and genetic disorders	Blindness congenital	(b) (6) 1964		Y
			Retinal anomaly congenital	(b) (6) 1964		Y
		Injury, poisoning and procedural complications	Exposure to communicable disease	01JAN2000	31DEC2000	N
	C4591001 1096 10961369	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN1957		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1096 10961371	Eye disorders	Cataract	06MAY2020	03AUG2020	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JUL2020	01JUL2020	N
				03AUG2020	03AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1096 10961377	Eye disorders	Glaucoma	01APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1096 10961381	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAY2020		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1974	31DEC1974	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN1974	31DEC1974	N
	C4591001 1096 10961383	Gastrointestinal disorders	Inguinal hernia	01JUL2017	31JUL2017	N
		Surgical and medical procedures	Hernia repair	01JUL2017	31JUL2017	N
			Umbilical hernia repair	01JUL2017	31JUL2017	N
	C4591001 1096 10961384	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1097 10971001	Blood and lymphatic system disorders	Leukocytosis	02JUL2020	05JUL2020	N
		Ear and labyrinth disorders	Ear pruritus	09SEP2019		Y
		Eye disorders	Dry eye	22OCT2019		Y
		Gastrointestinal disorders	Small intestinal obstruction	02JUL2020	05JUL2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Haematuria	02JUL2020	05JUL2020	N
			Renal mass	02JUL2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	27SEP2019		Y
	C4591001 1097 10971002	Cardiac disorders	Left ventricular failure	19MAY2020		Y
	C4591001 1097 10971004	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN2017		Y
	C4591001 1097 10971005	Cardiac disorders	Arteriosclerosis coronary artery	13JUL2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12APR2018		Y
		Nervous system disorders	Neuropathy peripheral	12APR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13JUL2018		Y
		Vascular disorders	Essential hypertension	12APR2018		Y
	C4591001 1097 10971006	Gastrointestinal disorders	Gastrooesophageal reflux disease	13MAR2018		Y
		General disorders and administration site conditions	Pain	13MAR2020		Y
		Investigations	Weight increased	19MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	13MAR2020		Y
			Vitamin D deficiency	23DEC2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	13MAR2018		Y
		Nervous system disorders	Neuropathy peripheral	13MAR2020		Y
		Psychiatric disorders	Anxiety	13MAR2018		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	13MAR2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13MAR2018		Y
		Vascular disorders	Essential hypertension	13MAR2020		Y
	C4591001 1097 10971008	Musculoskeletal and connective tissue disorders	Back pain	20JUL2020		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	20JUL2020		Y
	C4591001 1097 10971009	Cardiac disorders	Cardiac failure congestive	07NOV2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	19APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19APR2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	02AUG2018		Y
		Nervous system disorders	Neuropathy peripheral	19APR2018		Y
		Renal and urinary disorders	Chronic kidney disease	04NOV2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	19APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	19APR2018		Y
	C4591001 1097 10971010	Cardiac disorders	Arteriosclerosis coronary artery	12JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	12JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	12JUN2018		Y
		Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	04JAN2019		Y
		Nervous system disorders	Peroneal nerve palsy	12JUN2018		Y
		Psychiatric disorders	Depression	12JUN2018		Y
		Surgical and medical procedures	Coronary artery bypass	12JUN2018	12JUN2018	N
			Joint arthroplasty	30JUL2020	30JUL2020	N
		Vascular disorders	Essential hypertension	12JUN2020		Y
	C4591001 1097 10971011	Cardiac disorders	Atrial fibrillation	09APR2018		Y
		Metabolism and nutrition disorders	Gout	09APR2018		Y
			Hyperlipidaemia	09APR2018		Y
			Type 2 diabetes mellitus	09APR2018		Y
		Nervous system disorders	Transient ischaemic attack	09JUL2019	31DEC2019	N
		Psychiatric disorders	Depression	20NOV2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	09APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	20NOV2019		Y
		Vascular disorders	Hypertension	09APR2018		Y
	C4591001 1097 10971012	Gastrointestinal disorders	Colitis microscopic	01MAY2019	31MAY2019	N
		Surgical and medical procedures	Cheilectomy	01JAN1999	31DEC1999	N
			Eye muscle operation	01JAN1952	31DEC1952	N
				01JAN1973	31DEC1973	N
			Female sterilisation	01JAN1985	31DEC1985	N
	C4591001 1097 10971013	Ear and labyrinth disorders	Vertigo	07FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08MAY2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	31DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1097 10971014	Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Varicose vein operation	01JAN1998	31DEC1998	N
	C4591001 1097 10971015	Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1097 10971016	Cardiac disorders	Supraventricular tachycardia	26MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18OCT2018		Y
			Hypoglycaemia	26MAR2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	19AUG2020		Y
			Scoliosis	26MAR2018		Y
		Psychiatric disorders	Anxiety	26MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Dysphonia	26MAR2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis	27JUN2019		Y
	C4591001 1097 10971017	Metabolism and nutrition disorders	Gout	15APR2019		Y
			Hyperlipidaemia	03APR2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT2018		Y
			Osteoarthritis	29JUN2020		Y
		Nervous system disorders	Lumbar radiculopathy	04FEB2019		Y
			Neuropathy peripheral	01OCT2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	03APR2000		Y
		Surgical and medical procedures	Heart valve replacement	03APR2018	03APR2018	N
		Vascular disorders	Essential hypertension	03APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1097 10971019	Gastrointestinal disorders	Gastroesophageal reflux disease	25MAY2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	25MAY2018		Y
			Vitamin D deficiency	25MAY2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	25MAY2020		Y
		Psychiatric disorders	Depression	25MAY2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	25MAY2018		Y
		Vascular disorders	Essential hypertension	25MAY2020		Y
	C4591001 1097 10971020	Metabolism and nutrition disorders	Hypercholesterolaemia	27FEB2019		Y
			Hyperlipidaemia	23AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Vasomotor rhinitis	09MAR2020		Y
		Vascular disorders	Essential hypertension	09MAR2020		Y
	C4591001 1097 10971021	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Intestinal resection	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
			Thyroidectomy	01JAN1990	31DEC1990	N
	C4591001 1097 10971023	Gastrointestinal disorders	Gastroesophageal reflux disease	03JUN2018		Y
		Investigations	Blood glucose abnormal	13JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	04JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Essential hypertension	03JUN2018		Y
	C4591001 1097 10971024	Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1097 10971025	Cardiac disorders	Arteriosclerosis coronary artery	12JUN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12JUN2018		Y
			Type 2 diabetes mellitus	12JUN2018		Y
	C4591001 1097 10971026	Vascular disorders	Essential hypertension	12JUN2018		Y
		Cardiac disorders	Atrial fibrillation	10APR2018		Y
			Cardiac failure congestive	21AUG2018		Y
			Left ventricular failure	13APR2020		Y
		Endocrine disorders	Hypogonadism	09DEC2019		Y
			Hypothyroidism	15MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	10APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16MAY2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15MAY2020		Y
		Nervous system disorders	Normal pressure hydrocephalus	16MAY2018		Y
			Peroneal nerve palsy	16MAY2018		Y
		Psychiatric disorders	Depression	15MAY2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	16MAY2018		Y
	C4591001 1097 10971027	Vascular disorders	Essential hypertension	27JUN2018		Y
		Endocrine disorders	Hypothyroidism	19APR2018		Y
		Immune system disorders	Seasonal allergy	21MAY2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	21MAY2018		Y
			Intervertebral disc degeneration	19APR2018		Y
			Osteoarthritis	19APR2018		Y
			Rheumatoid arthritis	19APR2018		Y
		Nervous system disorders	Neuropathy peripheral	21MAY2018		Y
		Psychiatric disorders	Insomnia	19APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21MAY2018		Y
		Vascular disorders	Hypertension	18APR2018		Y
	C4591001 1097 10971028	Gastrointestinal disorders	Colitis	27MAR2020		Y
			Gastroesophageal reflux disease	31MAY2019		Y
			Irritable bowel syndrome	22MAR2018		Y
		Metabolism and nutrition disorders	Electrolyte imbalance	30APR2019	31MAY2019	N
			Hyperlipidaemia	22MAR2018		Y
			Type 2 diabetes mellitus	22MAR2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	22MAR2018		Y
			Intervertebral disc degeneration	22MAR2018		Y
			Osteoarthritis	22MAR2018		Y
			Tendonitis	03JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	27MAR2020		Y
		Nervous system disorders	Parkinson's disease	27MAR2020		Y
			Seizure	26DEC2019		Y
		Psychiatric disorders	Anxiety	22MAR2018		Y
			Depression	22MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	22MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	22MAR2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	22MAR2018		Y
	C4591001 1097 10971029	Blood and lymphatic system disorders	Anaemia	22MAR2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	22MAR2018		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	22MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22MAR2018		Y
			Obesity	22MAR2018		Y
			Type 2 diabetes mellitus	22MAR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	22MAR2018	31DEC2018	N
		Psychiatric disorders	Bipolar disorder	22MAR2018		Y
			Generalised anxiety disorder	22MAR2018		Y
			Insomnia	22MAR2018		Y
			Major depression	22MAR2018		Y
			Panic disorder	30APR2019		Y
			Post-traumatic stress disorder	22MAR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	22MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	22MAR2018		Y
			Chronic obstructive pulmonary disease	07MAR2018		Y
			Sleep apnoea syndrome	22MAR2018		Y
		Social circumstances	Dependence on oxygen therapy	22MAR2018		Y
	C4591001 1097 10971030	Gastrointestinal disorders	Gastroesophageal reflux disease	28MAR2018		Y
		Injury, poisoning and procedural complications	Femur fracture	28SEP2018	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	28MAR2018		Y
			Osteoporosis	28MAR2018		Y
		Nervous system disorders	Restless legs syndrome	28MAR2018		Y
		Psychiatric disorders	Anxiety	28MAR2018		Y
			Insomnia	11MAR2020		Y
		Vascular disorders	Deep vein thrombosis	18DEC2018	18DEC2018	N
	C4591001 1097 10971031	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08MAY2018		Y
			Type 2 diabetes mellitus	08MAY2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	22OCT2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Essential hypertension	08MAY2018		Y
	C4591001 1097 10971032	Endocrine disorders	Hypothyroidism	05APR2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05JUL2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05APR2018		Y
			Type 2 diabetes mellitus	05APR2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	05JUL2018		Y
			Osteoarthritis	05JUL2018		Y
		Nervous system disorders	Neuropathy peripheral	05JUL2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Gastrectomy	01MAR2018		Y
		Vascular disorders	Essential hypertension	05APR2018		Y
	C4591001 1097 10971033	Gastrointestinal disorders	Gastroesophageal reflux disease	09MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	09MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Major depression	09MAR2018		Y
		Renal and urinary disorders	Glomerulonephritis membranous	30APR2019		Y
		Vascular disorders	Essential hypertension	09MAR2018		Y
	C4591001 1097 10971034	Cardiac disorders	Left ventricular failure	05MAY2020		Y
		Congenital, familial and genetic disorders	Congenital cystic kidney disease	07NOV2019		Y
		Endocrine disorders	Hypothyroidism	17MAY2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	12SEP2019		Y
		Nervous system disorders	Neuropathy peripheral	17MAY2018		Y
		Renal and urinary disorders	Chronic kidney disease	05MAY2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	17MAY2018		Y
		Vascular disorders	Essential hypertension	17MAY2018		Y
	C4591001 1097 10971035	Metabolism and nutrition disorders	Hyperlipidaemia	09JUL2018		Y
		Vascular disorders	Hypertension	22OCT2018		Y
	C4591001 1097 10971036	Metabolism and nutrition disorders	Hyperlipidaemia	24MAY2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	24MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Neuropathy peripheral	24AUG2018		Y
		Vascular disorders	Essential hypertension	24MAY2018		Y
	C4591001 1097 10971037	Blood and lymphatic system disorders	Iron deficiency anaemia	17JAN2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	17JAN2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Injury, poisoning and procedural complications	Suture related complication	16JUL2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	21MAR2018		Y
		Nervous system disorders	Neuropathy peripheral	04APR2018		Y
		Psychiatric disorders	Anxiety	04APR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	26JUN2018		Y
		Vascular disorders	Essential hypertension	26JUL2018		Y
	C4591001 1097 10971038	Cardiac disorders	Arteriosclerosis coronary artery	29APR2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	19MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19MAR2018		Y
			Type 2 diabetes mellitus	16APR2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	27SEP2018		Y
			Osteoarthritis	27SEP2018		Y
		Nervous system disorders	Neuropathy peripheral	19MAR2018		Y
		Psychiatric disorders	Anxiety	19MAR2018		Y
			Depression	19MAR2018		Y
			Insomnia	19MAR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	24JUL2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	29APR2018		Y
		Vascular disorders	Essential hypertension	19MAR2018		Y
	C4591001 1097 10971039	Musculoskeletal and connective tissue disorders	Neck pain	07JAN2020		Y
			Osteoarthritis	07JAN2020		Y
		Nervous system disorders	Complex regional pain syndrome	07JAN2020		Y
		Psychiatric disorders	Anxiety disorder	07JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1097 10971042	Cardiac disorders	Atrial fibrillation	25JUN2020		Y
		Eye disorders	Cataract	09OCT2018		Y
		General disorders and administration site conditions	Pain	23DEC2019		Y
		Musculoskeletal and connective tissue disorders	Neck pain	14NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	09OCT2018	09OCT2018	N
		Nervous system disorders	Headache	09OCT2018		Y
		Psychiatric disorders	Insomnia	23DEC2019		Y
		Vascular disorders	Essential hypertension	27AUG2019		Y
	C4591001 1097 10971043	Cardiac disorders	Atrial fibrillation	24MAY2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	24MAY2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24MAY2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	24MAY2018		Y
		Vascular disorders	Essential hypertension	24MAY2018		Y
	C4591001 1097 10971044	Metabolism and nutrition disorders	Hyperlipidaemia	19JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	20JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	19JUL2018		Y
		Vascular disorders	Hypertension	19JUL2018		Y
	C4591001 1097 10971045	Gastrointestinal disorders	Gastroesophageal reflux disease	30APR2019		Y
		General disorders and administration site conditions	Fatigue	13FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Cellulitis	01MAY2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	17APR2018		Y
			Type 2 diabetes mellitus	17APR2018		Y
			Vitamin D deficiency	13FEB2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	13FEB2020	31DEC2020	N
		Nervous system disorders	Neuropathy peripheral	17APR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	17APR2018		Y
		Vascular disorders	Essential hypertension	17APR2018		Y
	C4591001 1097 10971047	Nervous system disorders	Migraine	19MAR2018		Y
	C4591001 1097 10971048	Eye disorders	Chorioretinopathy	23APR2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	23APR2019		Y
			Hypertriglyceridaemia	14APR2020		Y
		Vascular disorders	Essential hypertension	24APR2018		Y
	C4591001 1097 10971049	Gastrointestinal disorders	Gastroesophageal reflux disease	19JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	09MAR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	08MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	05MAR2019	30APR2019	N
		Nervous system disorders	Neuropathy peripheral	19JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Essential hypertension	02APR2019		Y
	C4591001 1097 10971050	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Colon operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1097 10971052	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2018		Y
			Intestinal obstruction	01JAN1974	31DEC1974	N
				01JAN1975	31DEC1975	N
				01JAN1999	31DEC1999	N
		Surgical and medical procedures	Appendicectomy	01JAN1957	31DEC1957	N
			Intestinal resection	01JAN1971	31DEC1971	N
			Nasal septal operation	01JAN2018	31DEC2018	N
	C4591001 1097 10971053	Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Hip arthroplasty	20AUG2012	20AUG2012	N
			Lipoma excision	01JAN2003	31DEC2003	N
			Neurectomy	01JAN2001	31DEC2001	N
				01JAN2004	31DEC2004	N
	C4591001 1097 10971054	Endocrine disorders	Hypogonadism	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1992		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1097 10971055	Surgical and medical procedures	Hip arthroplasty	01NOV2019	30NOV2019	N
	C4591001 1097 10971056	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01DEC2015		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2010	31DEC2010	N
			Shoulder arthroplasty	01JAN2012	31DEC2012	N
			Hypertension	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1097 10971058	Gastrointestinal disorders	Gastrooesophageal reflux disease	30JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	22OCT2019		Y
	C4591001 1097 10971059	Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1097 10971060	Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterosalpingo-oophorectomy	01JAN2000	31DEC2000	N
			Joint arthroplasty	01JAN2010	31DEC2017	N
			Keratomileusis	01JAN2004	31DEC2004	N
			Meniscus removal	01JAN2005	31DEC2005	N
			Nephrectomy	01JAN1980	31DEC1980	N
	C4591001 1097 10971061	Metabolism and nutrition disorders	Hyperlipidaemia	23MAR2018		Y
			Vitamin D deficiency	23MAR2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	23MAR2018		Y
			Intervertebral disc degeneration	23MAR2018		Y
		Psychiatric disorders	Anxiety	23MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Attention deficit hyperactivity disorder	23MAR2018		Y
			Depression	22APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	23MAR2018		Y
			Pulmonary fibrosis	01DEC2015		Y
		Vascular disorders	Hypertension	23MAR2018		Y
			Peripheral vascular disorder	18FEB2020		Y
	C4591001 1097 10971062	Endocrine disorders	Hypothyroidism	16APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16APR2018		Y
		Nervous system disorders	Tremor	16APR2018		Y
		Vascular disorders	Hypertension	16APR2018		Y
	C4591001 1097 10971064	Endocrine disorders	Hypogonadism	08MAY2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30MAY2019		Y
		Infections and infestations	Osteomyelitis	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	08MAY2018		Y
			Hyperlipidaemia	08MAY2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	31JAN2020		Y
			Osteoarthritis	08MAY2018		Y
		Psychiatric disorders	Depression	08MAY2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	31MAY2019		Y
		Vascular disorders	Hypertension	08MAY2018		Y
	C4591001 1097 10971065	Endocrine disorders	Hypothyroidism	23MAY2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23MAY2018		Y
		Nervous system disorders	Migraine	23MAY2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	23MAY2018		Y
	C4591001 1097 10971066	Metabolism and nutrition disorders	Hyperlipidaemia	26APR2018		Y
			Type 2 diabetes mellitus	14NOV2019		Y
			Vitamin B12 deficiency	17JUL2020		Y
		Nervous system disorders	Neuropathy peripheral	17JUL2020		Y
		Renal and urinary disorders	Neurogenic bladder	17JUL2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	26APR2018		Y
		Vascular disorders	Essential hypertension	26APR2018		Y
	C4591001 1097 10971067	Nervous system disorders	Cerebrovascular disorder	01JAN2003		Y
	C4591001 1097 10971068	Congenital, familial and genetic disorders	Familial mediterranean fever	03APR2018		Y
		Endocrine disorders	Hypothyroidism	07MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07MAR2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	22NOV2019		Y
			Intervertebral disc degeneration	08AUG2019		Y
			Osteoarthritis	07MAR2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	07MAR2018		Y
			Insomnia	07MAR2018		Y
		Vascular disorders	Essential hypertension	07MAR2018		Y
	C4591001 1097 10971074	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
		Surgical and medical procedures	Lipoma excision	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1097 10971075	Blood and lymphatic system disorders	Anaemia	12MAR2018		Y
		Cardiac disorders	Arteriosclerosis coronary artery	12MAR2018		Y
			Atrial fibrillation	12MAR2018		Y
			Ischaemic cardiomyopathy	12MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02MAR2018		Y
		Renal and urinary disorders	Nocturia	12MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	12MAR2018		Y
			Sleep apnoea syndrome	31MAY2019		Y
		Vascular disorders	Essential hypertension	12MAR2018		Y
	C4591001 1097 10971076	Metabolism and nutrition disorders	Hyperlipidaemia	06JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	14DEC2018		Y
		Vascular disorders	Essential hypertension	14DEC2018		Y
	C4591001 1097 10971077	Metabolism and nutrition disorders	Hyperlipidaemia	08JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	08JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Cough	08JUN2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2020	31JAN2020	N
			Mitral valve repair	01JAN2007	31DEC2007	N
			Retinal operation	01JAN2004	31DEC2004	N
	C4591001 1097 10971078	Gastrointestinal disorders	Gastroesophageal reflux disease	20APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	20APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	20APR2018		Y
		Nervous system disorders	Migraine	20APR2018		Y
		Psychiatric disorders	Anxiety	20APR2018		Y
	C4591001 1097 10971079	Cardiac disorders	Arteriosclerosis coronary artery	05NOV2019		Y
			Atrial fibrillation	05NOV2019		Y
		Endocrine disorders	Hypothyroidism	18APR2018		Y
			Thyroid mass	12MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05NOV2019		Y
			Lower gastrointestinal haemorrhage	07MAY2019	31MAY2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	18APR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	27AUG2018	30SEP2018	N
		Nervous system disorders	Dementia Alzheimer's type	30MAY2018		Y
		Psychiatric disorders	Anxiety	11FEB2020		Y
			Insomnia	12MAY2020		Y
		Renal and urinary disorders	Renal failure	09JUL2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	18APR2018		Y
		Surgical and medical procedures	Arterial stent insertion	18APR2018		Y
		Vascular disorders	Essential hypertension	18APR2018		Y
	C4591001 1097 10971082	Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1097 10971084	Endocrine disorders	Hypothyroidism	29JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	25MAY2020		Y
		Investigations	Catheterisation cardiac	06FEB2013	06FEB2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	13JUL2015		Y
			Type 2 diabetes mellitus	15DEC2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01MAY2012	10DEC2012	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Depression	26JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	15DEC2008		Y
		Surgical and medical procedures	Angioplasty	01OCT2003	01OCT2003	N
			Appendicectomy	19AUG2011	19AUG2011	N
			Bladder calculus removal	21APR2011	21APR2011	N
			Cataract operation	01JAN2014	31DEC2014	N
			Coronary arterial stent insertion	01MAY2008	01MAY2008	N
			Knee arthroplasty	26OCT2016	26OCT2016	N
				31MAY2005	31MAY2005	N
			Renal stone removal	06JUN2011	06JUN2011	N
			Rotator cuff repair	05OCT2011	05OCT2011	N
				30NOV2006	30NOV2006	N
		Vascular disorders	Hypertension	15DEC2015		Y
	C4591001 1097 10971087	Gastrointestinal disorders	Gastroesophageal reflux disease	02MAR2020		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	02MAR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Cholecystectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Essential hypertension	02MAR2020		Y
	C4591001 1097 10971090	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1097 10971091	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1097 10971092	Surgical and medical procedures	Tongue operation	01JAN2013	31DEC2013	N
	C4591001 1097 10971093	Gastrointestinal disorders	Gastroesophageal reflux disease	06NOV2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	20MAY2020		Y
		Vascular disorders	Hypertension	07DEC2018		Y
	C4591001 1097 10971094	Metabolism and nutrition disorders	Hyperglycaemia	19JUN2018		Y
			Hyperlipidaemia	20MAR2018		Y
			Hypomagnesaemia	12APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	12APR2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	20MAR2018		Y
	C4591001 1097 10971095	Infections and infestations	Hepatitis C	18MAR2019	18MAY2020	N
		Surgical and medical procedures	Hernia repair	09JUN2020	09JUN2020	N
	C4591001 1097 10971097	Injury, poisoning and procedural complications	Femur fracture	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1097 10971098	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
			Uterine cancer	01JAN2011	31DEC2011	N
		Psychiatric disorders	Insomnia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Breast reconstruction	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1097 10971099	Surgical and medical procedures	Elbow operation	01JAN2011	31DEC2011	N
	C4591001 1097 10971100	Gastrointestinal disorders	Gastroesophageal reflux disease	25NOV2019		Y
		Investigations	Biopsy breast	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Rheumatic fever	01JAN1958	31DEC1958	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1097 10971101	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Age-related macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1097 10971102	Cardiac disorders	Arteriosclerosis coronary artery	06APR2020		Y
			Left ventricular failure	23JUL2020		Y
		Ear and labyrinth disorders	Vertigo	23JUL2020	23JUL2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	30MAR2018		Y
			Hypertriglyceridaemia	06APR2020		Y
		Psychiatric disorders	Depression	30MAR2018		Y
			Insomnia	28JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	30MAR2018		Y
			Sleep apnoea syndrome	30MAR2018		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2006	31DEC2006	N
			Renal stone removal	01JAN1991	31DEC1991	N
		Vascular disorders	Essential hypertension	30MAR2018		Y
	C4591001 1097 10971103	Gastrointestinal disorders	Constipation	09DEC2019		Y
		Immune system disorders	Seasonal allergy	02APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02APR2018		Y
			Type 2 diabetes mellitus	02APR2018		Y
		Psychiatric disorders	Depression	23JUL2018		Y
		Surgical and medical procedures	Blepharoplasty	01NOV2019	30NOV2019	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01NOV2019	30NOV2019	N
		Vascular disorders	Essential hypertension	02APR2018		Y
	C4591001 1097 10971104	Eye disorders	Glaucoma	18APR2018		Y
		Infections and infestations	Pneumonia	14JUN2018	30JUN2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	02APR2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	20JUL2019		Y
			Spinal stenosis	18MAR2019		Y
		Nervous system disorders	Neuropathy peripheral	02APR2018		Y
		Respiratory, thoracic and mediastinal disorders	Cough	14JUN2018		Y
		Surgical and medical procedures	Intervertebral disc operation	10APR2000	10APR2019	N
			Knee arthroplasty	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder arthroplasty	01JAN2018	31DEC2018	N
			Spinal laminectomy	07JAN2020	07JAN2020	N
		Vascular disorders	Essential hypertension	02APR2018		Y
	C4591001 1097 10971105	Endocrine disorders	Hypothyroidism	10AUG2020		Y
		Gastrointestinal disorders	Bile acid malabsorption	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Aortic aneurysm	01JAN2019		Y
			Hypertension	01JAN2019		Y
	C4591001 1097 10971106	Investigations	Blood testosterone decreased	04JUN2018		Y
		Metabolism and nutrition disorders	Gout	04JUN2018		Y
			Hyperlipidaemia	04JUN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JUN2020		Y
			Osteoarthritis	13AUG2018		Y
		Nervous system disorders	Carpal tunnel syndrome	09JUL2020		Y
		Psychiatric disorders	Anxiety	04JUN2018		Y
			Attention deficit hyperactivity disorder	04JUN2018		Y
			Depression	04JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13AUG2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUN2020		Y
		Vascular disorders	Essential hypertension	04JUN2018		Y
	C4591001 1097 10971107	Endocrine disorders	Hypothyroidism	16MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16MAR2018		Y
			Type 2 diabetes mellitus	16MAR2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	16MAR2018		Y
			Osteoarthritis	16MAR2018		Y
			Osteoporosis	03FEB2020		Y
			Polymyalgia rheumatica	01MAY2018		Y
		Nervous system disorders	Lumbar radiculopathy	09SEP2019		Y
		Psychiatric disorders	Insomnia	03FEB2020		Y
		Renal and urinary disorders	Urinary incontinence	16MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10JUL2018		Y
		Vascular disorders	Hypertension	16MAR2018		Y
	C4591001 1097 10971108	Cardiac disorders	Arteriosclerosis coronary artery	16MAR2018		Y
			Atrial fibrillation	18AUG2020		Y
		Endocrine disorders	Hypogonadism	16MAR2018		Y
			Hypothyroidism	16MAR2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16MAR2018		Y
		General disorders and administration site conditions	Pain	16MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16MAR2018		Y
			Obesity	03FEB2020		Y
			Vitamin D deficiency	04APR2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	18AUG2020		Y
			Osteoarthritis	16MAR2018		Y
			Rheumatoid arthritis	16MAR2018		Y
		Nervous system disorders	Neuropathy peripheral	16MAR2018		Y
		Psychiatric disorders	Depression	16MAR2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	08AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	16MAR2018		Y
	C4591001 1097 10971109	Gastrointestinal disorders	Constipation	13MAR2019		Y
		Metabolism and nutrition disorders	Iron deficiency	12APR2018		Y
			Type 2 diabetes mellitus	12APR2018		Y
			Vitamin D deficiency	12APR2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	12APR2018		Y
			Intervertebral disc degeneration	12APR2018		Y
			Osteoarthritis	18AUG2020		Y
		Vascular disorders	Essential hypertension	12APR2018		Y
			Peripheral venous disease	12APR2018		Y
	C4591001 1097 10971110	Gastrointestinal disorders	Gastrooesophageal reflux disease	13APR2018		Y
		Infections and infestations	Skin candida	15JUN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13APR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Small intestine carcinoma	26MAY2018	31MAY2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	13APR2018		Y
	C4591001 1097 10971111	Endocrine disorders	Hypothyroidism	24APR2019		Y
		Gastrointestinal disorders	Constipation	06AUG2020		Y
		Infections and infestations	Urinary tract infection	06AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24SEP2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	06AUG2020		Y
		Vascular disorders	Essential hypertension	24SEP2018		Y
	C4591001 1097 10971112	Cardiac disorders	Atrial fibrillation	15MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertensive heart disease	12MAR2018		Y
		Gastrointestinal disorders	Irritable bowel syndrome	06AUG2020		Y
		Investigations	Prostatic specific antigen increased	12MAR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15MAR2018		Y
			Vitamin D deficiency	06AUG2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	02MAY2019		Y
			Tendonitis	12MAR2018		Y
		Nervous system disorders	Sciatica	02MAY2019		Y
		Renal and urinary disorders	Renal failure	09JUL2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	15MAR2018		Y
		Surgical and medical procedures	Skin neoplasm excision	06AUG2020	06AUG2020	N
		Vascular disorders	Essential hypertension	15MAR2018		Y
	C4591001 1097 10971113	Metabolism and nutrition disorders	Type 2 diabetes mellitus	21JUN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	21JUN2018		Y
		Nervous system disorders	Neuropathy peripheral	21JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21JUN2018		Y
		Skin and subcutaneous tissue disorders	Intertrigo	25AUG2020		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
	C4591001 1097 10971114	Endocrine disorders	Hypothyroidism	10APR2018		Y
		Gastrointestinal disorders	Barrett's oesophagus	10APR2018		Y
			Gastrooesophageal reflux disease	10APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10SEP2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	11MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2013	N
		Nervous system disorders	Cognitive disorder	03MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	03MAR2020		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Aortic aneurysm	01JAN2018		Y
			Essential hypertension	10APR2018		Y
	C4591001 1097 10971115	Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Large intestinal polypectomy	01JAN2012	31DEC2012	N
			Orthopaedic procedure	29FEB2020	29FEB2020	N
	C4591001 1097 10971118	Investigations	Glycosylated haemoglobin increased	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1097 10971121	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1097 10971122	Nervous system disorders	Parkinson's disease	01JAN2005		Y
		Reproductive system and breast disorders	Vaginal fistula	01JAN2018	31JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Colostomy	01JAN2018	31JAN2018	N
			Colostomy closure	01APR2018	30APR2018	N
	C4591001 1098 10981002	General disorders and administration site conditions	Oedema peripheral	14AUG2018		Y
		Nervous system disorders	Neuralgia	11AUG2020		Y
		Surgical and medical procedures	Salpingectomy	09JUL1977		Y
		Vascular disorders	Hypertension	24FEB2017		Y
	C4591001 1098 10981003	Ear and labyrinth disorders	Deafness bilateral	04OCT2018		Y
		Investigations	Blood cholesterol increased	20SEP2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1098 10981007	Cardiac disorders	Cardiac failure congestive	23SEP2019		Y
		Investigations	Blood cholesterol increased	15AUG2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	16AUG2017		Y
		Nervous system disorders	Polyneuropathy	15AUG2017		Y
		Renal and urinary disorders	Chronic kidney disease	11AUG2020		Y
		Vascular disorders	Hypertension	15AUG2017		Y
	C4591001 1098 10981008	Vascular disorders	Hypertension	05MAY2016		Y
	C4591001 1098 10981010	Investigations	Blood cholesterol increased	14APR2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	14APR2011		Y
		Vascular disorders	Hypertension	14APR2011		Y
	C4591001 1098 10981016	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Surgical and medical procedures	Salpingectomy	01JAN1991	31DEC1991	N
	C4591001 1098 10981017	Investigations	Blood cholesterol	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1098 10981019	Investigations	Blood cholesterol increased	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1098 10981021	Endocrine disorders	Hypothyroidism	17OCT2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	17OCT2017		Y
			Hypertriglyceridaemia	17OCT2017		Y
			Type 1 diabetes mellitus	09OCT2017		Y
		Vascular disorders	Hypertension	09OCT2017		Y
	C4591001 1098 10981022	Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1098 10981024	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Cardiac failure congestive	01JAN2018		Y
			Coronary artery disease	01JAN2016		Y
			Myocardial infarction	01JAN1996	31DEC1996	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	03AUG2020		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1098 10981026	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1970		Y
		Surgical and medical procedures	Salpingectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1098 10981033	Endocrine disorders	Hypothyroidism	27AUG2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24JAN2012		Y
		Vascular disorders	Hypertension	04JUN2013		Y
	C4591001 1098 10981034	Ear and labyrinth disorders	Vertigo positional	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	28JUN2015		Y
			Type 2 diabetes mellitus	17FEB2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	17FEB2010		Y
	C4591001 1098 10981036	Psychiatric disorders	Attention deficit hyperactivity disorder	29DEC2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1098 10981037	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	25MAR2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	13SEP2019		Y
	C4591001 1098 10981038	Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1098 10981040	Metabolism and nutrition disorders	Hyperlipidaemia	08JUL2019		Y
			Type 2 diabetes mellitus	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	22JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	08JAN2019		Y
	C4591001 1098 10981041	Endocrine disorders	Hyperthyroidism	24MAY2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1098 10981042	Investigations	Hormone level abnormal	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1964		Y
	C4591001 1098 10981044	General disorders and administration site conditions	Oedema	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1098 10981045	Endocrine disorders	Hypothyroidism	10DEC2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10DEC2014		Y
			Hypertriglyceridaemia	10DEC2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	27JAN2017		Y
	C4591001 1098 10981046	Endocrine disorders	Hypothyroidism	05JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05JAN2018		Y
			Type 2 diabetes mellitus	05JAN2018		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	05JAN2018		Y
	C4591001 1098 10981049	Metabolism and nutrition disorders	Hyperlipidaemia	09FEB2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	09FEB2014		Y
	C4591001 1098 10981050	General disorders and administration site conditions	Oedema peripheral	25JUL2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22APR2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN1959		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1098 10981051	Surgical and medical procedures	Salpingectomy	05JUL1984	05JUL1984	N
	C4591001 1098 10981053	Metabolism and nutrition disorders	Hyperlipidaemia	13JAN2009		Y
			Type 2 diabetes mellitus	13JAN2009		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	25NOV2008		Y
	C4591001 1098 10981058	Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1098 10981059	Endocrine disorders	Hypothyroidism	06FEB2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	06FEB2018		Y
	C4591001 1098 10981061	Metabolism and nutrition disorders	Type 2 diabetes mellitus	27AUG2017		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	07JAN2016		Y
	C4591001 1098 10981062	Metabolism and nutrition disorders	Hyperlipidaemia	25JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	25AUG2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	25JAN2018		Y
	C4591001 1098 10981063	Metabolism and nutrition disorders	Hyperlipidaemia	18JAN2017		Y
			Type 2 diabetes mellitus	18JAN2017		Y
		Vascular disorders	Hypertension	20MAR2018		Y
	C4591001 1098 10981066	Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Surgical and medical procedures	Spinal nerve stimulator implantation	01JAN2014		Y
	C4591001 1098 10981070	Metabolism and nutrition disorders	Hyperlipidaemia	21MAY2014		Y
			Type 2 diabetes mellitus	21MAY2014		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	21MAY2014		Y
		Vascular disorders	Hypertension	21MAY2014		Y
	C4591001 1098 10981071	Endocrine disorders	Hypothyroidism	16MAR2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16MAR2015		Y
			Type 2 diabetes mellitus	16MAR2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	01JAN2001	N
		Vascular disorders	Hypertension	16MAR2015		Y
	C4591001 1098 10981072	Metabolism and nutrition disorders	Gout	01JAN1995		Y
	C4591001 1098 10981078	Metabolism and nutrition disorders	Hyperlipidaemia	08FEB2012		Y
			Type 2 diabetes mellitus	08FEB2012		Y
		Vascular disorders	Hypertension	16MAY2016		Y
	C4591001 1098 10981080	Eye disorders	Myopia	01JAN1960		Y
		Renal and urinary disorders	Urinary retention	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2017		Y
	C4591001 1098 10981081	Endocrine disorders	Hypothyroidism	12JUL2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	08SEP2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23DEC2015	14MAR2017	N
			Hypertriglyceridaemia	23DEC2015	14MAR2017	N
		Vascular disorders	Hypertension	23DEC2015	14NOV2019	N
	C4591001 1098 10981082	Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	09DEC2014		Y
	C4591001 1098 10981083	Endocrine disorders	Hypothyroidism	11APR2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2005		Y
		Vascular disorders	Hypertension	16MAR2015		Y
	C4591001 1098 10981087	Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01OCT1988	31OCT1988	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1098 10981088	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
	C4591001 1098 10981092	Endocrine disorders	Hypoparathyroidism	09OCT2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	17OCT2014		Y
		Vascular disorders	Hypertension	17OCT2014		Y
	C4591001 1098 10981093	Metabolism and nutrition disorders	Hyperlipidaemia	21SEP2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1098 10981094	Metabolism and nutrition disorders	Hyperlipidaemia	24FEB2016		Y
			Type 2 diabetes mellitus	19JUN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	24FEB2016		Y
	C4591001 1098 10981102	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1098 10981105	Endocrine disorders	Hypothyroidism	03APR2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	03SEP2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	25SEP2018		Y
	C4591001 1098 10981107	Nervous system disorders	Nerve compression	01JUN2020		Y
	C4591001 1098 10981108	Metabolism and nutrition disorders	Hyperlipidaemia	21JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1098 10981109	Metabolism and nutrition disorders	Hyperlipidaemia	09JAN2015		Y
			Type 2 diabetes mellitus	09JAN2015		Y
	C4591001 1098 10981110	Surgical and medical procedures	Female sterilisation	01JAN1979	31DEC1979	N
	C4591001 1098 10981113	Endocrine disorders	Hypothyroidism	08MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08MAR2017		Y
			Type 2 diabetes mellitus	08MAR2017		Y
		Surgical and medical procedures	Oophorectomy bilateral	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	08MAR2017		Y
	C4591001 1098 10981118	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	05NOV2013		Y
	C4591001 1098 10981119	Social circumstances	Postmenopause	01JUL2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1098 10981123	Cardiac disorders	Cardiac failure congestive	01JAN2001		Y
		Surgical and medical procedures	Salpingectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1098 10981124	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1098 10981127	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anal cancer	01JAN2015	31DEC2016	N
		Nervous system disorders	Cerebrovascular accident	01JUN2019	30JUN2019	N
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1098 10981128	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1098 10981130	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Immune system disorders	Iodine allergy	01JAN1984		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11MAR2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1098 10981131	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Food allergy	01JAN1955		Y
				01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Heart valve replacement	01APR2016		Y
			Rhinoplasty	01JAN1995	31DEC1995	N
	C4591001 1098 10981133	Eye disorders	Eye inflammation	01MAR2020		Y
	C4591001 1098 10981135	Gastrointestinal disorders	Abdominal pain upper	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
	C4591001 1098 10981139	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1098 10981148	Metabolism and nutrition disorders	Hyperlipidaemia	08JAN2019		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	08JAN2019		Y
	C4591001 1098 10981149	Metabolism and nutrition disorders	Hyperlipidaemia	12DEC2017		Y
			Type 2 diabetes mellitus	12DEC2017		Y
		Vascular disorders	Hypertension	12DEC2017		Y
	C4591001 1098 10981150	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1098 10981157	Hepatobiliary disorders	Hepatic cirrhosis	01JAN2017		Y
		Infections and infestations	Hepatitis C	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	19FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Renal and urinary disorders	Chronic kidney disease	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1098 10981158	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2011		Y
	C4591001 1098 10981159	Cardiac disorders	Cardiac failure congestive	01JAN1994		Y
		Eye disorders	Cataract	01JAN2006		Y
			Glaucoma	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1098 10981162	Infections and infestations	Hepatitis C	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01DEC2000	31DEC2000	N
	C4591001 1098 10981164	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2018		Y
		Social circumstances	Hearing aid user	01JUL2017		Y
				01JUN2017		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1098 10981165	Reproductive system and breast disorders	Menopausal symptoms	01JAN2000		Y
		Vascular disorders	Hypertension	25APR2019		Y
	C4591001 1098 10981167	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981171	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	31MAR2014		Y
	C4591001 1098 10981172	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
		Nervous system disorders	Diabetic neuropathy	01JUN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1098 10981173	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1098 10981174	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1098 10981175	Surgical and medical procedures	Vasectomy	01JAN2002		Y
	C4591001 1098 10981178	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN1976		Y
	C4591001 1098 10981182	Cardiac disorders	Aortic valve incompetence	01JAN1954		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2014		Y
					31DEC2014	N
	C4591001 1098 10981190	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Knee arthroplasty	01OCT2019	01OCT2019	N
				09MAR2020	09MAR2020	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1098 10981193	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
	C4591001 1098 10981195	Endocrine disorders	Thyroid cyst	01JAN1985		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1983		Y
				01JAN1995		Y
			Seasonal allergy	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1983		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN1995		Y
			Varicose vein	01JAN1952		Y
	C4591001 1098 10981201	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01AUG2018		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1098 10981202	Cardiac disorders	Left ventricular failure	01OCT2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1993		Y
			Haemorrhoids	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01MAR2020	31MAR2020	N
		Investigations	Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1956		Y
			Sleep apnoea syndrome	01JAN1996		Y
		Social circumstances	Hearing aid user	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1098 10981203	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Hyperlipidaemia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1098 10981204	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1098 10981208	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Surgical and medical procedures	Exeresis	01JAN2018	31DEC2018	N
			Stent placement	01JAN1996	31DEC1996	N
				01JAN2001	31DEC2001	N
	C4591001 1098 10981209	Gastrointestinal disorders	Coeliac disease	01JAN2008		Y
			Gastrooesophageal reflux disease	01JAN2013		Y
		Infections and infestations	Fungal skin infection	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1098 10981211	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1098 10981212	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2020		Y
	C4591001 1098 10981213	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2016		Y
			Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1098 10981214	Immune system disorders	Drug hypersensitivity	01JAN1952		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1098 10981215	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1098 10981221	Surgical and medical procedures	Nasal septal operation	01JAN2018	31DEC2018	N
	C4591001 1098 10981222	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1098 10981223	Metabolism and nutrition disorders	Hyperlipidaemia	15APR2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	05JUN2020		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1098 10981225	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1098 10981227	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1098 10981228	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1977	31DEC1977	N
	C4591001 1098 10981233	Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
			Obesity	01JAN2000		Y
			Vitamin D deficiency	01JAN2019		Y
		Surgical and medical procedures	Gastric banding	01JAN2008	31DEC2008	N
	C4591001 1098 10981237	Vascular disorders	Hypertension	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04JUN2000		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1098 10981239	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1098 10981245	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1098 10981248	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1098 10981249	Gastrointestinal disorders	Colitis ulcerative	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1965		Y
	C4591001 1098 10981250	Injury, poisoning and procedural complications	Road traffic accident	25SEP2020	25SEP2020	N
		Musculoskeletal and connective tissue disorders	Back pain	25SEP2020		Y
	C4591001 1098 10981255	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1098 10981256	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin B12 deficiency	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2015		Y
			Spinal osteoarthritis	01JAN1991		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Coronary artery bypass	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1098 10981257	Cardiac disorders	Cardiac failure congestive	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Obesity	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Nervous system disorders	Cerebrovascular accident	13JUL2007	13JUL2007	N
			Diabetic neuropathy	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Spinal fusion surgery	18SEP2020	18SEP2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1098 10981261	Eye disorders	Myopia	01JAN1979		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1101 11011002	Infections and infestations	Sinusitis	01JAN2015	31DEC2015	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
			Intervertebral disc protrusion	01JAN2019		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011003	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1101 11011006	Blood and lymphatic system disorders	Anaemia	01JAN1975	31DEC1975	N
		Ear and labyrinth disorders	Deafness	01JAN2009		Y
			Tinnitus	01JAN1980		Y
			Vertigo	01JAN2013		Y
		Eye disorders	Visual acuity reduced	01JAN1959		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN2014		Y
			Rubber sensitivity	01JAN2014		Y
		Infections and infestations	Staphylococcal infection	01JAN1975	31DEC1975	N
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	14JUL1999	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983		Y
			Sinus congestion	01JAN1964		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Breast conserving surgery	21JUL1995	21JUL1995	N
			Hysterectomy	01NOV2018	30NOV2018	N
		Vascular disorders	Peripheral venous disease	01JAN2018		Y
	C4591001 1101 11011008	Eye disorders	Visual acuity reduced	01JAN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diverticulum	01JAN2013		Y
			Gastric ulcer	01JAN1980		Y
		Immune system disorders	Food allergy	01JAN1980		Y
		Infections and infestations	Pneumonia	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1969		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
			Rhinitis allergic	01JAN1980		Y
		Social circumstances	Menopause	01JAN2002		Y
	C4591001 1101 11011009	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1101 11011011	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Myocardial infarction	01JAN1990	31DEC1990	N
		Ear and labyrinth disorders	Deafness	01JAN1995		Y
			Tinnitus	01JAN1995		Y
		General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
				01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2018	31DEC2018	N
			Migraine	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Gastric bypass	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1101 11011017	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Haemorrhoids	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2008	31DEC2008	N
			Osteoarthritis	01JAN2008	31DEC2008	N
		Nervous system disorders	Headache	01JAN1990		Y
			Migraine	01JAN2000		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1101 11011025	Ear and labyrinth disorders	Deafness bilateral	01JAN2007		Y
			Tinnitus	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
	C4591001 1101 11011027	Vascular disorders	Hypertension	01JAN1996		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
			Vertigo	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1101 11011031	Surgical and medical procedures	Female sterilisation	01JAN1976		Y
		Eye disorders	Cataract	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
				01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1983		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN1983		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2000	31DEC2000	N
	C4591001 1101 11011032	Vascular disorders	Hypertension	01JAN1980		Y
		Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Bundle branch block left	01JAN2016		Y
			Cardiomyopathy	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1101 11011036	Cardiac disorders	Atrial fibrillation	01MAR2017		Y
			Palpitations	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2012	N
				26SEP2001	26SEP2001	N
			Intracranial aneurysm	27MAY2018	27MAY2018	N
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1101 11011037	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1950		Y
			Sinus congestion	01JAN1950		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1101 11011043	Investigations	Prostatic specific antigen increased	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
			Peripheral arterial occlusive disease	01JAN2010		Y
	C4591001 1101 11011047	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood triglycerides increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Urinary incontinence	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1101 11011049	Investigations	High density lipoprotein decreased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1101 11011050	Ear and labyrinth disorders	Deafness bilateral	01JAN2020		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
			Blood testosterone decreased	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2004		Y
			Hypoglycaemia	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1977		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1101 11011054	Ear and labyrinth disorders	Deafness bilateral	01JAN1963		Y
			Tinnitus	01JAN1963		Y
		Eye disorders	Visual acuity reduced	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1101 11011055	Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2017	30APR2017	N
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1101 11011063	Ear and labyrinth disorders	Tinnitus	01JUN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				01JAN2000		Y
				01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01AUG2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1101 11011064	Ear and labyrinth disorders	Deafness bilateral	01JAN1960		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2011		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
			Blood triglycerides increased	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
	C4591001 1101 11011066	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002		Y
	C4591001 1101 11011068	Cardiac disorders	Coronary artery disease	01JAN2000		Y
			Ventricular extrasystoles	01JAN2018		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1984		Y
			Tinnitus	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
			Haemorrhoids	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1995		Y
	C4591001 1101 11011077	Investigations	Blood cholesterol increased	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1101 11011081	Investigations	Blood cholesterol increased	01JAN2010		Y
		Nervous system disorders	Nerve compression	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y
			Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1101 11011082	Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1101 11011083	Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
		Psychiatric disorders	Depression	01JUN2020		Y
	C4591001 1101 11011086	Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2004		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN1966		Y
			Coeliac disease	01JAN2004		Y
		Immune system disorders	Food allergy	01JAN1964		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
			Sleep apnoea syndrome	01JAN2020		Y
	C4591001 1101 11011092	Ear and labyrinth disorders	Deafness bilateral	01JAN1969		Y
			Tinnitus	01JAN1969		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Blood triglycerides increased	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1101 11011093	Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
	C4591001 1101 11011095	Cardiac disorders	Myocardial infarction	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Nervous system disorders	Carotid artery disease	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2016	30SEP2016	N
	C4591001 1101 11011098	Cardiac disorders	Bradycardia	01JAN2005		Y
		Eye disorders	Visual acuity reduced	01JAN2008		Y
		Investigations	Blood triglycerides increased	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1966		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1101 11011099	Eye disorders	Visual acuity reduced	01JAN1957		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JUN2010	30JUN2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011102	Eye disorders	Visual acuity reduced	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Renal and urinary disorders	Incontinence	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1101 11011103	Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01APR2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1101 11011104	Ear and labyrinth disorders	Tinnitus	01JAN1999		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1994		Y
		Investigations	Blood cholesterol increased	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
	C4591001 1101 11011109	Immune system disorders	Allergy to animal	01JAN1983		Y
			Dust allergy	01JAN1983		Y
			Mycotic allergy	01JAN1983		Y
			Seasonal allergy	01JAN1983		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
			Rhinitis allergic	01JAN1968		Y
			Sinus congestion	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1101 11011112	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Allergy to animal	01JAN1972		Y
			Drug hypersensitivity	01JAN1975		Y
			Food allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
	C4591001 1101 11011116	Cardiac disorders	Coronary artery disease	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1963		Y
			Rosacea	01JAN1995		Y
	C4591001 1101 11011119	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Cardiac disorders	Supraventricular tachycardia	01JAN1974		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
			Hiatus hernia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1101 11011120	Infections and infestations	Urinary tract infection	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1107 11071001	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Investigations	Blood testosterone decreased	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Essential tremor	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071004	Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
	C4591001 1107 11071005	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1107 11071007	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1980	31DEC1980	N
		Vascular disorders	Hot flush	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN2017		Y
	C4591001 1107 11071008	Injury, poisoning and procedural complications	Limb traumatic amputation	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1107 11071011	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
	C4591001 1107 11071014	Endocrine disorders	Goitre	01JAN1980	31DEC1991	N
			Hypothyroidism	01JAN1991		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1107 11071021	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Overweight	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071023	General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Overweight	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
			Depression	01JAN1994		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1107 11071024	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
	C4591001 1107 11071029	Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
			Meniere's disease	01JAN2015		Y
		Eye disorders	Cataract	01JAN2019	22JUN2020 29JUN2020	N N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Overweight	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JUN2020	14JUL2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Cataract operation	22JUN2020	22JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				29JUN2020	29JUN2020	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1107 11071030	Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1107 11071035	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978		Y
	C4591001 1107 11071036	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31JAN2020	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2020	31JAN2020	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1107 11071038	Cardiac disorders	Arrhythmia	28AUG2019	01OCT2019	N
		Endocrine disorders	Goitre	01JAN2008	31DEC2008	N
			Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01OCT2019	01OCT2019	N
			Thyroidectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071040	Endocrine disorders	Hypergonadism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood pressure increased	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN1980		Y
		Renal and urinary disorders	Nocturia	01JAN2015		Y
	C4591001 1107 11071041	Metabolism and nutrition disorders	Overweight	01JAN2015		Y
			Vitamin B12 deficiency	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	19FEB1980	19FEB1980	N
	C4591001 1107 11071042	Endocrine disorders	Hypothyroidism	01JAN2010		Y
			Thyroid mass	01JAN1975	31DEC1975	N
				01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1975	31DEC1975	N
				01JAN2005	31DEC2005	N
	C4591001 1107 11071043	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hypercholesterolaemia	01JAN1997		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Gastrectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1997		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071044	Gastrointestinal disorders	Abdominal pain upper	01MAR2020	12SEP2020	N
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2020		Y
			Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1107 11071045	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Head titubation	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1107 11071047	Infections and infestations	Diverticulitis	01JAN2010	31DEC2010	N
		Investigations	Cardiac murmur	(b) (6) 1958		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Colectomy	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071048	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2018		Y
			Overweight	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1107 11071050	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2012	N
		Nervous system disorders	Headache	01JAN1976		Y
			Migraine	01JAN1978		Y
			Sciatica	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN2013		Y
			Hypertension	01JAN2000		Y
	C4591001 1107 11071053	Ear and labyrinth disorders	Hypoacusis	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
	C4591001 1107 11071060	Investigations	Cardiac murmur	(b) (6) 1956		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Overweight	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1107 11071061	Eye disorders	Myopia	01JAN1960	31DEC2000	N
		Infections and infestations	Conjunctivitis	03AUG2020	07AUG2020	N
		Investigations	Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01FEB2019	31MAR2019	N
		Renal and urinary disorders	Nocturia	01JAN2019		Y
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Skin neoplasm excision	01MAR2019	31MAR2019	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1107 11071062	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Psychiatric disorders	Libido decreased	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
	C4591001 1107 11071064	Congenital, familial and genetic disorders	Limb malformation	(b) (6) 1963	31DEC1979	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	(b) (6) 1963		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Leg amputation	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1107 11071068	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Overweight	01JAN2013		Y
		Reproductive system and breast disorders	Uterine scar	01JAN1994	25JUN1996	N
		Surgical and medical procedures	Hysterectomy	25JUN1996	25JUN1996	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071073	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1107 11071075	Eye disorders	Glaucoma	01JAN2019		Y
		Infections and infestations	Herpes simplex	01JAN1996		Y
		Investigations	Cardiac murmur	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1107 11071076	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071077	Infections and infestations	Oral herpes	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071078	Metabolism and nutrition disorders	Overweight	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
	C4591001 1107 11071080	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01MAY1989	31MAY1989	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1107 11071082	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2019	31MAY2020	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Surgical and medical procedures	Skin neoplasm excision	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1107 11071084	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2013	31DEC2013	N
			Uterine leiomyoma	01JAN2011	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1107 11071085	Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1107 11071090	Cardiac disorders	Coronary artery disease	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1990		Y
		Surgical and medical procedures	Leg amputation	01JAN2013	31DEC2013	N
		Vascular disorders	Deep vein thrombosis	01JAN2015	31DEC2015	N
			Hypertension	01JAN2004		Y
			Peripheral vascular disorder	01JAN1999		Y
	C4591001 1107 11071091	Immune system disorders	Seasonal allergy	01JAN1956		Y
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01MAR1981	31MAR1981	N
		Nervous system disorders	Restless legs syndrome	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01MAR1981	31MAR1981	N
			Oophorectomy	01MAR1981	31MAR1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypotension	01FEB2019		Y
	C4591001 1107 11071092	Cardiac disorders	Arrhythmia	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN1950		Y
	C4591001 1107 11071093	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1107 11071094	Infections and infestations	Appendicitis	01JAN2017	31JAN2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendectomy	01JAN2017	31JAN2017	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1107 11071099	Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
	C4591001 1107 11071103	Gastrointestinal disorders	Duodenal ulcer	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1955		Y
		Renal and urinary disorders	Urinary retention	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1107 11071107	Cardiac disorders	Coronary artery disease	01NOV2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31MAY2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2016	31MAY2016	N
			Coronary arterial stent insertion	01NOV2015	30NOV2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071108	Immune system disorders	Seasonal allergy	01JAN1970		Y
	C4591001 1107 11071113	Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
	C4591001 1107 11071116	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Overweight	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN1992		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071117	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1107 11071119	Cardiac disorders	Aortic valve disease	01JAN2012	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071121	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	10AUG2020	N
		Renal and urinary disorders	Pollakiuria	01JAN2017		Y
		Surgical and medical procedures	Skin neoplasm excision	10AUG2020	10AUG2020	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1107 11071127	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Hypercholesterolaemia	01JAN2019		Y
	C4591001 1107 11071128	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1987	31DEC1987	N
			Endometrial ablation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1107 11071131	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
	C4591001 1107 11071132	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01FEB2020		Y
			Depression	01JAN2014		Y
			Insomnia	01JUN1982		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1975	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1107 11071135	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1107 11071137	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JUL2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle twitching	01JAN2014		Y
			Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1107 11071140	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1975		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2017		Y
			Raynaud's phenomenon	01JAN2010		Y
	C4591001 1107 11071143	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1107 11071147	Hepatobiliary disorders	Cholelithiasis	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2002	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
			Oophorectomy	01JAN2003	31DEC2003	N
	C4591001 1107 11071148	Cardiac disorders	Aortic valve incompetence	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1979	31DEC1993	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Female sterilisation	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1107 11071149	Cardiac disorders	Aortic valve stenosis	01JAN2016	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2017	31DEC2017	N
	C4591001 1107 11071150	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Overweight	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2007	31DEC2007	N
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071153	Cardiac disorders	Arrhythmia	01JAN2017	31DEC2017	N
		Endocrine disorders	Hypogonadism	01JAN2011		Y
			Hypothyroidism	01JAN1991		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAY2012	30JUN2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Brachytherapy to prostate	01JUN2012	30JUN2012	N
			Cardiac pacemaker insertion	01JAN2017	31DEC2017	N
		Vascular disorders	Hypotension	01JAN2020		Y
	C4591001 1107 11071158	Eye disorders	Cataract	01JAN2015	31DEC2018	N
			Vitreous haemorrhage	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Eye laser surgery	01JAN2015	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1976	31DEC1976	N
	C4591001 1107 11071159	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1955		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	01FEB2011	31AUG2011	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC1990	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN1990	31DEC1992	N
		Surgical and medical procedures	Breast conserving surgery	01FEB2011	28FEB2011	N
			Female sterilisation	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1107 11071166	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Abdominal adhesions	01JAN2001	31DEC2001	N
			Gastrooesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Overweight	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1983	31DEC1983	N
			Gastric bypass	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071167	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Teratoma	01JAN2001	31DEC2001	N
				01JAN2015	31DEC2015	N
			Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Abdominal operation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2009	31DEC2009	N
			Oophorectomy	01JAN2001	31DEC2001	N
	C4591001 1107 11071169	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	07JUL2020		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1107 11071170	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Overweight	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2015	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2017	N
			Thyroidectomy	01JAN2016	31DEC2016	N
	C4591001 1107 11071172	Injury, poisoning and procedural complications	Limb injury	01JAN2006	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Surgical and medical procedures	Limb operation	01JAN2015	31DEC2015	N
	C4591001 1107 11071173	Hepatobiliary disorders	Cholelithiasis	01JUL2001	27DEC2001	N
		Infections and infestations	Cystitis	01JUL2020		Y
			Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2003		Y
		Nervous system disorders	Sinus headache	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1998	N
		Surgical and medical procedures	Cholecystectomy	27DEC2001	27DEC2001	N
			Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1107 11071175	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1107 11071176	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
	C4591001 1107 11071182	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1990	N
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2005	31DEC2005	N
			Oophorectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071183	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1107 11071185	Endocrine disorders	Hypogonadism	01JAN2011		Y
			Hypothyroidism	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1107 11071187	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Infections and infestations	Genital herpes	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2018		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01MAR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1994		Y
	C4591001 1107 11071189	Endocrine disorders	Hypogonadism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Overweight	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1107 11071191	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	20JUL2020	N
			Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Toe operation	20JUL2020	20JUL2020	N
	C4591001 1107 11071192	Endocrine disorders	Hypogonadism	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1107 11071194	Gastrointestinal disorders	Constipation	01MAR2020		Y
		Injury, poisoning and procedural complications	Intervertebral disc injury	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071196	Gastrointestinal disorders	Diverticulum	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
			Vitamin B12 deficiency	05FEB2020		Y
		Nervous system disorders	Temporal lobe epilepsy	01AUG2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1107 11071197	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAR2019		Y
			Hiatus hernia	01JAN2010		Y
			Oesophageal disorder	(b) (6) 1959		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Oesophageal dilation procedure	01JAN2015	31DEC2015	N
	C4591001 1107 11071201	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1107 11071202	Eye disorders	Eye movement disorder	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1980		Y
	C4591001 1107 11071206	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071207	Cardiac disorders	Supraventricular tachycardia	01JAN2009		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2012	31DEC2012	N
	C4591001 1107 11071208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Injury, poisoning and procedural complications	Limb traumatic amputation	01JAN1954	31DEC1954	N
		Investigations	Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1107 11071210	Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01FEB2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2005	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1107 11071214	Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Overweight	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2001		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1107 11071216	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1107 11071217	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091005	Immune system disorders	Drug hypersensitivity	01DEC1961		Y
	C4591001 1109 11091008	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1965		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1988		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2017	31MAY2017	N
			Hysterectomy	01JAN1995		Y
	C4591001 1109 11091009	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Psychiatric disorders	Anxiety	01APR2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091012	Endocrine disorders	Thyroid mass	01JAN2000		Y
		Eye disorders	Cataract	01JAN2000	15AUG2008	N
		Gastrointestinal disorders	Dyspepsia	01JAN1980		Y
			Gastrooesophageal reflux disease	01JAN1980		Y
			Haemorrhoids	01JAN1980		Y
			Intestinal polyp	01JAN1978	31JAN2010	N
		Hepatobiliary disorders	Cholecystitis	01JAN2010	31JAN2010	N
		Immune system disorders	Seasonal allergy	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1995	31JAN1995	N
			Chronic sinusitis	01JAN1979		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
				15JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1969	31JAN2004	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1979		Y
			Sleep apnoea syndrome	01JAN1979		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31JAN1995	N
			Cholecystectomy	01JAN2010	31JAN2010	N
			Lithotripsy	01JAN2004	31JAN2004	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1109 11091025	Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
			Neck pain	01JAN1997		Y
		Surgical and medical procedures	Limb operation	01JAN2012	01JAN2012	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1109 11091026	Infections and infestations	Varicella	01JAN1951	01JAN1951	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2000		Y
	C4591001 1109 11091029	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2010	01JAN2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1109 11091031	Gastrointestinal disorders	Dyspepsia	01JAN1970		Y
			Haemorrhoids	01APR2008		Y
		Infections and infestations	Measles	01JAN1965	02JAN1965	N
			Pneumonia	01JAN1965	01JAN1965	N
			Varicella	01JAN1960		Y
		Investigations	Colonoscopy	01JUN2020	01JUN2020	N
			Endoscopy	01JAN2019	01JAN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008		Y
			Osteoarthritis	01JAN2008	01JAN2017	N
				01JUL2008		Y
				20AUG2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	09OCT2014	09OCT2014	N
		Surgical and medical procedures	Hernia repair	01MAY2014	01MAY2014	N
			Knee arthroplasty	01JAN2017	01JAN2017	N
			Tonsillectomy	01JAN1962	01JAN1962	N
			Vasectomy	01JAN1977	31JAN1977	N
		Vascular disorders	Hypertension	(b) (6) 1949		Y
	C4591001 1109 11091032	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2019		Y
	C4591001 1109 11091034	Immune system disorders	Seasonal allergy	(b) (6) 1958		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Osteoarthritis	01FEB2019		Y
		Social circumstances	Postmenopause	29MAY2012		Y
	C4591001 1109 11091035	Gastrointestinal disorders	Constipation	01JAN2000		Y
		Investigations	Colonoscopy	01FEB2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2001		Y
			Osteoarthritis	01JAN2010		Y
				01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2018	01JAN2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091036	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Bipolar disorder	01JAN1985		Y
			Major depression	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
	C4591001 1109 11091037	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Investigations	Colonoscopy	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Amnesia	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2017		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	01JAN2010	N
			Thyroid operation	01JAN2010		Y
			Tonsillectomy	01JAN2017		Y
	C4591001 1109 11091038	Infections and infestations	Vaginal infection	01JAN2005		Y
		Investigations	Mammogram	01APR2017	01APR2017	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2005		Y
	C4591001 1109 11091039	Infections and infestations	Onychomycosis	01JAN2010		Y
		Investigations	Colonoscopy	01AUG2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2003		Y
	C4591001 1109 11091040	Nervous system disorders	Complex regional pain syndrome	01JAN2007		Y
			Restless legs syndrome	01JAN2014		Y
		Surgical and medical procedures	Gastric bypass	01JAN2002		Y
	C4591001 1109 11091042	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Renal and urinary disorders	Hypercalciuria	01JAN2005		Y
			Hypertonic bladder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1109 11091044	Gastrointestinal disorders	Crohn's disease	01JAN1985		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2000		Y
	C4591001 1109 11091045	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1995	31JAN1995	N
			Shoulder operation	01JAN2006	31JAN2006	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091049	Endocrine disorders	Basedow's disease	01JAN1979	31JAN1980	N
		Infections and infestations	Herpes virus infection	01JAN1980		Y
		Investigations	Colonoscopy	01JAN2013		Y
		Surgical and medical procedures	Neck surgery	01DEC2018	01DEC2018	N
			Spinal fusion surgery	01JAN2020		Y
	C4591001 1109 11091050	Investigations	Colonoscopy	01JAN2010	31JAN2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31JAN2015	N
			Cholecystectomy	01JAN1995	31JAN1995	N
			Polypectomy	01JAN2018	31JAN2018	N
			Vasectomy	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1109 11091051	Endocrine disorders	Hypothyroidism	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2013	01JAN2013	N
			Cardiac pacemaker insertion	01JAN2011		Y
			Coronary arterial stent insertion	01JAN2012	01JAN2012	N
	C4591001 1109 11091053	Cardiac disorders	Arrhythmia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1971	31JAN1971	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1971	31JAN1971	N
			Bunion operation	03JAN2000	03JAN2000	N
			Female sterilisation	01JAN1973		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1109 11091064	Metabolism and nutrition disorders	Hypercholesterolaemia	31JAN2010		Y
	C4591001 1109 11091065	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1109 11091069	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Infections and infestations	Appendicitis	01JAN1970	31JAN1970	N
		Investigations	Colonoscopy	01JAN2015	31JAN2015	N
			Endoscopy	01JAN2015	31JAN2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2000	31JAN2000	N
		Psychiatric disorders	Depression	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Renal impairment	01JAN2013		Y
		Surgical and medical procedures	Appendectomy	01JAN1970	31JAN1970	N
			Hernia repair	01JAN2002	31JAN2002	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1109 11091072	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Colonoscopy	01JAN2015	31JAN2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31JAN2016	N
		Surgical and medical procedures	Corneal transplant	01JAN1992	31JAN1992	N
			Eye operation	01JAN2015	31JAN2015	N
			Rotator cuff repair	01JAN2009	31JAN2009	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091073	Cardiac disorders	Myocardial infarction	01JAN2001	31JAN2001	N
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Investigations	Colonoscopy	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012		Y
			Hypercholesterolaemia	01JAN2001		Y
		Surgical and medical procedures	Knee operation	01JAN1976		Y
			Wrist surgery	01JAN1994	31JAN1994	N
	C4591001 1109 11091074	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Bladder operation	01JAN2004		Y
			Cardiac ablation	01JAN2005	31JAN2005	N
			Cholecystectomy	01JAN2001	31JAN2001	N
			Hernia repair	01JAN2002	31JAN2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091076	Hepatobiliary disorders	Cholecystitis	01JAN2014	31JAN2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31JAN2014	N
			Vasectomy	01JAN1979	31JAN1979	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091079	Investigations	Arthroscopy	01JAN2000	31JAN2000	N
				01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	21NOV2019		Y
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1989	31JAN1989	N
			Spinal operation	01JAN2001	31JAN2001	N
			Vasectomy	01JAN1986	31DEC1986	N
	C4591001 1109 11091081	Psychiatric disorders	Insomnia	01JAN1990		Y
		Surgical and medical procedures	Limb operation	01JAN2020	01JAN2020	N
			Spinal laminectomy	01SEP2002	30SEP2002	N
			Umbilical hernia repair	01JUL1970	01JUL1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091084	Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091085	Hepatobiliary disorders	Cholecystitis	01JAN2019	01JAN2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Injury, poisoning and procedural complications	Animal bite	01JAN1985	01JAN1985	N
		Nervous system disorders	Narcolepsy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	01JAN2019	N
			Ovarian cystectomy	01JAN1981	01JAN1981	N
			Wound closure	01JAN1985	01JAN1985	N
	C4591001 1109 11091087	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1109 11091088	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091089	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Tendon sheath incision	01JAN2017		Y
	C4591001 1109 11091090	Infections and infestations	Oral herpes	01JAN1970		Y
			Tuberculosis	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1975		Y
			Post herpetic neuralgia	01JAN2002	01JAN2002	N
			Tremor	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1998		Y
		Surgical and medical procedures	Hernia repair	01JAN2004	01JAN2004	N
				01JAN2005	31DEC2005	N
	C4591001 1109 11091091	Endocrine disorders	Diabetes insipidus	01OCT2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01OCT2011	01OCT2011	N
		Surgical and medical procedures	Pituitary tumour removal	01OCT2011	01OCT2011	N
	C4591001 1109 11091093	Surgical and medical procedures	Aortic valve repair	01JAN2011	01JAN2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1109 11091094	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Renal cyst	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091095	Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2005	31DEC2005	N
				01JAN2017	31DEC2017	N
	C4591001 1109 11091096	Gastrointestinal disorders	Constipation	10JAN1995		Y
			Haemorrhoids	10JAN1995		Y
			Large intestine polyp	10JAN2017	10JAN2017	N
		Immune system disorders	Seasonal allergy	10JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	10JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10JAN2000		Y
			Back pain	10JAN2017		Y
			Osteoarthritis	10JAN2015		Y
				10JAN2017		Y
			Osteoporosis	10JAN2014		Y
			Spinal osteoarthritis	10JAN2015		Y
		Social circumstances	Postmenopause	10JAN1989		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2011	01JAN2011	N
			Varicose vein operation	10JAN2002	10JAN2002	N
	C4591001 1109 11091097	Gastrointestinal disorders	Constipation	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Neck pain	01JAN1980		Y
			Osteoarthritis	01JAN2010		Y
				01JAN2016		Y
		Nervous system disorders	Facial paralysis	01JAN2009		Y
			Tremor	01JAN2005		Y
		Renal and urinary disorders	Nocturia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31JAN2015	N
			Fracture treatment	01JAN2010	31JAN2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal fusion surgery	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1109 11091101	Immune system disorders	Seasonal allergy	01JAN1971		Y
		Metabolism and nutrition disorders	Gout	01JAN1985		Y
			Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1995		Y
			Spinal osteoarthritis	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Spinal nerve stimulator implantation	01JAN2014	31DEC2014	N
			Thyroidectomy	01JAN2000	01JAN2000	N
	C4591001 1109 11091104	Vascular disorders	Hypertension	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1976	31JAN1976	N
			Metabolic surgery	01JAN1996		Y
	C4591001 1109 11091107	Vascular disorders	Hypertension	01JAN2010		Y
		Cardiac disorders	Arrhythmia	01JAN2010		Y
		General disorders and administration site conditions	Hernia	01JAN2000	31JAN2000	N
		Surgical and medical procedures	Hernia repair	01JAN2000	31JAN2000	N
			Sinus operation	01JAN2000	31JAN2000	N
	C4591001 1109 11091111	Gastrointestinal disorders	Diverticulum	01JAN1998		Y
			Haemorrhoids	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1962	31JAN1962	N
		Investigations	Colonoscopy	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1997	31JAN1997	N
		Psychiatric disorders	Anxiety	01JUN2018		Y
			Depression	01JAN1995		Y
			Post-traumatic stress disorder	01JUN2018		Y
		Reproductive system and breast disorders	Cystocele	01OCT2019		Y
			Rectocele	01OCT2019		Y
		Surgical and medical procedures	Appendectomy	01JAN1962	31JAN1962	N
			Cataract operation	01OCT2019	31OCT2019	N
			Female sterilisation	01JAN1988	31JAN1988	N
			Limb operation	01JAN2002	31JAN2002	N
				01JAN2006	31JAN2006	N
			Polypectomy	01JAN2020	31JAN2020	N
		Vascular disorders	Deep vein thrombosis	01JAN2014		Y
			Hot flush	01JAN2017		Y
			Hypertension	01JAN2000		Y
	C4591001 1109 11091113	Infections and infestations	Vaginal infection	01JAN2000		Y
		Investigations	Colonoscopy	01JAN2014	31JAN2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31JAN2019	N
			Squamous cell carcinoma	01JAN2020	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091114	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
		Investigations	Colonoscopy	01JAN2013	31JAN2013	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2013		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1109 11091116	Surgical and medical procedures	Shoulder operation	01JAN2008	31JAN2008	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31JAN2016	N
			Hysterectomy	01JUN2015	30JUN2015	N
			Joint arthroplasty	01JUN2012	30JUN2012	N
	C4591001 1109 11091118	Injury, poisoning and procedural complications	Hand fracture	01JAN2020	31JAN2020	N
		Investigations	Arthroscopy	01JAN1997	31JAN1997	N
			Colonoscopy	01JAN2017	31JAN2017	N
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Ear tube insertion	01JAN2010	31JAN2010	N
			Hernia repair	01JAN2006	31JAN2006	N
			Nasal septal operation	01JAN1983	31JAN1983	N
			Vasectomy	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091119	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Colonoscopy	01JAN2016	31JAN2016	N
			Endoscopy	01JAN2016	31JAN2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31JAN2000	N
		Nervous system disorders	Migraine	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31JAN2002	N
			Mastectomy	01JAN2000	31JAN2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091120	Investigations	Cardiac murmur	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001		Y
			Spinal osteoarthritis	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1109 11091121	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
			Osteoporosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1988	31JAN1988	N
		Renal and urinary disorders	Bladder prolapse	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1980	31JAN1980	N
			Wrist surgery	01JAN2002	31JAN2002	N
	C4591001 1109 11091123	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Investigations	Colonoscopy	01JAN2008	31JAN2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Surgical and medical procedures	Colon operation	01JAN2008		Y
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091124	Eye disorders	Glaucoma	01JAN1984		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
	C4591001 1109 11091128	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31JAN2005	N
			Squamous cell carcinoma	01JAN2009	31JAN2009	N
				01JAN2011	31JAN2011	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2005	31JAN2005	N
				01JAN2006	31JAN2006	N
			Intervertebral disc operation	01JAN2017	31JAN2017	N
			Umbilical hernia repair	01JAN1980	31JAN1980	N
	C4591001 1109 11091130	Cardiac disorders	Arrhythmia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Injury, poisoning and procedural complications	Splenic injury	01JAN1956	01JAN1956	N
		Investigations	Colonoscopy	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31JAN2009	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2009	31JAN2009	N
			Hysterectomy	01JAN1975		Y
			Splenectomy	01JAN1956	31JAN1956	N
			Umbilical hernia repair	01JAN2019	31JAN2019	N
	C4591001 1109 11091131	Infections and infestations	Hepatitis A	01JAN1989		Y
			Sinusitis	01JAN1980		Y
		Investigations	Colonoscopy	01JAN2009	31JAN2009	N
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Appendectomy	01JAN2012	31JAN2012	N
			Bunion operation	01JAN1992	31JAN1992	N
			Keratomileusis	21JAN2000	21JAN2000	N
			Knee operation	01JAN2011	31JAN2014	N
	C4591001 1109 11091133	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Infections and infestations	Diverticulitis	01MAR2014	31MAR2014	N
		Investigations	Colonoscopy	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
			Spinal osteoarthritis	01APR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1969	31DEC1969	N
		Nervous system disorders	Transient ischaemic attack	01MAR2014	01MAR2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Hernia repair	01APR2017	01APR2017	N
		Vascular disorders	Hypertension	01MAR2013	01JUL2016	N
	C4591001 1109 11091135	Surgical and medical procedures	Hysterectomy	16OCT1990	16OCT1990	N
	C4591001 1109 11091138	Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091139	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2005		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2014	31JAN2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091140	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2019		Y
			Type 2 diabetes mellitus	01MAR2019		Y
		Vascular disorders	Hypertension	01MAR2019		Y
			Thrombosis	01MAR2019		Y
	C4591001 1109 11091141	Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Neck injury	01JAN2016		Y
			Nerve injury	01JAN2016		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01APR2018		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1967	31DEC1967	N
			Hysterectomy	01JAN1988	31DEC1988	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck surgery	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1967	31DEC1967	N
			Urinary bladder suspension	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01APR2018		Y
	C4591001 1109 11091142	Investigations	Colonoscopy	01FEB2019	28FEB2019	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1983	31JAN1983	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1988	31JAN1988	N
			Female sterilisation	01JAN1989	31JAN1989	N
			Gastric operation	01JAN2014	31JAN2014	N
	C4591001 1109 11091143	Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091149	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1981	11JAN1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1934	31JAN1981	N
			Oophorectomy	01JAN1981	31JAN1981	N
	C4591001 1109 11091151	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091152	Infections and infestations	Appendicitis	01JAN2018	31JAN2018	N
		Investigations	Colonoscopy	01JAN2018	31JAN2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endoscopy	01JAN2018	31JAN2018	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
				01JAN2013		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012	31JAN2012	N
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31JAN2018	N
			Knee arthroplasty	01JAN2011	31JAN2011	N
			Prostatectomy	01JAN2012	31JAN2012	N
			Shoulder operation	01JAN2006	31JAN2006	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091153	Psychiatric disorders	Major depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31JAN1987	N
	C4591001 1109 11091154	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31JAN2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091155	Investigations	Colonoscopy	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31JAN2010	N
	C4591001 1109 11091157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1965	31JAN1965	N
		Investigations	Colonoscopy	01JAN2018	31JAN2018	N
			Endoscopy	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31JAN1965	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091161	Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1109 11091162	Infections and infestations	Hepatitis C	01JAN2014		Y
		Investigations	Colonoscopy	01JAN2018	31JAN2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
			Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1109 11091163	Endocrine disorders	Thyroid disorder	01JAN2000		Y
		Investigations	Colonoscopy	01JAN2018	31JAN2018	N
		Nervous system disorders	Essential tremor	01JAN2017		Y
		Surgical and medical procedures	Colectomy	01JAN2017	31JAN2017	N
			Hernia repair	01JAN2002	31JAN2002	N
			Joint dislocation reduction	12JUN2020	12JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Polypectomy	01JAN2018	31JAN2018	N
	C4591001 1109 11091164	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1109 11091165	Investigations	Colonoscopy	01JAN2020	01JAN2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Surgical and medical procedures	Knee arthroplasty	03OCT2013	03OCT2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091166	Endocrine disorders	Hypogonadism	01JAN2015		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2020		Y
			Gastrooesophageal reflux disease	10JAN2002		Y
			Irritable bowel syndrome	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Investigations	Colonoscopy	01JAN2015	31JAN2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
			Osteoarthritis	10JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016		Y
			Restless legs syndrome	10JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Insomnia	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31JAN2017	N
			Knee operation	01JAN2010	31JAN2010	N
	C4591001 1109 11091167	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUL1961		Y
		Immune system disorders	Seasonal allergy	01JAN2009		Y
		Investigations	Endoscopy	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992		Y
		Surgical and medical procedures	Caesarean section	01JAN1983	31JAN1983	N
			Hysterectomy	01JAN2000	31JAN2000	N
	C4591001 1109 11091168	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endocrine neoplasm malignant	01JAN2007	31JAN2008	N
	C4591001 1109 11091169	Gastrointestinal disorders	Inguinal hernia	13APR2012	13APR2012	N
		Investigations	Colonoscopy	01JAN2017	31JAN2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	17SEP2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01APR2014	01APR2014	N
			Cholecystectomy	01JAN1983	01JAN1983	N
			Inguinal hernia repair	13APR2012	13APR2012	N
			Shoulder operation	01OCT2013	01OCT2013	N
			Sterilisation	01JAN1979	01JAN1979	N
		Vascular disorders	Deep vein thrombosis	01JAN2002	28FEB2002	N
			Hypertension	01JAN2002		Y
	C4591001 1109 11091170	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091171	Immune system disorders	Seasonal allergy	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31JAN2001	N
			Oophorectomy	01JUL1999	01JUL1999	N
			Polypectomy	01JAN1985	31JAN1985	N
			Colonoscopy	01JAN2010	31JAN2010	N
	C4591001 1109 11091172	Investigations	Colonoscopy	01JAN2010	31JAN2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1109 11091173	Investigations	Colonoscopy	01JAN2000	31JAN2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Stent placement	01JAN2000	01JAN2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091174	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	31JAN2020	N
			Umbilical hernia	01JAN1966	31JAN1966	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006	31JAN2020	N
			Back pain	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hernia repair	01JAN1966	31JAN1966	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091175	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hot flush	01JAN2000		Y
			Hypertension	01JAN2000		Y
	C4591001 1109 11091177	Vascular disorders	Deep vein thrombosis	01JAN2002	31DEC2005	N
	C4591001 1109 11091179	Gastrointestinal disorders	Umbilical hernia	01JAN1990	31DEC1990	N
		Infections and infestations	Appendicitis	18JUL1999	18JUL1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
				01JAN2011		Y
			Neck pain	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01NOV2017		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	18JUL1999	18JUL1999	N
			Carpal tunnel decompression	01JAN2017	01JAN2017	N
			Hysterectomy	31DEC1998	31DEC1998	N
	C4591001 1109 11091181	Cardiac disorders	Bundle branch block left	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Endometrial ablation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091182	Hepatobiliary disorders	Cholecystitis	01JAN2013	01JAN2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN2011	24OCT2011	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	01JAN2013	N
			Spinal fusion surgery	01JAN2001	01JAN2001	N
	C4591001 1109 11091188	Hepatobiliary disorders	Cholecystitis	01JAN2010	01JAN2010	N
		Immune system disorders	Seasonal allergy	01JAN1956		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	01JAN2010	N
			Muscle operation	01JAN2007	01JAN2007	N
	C4591001 1109 11091189	Eye disorders	Cataract	01OCT2019	31OCT2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1988	31DEC1988	N
				01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091191	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Fracture treatment	01JAN1984	01JAN1984	N
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	01JAN2015		Y
	C4591001 1109 11091192	Endocrine disorders	Hypothyroidism	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
			Herpes simplex	01JAN1973		Y
			Herpes zoster	01JAN2014	31DEC2014	N
			Pneumonia	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2012	31DEC2012	N
			Rib fracture	01JAN2005	31DEC2005	N
				01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1982	31DEC1982	N
			Squamous cell carcinoma	01JAN1982	31DEC1982	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1982		Y
			Urticaria	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
	C4591001 1109 11091193	Eye disorders	Cataract	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
	C4591001 1109 11091194	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1968	01JAN1968	N
		Investigations	Arthroscopy	01JAN2016	01JAN2016	N
			Biopsy breast	01JAN1981	01JAN1981	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1968	01JAN1968	N
	C4591001 1109 11091195	Infections and infestations	Appendicitis	01JAN2010	01JAN2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	20APR2019		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Appendectomy	01JAN2010	01JAN2010	N
			Tenoplasty	01JAN2017	01JAN2017	N
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1109 11091196	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1109 11091200	Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091201	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	01JAN2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091202	Cardiac disorders	Myocardial infarction	01JAN2011	01JAN2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hairy cell leukaemia	01JAN1999	01JAN1999	N
				01JAN2013	01JAN2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2013	01JAN2013	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091203	Metabolism and nutrition disorders	Hypercholesterolaemia	10AUG2011		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10AUG2012		Y
			Spinal osteoarthritis	10AUG2012		Y
		Nervous system disorders	Diabetic neuropathy	10AUG2011		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
			Sleep apnoea syndrome	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1109 11091206	Eye disorders	Dry eye	01JAN2012		Y
		Investigations	Arthroscopy	01JAN2010	01JAN2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1998		Y
		Surgical and medical procedures	Knee operation	01JAN2000	01JAN2000	N
			Vasectomy	01JAN1976	01JAN1976	N
		Vascular disorders	Hypertension	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091207	Infections and infestations	Herpes simplex	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	01JAN2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Inguinal hernia repair	01JAN2013	31DEC2013	N
			Prostatectomy	01JAN2017	01JAN2017	N
			Vasectomy	01JAN1996	01JAN1996	N
	C4591001 1109 11091208	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Investigations	Arthroscopy	01JAN1963	31DEC1963	N
				01JAN1964	31DEC1964	N
				01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998	01JAN1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	01JAN1998	N
	C4591001 1109 11091209	Cardiac disorders	Arrhythmia	01JAN2015		Y
		Endocrine disorders	Thyroid mass	01JAN2014		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Deep vein thrombosis	01JAN2014	01JAN2014	N
	C4591001 1109 11091210	Surgical and medical procedures	Vasectomy	01JAN2005	01JAN2005	N
	C4591001 1109 11091212	Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01MAY2000		Y
	C4591001 1109 11091217	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1987	31DEC1987	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1109 11091218	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31JUL2010	N
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1109 11091220	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091222	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Constipation	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoids	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JUN2017		Y
		Infections and infestations	Appendicitis	01JAN1943	31DEC1943	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Muscle spasms	01JAN2014		Y
		Nervous system disorders	Sciatica	01JUL2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1950	31DEC1950	N
			Appendicectomy	01JAN1943	31DEC1943	N
			Cataract operation	01JAN2005	31DEC2005	N
			Haemorrhoid operation	01JAN1975		Y
			Hip arthroplasty	01JAN2006	31DEC2006	N
			Knee arthroplasty	01JAN2004	31DEC2004	N
			Prostatic operation	12DEC2018	12DEC2018	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01MAY2017	31MAY2017	N
			Spinal nerve stimulator implantation	01FEB2012	29FEB2012	N
				01JUN2008	30JUN2008	N
			Spinal nerve stimulator removal	06MAY2016	06MAY2016	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Umbilical hernia repair	01DEC2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091224	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091227	Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1109 11091229	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091233	Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Social circumstances	Postmenopause	20SEP2010		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2001	31DEC2001	N
	C4591001 1109 11091235	Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091237	Blood and lymphatic system disorders	Anaemia	01JAN2014		Y
		Endocrine disorders	Hyperthyroidism	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1109 11091239	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995	01JAN1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013	01JAN2013	N
			Skin neoplasm excision	01JAN2015	01JAN2015	N
	C4591001 1109 11091240	Investigations	Arthroscopy	01JAN1996	01JAN1996	N
			Colonoscopy	01JAN2017	01JAN2017	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	01JAN2018	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1109 11091241	Surgical and medical procedures	Spinal operation	01JAN2016	01JAN2016	N
	C4591001 1109 11091243	Metabolism and nutrition disorders	Hypercholesterolaemia	02MAY2004		Y
	C4591001 1109 11091244	Cardiac disorders	Supraventricular tachycardia	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	01JAN2015	N
		Vascular disorders	Raynaud's phenomenon	01JAN2015		Y
	C4591001 1109 11091247	Nervous system disorders	Neuralgia	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2020		Y
	C4591001 1109 11091248	Investigations	Colonoscopy	01JAN2017	31DEC2017	N
	C4591001 1109 11091253	Cardiac disorders	Arrhythmia	07JAN2020		Y
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
			Endoscopy	01JAN2019	31DEC2019	N
	C4591001 1109 11091254	Endocrine disorders	Hypothyroidism	01JAN2012		Y
	C4591001 1109 11091255	Nervous system disorders	Parkinson's disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091257	Endocrine disorders	Hypogonadism	01JAN2016		Y
		Surgical and medical procedures	Polypectomy	01JAN2019		Y
	C4591001 1109 11091262	Cardiac disorders	Supraventricular tachycardia	01MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2013		Y
			Osteopenia	01DEC2018		Y
			Plantar fascial fibromatosis	01JAN2016		Y
		Vascular disorders	Hypotension	01DEC2018		Y
	C4591001 1109 11091263	Social circumstances	Postmenopause	01JAN2006	31DEC2006	N
	C4591001 1109 11091264	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1109 11091265	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Varices oesophageal	01JAN2015		Y
		Hepatobiliary disorders	Hepatobiliary disease	01JAN2015		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Cardiac operation	01JAN2005	01JAN2005	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lung operation	01JAN1994	01JAN1994	N
			Pharyngeal operation	01JAN1979	01JAN1979	N
	C4591001 1109 11091269	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2020		Y
		Nervous system disorders	Amnesia	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN1972		Y
			Sleep disorder	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Sinus operation	13MAY2019	13MAY2019	N
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1109 11091270	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Glaucoma	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Deep vein thrombosis	01JAN2016	31DEC2016	N
	C4591001 1109 11091271	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Gouty arthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1109 11091272	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2009		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2012		Y
			Reaction to food additive	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091273	Eye disorders	Cataract	01JAN2018	31AUG2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091274	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091276	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	01DEC2012	N
		Nervous system disorders	Migraine	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	01JAN2019	N
	C4591001 1109 11091277	Immune system disorders	Drug hypersensitivity	(b) (6) 1963		Y
		Surgical and medical procedures	Vasectomy	01JUN1999	01JUN1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091279	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1109 11091280	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Investigations	Heart rate irregular	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091281	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Mastectomy	01JAN2017	31DEC2017	N
	C4591001 1109 11091282	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091283	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	26FEB2013	31DEC2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cardiac ablation	01JUN2019	01JUN2019	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1109 11091284	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01DEC2019	31DEC2019	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1109 11091285	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091286	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2016		Y
		Nervous system disorders	Neuropathy peripheral	01NOV2018		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1109 11091289	Gastrointestinal disorders	Intestinal obstruction	01JAN1979	31DEC1979	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1988	31DEC1988	N
			Malignant melanoma	01APR2019	01APR2019	N
			Squamous cell carcinoma	01JAN1988	31DEC1988	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Intestinal resection	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091290	Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2004	31DEC2004	N
				01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hot flush	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091291	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1109 11091292	Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1109 11091293	Cardiac disorders	Cardiac failure congestive	01JAN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		General disorders and administration site conditions	Ulcer	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	02SEP2020	N
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Surgical and medical procedures	Heart valve replacement	01JAN2013	01JAN2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1109 11091294	Immune system disorders	Hypersensitivity	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091295	Gastrointestinal disorders	Haemorrhoids	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091296	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1109 11091297	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN1975		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	01JAN1975	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1109 11091298	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091299	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
			Osteopenia	01JUL2020		Y
			Spinal osteoarthritis	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1978		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091300	Hepatobiliary disorders	Cholecystitis	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
	C4591001 1109 11091302	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091305	Gastrointestinal disorders	Constipation	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1109 11091306	Endocrine disorders	Hypothyroidism	01JAN1979		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	01JAN2005	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	01JAN2005	N
	C4591001 1109 11091307	Gastrointestinal disorders	Barrett's oesophagus	01JAN2014		Y
			Gastrooesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Renal impairment	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
			Oophorectomy bilateral	01JAN2016	31DEC2016	N
	C4591001 1109 11091312	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hyperlipidaemia	01JAN2000		Y
	C4591001 1109 11091313	Surgical and medical procedures	Coronary arterial stent insertion	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091317	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1109 11091318	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091322	Immune system disorders	Drug hypersensitivity	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1109 11091323	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1109 11091325	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091327	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1109 11091328	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1109 11091334	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01OCT2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1109 11091341	Gastrointestinal disorders	Peptic ulcer	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1109 11091342	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Investigations	Human papilloma virus test positive	01JAN1966	31DEC1966	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Parkinson's disease	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1109 11091344	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1109 11091345	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091346	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
			Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1965		Y
	C4591001 1109 11091347	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091348	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN1998		Y
				01JAN2000		Y
				01JAN2006		Y
				01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
		Nervous system disorders	Transient ischaemic attack	01DEC2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1109 11091351	Immune system disorders	Seasonal allergy	01JAN1947		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950		Y
		Social circumstances	Postmenopause	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091354	Metabolism and nutrition disorders	Gout	01JAN2020		Y
			Hypercholesterolaemia	01JAN2010		Y
	C4591001 1109 11091356	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1109 11091358	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091359	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
	C4591001 1109 11091363	Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091364	Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091365	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1109 11091366	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Surgical and medical procedures	Gastric bypass	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1109 11091367	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091368	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091369	Immune system disorders	Allergy to arthropod sting	01JAN2012		Y
	C4591001 1109 11091371	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1109 11091374	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1109 11091376	Ear and labyrinth disorders	Deafness bilateral	01JAN2016		Y
		Eye disorders	Eye inflammation	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
		Nervous system disorders	Epilepsy	01JAN1996		Y
		Psychiatric disorders	Bipolar disorder	01JAN1994		Y
	C4591001 1109 11091377	Immune system disorders	Seasonal allergy	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1109 11091379	Eye disorders	Glaucoma	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2011	31JAN2011	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
	C4591001 1109 11091380	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
	C4591001 1109 11091381	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091384	Cardiac disorders	Myocardial infarction	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091385	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091386	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091387	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1109 11091388	Social circumstances	Postmenopause	01JAN1994		Y
	C4591001 1109 11091389	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
	C4591001 1109 11091390	Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1109 11091394	Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091398	Infections and infestations	Herpes simplex	01JAN1978		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091399	Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1995		Y
	C4591001 1109 11091401	Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1109 11091405	Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1109 11091407	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01NOV2011	30NOV2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091408	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1995		Y
			Rubber sensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1109 11091409	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1109 11091410	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
				01JAN1980		Y
	C4591001 1109 11091411	Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091413	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1109 11091421	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1109 11091423	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1109 11091429	Musculoskeletal and connective tissue disorders	Osteoporosis	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1109 11091430	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091431	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091433	Investigations	Biopsy breast normal	01JUN2019	01JUN2019	N
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1109 11091438	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091443	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Hypogonadism	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Insomnia	01JAN1995		Y
		Vascular disorders	Deep vein thrombosis	01JAN2018		Y
			Hypertension	01JAN2018		Y
	C4591001 1109 11091445	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091447	Injury, poisoning and procedural complications	Nerve injury	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Surgical and medical procedures	Spinal operation	01AUG2011	31AUG2011	N
			Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1109 11091449	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1109 11091451	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2000	01JAN2000	N
	C4591001 1109 11091452	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1949		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1957		Y
		Surgical and medical procedures	Hysterectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091454	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1109 11091456	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Deep vein thrombosis	01JAN1994		Y
			Hypertension	01MAR2020		Y
	C4591001 1109 11091458	Social circumstances	Postmenopause	10JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	10JAN2014	10JAN2014	N
			Coronary artery bypass	10JAN2008	10JAN2008	N
	C4591001 1109 11091460	Nervous system disorders	Parkinson's disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091461	Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1109 11091463	Gastrointestinal disorders	Gastritis	01JAN2020		Y
			Pancreatitis	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2012		Y
	C4591001 1109 11091464	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2007		Y
			Insomnia	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1109 11091469	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091470	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091471	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1109 11091474	General disorders and administration site conditions	Oedema peripheral	01JAN1996		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091475	Cardiac disorders	Angina pectoris	01JAN1992		Y
			Coronary artery disease	01JAN1992		Y
		Endocrine disorders	Addison's disease	01JAN2016		Y
		General disorders and administration site conditions	Oedema	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1986		Y
		Psychiatric disorders	Depression	01JAN1948		Y
		Renal and urinary disorders	Nephritis	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Seborrhoea	01JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JAN1998	31DEC1998	N
			Vasectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1109 11091480	Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1109 11091481	Infections and infestations	Fungal skin infection	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1976		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1109 11091482	Cardiac disorders	Atrial fibrillation	01JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Cardiac ablation	15SEP2019	15SEP2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091486	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091487	Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1109 11091490	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	31DEC1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1109 11091491	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091493	Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01MAY2004	31MAY2004	N
	C4591001 1109 11091500	Infections and infestations	Herpes simplex	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1109 11091501	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1109 11091503	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1109 11091504	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1109 11091505	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
	C4591001 1109 11091510	Gastrointestinal disorders	Gastroesophageal reflux disease	11SEP2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1109 11091519	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
	C4591001 1109 11091527	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1109 11091533	Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1109 11091537	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1109 11091542	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1109 11091543	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
	C4591001 1109 11091544	Social circumstances	Postmenopause	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1109 11091552	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
			Irritable bowel syndrome	01JAN2011		Y
		Infections and infestations	Hepatitis C	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1109 11091558	Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Hepatitis C	01JAN2005	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1109 11091559	Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091560	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	(b) (6) 1941		Y
	C4591001 1109 11091561	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1109 11091562	Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1109 11091564	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1110 11101003	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Paraesthesia	01JAN2019		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2012		Y
	C4591001 1110 11101004	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
	C4591001 1110 11101005	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1110 11101008	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1110 11101014	Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2014	N
	C4591001 1110 11101015	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1110 11101017	Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1110 11101018	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1110 11101023	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1110 11101024	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101029	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2016		Y
			Type 2 diabetes mellitus	01JUN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JUN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JUN2016		Y
		Vascular disorders	Hypertension	01JUN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101031	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Sleep disorder	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101036	Cardiac disorders	Atrial fibrillation	01SEP2019		Y
		Social circumstances	Postmenopause	01JAN1992		Y
	C4591001 1110 11101043	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101046	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
	C4591001 1110 11101047	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2017		Y
		Nervous system disorders	Neuralgia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101048	Nervous system disorders	Seizure	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1110 11101049	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101051	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
	C4591001 1110 11101055	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JUL2000		Y
	C4591001 1110 11101056	Infections and infestations	Herpes simplex	01JAN2010		Y
		Psychiatric disorders	Affective disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1110 11101060	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01MAY2018		Y
	C4591001 1110 11101061	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1110 11101063	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01FEB2016	29FEB2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101067	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1110 11101070	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1110 11101071	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101073	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Renal and urinary disorders	Urinary retention	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101074	Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Infections and infestations	Diverticulitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Colectomy	04AUG2011	04AUG2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1110 11101079	Eye disorders	Glaucoma	01SEP2017		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1110 11101087	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1992	31DEC1992	N
				01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
				01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1110 11101088	Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Cardiac disorders	Arrhythmia	01FEB2020		Y
		Eye disorders	Glaucoma	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101089	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
		Nervous system disorders	Tremor	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Prostatectomy	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101090	Immune system disorders	Hypersensitivity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1110 11101093	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 1953	17JAN2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Aortic valve replacement	17JAN2017	17JAN2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101097	Injury, poisoning and procedural complications	Ankle fracture	29JUN2018	29JUN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	01JUL2010	N
		Surgical and medical procedures	Abdominoplasty	02AUG2005	02AUG2005	N
			Ankle operation	29JUN2018	29JUN2018	N
			Caesarean section	19SEP1999	19SEP1999	N
			Intervertebral disc operation	01JUL2010	01JUL2010	N
	C4591001 1110 11101098	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1110 11101101	Gastrointestinal disorders	Umbilical hernia	01JAN2017		Y
	C4591001 1110 11101103	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101108	Gastrointestinal disorders	Constipation	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Dust allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Schizophrenia	01JAN2014		Y
		Renal and urinary disorders	Polyuria	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1110 11101109	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101112	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Postmenopause	01NOV2010		Y
	C4591001 1110 11101115	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1110 11101118	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101119	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101120	Hepatobiliary disorders	Cholecystitis	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	16OCT2018	N
				01SEP2000	30SEP2010	N
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Knee arthroplasty	01SEP2010	30SEP2010	N
				16OCT2018	16OCT2018	N
		Vascular disorders	Hypertension	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101121	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1110 11101124	Congenital, familial and genetic disorders	Type V hyperlipidaemia	08MAR2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1110 11101128	Musculoskeletal and connective tissue disorders	Synovial cyst	01FEB2020	16FEB2021	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101129	Ear and labyrinth disorders	Vertigo	01JUL2020	31JUL2020	N
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1110 11101130	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1110 11101133	Endocrine disorders	Hyperthyroidism	01NOV2015		Y
		Eye disorders	Cataract	01JAN2001	31DEC2001	N
			Diabetic retinopathy	23JUL2019		Y
		Gastrointestinal disorders	Faeces soft	01JAN2015		Y
			Gastrooesophageal reflux disease	28MAY2017		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	29NOV2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2001	31DEC2001	N
			Knee operation	01JAN1992	31DEC1992	N
	C4591001 1110 11101134	Immune system disorders	Hypersensitivity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01FEB2008	31AUG2008	N
		Surgical and medical procedures	Breast conserving surgery	01AUG2008	31AUG2008	N
	C4591001 1110 11101135	Psychiatric disorders	Major depression	01DEC2019		Y
	C4591001 1110 11101136	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2018	05AUG2019	N
		Psychiatric disorders	Sleep disorder	01JUN2020		Y
		Surgical and medical procedures	Knee arthroplasty	05AUG2019	05AUG2019	N
	C4591001 1110 11101137	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Gastrointestinal disorders	Pancreatic failure	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101138	Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1110 11101140	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1110 11101142	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Renal and urinary disorders	Nephrolithiasis	01SEP2005	31OCT2005	N
		Surgical and medical procedures	Renal stone removal	01OCT2005	31OCT2005	N
				01SEP2005	30SEP2005	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1110 11101143	Cardiac disorders	Diastolic dysfunction	13MAR2020		Y
		Eye disorders	Diabetic retinopathy	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2005		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101147	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1110 11101150	Eye disorders	Glaucoma	01MAY2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05JUN2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101152	Injury, poisoning and procedural complications	Gun shot wound	01APR1992	01APR1992	N
		Surgical and medical procedures	Abdominal operation	01APR1992	01APR1992	N
	C4591001 1110 11101153	Infections and infestations	Appendicitis	01JUL1972	31JUL1972	N
		Surgical and medical procedures	Appendicectomy	01JUL1972	31JUL1972	N
	C4591001 1110 11101159	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1953		Y
	C4591001 1110 11101160	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1110 11101166	Gastrointestinal disorders	Gastritis	01JAN2000		Y
		Infections and infestations	Hepatitis C	01JAN2003	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1110 11101169	Infections and infestations	Appendicitis	01JUL2011	31JUL2011	N
		Surgical and medical procedures	Appendicectomy	01JUL2011	31JUL2011	N
	C4591001 1110 11101170	Hepatobiliary disorders	Cholecystitis	01JAN1980	31DEC1980	N
	C4591001 1110 11101171	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Glaucoma	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1110 11101172	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Alcohol use disorder	01JAN1979		Y
			Anxiety	01JAN2019		Y
			Cyclothymic disorder	01MAR2015		Y
	C4591001 1110 11101173	Congenital, familial and genetic disorders	Urethral valves	01JUN1978	30JUN1978	N
		Injury, poisoning and procedural complications	Joint dislocation	01AUG1980	31AUG1980	N
		Surgical and medical procedures	Joint dislocation reduction	01AUG1980	31AUG1980	N
			Urethral operation	01JUN1978	30JUN1978	N
	C4591001 1110 11101176	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2014		Y
		Social circumstances	Postmenopause	14NOV1991		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101178	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101179	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101184	Eye disorders	Cataract	01JAN2009	31DEC2011	N
					31DEC2012	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1110 11101185	Renal and urinary disorders	Hydronephrosis	01JAN1996		Y
			Nephrolithiasis	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	12JUL1994	12JUL1994	N
			Nephrectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101188	Cardiac disorders	Coronary artery disease	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1110 11101190	Hepatobiliary disorders	Cholelithiasis	31AUG2019	01SEP2019	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01AUG2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	02MAR1975	30JUN2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01SEP2019	01SEP2019	N
			Hysterectomy	01JUN2006	30JUN2006	N
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1110 11101191	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Appendicitis	01FEB2017	28FEB2017	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	25MAR2009	N
		Surgical and medical procedures	Appendectomy	01FEB2017	28FEB2017	N
			Hysterectomy	25MAR2009	25MAR2009	N
	C4591001 1110 11101192	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1110 11101193	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
	C4591001 1110 11101197	Injury, poisoning and procedural complications	Meniscus injury	01DEC1995	31DEC1995	N
				01JAN1995	31DEC1995	N
		Surgical and medical procedures	Knee operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1110 11101202	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101207	Gastrointestinal disorders	Umbilical hernia	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Umbilical hernia repair	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101208	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1980		Y
	C4591001 1110 11101209	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2005	31DEC2005	N
				01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
			Lipoma excision	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101210	Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Surgical and medical procedures	Cataract operation	01APR2016	30APR2016	N
				01FEB2017	28FEB2017	N
			Retinopexy	10OCT2019	10OCT2019	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1110 11101215	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
		Social circumstances	Menopause	01JAN1978		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1110 11101218	Renal and urinary disorders	Cystitis interstitial	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1110 11101225	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2019		Y
	C4591001 1110 11101228	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1110 11101232	Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Infections and infestations	Infectious mononucleosis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1110 11101233	Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Surgical and medical procedures	Face lift	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1110 11101239	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1110 11101241	Gastrointestinal disorders	Inguinal hernia	01JAN1971	31DEC1971	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1967		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1968		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1971	31DEC1971	N
	C4591001 1110 11101245	Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN1994		Y
	C4591001 1110 11101248	Infections and infestations	Onychomycosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JUL2018	31JUL2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2007		Y
	C4591001 1110 11101249	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1110 11101251	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
	C4591001 1110 11101252	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1110 11101253	Surgical and medical procedures	Vasectomy	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101254	Injury, poisoning and procedural complications	Ankle fracture	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
			Malignant melanoma	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ovarian adenoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Ankle operation	01JAN2003	31DEC2003	N
			Oophorectomy	01JAN2007	31DEC2007	N
			Skin neoplasm excision	01JAN2001	31DEC2001	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1110 11101255	Psychiatric disorders	Schizophrenia	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1110 11101256	Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	11APR1987	11APR1987	N
	C4591001 1110 11101258	Gastrointestinal disorders	Umbilical hernia	01FEB2011	28FEB2011	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Ankle fracture	01FEB2012	29FEB2012	N
		Investigations	Blood testosterone decreased	01APR2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Psychiatric disorders	Anxiety	01APR2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1987		Y
		Surgical and medical procedures	Ankle operation	01FEB2012	29FEB2012	N
			Umbilical hernia repair	01FEB2011	28FEB2011	N
	C4591001 1110 11101259	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1110 11101260	Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101262	Eye disorders	Glaucoma	01JAN2012		Y
		Infections and infestations	Hepatitis B	01JAN1976	31DEC1976	N
	C4591001 1110 11101263	Psychiatric disorders	Depression	01DEC2018		Y
			Insomnia	01DEC2018		Y
	C4591001 1110 11101267	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1110 11101270	Infections and infestations	Hepatitis C	19DEC2015	06FEB2020	N
			Tonsillitis	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Ligament rupture	01APR2006	30APR2006	N
				01FEB1996	29FEB1996	N
		Surgical and medical procedures	Ligament operation	01APR2006	30APR2006	N
				01FEB1996	29FEB1996	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1110 11101272	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
	C4591001 1110 11101276	Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN1978	31DEC1978	N
		Social circumstances	Postmenopause	23MAR2016		Y
		Surgical and medical procedures	Synovial cyst removal	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101277	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
			Atrial flutter	01JAN2019	30JUN2019	N
		Infections and infestations	Hepatitis B	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Dyslipidaemia	26MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01JAN1977		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01JUN2019	30JUN2019	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
				01JAN2016	31DEC2016	N
			Large intestinal polypectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1110 11101279†	Injury, poisoning and procedural complications	Tendon rupture	01NOV2016	06NOV2016	N
		Investigations	HIV test positive	23MAR2007		Y
		Surgical and medical procedures	Tenoplasty	06NOV2016	06NOV2016	N
	C4591001 1110 11101281	Endocrine disorders	Hypothyroidism	01JAN1981		Y
		Injury, poisoning and procedural complications	Eyelid contusion	18SEP2020	18SEP2020	N
			Fall	18SEP2020	18SEP2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1110 11101284	Injury, poisoning and procedural complications	Meniscus injury	01MAR2020		Y
			Tendon rupture	01MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01MAR2020		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101285	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1110 11101288	Infections and infestations	Appendicitis perforated	01MAR2015	31MAR2015	N
			Peritonitis	01MAR2015	31MAR2015	N
		Surgical and medical procedures	Colectomy	01MAR2015	31MAR2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1110 11101289	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2001		Y
		Social circumstances	Postmenopause	15DEC2006		Y
		Surgical and medical procedures	Gastrectomy	16OCT2019	16OCT2019	N
	C4591001 1110 11101291	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Migraine	09JUN2020	10JUN2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101295	Hepatobiliary disorders	Cholecystitis	01SEP2014	30SEP2014	N
		Surgical and medical procedures	Caesarean section	18MAY1986	18MAY1986	N
			Cholecystectomy	01SEP2014	30SEP2014	N
			Female sterilisation	08FEB1991	08FEB1991	N
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 1110 11101296	Gastrointestinal disorders	Inguinal hernia	01SEP2018	03OCT2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip and/or oral cavity cancer	01JAN2008	08FEB2018	N
		Surgical and medical procedures	Bone graft	23APR2019	23APR2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				23OCT2018	23OCT2018	N
			Cancer surgery	24OCT2017	24OCT2017	N
			Dental implantation	23APR2019	23APR2019	N
			Hyperbaric oxygen therapy	01AUG2018	31OCT2018	N
			Inguinal hernia repair	03OCT2018	03OCT2018	N
	C4591001 1110 11101297	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1110 11101299	Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Renal and urinary disorders	Urinary retention	01MAY2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Prostatectomy	01AUG2020	01OCT2020	N
			Tonsillectomy	01JAN1957	31DEC1957	N
	C4591001 1110 11101301	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101302	Cardiac disorders	Coronary artery disease	01APR2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Surgical and medical procedures	Coronary artery surgery	01APR2017	30APR2017	N
	C4591001 1110 11101303	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2020		Y
	C4591001 1110 11101304	Social circumstances	Postmenopause	09OCT2015		Y
		Surgical and medical procedures	Abdominoplasty	20DEC2012	20DEC2012	N
			Female sterilisation	08APR1990	08APR1990	N
			Mammoplasty	16JUL1999	16JUL1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101307	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1110 11101310	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1110 11101312	Eye disorders	Glaucoma	01JAN1995	31DEC2017	N
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Glaucoma surgery	01JAN2017	31DEC2017	N
	C4591001 1110 11101315	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2018		Y
			Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1110 11101324	Eye disorders	Glaucoma	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1110 11101332	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
	C4591001 1110 11101334	Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01FEB2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101335	Cardiac disorders	Cardiac failure congestive	01JAN2016		Y
			Coronary artery disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
	C4591001 1110 11101336	Gastrointestinal disorders	Pancreatitis	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Investigations	Endoscopic retrograde cholangiopancreatography	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2012	31DEC2012	N
			Renal cancer	01JAN2013	31DEC2013	N
			Renal cancer	01JAN2016	31DEC2017	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Cancer surgery	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Polypectomy	01JAN1994	31DEC1994	N
			Synovial cyst removal	01JAN1998	31DEC1998	N
			Transurethral bladder resection	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1110 11101339	Gastrointestinal disorders	Barrett's oesophagus	01JAN1997		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Retinoblastoma	01JAN1945	31DEC1945	N
		Nervous system disorders	Lumbar radiculopathy	01NOV2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1970		Y
		Surgical and medical procedures	Eye excision	01JAN1945	31DEC1945	N
			Intervertebral disc operation	01MAR2020	31MAR2020	N
			Spinal operation	01JAN2020	31JAN2020	N
	C4591001 1110 11101340	Vascular disorders	Hypertension	01JAN1990		Y
		Congenital, familial and genetic disorders	Poland's syndrome	(b) (6) 1946		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Parkinson's disease	01JAN2017		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1999		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Abdominoplasty	01JAN1987	31DEC1987	N
			Appendicectomy	01JAN1969	31DEC1969	N
			Breast reconstruction	01JAN1960	31DEC1960	N
			Cholecystectomy	01JAN2001	31DEC2001	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1987	31DEC1987	N
			Meniscus operation	01JAN2000	31DEC2000	N
			Urinary incontinence surgery	01JUL2009	31JUL2009	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1110 11101351	Cardiac disorders	Mitral valve prolapse	01JAN1966		Y
		Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2018		Y
			Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JUN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1110 11101355	Injury, poisoning and procedural complications	Stress fracture	01MAY2020		Y
			Tibia fracture	01JUL2017	31JUL2017	N
		Surgical and medical procedures	Open reduction of fracture	01JUL2017	31JUL2017	N
		Vascular disorders	Deep vein thrombosis	01MAY2019		Y
	C4591001 1110 11101357†	Investigations	HIV test positive	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN2011		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
			Upper-airway cough syndrome	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1110 11101359	Blood and lymphatic system disorders	Anaemia	01AUG2020		Y
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1110 11101362	Eye disorders	Eyelid ptosis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01FEB2020		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
			Insomnia	01NOV2019		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2018	31DEC2018	N
			Sebaceous cyst excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1110 11101363	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2006	30JUN2006	N
		Surgical and medical procedures	Colectomy	01JUN2006	30JUN2006	N
	C4591001 1110 11101367	Metabolism and nutrition disorders	Type 2 diabetes mellitus	29JUL2011		Y
	C4591001 1110 11101368	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUL2020		Y
			Osteoarthritis	01JAN2014	31DEC2015	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1971		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1110 11101369	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1992		Y
		Metabolism and nutrition disorders	Gout	01JAN1988		Y
			Hypercholesterolaemia	01JAN1988		Y
	C4591001 1110 11101373†	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Hepatobiliary disorders	Gallbladder rupture	01JAN2017	31DEC2017	N
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Herpes simplex	01JAN1996		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1982	31DEC1982	N
		Investigations	HIV test positive	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Lactose intolerance	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
			Bone operation	01JAN1982	31DEC1982	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Splenectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1110 11101376	Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31MAY2006	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005		Y
			Mastectomy	01MAY2006	31MAY2006	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1110 11101378	Gastrointestinal disorders	Inguinal hernia	01JAN1989	31DEC1989	N
				01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1989	31DEC1989	N
				01JAN1993	31DEC1993	N
	C4591001 1111 11111002	Eye disorders	Cataract	01JAN2017		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	15MAY2020		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1111 11111003	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Myopia	01JAN1969		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2000	31DEC2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
			Vitamin B12 deficiency	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1960		Y
			Osteopenia	01JAN2001	31DEC2020	N
			Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01JAN1979		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1970	31DEC1970	N
	C4591001 1111 11111004	Cardiac disorders	Coronary artery disease	01JUL2012		Y
			Myocardial infarction	01JUL2012	31JUL2012	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2006	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
			Malignant melanoma	01JUL2017	31DEC2017	N
			Squamous cell carcinoma of skin	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUL2012	31JUL2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111005	Ear and labyrinth disorders	Vertigo positional	01JAN1998		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2003		Y
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
			Vitamin D deficiency	01JAN2000		Y
		Psychiatric disorders	Libido decreased	01JAN2018		Y
		Social circumstances	Postmenopause	01APR2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
	C4591001 1111 11111006	Infections and infestations	Lyme disease	01JAN1997	31DEC1997	N
	C4591001 1111 11111007	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Endocrine disorders	Hyperaldosteronism	01JAN2015		Y
			Hypothyroidism	01JAN1980		Y
		Eye disorders	Glaucoma	01JAN2013		Y
		General disorders and administration site conditions	Oedema	01JAN2006		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1985		Y
			Gout	01JAN2014		Y
			Iron deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2015		Y
			Spinal osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Squamous cell carcinoma of skin	01JAN2016	31DEC2016	N
		Nervous system disorders	Lumbar radiculopathy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2006		Y
			Sleep apnoea syndrome	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1111 11111008	Gastrointestinal disorders	Colitis	01FEB2019	31MAR2019	N
			Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2007		Y
			Seasonal allergy	01DEC2006		Y
		Infections and infestations	Urinary tract infection	01JAN1970		Y
		Injury, poisoning and procedural complications	Meniscus injury	01SEP2001	30SEP2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2008		Y
			Osteoarthritis	01JAN2001		Y
			Spondylolisthesis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012		Y
			Sciatica	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	31JAN2020	04FEB2020	N
		Social circumstances	Postmenopause	01NOV2001	30NOV2001	N
		Surgical and medical procedures	Hip arthroplasty	01SEP2001	30SEP2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01OCT2002	31OCT2002	N
	C4591001 1111 11111010	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2005		Y
			Transient ischaemic attack	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2017		Y
			Libido decreased	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01FEB2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Mediastinal mass	01JAN2019		Y
			Pulmonary mass	01JAN2019		Y
		Surgical and medical procedures	Hernia repair	01JAN1982	31DEC1982	N
				01JAN2018	31DEC2018	N
			Mitral valve replacement	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1111 11111011	Blood and lymphatic system disorders	Anaemia	01JAN2019	31DEC2020	N
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Cataract	01JAN2019		Y
			Glaucoma	01JAN2019		Y
			Macular degeneration	01JAN2019		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Hepatic steatosis	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Metabolism and nutrition disorders	Gout	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteoarthritis	01JAN1985		Y
			Osteopenia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
			Uterine leiomyoma	01JAN1970	31DEC1988	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1988		Y
			Diabetic neuropathy	01JAN2000		Y
			Tremor	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Renal and urinary disorders	Incontinence	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1960		Y
			Granuloma annulare	01JAN2018		Y
			Rosacea	01JAN1980	31DEC1985	N
	C4591001 1111 11111013	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1978		Y
			Large intestine polyp	01JAN1999	31DEC1999	N
			Peptic ulcer	01JAN1978	31DEC1978	N
		Infections and infestations	Fungal skin infection	01JAN2020		Y
			Urinary tract infection	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1980	31DEC1980	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111014	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Constipation	01JAN1962		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018		Y
			Osteoarthritis	01JAN1990		Y
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
		Nervous system disorders	Migraine	01JAN1955	31DEC1982	N
			Sciatica	01JAN1962		Y
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN1982		Y
		Surgical and medical procedures	Hernia repair	01JAN1990	31DEC1990	N
			Rotator cuff repair	01JAN2009	31DEC2009	N
				01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1111 11111015	Immune system disorders	Multiple allergies	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1111 11111016	General disorders and administration site conditions	Peripheral swelling	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Head injury	01JAN2000	31DEC2000	N
			Lower limb fracture	01JAN1970	31DEC1970	N
			Upper limb fracture	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1111 11111017	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Hypermetropia	01JAN1958		Y
			Macular degeneration	01JAN2002		Y
			Myopia	01JAN1985		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1964		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1992		Y
	C4591001 1111 11111019	Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Surgical and medical procedures	Meniscus operation	01JAN1990	31DEC1990	N
			Spinal laminectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1111 11111020	Eye disorders	Myopia	01JAN1966		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2009	31DEC2009	N
				01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
	C4591001 1111 11111021	Psychiatric disorders	Depression	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1997	31DEC1997	N
			Testis cancer	01JAN2011	31DEC2011	N
	C4591001 1111 11111025	Surgical and medical procedures	Inguinal hernia repair	01JAN2012	31DEC2012	N
		Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Eye disorders	Myopia	01JAN1960		Y
			Retinal tear	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2010		Y
			Overweight	01JAN2000		Y
		Psychiatric disorders	Libido decreased	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
				01MAY2020	31MAY2020	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111026	Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1973		Y
		Investigations	Echocardiogram	01JUL2019	31JUL2019	N
				01SEP2019	30SEP2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Paget's disease of nipple	01JAN1998	31DEC1998	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980	31DEC1980	N
				01JAN1981	31DEC1981	N
			Headache	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1980	31DEC1980	N
				01JAN1981	31DEC1981	N
			Cataract operation	01JAN2019	31DEC2019	N
			Tonsillectomy	01OCT1951	31OCT1951	N
			Familial tremor	01JAN1980		Y
	C4591001 1111 11111027	Congenital, familial and genetic disorders				
		Eye disorders	Myopia	01MAR2002		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
			Overweight	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2000	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
			Muscle spasms	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Amnesia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intervertebral disc operation	26JUN2008	26JUN2008	N
			Keratomileusis	01JAN2002	31DEC2002	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01OCT2001	31OCT2001	N
			Spinal operation	01SEP1999	30SEP1999	N
		Vascular disorders	Poor peripheral circulation	01JAN1995		Y
	C4591001 1111 11111028	Eye disorders	Cataract	01JAN2007	31DEC2007	N
			Hypermetropia	01JAN2007		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1958	31DEC1958	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2008	31DEC2010	N
			Upper limb fracture	01JAN2013	31DEC2013	N
		Investigations	Biopsy breast	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1958	31DEC1958	N
			Female sterilisation	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1111 11111030	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2014	31DEC2017	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111031	Vascular disorders	Aortic aneurysm	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Eye disorders	Cataract	01JAN2019	31JAN2019	N
			Myopia	01JAN1998		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1981	31DEC1981	N
		Immune system disorders	Anaphylactic reaction	01JAN2010		Y
			Seasonal allergy	01JAN2013	31DEC2013	N
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Injury corneal	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2020		Y
		Social circumstances	Menopause	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Cataract operation	01JAN2019	31JAN2019	N
			Cholecystectomy	01JAN1981	31DEC1981	N
			Corneal operation	01JAN1992	31DEC1992	N
			Intraocular lens implant	01JAN2019		Y
			Nasal septal operation	01JAN2005	31DEC2005	N
	C4591001 1111 11111032	Vascular disorders	Hypertension	01JAN2010		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1999		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1989	31DEC1989	N
			Peripheral nerve injury	01JAN1987	31DEC1987	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Sciatica	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
			Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Ligament operation	01JAN1989	31DEC1989	N
			Peripheral nerve operation	01JAN1987	31DEC1987	N
			Rhinoplasty	01JAN1982	31DEC1982	N
			Spinal fusion surgery	01JAN1999	31DEC1999	N
			Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1111 11111033	Ear and labyrinth disorders	Deafness	01JAN1945		Y
		Eye disorders	Myopia	01JAN1950		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2018		Y
		Infections and infestations	Appendicitis perforated	01JAN1956	31DEC1956	N
		Injury, poisoning and procedural complications	Head injury	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Adenoidectomy	01JAN1956	31DEC1956	N
			Appendicectomy	01JAN1956	31DEC1956	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1946	31DEC1946	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1111 11111034	Eye disorders	Myopia	01JAN2005		Y
		Infections and infestations	Osteomyelitis	01JAN1975	31DEC1975	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Knee operation	01JAN1975	31DEC1975	N
	C4591001 1111 11111035	Eye disorders	Dry eye	01JAN2005		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Prostatitis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1993	31DEC2013	N
		Surgical and medical procedures	Nasal septal operation	01JAN2013	31DEC2013	N
	C4591001 1111 11111036	Ear and labyrinth disorders	Deafness	01JAN2017		Y
		Eye disorders	Myopia	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1111 11111037	Skin and subcutaneous tissue disorders	Eczema	01NOV2019	30APR2020	N
		Eye disorders	Cataract	01JAN2018		Y
			Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Diverticulum	01JAN2015		Y
			Inguinal hernia	01JAN2013	31DEC2013	N
			Large intestine polyp	01JAN2015	31DEC2015	N
			Umbilical hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Food allergy	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1959	31DEC1959	N
				01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2003		Y
		Social circumstances	Hearing aid user	01JAN2004		Y
	C4591001 1111 11111038	Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2014	31DEC2014	N
				01MAR2020	31MAR2020	N
		Injury, poisoning and procedural complications	Head injury	01JAN1976	31DEC1976	N
			Wrist fracture	01JAN1967	31DEC1967	N
		Investigations	Blood triglycerides increased	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2006	31DEC2006	N
			Squamous cell carcinoma of skin	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1111 11111039	Endocrine disorders	Hypothyroidism	01JAN1983		Y
		Eye disorders	Hypermetropia	01JAN1988		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN1998	31DEC1998	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Overweight	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Muscle spasms	01JUL2020	01SEP2020	N
		Nervous system disorders	Transient ischaemic attack	01APR2020	30APR2020	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1111 11111041	Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y
		General disorders and administration site conditions	Hernia	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Rotator cuff syndrome	01JAN2007	31DEC2007	N
		Nervous system disorders	Sciatica	01JAN2000		Y
			Tremor	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Drug delivery device placement	01JAN2015	31DEC2018	N
			Intervertebral disc operation	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
				01JAN2014	31DEC2014	N
	C4591001 1111 11111042	Eye disorders	Hypermetropia	01JAN1983		Y
			Myopia	01JAN1983		Y
		Metabolism and nutrition disorders	Overweight	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Sciatica	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1970	31DEC1970	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1111 11111043	Ear and labyrinth disorders	Deafness bilateral	01JAN2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2019		Y
			Myopia	01JAN1962		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1973	31DEC1973	N
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
			Fungal skin infection	01JAN2018	31DEC2018	N
		Investigations	Smear cervix abnormal	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1998		Y
			Vitamin D deficiency	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
			Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN1990	31DEC1990	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2018	N
			Diabetic neuropathy	01JAN1998		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2011		Y
			Nephrolithiasis	01JAN2001		Y
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
			Cholecystectomy	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1973	31DEC1973	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1111 11111044	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2016	31DEC2016	N
	C4591001 1111 11111045	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Overweight	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1961		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1111 11111046	Blood and lymphatic system disorders	Lymphatic disorder	01JAN2014	31DEC2014	N
		Cardiac disorders	Mitral valve prolapse	01JAN1980		Y
		Eye disorders	Myopia	01JAN1972		Y
		Gastrointestinal disorders	Constipation			Y
			Diverticulum	01JAN2016		Y
			Irritable bowel syndrome	01JAN2010		Y
			Large intestine polyp	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1981		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Vitamin D deficiency	01JAN2017	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1974		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1971	31DEC1994	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2009	31DEC2009	N
			Headache	01JAN1975		Y
			Migraine	01JAN1975		Y
			Sciatica	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1966		Y
			Insomnia	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Spinal fusion surgery	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1111 11111047	Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
			Vertigo	01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Hypermetropia	01JAN1965		Y
			Myopia	01JAN1965		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Overweight	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2001		Y
			Vitamin D deficiency	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
			Desmoid tumour	01JAN1985	31DEC1985	N
			Malignant melanoma	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1111 11111049	Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Overweight	01JAN1951		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC2001	N
			Keratomileusis	01JAN2001	31DEC2001	N
			Spinal operation	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1111 11111055	Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2014		Y
		Injury, poisoning and procedural complications	Upper limb fracture	19JUL2019	19JUL2019	N
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Bone pain	19JUL2019		Y
			Intervertebral disc protrusion	01JAN2001	31DEC2001	N
			Osteopenia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN1989		Y
			Migraine	01JAN1989		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Bone operation	15AUG2019	15AUG2019	N
			Intervertebral disc operation	01FEB2001	28FEB2001	N
	C4591001 1111 11111056	Eye disorders	Hypermetropia	01JAN1995		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2005		Y
			Large intestine polyp	01JUL2020	31JUL2020	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Overweight	01JAN1991		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2019	31DEC2020	N
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1111 11111058	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephropathy	01JAN2002		Y
		Social circumstances	Organ donor	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Vasectomy	01JAN1984	31DEC1984	N
	C4591001 1111 11111059	Ear and labyrinth disorders	Deafness	01JAN1970		Y
			Vertigo	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Large intestine polyp	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1975		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
			Prostate cancer	01JAN2013	31DEC2014	N
				01JAN2014	31DEC2014	N
			Squamous cell carcinoma of skin	01JAN1975	31DEC1975	N
				01JAN2012	31DEC2012	N
		Nervous system disorders	Headache	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Restless legs syndrome	01JAN1999		Y
		Psychiatric disorders	Libido decreased	01JAN2014		Y
			Post-traumatic stress disorder	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
			Brachytherapy to prostate	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1111 11111062	Eye disorders	Myopia	01JAN1967		Y
			Strabismus	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Colitis ulcerative	01JUL2019		Y
			Dyspepsia	01JAN2016		Y
		Infections and infestations	Appendicitis perforated	01JAN2019	31DEC2019	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Obesity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Fibromyalgia	01JAN2020		Y
			Muscle spasms	01JAN1998		Y
			Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1996	31DEC1996	N
			Urinary incontinence surgery	01JAN2009	31DEC2009	N
			Uterine dilation and curettage	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1111 11111063	Vascular disorders	Hypertension	01JAN2005		Y	
		Endocrine disorders	Hypothyroidism	01JAN2010		Y	
		Eye disorders	Myopia	01JAN1968		Y	
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y	
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y	
			Vitamin D deficiency	01JAN2010		Y	
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y	
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN1964	31DEC1972	N	
			Eczema	01JAN1954	31DEC2010	N	
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N	
					27JUN2020	27JUN2020	N
			Corneal transplant	01JAN2009	31DEC2009	N	
			Hysterectomy	01JAN2000	31DEC2000	N	
			Large intestinal polypectomy	01JAN2017	31DEC2017	N	
	C4591001 1111 11111065	Vascular disorders	Hypertension	01JAN2017		Y	
		Ear and labyrinth disorders	Deafness	01JAN2010		Y	
		Gastrointestinal disorders	Large intestine polyp	01JAN2010	31DEC2010	N	
		Infections and infestations	Herpes simplex	01JAN1990		Y	
			Onychomycosis	01JAN2018		Y	
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2005		Y	
			Vitamin D deficiency	01JAN2010		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N	
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2013		Y	
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1957		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111066	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Ear and labyrinth disorders	Deafness	01JAN2013		Y
		Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2015	31DEC2015	N
		Infections and infestations	Urinary tract infection	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN2018	31DEC2018	N
			Squamous cell carcinoma of skin	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1111 11111067	Surgical and medical procedures	Nephrectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
		Eye disorders	Retinal tear	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2019	31DEC2019	N
			Cervical vertebral fracture	01JAN2019	31DEC2019	N
		Investigations	Biopsy breast normal	01JAN1992	31DEC1992	N
			Catheterisation cardiac	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1971		Y
			Osteoarthritis	12DEC2019		Y
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2017	31DEC2017	N	
	Nervous system disorders	Migraine with aura	01JAN1985		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1976	31DEC1976	N
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Ankle operation	01JAN2011	31DEC2011	N
				05FEB2020	31DEC2020	N
			Carotid artery stent insertion	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Retinal operation	01JAN2017	31DEC2017	N
		Vascular disorders	Aneurysm	01JAN2017	31DEC2017	N
			Hypertension	01JAN1990		Y
	C4591001 1111 11111070	Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Myopia	01JAN1949		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01MAR2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1111 11111071	Eye disorders	Myopia	01JAN1974		Y
		Gastrointestinal disorders	Abdominal distension	01JUN2019	31DEC2019	N
			Gastrointestinal ulcer haemorrhage	01JAN1993	31DEC1993	N
			Gastrooesophageal reflux disease	01JAN1990		Y
			Large intestine polyp	01JAN2004	31DEC2004	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1980		Y
		Surgical and medical procedures	Abdominal exploration	01JUN2019	30JUN2019	N
			Micrographic skin surgery	01JAN2016	31DEC2016	N
	C4591001 1111 11111073	Cardiac disorders	Myocardial infarction	01JUN2008	30JUN2008	N
		Eye disorders	Hypermetropia	01JAN1999		Y
			Myopia	01JAN1971		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Overweight	01JAN1953		Y
			Type 2 diabetes mellitus	01JAN1999		Y
			Vitamin B12 deficiency	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUN2008	30JUN2008	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1111 11111074	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Libido decreased	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1111 11111075	Eye disorders	Cataract	01JAN2015		Y
			Myopia	01JAN1964		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1111 11111076	Eye disorders	Myopia	01JAN1962		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Urinary tract infection	01JAN1995	31DEC1995	N
				01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1111 11111077	Blood and lymphatic system disorders	Anaemia	01JAN1969	31DEC2015	N
		Cardiac disorders	Coronary artery disease	01JAN2018	31DEC2018	N
			Myocardial infarction	01JAN2018	31DEC2018	N
		Ear and labyrinth disorders	Deafness	01JAN1969		Y
		Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1974	31DEC2015	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2018	31DEC2018	N
			Heart valve replacement	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1111 11111080	Cardiac disorders	Ventricular extrasystoles	01JAN2019		Y
		Eye disorders	Hypermetropia	01JAN1986		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1990	31DEC2008	N
			Scoliosis	01JAN1966		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN1990	31DEC2008	N
			Thyroidectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111084	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN1965		Y
		Renal and urinary disorders	Nephrolithiasis	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1111 11111085	Endocrine disorders	Hypogonadism	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2018		Y
	C4591001 1111 11111088	Ear and labyrinth disorders	Deafness	01JAN1980		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Infections and infestations	Tinea versicolour	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1111 11111091	Eye disorders	Hypermetropia	01JAN2019		Y
		Gastrointestinal disorders	Pancreatitis	01OCT2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
	C4591001 1111 11111092	Eye disorders	Hypermetropia	01JAN2004		Y
		Metabolism and nutrition disorders	Overweight	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1983		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1111 11111093	Eye disorders	Hypermetropia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013	31DEC2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1111 11111094	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Eye disorders	Hypermetropia	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1965	31DEC1965	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Heart rate irregular	01JAN2016	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Overweight	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip neoplasm malignant stage unspecified	01JAN2010	31DEC2011	N
			Prostate cancer	01MAR2019	31OCT2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
			Prostatomegaly	01MAR2019	31OCT2019	N
		Surgical and medical procedures	Coronary arterial stent insertion	01DEC2011	31DEC2011	N
				01OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111095	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1111 11111096	Cardiac disorders	Atrioventricular block	01JAN2010	31DEC2010	N
		Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Jaw fracture	01JAN1990	31DEC1990	N
			Limb crushing injury	01JAN2015	31DEC2015	N
			Rib fracture	01JAN1990	31DEC1990	N
			Traumatic lung injury	01JAN1990	31DEC1990	N
		Investigations	Catheterisation cardiac	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1947		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1111 11111100	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Ear and labyrinth disorders	Vertigo	01JAN2016		Y
		Eye disorders	Hypermetropia	01JAN2016		Y
			Myopia	01JAN1978		Y
		Gastrointestinal disorders	Constipation	01JAN2009		Y
			Dyspepsia	01JAN2015		Y
			Gastrooesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2007		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
		Injury, poisoning and procedural complications	Foot fracture	28JUL2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Vitamin D deficiency	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2005		Y
			Osteopenia	01FEB2020		Y
		Nervous system disorders	Sciatica	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2001		Y
			Insomnia	01AUG2019		Y
			Libido decreased	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JUL1997		Y
		Vascular disorders	Deep vein thrombosis	01JAN2007	31DEC2007	N
	C4591001 1111 1111102	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Hypermetropia	01JAN2019		Y
			Myopia	01JAN1966		Y
		Infections and infestations	Appendicitis	01JAN1988	31DEC1988	N
			Onychomycosis	01JAN2018		Y
			Pneumonia	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1992	31DEC2008	N
		Psychiatric disorders	Bipolar disorder	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1988	31DEC1988	N
			Breast conserving surgery	01JAN1974	31DEC1994	N
			Hysterectomy	01JAN1988	31DEC1988	N
				01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111103	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN2004		Y
			Myopia	01JAN2004		Y
		Gastrointestinal disorders	Diverticulum	01JAN2015		Y
		Infections and infestations	Onychomycosis	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1997		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Libido decreased	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2013	31DEC2013	N
				01JAN2019	31DEC2019	N
	C4591001 1111 11111106	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2017		Y
			Myopia	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN1989		Y
				01JAN1994		Y
			Seasonal allergy	01JAN1988		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1989	31DEC1989	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1111 11111107	Cardiac disorders	Coronary artery disease	01JAN2008		Y
			Myocardial infarction	01JAN2008	31DEC2008	N
		Eye disorders	Cataract	01JAN2006	31DEC2008	N
			Glaucoma	01JAN1985	31DEC2008	N
			Hypermetropia	01JAN1985		Y
			Myopia	01JAN1985		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN1987		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hypercholesterolaemia	01JAN2008		Y
			Overweight	01JAN1985		Y
		Psychiatric disorders	Libido decreased	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Coronary arterial stent insertion	01JAN2008	31DEC2008	N
			Vasectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1111 11111108	Eye disorders	Cataract	01MAR2020		Y
			Hypermetropia	01JAN1975		Y
			Myopia	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1997		Y
			Depression	01JAN1997		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN1995		Y
	C4591001 1111 11111109	Congenital, familial and genetic disorders	Porokeratosis	01JAN2013		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Overweight	01JAN1970		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1997	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Endometrial ablation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1111 11111110	Blood and lymphatic system disorders	Anaemia	01JAN2014		Y
		Ear and labyrinth disorders	Deafness	01JAN1975		Y
			Vertigo	01JAN2008	31DEC2009	N
		Eye disorders	Cataract	01JAN2019		Y
			Myopia	01JAN1963		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Diarrhoea	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2015		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1978	31DEC1978	N
			Nonalcoholic fatty liver disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Fall	01JAN2014	31DEC2014	N
			Head injury	01JAN1975	31DEC1975	N
				01JAN2014	31DEC2014	N
			Road traffic accident	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
			Type 2 diabetes mellitus	01AUG2019		Y
			Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1981	31DEC1981	N
		Nervous system disorders	Headache	01JAN1975		Y
			Sciatica	01JAN1975	31DEC1982	N
			Seizure	01JAN1975	31DEC1975	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1976	31DEC1976	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cholelithotomy	01JAN1978	31DEC1978	N
			Female sterilisation	01JAN1989	31DEC1989	N
			Influenza immunisation	01AUG2019	31AUG2019	N
			Ovarian cystectomy	01JAN1976	31DEC1976	N
			Ovarian lesion excision	01JAN1981	31DEC1981	N
			Skin neoplasm excision	01JAN2015	31MAY2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
			Peripheral vascular disorder	01JAN2018		Y
			Poor peripheral circulation	01JAN2000		Y
	C4591001 1111 11111111	Cardiac disorders	Atrial fibrillation	01JAN2017	31DEC2017	N
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Dry eye	01JAN2015		Y
			Glaucoma	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1999		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
			Osteopenia	01JAN2016		Y
			Spinal osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2015	31DEC2015	N
			Squamous cell carcinoma	12JUN2020	12JUN2020	N
		Nervous system disorders	Sciatica	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Renal and urinary disorders	Dysuria	01JAN2013		Y
		Reproductive system and breast disorders	Cystocele	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1978		Y
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lower oesophageal sphincter magnetic augmentation	29JUN2020	29JUN2020	N
	C4591001 1111 11111112	Vascular disorders	Hypertension	01JAN2009		Y
		Ear and labyrinth disorders	Deafness	01JAN1983		Y
		Eye disorders	Diplopia	01JAN1998		Y
			Myopia	01JAN1998		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2005		Y
			Large intestine polyp	01JAN2002	31DEC2002	N
		General disorders and administration site conditions	Peripheral swelling	01JAN1983		Y
		Infections and infestations	Helicobacter infection	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Post-traumatic neck syndrome	01JAN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Articular calcification	01JUL2020		Y
			Back pain	01JAN2020		Y
			Muscle spasms	01JAN2020		Y
			Osteoarthritis	01JAN2020		Y
		Nervous system disorders	Myasthenia gravis	01AUG2013		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	24JUL2020		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2018	31DEC2020	N
		Surgical and medical procedures	Varicose vein operation	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2012		Y
			Poor peripheral circulation	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111114	Ear and labyrinth disorders	Vertigo	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01NOV1986	30NOV1988	N
		Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN1977		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
			Gastrooesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC2014	N
		Metabolism and nutrition disorders	Overweight	01JAN1989		Y
		Nervous system disorders	Headache	01JAN1980		Y
			Migraine	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
	C4591001 1111 11111116	Eye disorders	Myopia	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Head injury	01NOV1982	30NOV1982	N
			Road traffic accident	01NOV1982	30NOV1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Vitamin B12 deficiency	01JAN2000		Y
			Vitamin D deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111118	Ear and labyrinth disorders	Deafness	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1986		Y
		Gastrointestinal disorders	Diverticulum	01JAN1998	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Intestinal operation	01JAN2019	31DEC2019	N
	C4591001 1111 1111120	Eye disorders	Hypermetropia	01JAN2000		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2001		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Infections and infestations	Urinary tract infection	01JAN1965	31DEC2017	N
		Investigations	Blood triglycerides increased	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Overweight	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1969		Y
		Nervous system disorders	Migraine	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Stent placement	01NOV2019	30NOV2019	N
		Vascular disorders	Deep vein thrombosis	01NOV2001	31OCT2015	N
			Poor peripheral circulation	01JAN2001		Y
	C4591001 1111 1111122	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
		Infections and infestations	Fungal skin infection	01JAN1965		Y
		Investigations	Heart rate irregular	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1980		Y
			Vitamin B12 deficiency	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
				01JAN2020	31JAN2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Fasciotomy	01APR2020	30APR2020	N
		Vascular disorders	Hypertension	01JAN1980		Y
		Eye disorders	Myopia	01JAN1967		Y
	C4591001 1111 11111123	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2019	31AUG2019	N
			Malignant melanoma	01JAN2003	31DEC2003	N
			Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1111 11111124	Cardiac disorders	Coronary artery disease	01JAN2014	31DEC2014	N
			Myocardial infarction	01JAN2014	31DEC2014	N
		Eye disorders	Cataract	01JAN2008	31DEC2010	N
			Myopia	01JAN1950		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Investigations	Heart rate irregular	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Overweight	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1111 11111125	Eye disorders	Glaucoma	01JAN2015		Y
			Myopia	01JAN1960		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2013	31DEC2013	N
			Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN2010		Y
		Nervous system disorders	Tremor	01JAN2012		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1989	31DEC1989	N
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Uterine polypectomy	01JAN2010	31DEC2010	N
	C4591001 1111 11111126	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1984	31DEC1984	N
			Ligament injury	01JAN1980	31DEC1980	N
		Nervous system disorders	Headache	01JAN1993		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC1980	N
	C4591001 1111 11111127	Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN1990		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1111 11111128	Surgical and medical procedures	Mammoplasty	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1111 11111129	Eye disorders	Hypermetropia	01JAN1995		Y
			Myopia	01JAN1995		Y
		Gastrointestinal disorders	Diverticulum	01JAN2013		Y
		Investigations	Blood triglycerides increased	01JAN2013		Y
	C4591001 1111 11111131	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Eye disorders	Cataract	01JAN2015	31DEC2016	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Investigations	Blood triglycerides increased	01JAN2010		Y
			Heart rate irregular	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Overweight	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1111 11111133	Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2020		Y
		Surgical and medical procedures	Meniscus removal	01SEP1979	30SEP1979	N
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1111 11111134	Eye disorders	Cataract	01JAN2003	31DEC2004	N
				01JAN2012	31DEC2014	N
			Glaucoma	01JAN2016		Y
			Hypermetropia	01JAN2004		Y
			Myopia	01JAN1959	31DEC2014	N
			Retinal detachment	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN1995		Y
			Inguinal hernia	01JAN1956	31DEC1956	N
				01JAN1961	31DEC1961	N
				01JAN1994	31DEC1994	N
			Large intestine polyp	01JAN2010	31DEC2010	N
				01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1964	31DEC1964	N
			Scapula fracture	01JAN1966	31DEC1966	N
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1111 1111135	Eye disorders	Myopia	01JAN1966	31DEC2000	N
		Gastrointestinal disorders	Large intestine polyp	01MAY2018	31MAY2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
				01JAN2018		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2018	31JAN2018	N
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1111 1111136	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Cataract	01JAN2014		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2019	31AUG2019	N
			Volvulus	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Overweight	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2004		Y
		Surgical and medical procedures	Colectomy	01JAN2002	31DEC2002	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1111 11111137	Blood and lymphatic system disorders	Anaemia	01JAN1978		Y
		Endocrine disorders	Thyroid mass	01JUN2020		Y
		Eye disorders	Cataract	01JAN2017		Y
			Myopia	01JAN1972		Y
		Gastrointestinal disorders	Diverticulum	01JAN2011	31DEC2011	N
			Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Overweight	01JAN1985	31DEC2016	N
			Type 2 diabetes mellitus	01JAN1999		Y
			Vitamin B12 deficiency	01JAN2014		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1111 11111140	Cardiac disorders	Extrasystoles	21AUG2020		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Myopia	01JAN1963		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01NOV2019	30NOV2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Scoliosis	01JAN1965		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
			Spinal rod insertion	03MAR1981	30NOV1982	N
			Turbinectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1111 11111141	Gastrointestinal disorders	Haemorrhoids	01JAN2001	31DEC2001	N
			Large intestine polyp	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010	31DEC2010	N
			Back pain	01JAN2007		Y
			Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2009	N
			Squamous cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Tension headache	01JAN2018		Y
		Renal and urinary disorders	Micturition disorder	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1111 11111147	Eye disorders	Keratoconus	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Nervous system disorders	Sinus headache	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Corneal implant	01JAN2010	31DEC2010	N
			Tendon sheath incision	01JAN2018	31DEC2018	N
	C4591001 1111 11111149	Gastrointestinal disorders	Dyspepsia	01JUN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Overweight	01FEB2017		Y
		Vascular disorders	White coat hypertension	01JAN2010		Y
	C4591001 1111 11111150	Surgical and medical procedures	Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1111 11111152	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1111 11111153	Eye disorders	Myopia	01JAN1981		Y
		Gastrointestinal disorders	Diverticulum	01JAN2013		Y
			Irritable bowel syndrome	01JAN1986		Y
			Large intestine polyp	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Sciatica	01JAN2005		Y
		Social circumstances	Postmenopause	01FEB2019		Y
	C4591001 1111 11111154	Eye disorders	Hypermetropia	01JAN2002		Y
			Myopia	01JAN2002		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1111 11111157	Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Eye disorders	Cataract	01JAN2015		Y
			Hypermetropia	01JAN1963		Y
			Myopia	01JAN1963		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Infections and infestations	Hordeolum	01JAN2010		Y
			Onychomycosis	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Essential tremor	01JAN1986		Y
			Headache	01JAN1973		Y
			Sciatica	01JAN2010		Y
		Renal and urinary disorders	Micturition urgency	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1111 11111158	Blood and lymphatic system disorders	Thrombocytopenia	18DEC2006		Y
		Cardiac disorders	Myocardial infarction	11APR2019	11APR2019	N
		Eye disorders	Hypermetropia	01JAN1968		Y
			Myopia	01JAN1968		Y
		Gastrointestinal disorders	Diverticulum	01JAN1995		Y
			Dyspepsia	01JAN1995		Y
			Inguinal hernia	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood triglycerides increased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Overweight	01JAN2000		Y
			Back pain	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dupuytren's contracture	01JAN2000		Y
			Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Nervous system disorders	Basal cell carcinoma	01JAN1990	31DEC1990	N
			Non-Hodgkin's lymphoma	08AUG2006	31DEC2006	N
		Renal and urinary disorders	Headache	01JAN1956		Y
			Sciatica	01JAN2012		Y
		Reproductive system and breast disorders	Micturition urgency	01JAN2016		Y
		Vascular disorders	Erectile dysfunction	01JAN2016		Y
			Varicose vein	01JAN1980		Y
	C4591001 1111 11111160	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1961		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN2016	31DEC2016	N
		Nervous system disorders	Transient ischaemic attack	01JAN2011	31DEC2011	N
		Renal and urinary disorders	Nephrolithiasis	01SEP2019	14JUN2020	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1111 11111161	Ear and labyrinth disorders	Vertigo	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	01SEP2002		Y
			Myopia	01JAN1967		Y
		Infections and infestations	Onychomycosis	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Rotator cuff syndrome	01JAN1999	31DEC1999	N
				01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
			Skin papilloma	01JAN2003		Y
	C4591001 1111 11111162	Cardiac disorders	Mitral valve prolapse	01JAN1980		Y
		Ear and labyrinth disorders	Deafness	01JAN1970		Y
		Eye disorders	Myopia	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1111 11111163	Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Investigations	Heart rate irregular	01JAN1988	31DEC2008	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111164	Blood and lymphatic system disorders	Anaemia	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1960		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1111 11111165	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1999	31AUG2020	N
			Squamous cell carcinoma of skin	01JAN1999	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111167	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN1962		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2010		Y
			Psoriasis	01JAN2015		Y
	C4591001 1111 11111168	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1999	31DEC1999	N
				10JUL2020	10JUL2020	N
	C4591001 1111 11111173	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Eye disorders	Cataract	01JAN2015	31DEC2018	N
		Gastrointestinal disorders	Diarrhoea	01JAN2015		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN1980		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Infections and infestations	Urinary tract infection	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1111 11111174	Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN1985		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Investigations	Blood triglycerides increased	01JAN2017		Y
			Heart rate irregular	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004		Y
	C4591001 1111 11111175	Eye disorders	Hypermetropia	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31MAY2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01NOV2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1111 11111178	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Eye disorders	Cataract	01APR2018		Y
			Myopia	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Constipation	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1993	31DEC1993	N
			Upper limb fracture	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
			Osteoporosis	01AUG2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1111 11111181	Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2016		Y
			Myopia	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1111 11111182	Ear and labyrinth disorders	Vertigo	01JAN2010	31DEC2013	N
		Eye disorders	Glaucoma	01JAN2000		Y
			Myopia	01JAN1976		Y
		Gastrointestinal disorders	Diverticulum	01JAN2019		Y
			Dyspepsia	01JAN2017		Y
				01JAN2018	31DEC2018	N
			Large intestine polyp	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Hepatic steatosis	01MAR2017		Y
		Immune system disorders	Multiple allergies	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN1996		Y
			Blood triglycerides increased	01JAN2012		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	27MAR2020		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1111 11111185	Ear and labyrinth disorders	Deafness	01JAN1995		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Optic ischaemic neuropathy	01JAN2013		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2019	31DEC2019	N
		Infections and infestations	Onychomycosis	01JAN1980	31DEC2005	N
		Injury, poisoning and procedural complications	Skeletal injury	01JAN1966	31DEC1966	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1980	31DEC1980	N
			Squamous cell carcinoma	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Micturition disorder	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
			Prostatomegaly	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111186	Vascular disorders	Hypertension	01JAN2010		Y
		Cardiac disorders	Coronary artery disease	01JAN2010		Y
	C4591001 1111 11111187	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Investigations	Heart rate irregular	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1960		Y
		Surgical and medical procedures	Prostatomegaly	01JAN2014	31DEC2014	N
			Cardiac pacemaker insertion	01JAN2005		Y
			Coronary artery bypass	01JAN2016	31DEC2016	N
			Vascular disorders	Hypertension	01JAN2005	
	C4591001 1111 11111190	Congenital, familial and genetic disorders	Factor V deficiency	01JAN2015		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Myopia	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Colon cancer	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1111 11111190	Congenital, familial and genetic disorders	Cancer gene carrier	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN1980	31DEC1980	N
			Uterine leiomyoma	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cervical radiculopathy	01JAN2015		Y
			Migraine	01JAN1962		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01DEC2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN1969	31DEC1969	N
			Spinal fusion surgery	26FEB2020	26FEB2020	N
		Vascular disorders	Lymphoedema	01FEB2017		Y
	C4591001 1111 11111193	Gastrointestinal disorders	Constipation	01JAN2019		Y
			Dyspepsia	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
		Psychiatric disorders	Libido decreased	01JAN2018		Y
		Social circumstances	Alcohol use			Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1111 11111194	Eye disorders	Myopia	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Overweight	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
			Skin cancer	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1111 11111195	Gastrointestinal disorders	Crohn's disease	01JAN1970		Y
			Impaired gastric emptying	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1111 11111196	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1111 11111197	Cardiac disorders	Aortic valve stenosis	01JAN2010		Y
			Coronary artery disease	01JAN2009	31DEC2009	N
		Eye disorders	Macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Diverticulum	10MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Hypertriglyceridaemia	01JAN2008		Y
			Overweight	01JAN1970		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin B12 deficiency	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018		Y
			Benign laryngeal neoplasm	22MAY2020	22MAY2020	N
			Skin cancer	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2017		Y
			Coronary artery bypass	01NOV2009	30NOV2009	N
			Penile prosthesis insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1111 11111198	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1111 11111199	Eye disorders	Myopia	01JAN1996		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2003	31DEC2003	N
			Large intestine polyp	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2010	31DEC2010	N
				01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
	C4591001 1111 11111201	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Investigations	Heart rate irregular	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Overweight	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
			Osteoporosis	01JAN2017		Y
		Nervous system disorders	Transient global amnesia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1111 11111202	Gastrointestinal disorders	Constipation	01JAN1991		Y
		Immune system disorders	Multiple allergies	01JAN1959		Y
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
		Nervous system disorders	Amnesia	01JAN2000		Y
			Headache	01JAN1989		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Morton's neuralgia	01JAN1992	31DEC1992	N
			Tremor	01JAN2014		Y
		Psychiatric disorders	Bipolar I disorder	01JAN1992		Y
			Libido decreased	01JAN1991		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1968		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1958	31DEC1958	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Spinal fracture treatment	01JAN1989	31DEC1989	N
			Spinal laminectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1111 1111204	Eye disorders	Hypermetropia	01JAN2001		Y
			Myopia	01JAN2001		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAY2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2006	31DEC2006	N
	C4591001 1111 1111205	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1980		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
	C4591001 1111 11111206	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
			Osteopenia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1111 11111207	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121002	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1973		Y
	C4591001 1112 11121003	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	01JAN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1112 11121005	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Investigations	Blood testosterone decreased	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2019		Y
			Hyperlipidaemia	01JAN2010		Y
	C4591001 1112 11121007	Vascular disorders	Hypertension	01JAN2006		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2012		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	01JAN2009	N
		Nervous system disorders	Headache	20APR2014		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	01JAN2009	N
		Vascular disorders	Hot flush	01JAN2010		Y
			Hypertension	01JAN2010		Y
	C4591001 1112 11121010	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
	C4591001 1112 11121023	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Headache	01JAN2012		Y
			Neuralgia	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1970		Y
	C4591001 1112 11121029	General disorders and administration site conditions	Pain	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1112 11121030	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121032	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Obesity	01JAN2018		Y
	C4591001 1112 11121034	Eye disorders	Glaucoma	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1112 11121036	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1112 11121037	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	13JUN1988	13JUN1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121041	Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1112 11121043	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2017		Y
			Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1112 11121051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Food allergy	01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01NOV2016	01NOV2016	N
	C4591001 1112 11121052	Reproductive system and breast disorders	Ovarian cyst	01JUN1993	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01DEC1993	31DEC1993	N
	C4591001 1112 11121057	Renal and urinary disorders	Neurogenic bladder	01JAN1990		Y
	C4591001 1112 11121059	Injury, poisoning and procedural complications	Wrist fracture	01AUG2018	31AUG2018	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Internal fixation of fracture	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1112 11121060	Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1112 11121063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JUL1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN1999	01JAN2000	N
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1112 11121065	Congenital, familial and genetic disorders	Glucose-6-phosphate dehydrogenase deficiency	01JAN1983		Y
		Vascular disorders	Deep vein thrombosis	01JAN2015		Y
	C4591001 1112 11121067	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Nervous system disorders	Headache	01JAN1970		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1981	31JAN1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1981		Y
		Surgical and medical procedures	Hysterectomy	01JAN1981	31JAN1981	N
	C4591001 1112 11121068	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		General disorders and administration site conditions	Pain	01JAN2014		Y
		Immune system disorders	Rubber sensitivity	01JAN2014		Y
	C4591001 1112 11121072	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1112 11121074	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
	C4591001 1112 11121075	Endocrine disorders	Goitre	01JAN2018	28FEB2019	N
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Thyroidectomy	01FEB2019	28FEB2019	N
	C4591001 1112 11121076	Gastrointestinal disorders	Impaired gastric emptying	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1112 11121079	Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1112 11121084	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1112 11121086	Metabolism and nutrition disorders	Obesity	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121089	Immune system disorders	Food allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1112 11121093	Infections and infestations	Herpes simplex	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121094	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121095	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121096	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
	C4591001 1112 11121097	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
				01JAN1964		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1112 11121099	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Surgical and medical procedures	Spinal operation	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1112 11121108	Cardiac disorders	Supraventricular tachycardia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Reproductive system and breast disorders	Cervical polyp	01OCT2019	31JAN2020	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2020	31JAN2020	N
	C4591001 1112 11121111	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121112	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121113	Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
	C4591001 1112 11121116	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
	C4591001 1112 11121118	Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1112 11121120	Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1112 11121129	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01AUG2019		Y
	C4591001 1112 11121131	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1112 11121133	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31MAY2020	N
		Surgical and medical procedures	Uterine dilation and curettage	01MAY2020	31MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121134	Surgical and medical procedures	Vasectomy	01JAN2014		Y
	C4591001 1112 11121140	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1112 11121141	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01DEC2017	31DEC2017	N
		Surgical and medical procedures	Skin neoplasm excision	01DEC2017	31DEC2017	N
	C4591001 1112 11121142	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Obesity	01JAN2010	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Gastrectomy	01SEP2017	30SEP2017	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1112 11121143	Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
			Drug hypersensitivity	01JAN1972		Y
	C4591001 1112 11121144	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Osteoporosis	01JAN2012		Y
			Spinal osteoarthritis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2019	30JUN2019	N
		Surgical and medical procedures	Bladder repair	01JUN2019	30JUN2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121145	Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121149	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1112 11121150	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	31DEC2002	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Oophorectomy	01JAN2002	31DEC2002	N
	C4591001 1112 11121153	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1112 11121164	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1112 11121166	Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121167	Blood and lymphatic system disorders	Thrombocytopenia	01JAN1987		Y
		Cardiac disorders	Atrial fibrillation	09MAR2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	09MAR2015	09MAR2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121168	Cardiac disorders	Atrial fibrillation	01JAN2003		Y
			Coronary artery disease	01JAN2003		Y
		Endocrine disorders	Hypogonadism	01JAN1996		Y
		Investigations	Blood testosterone decreased	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2018		Y
			Seborrhoeic dermatitis	01JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012		Y
			Hip arthroplasty	30JUL2019	30JUL2019	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1996		Y
				01JAN2012		Y
	C4591001 1112 11121170	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018	28FEB2018	N
		Surgical and medical procedures	Knee arthroplasty	01FEB2018	28FEB2018	N
	C4591001 1112 11121172	Eye disorders	Glaucoma	01JAN1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
	C4591001 1112 11121176	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121179	Cardiac disorders	Atrial fibrillation	01JAN2013		Y
	C4591001 1112 11121181	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121182	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121195	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
			Umbilical hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
	C4591001 1112 11121196	Cardiac disorders	Arrhythmia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019	31MAY2019	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Surgical and medical procedures	Shoulder arthroplasty	01MAY2019	31MAY2019	N
	C4591001 1112 11121202	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1112 11121203	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1112 11121205	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Food allergy	01JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1112 11121209	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1990		Y
	C4591001 1112 11121210	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1112 11121211	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1981	31DEC1982	N
		Social circumstances	Postmenopause	01JAN1982		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1112 11121212	Immune system disorders	Drug hypersensitivity	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Seizure	01JAN1963		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1112 11121219	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1112 11121220	Cardiac disorders	Coronary artery disease	01JUN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN1970		Y
			Iodine allergy	01JAN1966		Y
			Seasonal allergy	01SEP2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUN2019	30JUN2019	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1112 11121221	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1112 11121222	Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1112 11121223	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01MAY2020		Y
		Psychiatric disorders	Depression	01JUL2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN1991	31DEC1991	N
	C4591001 1112 11121227	Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Immune system disorders	Seasonal allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hyperlipidaemia	01JAN1980		Y
			Obesity	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1112 11121230	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2019	31DEC2019	N
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JUN2019		Y
		Surgical and medical procedures	Toe operation	01JUN2019	30JUN2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121232	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
		Social circumstances	Postmenopause	01MAR2016		Y
	C4591001 1112 11121233	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
	C4591001 1112 11121235	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1112 11121236	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121238	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypokalaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121241	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121247	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1112 11121248	Immune system disorders	Seasonal allergy	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2020		Y
	C4591001 1112 11121255	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1984	31DEC1984	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121257	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	18AUG2020	N
		Surgical and medical procedures	Knee arthroplasty	18AUG2020	18AUG2020	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121262	Cardiac disorders	Coronary artery disease	06AUG2019		Y
			Myocardial infarction	06AUG2019	06AUG2019	N
		Injury, poisoning and procedural complications	Ulna fracture	01AUG2020	01AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017		Y
		Nervous system disorders	Memory impairment	02MAR2020		Y
			Neuropathy peripheral	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Angioplasty	06AUG2019	06AUG2019	N
			Bone operation	01AUG2020	01AUG2020	N
	C4591001 1112 11121267	Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	08APR1988	08APR1988	N
	C4591001 1112 11121274	Gastrointestinal disorders	Hiatus hernia	01JAN2013		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	31DEC1997	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Mastectomy	15JUL1997	15JUL1997	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1112 11121276	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1112 11121277	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2016	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1112 11121278	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Nervous system disorders	Essential tremor	01JAN1991		Y
	C4591001 1112 11121279	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1112 11121280	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
			Obesity	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2015		Y
	C4591001 1112 11121285	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1112 11121287	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN1975		Y
			Seasonal allergy	01JAN1965		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	25MAR2016		Y
	C4591001 1112 11121288	Endocrine disorders	Hypogonadism	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01MAR2020		Y
			Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
	C4591001 1112 11121292	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1112 11121294	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121295	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN1992		Y
				01JAN1996		Y
				01JAN2010		Y
			Seasonal allergy	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	05DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Knee arthroplasty	05DEC2018	05DEC2018	N
	C4591001 1112 11121302	Gastrointestinal disorders	Abdominal hernia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
	C4591001 1112 11121306	Eye disorders	Dry eye	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1112 11121309	Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JUN2019		Y
		Nervous system disorders	Transient ischaemic attack	01JUN2019	30JUN2019	N
		Renal and urinary disorders	Urinary retention	01DEC2019		Y
	C4591001 1112 11121311	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
	C4591001 1112 11121312	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Obesity	01JUN2020		Y
		Psychiatric disorders	Post-traumatic stress disorder	01APR2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1112 11121314	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1112 11121316	Cardiac disorders	Cardiac failure congestive	01JAN2003		Y
			Supraventricular tachycardia	01JAN2016		Y
		Endocrine disorders	Hypoparathyroidism	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypothyroidism	01JAN1984		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
		Metabolism and nutrition disorders	Gout	01JAN2012		Y
			Hypercholesterolaemia	01JAN2003		Y
			Obesity	01JAN2005		Y
			Vitamin B12 deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Osteopenia	01JAN2015		Y
			Spondylolisthesis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour	01JAN2014	31DEC2015	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN2015	31DEC2015	N
			Parathyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1112 11121321	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121325	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lentigo maligna	25APR2020	03SEP2020	N
				25AUG2020	03SEP2020	N
			Melanocytic naevus	25AUG2020	25AUG2020	N
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	01JAN1987	N
			Skin lesion removal	03SEP2020	03SEP2020	N
			Skin neoplasm excision	25AUG2020	25AUG2020	N
	C4591001 1112 11121327	Metabolism and nutrition disorders	Gout	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1112 11121329	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1112 11121330	Endocrine disorders	Hypothyroidism	01OCT1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1995		Y
				01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1112 11121334	Eye disorders	Glaucoma	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1112 11121337	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN1980		Y
			Oesophageal stenosis	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1947		Y
		Infections and infestations	Diverticulitis	01JAN2013		Y
		Injury, poisoning and procedural complications	Foot fracture	20JAN2020	20JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Osteopenia	01JAN2013		Y
		Nervous system disorders	Meralgia paraesthetica	01JAN2005		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01APR2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1972	31DEC1974	N
			Vulvovaginal dryness	01SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Rhinitis perennial	01JAN1955		Y
		Surgical and medical procedures	Foot operation	20JAN2020	20JAN2020	N
			Hysterectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1112 11121338	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01APR2018	30JUN2018	N
		Surgical and medical procedures	Lithotripsy	01JUN2018	30JUN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1112 11121340	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Nervous system disorders	Migraine	01JAN1984		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis perennial	01JAN1972		Y
	C4591001 1112 11121344	Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Obesity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1112 11121347	Cardiac disorders	Myocardial infarction	19SEP2019	19SEP2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	19SEP2019	19SEP2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1112 11121348	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
			Seasonal allergy	01JAN1980		Y
		Reproductive system and breast disorders	Pelvic pain	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1112 11121349	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	03FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01SEP2010	30APR2011	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Brachytherapy	01FEB2011	28FEB2011	N
			Radiotherapy	01APR2011	30APR2011	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1112 11121350	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	01JAN1988	N
	C4591001 1114 11141004	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Macular degeneration	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN1970		Y
			Muscle spasms	01JAN2018		Y
		Nervous system disorders	Dementia	01JUN2017		Y
		Psychiatric disorders	Depression	01JUN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01DEC2017		Y
		Surgical and medical procedures	Dupuytren's contracture operation	01JAN1970	31DEC1970	N
	C4591001 1114 11141005	Eye disorders	Myopia	01JAN1960		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
			Seasonal allergy	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1114 11141006	Cardiac disorders	Acute myocardial infarction	01AUG2005	01AUG2005	N
			Angina pectoris	01JAN2005		Y
			Coronary artery disease	01AUG2005		Y
		Eye disorders	Cataract	01JAN2020		Y
			Eye disorder	01AUG2019	12AUG2020	N
		Immune system disorders	Drug hypersensitivity	01AUG2005		Y
			Seasonal allergy	01APR2010		Y
		Injury, poisoning and procedural complications	Periorbital haemorrhage	12AUG2020		Y
		Investigations	Ejection fraction abnormal	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2005		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JUN2018	30JUN2019	N
			Osteoarthritis	01JAN1967		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2011	31DEC2011	N
			Knee arthroplasty	01JAN2020	31JAN2020	N
			Skin cyst excision	12AUG2020	12AUG2020	N
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1114 11141011	Ear and labyrinth disorders	Tinnitus	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1114 11141017	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Pain in extremity	07AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2012	01JAN2012	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012		Y
	C4591001 1114 11141018	Eye disorders	Myopia	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1114 11141019	Eye disorders	Myopia	01JAN1960		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
	C4591001 1114 11141020	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Hypermetropia	01JAN1969	31AUG2014	N
			Myopia	01AUG2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Device allergy	01JAN1961		Y
			Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01AUG2000	31AUG2000	N
	C4591001 1114 11141022	Cardiac disorders	Coronary artery disease	01JAN2007		Y
		Eye disorders	Myopia	01JAN1980		Y
			Presbyopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1114 11141023	Endocrine disorders	Oestrogen deficiency	01JAN1990		Y
		Eye disorders	Myopia	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1988		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990		Y
	C4591001 1114 11141025	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Diverticulum	01JAN2012		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2004		Y
		Immune system disorders	Allergy to animal	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1114 11141028	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1114 11141030	Eye disorders	Presbyopia	01JAN2016		Y
		Immune system disorders	Allergy to surgical sutures	01JAN2000		Y
			Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1114 11141031	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Myopia	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1114 11141032	Endocrine disorders	Oestrogen deficiency	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2012		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1998		Y
			Intervertebral disc degeneration	01JAN1998		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2003	N
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1114 11141035	Eye disorders	Presbyopia	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1114 11141036	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01APR1955		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Nervous system disorders	Headache	01APR1955		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Fracture treatment	31JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1114 11141043	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1114 11141044	Gastrointestinal disorders	Constipation	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Neck pain	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN1982		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
		Vascular disorders	Hot flush	01JAN2017		Y
			Hypertension	01JAN2015		Y
	C4591001 1114 11141045	Cardiac disorders	Mitral valve prolapse	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Cardiac murmur	01JAN1968		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Phlebectomy	01JUL2020	31JUL2020	N
		Vascular disorders	Varicose vein	01JAN1987	31JUL2020	N
	C4591001 1114 11141046	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Astigmatism	01JAN1958		Y
			Presbyopia	01JAN1958		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1114 11141047	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1114 11141048	Cardiac disorders	Coronary artery disease	01NOV2016		Y
		Eye disorders	Cataract	01SEP2019	30SEP2019	N
			Dry eye	01JAN2017		Y
		General disorders and administration site conditions	Non-cardiac chest pain	01NOV2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	04JUL2020	04JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2010		Y
			Intervertebral disc protrusion	04JUL2020	04JUL2020	N
			Osteoarthritis	01NOV2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01MAR2019	31MAR2019	N
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Cancer surgery	01MAR2010	31MAR2010	N
			Cataract operation	01SEP2019	30SEP2019	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Spinal fusion surgery	04JUL2020	04JUL2020	N
			Vascular graft	01NOV2010	30NOV2010	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1114 11141049	Endocrine disorders	Oestrogen deficiency	01JAN2008		Y
		Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1114 11141050	Ear and labyrinth disorders	Deafness	01JAN1991		Y
		Eye disorders	Presbyopia	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	18AUG2005		Y
			Osteoporosis	01JAN2010		Y
			Rheumatoid arthritis	01JAN2010		Y
			Rotator cuff syndrome	01JUL2016	01AUG2016	N
		Psychiatric disorders	Depression	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01AUG2016	01AUG2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1114 11141052	Eye disorders	Myopia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1971		Y
		Reproductive system and breast disorders	Uterine prolapse	01NOV2007	30NOV2007	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01NOV2007	30NOV2007	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hot flush	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1114 11141055	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1982		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Foot fracture	21JAN2020	21JAN2020	N
			Forearm fracture	21JAN2020	21JAN2020	N
			Hand fracture	21JAN2020	21JAN2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Finger repair operation	21JAN2020	21JAN2020	N
			Fracture treatment	21JAN2020	21JAN2020	N
			Limb operation	21JAN2020	21JAN2020	N
	C4591001 1114 11141056	Eye disorders	Eyelid ptosis	01JAN2015	31DEC2015	N
			Myopia	01JAN1990		Y
			Presbyopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2020		Y
			Pain in extremity	01JAN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01SEP2018	30SEP2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
			Dyspnoea	16JUL2020	20JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ptosis repair	01JAN2015	31DEC2015	N
			Renal stone removal	01SEP2018	30SEP2018	N
			Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1114 11141057	Endocrine disorders	Basedow's disease	01JAN1998		Y
		Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1114 11141058	Cardiac disorders	Atrial fibrillation	01JUN2016		Y
		Immune system disorders	Seasonal allergy	01APR2012		Y
		Investigations	HLA marker study	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2017		Y
		Psychiatric disorders	Anxiety	01MAR2015		Y
			Depression	01MAR2015		Y
			Insomnia	01MAR2015		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1114 11141059	Endocrine disorders	Hypothyroidism	01JAN1996		Y
			Oestrogen deficiency	01JAN2016		Y
		Eye disorders	Myopia	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Progesterone decreased	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1114 11141060	Endocrine disorders	Hypothyroidism	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Food allergy	01JAN1980		Y
			Seasonal allergy	01APR1955		Y
		Psychiatric disorders	Anxiety	01JAN1978		Y
			Depression	01JAN1978		Y
		Reproductive system and breast disorders	Pelvic pain	01NOV1979	30NOV1980	N
			Vaginal prolapse	01APR2020	30APR2020	N
		Surgical and medical procedures	Hysterectomy	01NOV1980	30NOV1980	N
			Vaginal prolapse repair	01APR2020	30APR2020	N
		Vascular disorders	White coat hypertension	01JAN1955		Y
	C4591001 1114 11141066	Eye disorders	Presbyopia	01JAN2005		Y
		Infections and infestations	Urinary tract infection	01JAN2015		Y
		Injury, poisoning and procedural complications	Meniscus injury	01APR2016	31JUL2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Meniscus operation	01JUL2016	31JUL2016	N
	C4591001 1114 11141067	Immune system disorders	Seasonal allergy	01APR1960		Y
	C4591001 1114 11141071	Eye disorders	Myopia	01JAN1968		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1114 11141077	Surgical and medical procedures	Hernia repair	01JAN2019	31DEC2019	N
		Ear and labyrinth disorders	Tinnitus	01JAN2006		Y
		Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1114 11141078	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1989	01JAN1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	01JAN1989	N
	C4591001 1114 11141080	Infections and infestations	Staphylococcal infection	01JAN2017		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2005	01JAN2018	N
					01NOV2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	14NOV2018		Y
			Type 2 diabetes mellitus	01JAN1986		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Leg amputation	01JAN2018	01JAN2018	N
				01NOV2012	01NOV2012	N
		Vascular disorders	Hypertension	03NOV2017		Y
	C4591001 1114 11141082	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1979		Y
				01JAN1994		Y
				01JAN2000		Y
	C4591001 1114 11141086	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN1990		Y
				01JAN1995		Y
				01JAN2009		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Meniscus injury	01AUG2017	31AUG2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000		Y
			Osteoarthritis	01JAN2017	05NOV2019	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	25NOV2019	25NOV2019	N
			Meniscus operation	01JAN2018	31DEC2018	N
	C4591001 1114 11141088	Endocrine disorders	Goitre	01JAN2018		Y
		Eye disorders	Myopia	01JAN1967		Y
		Gastrointestinal disorders	Large intestine polyp	01JUN2019	30JUN2019	N
		Infections and infestations	Onychomycosis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
	C4591001 1114 11141090	Surgical and medical procedures	Large intestinal polypectomy	01JUN2019	30JUN2019	N
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2003	01JAN2004	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2018		Y
	C4591001 1114 11141091	Surgical and medical procedures	Prostatectomy	01JAN2004	01JAN2004	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Astigmatism	01JAN1954		Y
			Presbyopia	01JAN1954		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Female sterilisation	09JUN1984	09JUN1984	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1114 11141092	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1114 11141094	Eye disorders	Astigmatism	01JAN1990		Y
			Presbyopia	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1114 11141099	Endocrine disorders	Oestrogen deficiency	01JAN1997		Y
		Eye disorders	Presbyopia	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Osteoarthritis	01JAN2013	10NOV2017	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1992	01NOV1997	N
		Surgical and medical procedures	Hysterectomy	01NOV1997	01NOV1997	N
			Knee arthroplasty	01NOV2017	01NOV2017	N
	C4591001 1114 11141101	Cardiac disorders	Atrial fibrillation	12OCT2019		Y
			Myocardial infarction	12OCT2019	12OCT2019	N
		Endocrine disorders	Hypothyroidism	01NOV2018		Y
			Oestrogen deficiency	01JAN1998		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2003		Y
			Pancreatitis chronic	01JUL2003		Y
		Immune system disorders	Contrast media allergy	01JAN1985		Y
			Drug hypersensitivity	01AUG2010		Y
				01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Wrist fracture	01MAR2015	30JUN2015	N
				01OCT2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JUN2018		Y
			Osteoarthritis	01JAN1995	30SEP2015	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Cystitis interstitial	01MAY2020		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN1996	31DEC1998	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1965		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Implantable cardiac monitor insertion	01JAN2020	31JAN2020	N
			Knee arthroplasty	01SEP2015	30SEP2015	N
	C4591001 1114 11141102	Eye disorders	Myopia	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Enchondromatosis	01JAN2013		Y
			Malignant melanoma	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1114 11141104	Psychiatric disorders	Mood swings	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1114 11141107	Eye disorders	Myopia	01JAN1951		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1950		Y
		Social circumstances	Postmenopause	01JAN1987		Y
	C4591001 1114 11141108	Eye disorders	Myopia	01JAN1969		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Humerus fracture	05JAN2017	08JAN2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1114 11141110	Surgical and medical procedures	Bone operation	08JAN2017	08JAN2017	N
		Eye disorders	Glaucoma	01AUG2019		Y
			Presbyopia	01JAN1969		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01AUG2019		Y
		Surgical and medical procedures	Transurethral prostatectomy	01FEB2020	29FEB2020	N
	C4591001 1114 11141112	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Eye disorders	Myopia	01JAN1969		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019	30JUN2019	N
					30JUN2020	N
			Neuropathy peripheral	01JAN2015		Y
			Optic neuritis	01JAN2015		Y
			Peroneal nerve palsy	01OCT2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
			Emphysema	01JAN2007		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JUN2019	30JUN2019	N
				01JUN2020	30JUN2020	N
			Coronary artery bypass	01JAN2018	31JAN2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1114 11141114	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1114 11141116	Eye disorders	Myopia	01JAN1958		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhonchi	20AUG2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1114 11141120	Immune system disorders	Drug hypersensitivity	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1114 11141122	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Lymphangiectasia intestinal	01JAN1966		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014		Y
			Ovarian germ cell teratoma benign	01JAN2010	01JAN2010	N
		Nervous system disorders	Migraine	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	01JAN2010	N
			Skin neoplasm excision	17AUG2020	17AUG2020	N
	C4591001 1114 11141124	Vascular disorders	Lymphoedema	01JAN1993		Y
		Eye disorders	Presbyopia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Intervertebral disc protrusion	01JAN2006		Y
			Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1114 11141125	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	31DEC2019	N
				01JAN2019		Y
	C4591001 1114 11141126	Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
		Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Eye disorders	Macular degeneration	01JAN2018		Y
			Myopia	01JAN1950		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
			Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1116 11161001	Metabolism and nutrition disorders	Obesity	01JAN1995	31DEC1999	N
			Type 2 diabetes mellitus	01JAN1995	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161004	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Macular degeneration	01JAN2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2010	31JAN2010	N
		Renal and urinary disorders	Urinary retention	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161005	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2008		Y
			Rash	01JUL2020	31OCT2020	N
	C4591001 1116 11161013	Eye disorders	Cataract	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 1 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Seizure	01JAN2019		Y
	C4591001 1116 11161016	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Eye disorders	Glaucoma	01JAN2015		Y
		Surgical and medical procedures	Gastric bypass	01JAN2015	31JAN2015	N
			Gastric stapling	01JAN1994	31DEC1994	N
	C4591001 1116 11161017	Injury, poisoning and procedural complications	Wrist fracture	01JAN1975	31DEC1975	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Catheterisation cardiac	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01OCT2007	31OCT2007	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2004		Y
		Surgical and medical procedures	Pneumonectomy	01OCT2007	31OCT2007	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1116 11161019	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Thyroidectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Renal and urinary disorders	Urinary retention	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161021	Cardiac disorders	Bradycardia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2017		Y
	C4591001 1116 11161024	Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161025	Social circumstances	Postmenopause	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1116 11161026	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
			Tremor	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2014		Y
			Mania	01JAN2012		Y
	C4591001 1116 11161027	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Multiple allergies	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Muscle spasms	01JAN2012		Y
			Osteoporosis	01JAN2012		Y
	C4591001 1116 11161028	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Multiple allergies	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2010	31DEC2011	N
	C4591001 1116 11161030	Cardiac disorders	Atrial fibrillation	01DEC2018	31DEC2018	N
		Gastrointestinal disorders	Gastric ulcer	01JAN2020	31JAN2020	N
			Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2002	31DEC2002	N
		Nervous system disorders	Essential tremor	01JAN2018		Y
			Migraine	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	01DEC2018	31DEC2018	N
			Cardiac pacemaker insertion	01DEC2018		Y
			Prostatic operation	01JAN2002	31DEC2002	N
			Transfusion	01JAN2020	31JAN2020	N
	C4591001 1116 11161031	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2017		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
	C4591001 1116 11161032	Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161033	Gastrointestinal disorders	Gastroesophageal reflux disease	01APR2020		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
	C4591001 1116 11161034	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1116 11161035	Renal and urinary disorders	Pollakiuria	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Aortic aneurysm	01JAN2013		Y
			Hypertension	01JAN2000		Y
	C4591001 1116 11161037	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN2000	31DEC2000	N
	C4591001 1116 11161038	Cardiac disorders	Myocardial ischaemia	20MAR2020		Y
		Gastrointestinal disorders	Dyspepsia	20MAR2020		Y
		Investigations	Blood cholesterol increased	20MAR2020		Y
		Surgical and medical procedures	Coronary artery bypass	20MAR2020	20MAR2020	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1116 11161039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Gastrectomy	01JAN2012	31DEC2012	N
	C4591001 1116 11161045	Gastrointestinal disorders	Rectal haemorrhage	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2016	N
	C4591001 1116 11161046	Congenital, familial and genetic disorders	Heart disease congenital	(b) (6) 1940		Y
		Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Gastrointestinal disorders	Diverticulum	01JAN1990		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1980		Y
		Nervous system disorders	Presyncope	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01JUL1991	31JUL1991	N
			Mammoplasty	01JAN1989	31DEC1989	N
			Rectocele repair	01JAN2006	31DEC2006	N
			Urinary bladder suspension	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1116 11161048	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1985	31DEC1985	N
			Breast reconstruction	01JAN1990	31DEC1990	N
			Mastectomy	01JAN1985	31DEC1985	N
	C4591001 1116 11161051	Endocrine disorders	Hyperthyroidism	01JAN1996	31DEC1996	N
			Hypothyroidism	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal cancer	01JAN2003	31DEC2004	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Anorectal operation	01JAN2003	31DEC2003	N
			Hand repair operation	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Thyroidectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1116 11161052	Investigations	Blood cholesterol increased	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161056	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Endocrine disorders	Basedow's disease	01OCT2005	31DEC2018	N
		Eye disorders	Glaucoma	01JAN2018		Y
			Macular degeneration	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Investigations	Blood triglycerides increased	01JAN1969		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	25OCT2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	11FEB2020	11FEB2020	N
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Joint manipulation	25OCT2019	25OCT2019	N
			Nasal septal operation	11FEB2020	11FEB2020	N
	C4591001 1116 11161057	Endocrine disorders	Hyperthyroidism	01JAN1986		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	31JAN2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161060	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2020		Y
			Osteoporosis	25JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JUN1972	01JUN1972	N
		Nervous system disorders	Sciatica	01JAN2020		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JUN1972	01JUN1972	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1116 11161061	Eye disorders	Cataract	01JAN2015		Y
			Glaucoma	01JAN2014		Y
		Injury, poisoning and procedural complications	Nerve injury	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161062	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
	C4591001 1116 11161063	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161064	Cardiac disorders	Tachycardia	01AUG2019		Y
		Eye disorders	Macular degeneration	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2008		Y
			Dyspepsia	01JAN2008		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1973	31DEC1973	N
		Investigations	Blood cholesterol increased	01JUL2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1974	31DEC1974	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01AUG2019	31AUG2019	N
			Cholecystectomy	01JAN1973	31DEC1973	N
			Hysterectomy	01NOV1974	30NOV1974	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1116 11161067	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161070	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Clear cell renal cell carcinoma	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Renal tumour excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1116 11161073	Hepatobiliary disorders	Gallbladder disorder	01JAN2006	31DEC2006	N
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN2016	31DEC2016	N
			Limb injury	01APR2015	31DEC2017	N
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2004	31DEC2006	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Hypoaesthesia	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Incontinence	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Gastric bypass	01AUG2005	31AUG2005	N
			Haematoma evacuation	25AUG2020	25AUG2020	N
			Joint arthroplasty	01JAN2016	31DEC2016	N
			Limb operation	01JAN2001	31DEC2001	N
			Shoulder arthroplasty	01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Haematoma	25AUG2020	25AUG2020	N
	C4591001 1116 11161074	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Empyema	01JAN1988	31DEC1988	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01APR2020		Y
			Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1988		Y
			Emphysema	01JAN2000		Y
			Hypoxia	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
			Vaginal operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161075	Investigations	Blood cholesterol increased	01JAN2018		Y
		Nervous system disorders	Parkinson's disease	01FEB2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018		Y
	C4591001 1116 11161077	Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Irritable bowel syndrome	01JAN2010		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01MAR2012	31MAR2012	N
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	01MAR2012	31MAR2012	N
			Implantable cardiac monitor insertion	01FEB2015	31OCT2018	N
			Oophorectomy bilateral	01AUG2019	31AUG2019	N
			Photorefractive keratectomy	01OCT2004	31OCT2004	N
			Punctal plug insertion	01DEC2017	31DEC2017	N
			Urinary bladder suspension	01JAN2012	31JAN2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vaginal prolapse repair	01AUG2019	31AUG2019	N
	C4591001 1116 11161080	Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	24JUL2013	31AUG2015	N
			Fibroma	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Oophorectomy bilateral	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161081	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Surgical and medical procedures	Limb operation	01JAN2013	31DEC2013	N
	C4591001 1116 11161084	Endocrine disorders	Hyperprolactinaemia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	21FEB2020		Y
		Nervous system disorders	Migraine	01JAN2011		Y
		Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1116 11161086	Cardiac disorders	Coronary artery occlusion	01DEC2015	31DEC2015	N
			Ventricular extrasystoles	01DEC2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Retinal detachment	01JAN2020	31JAN2020	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
			Colonoscopy	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01DEC2015	31DEC2015	N
			Eye laser surgery	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1116 11161087	Eye disorders	Retinal tear	01JAN2005	31DEC2005	N
		Infections and infestations	Appendicitis	01JAN1958	31DEC1958	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1996	31DEC1996	N
	C4591001 1116 11161088	Hepatobiliary disorders	Gallbladder disorder	01JUN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Renal and urinary disorders	Bladder spasm	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1116 11161089	Eye disorders	Macular degeneration	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Infections and infestations	Poliomyelitis	01JAN1954	31DEC1954	N
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Renal and urinary disorders	Pollakiuria	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161090	Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161092	Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1116 11161093	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01MAR2020		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1980	31DEC1980	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Calculus bladder	01MAR2020		Y
		Surgical and medical procedures	Fracture treatment	01MAR2017	31MAR2017	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
	C4591001 1116 11161094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Vascular stent occlusion	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Investigations	Blood cholesterol increased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prostatic specific antigen increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1985		Y
		Cardiac disorders	Bradycardia	01AUG2018		Y
	C4591001 1116 11161095	Gastrointestinal disorders	Inguinal hernia	01JAN1982	31DEC1982	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Insomnia	01AUG2018		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1956	31DEC1956	N
			Female sterilisation	01JAN1981	31DEC1981	N
				01JAN1985	31DEC1985	N
			Inguinal hernia repair	01JAN1982	31DEC1982	N
	C4591001 1116 11161096	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161097	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1998		Y
			Vertebral osteophyte	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1116 11161098	Investigations	Blood cholesterol increased	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1116 11161102	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
				01JAN2005	31DEC2007	N
			Back pain	01JAN2000		Y
			Intervertebral disc degeneration	01JAN2000	31DEC2000	N
			Osteonecrosis	01JAN2018	31DEC2018	N
			Spinal stenosis	01JAN2000	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1997	31DEC1997	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Neck surgery	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01FEB2020		Y
			Spinal operation	01JAN2000	31DEC2000	N
				01JAN2011	31DEC2011	N
				01JAN2018	31DEC2018	N
			Sterilisation	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1116 11161106	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1950		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1970	31DEC1970	N
		Nervous system disorders	Neuralgia	01JAN1972		Y
		Surgical and medical procedures	Hysterectomy	01JAN1970	31DEC1970	N
			Spinal fusion surgery	01JAN1976	31DEC1976	N
	C4591001 1116 11161109	Vascular disorders	Hypertension	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Precancerous cells present	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2013	31DEC2013	N
	C4591001 1116 11161111	Vascular disorders	Hypertension	01JAN2005		Y
		Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1116 11161112	Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161114	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
			Coronary artery disease	01JAN2001		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2001		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
			Coronary arterial stent insertion	01JAN2001	31DEC2001	N
			Coronary artery bypass	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1116 11161116	Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1116 11161117	Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161118	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Renal stone removal	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161120	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2007	31DEC2007	N
			Trigger finger	01JAN1995	31DEC2014	N
		Nervous system disorders	Sciatica	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN1985	31DEC1985	N
			Gastric bypass	01NOV2005	30NOV2005	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Peripheral nerve operation	01JAN2007	31DEC2007	N
			Tendon sheath incision	01JAN1995	31DEC2014	N
			Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1116 11161121	Infections and infestations	Lyme disease	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1998	31DEC1998	N
	C4591001 1116 11161122	Cardiac disorders	Myocardial infarction	01SEP2011	30SEP2011	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Coronary artery bypass	01SEP2011	30SEP2011	N
			Radiotherapy to prostate	01JAN2013	31DEC2013	N
	C4591001 1116 11161123	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Nasal septal operation	17MAR2020	17MAR2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161124	Cardiac disorders	Cardiac disorder	01OCT2015		Y
			Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2013		Y
			Insomnia	01JAN2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
				01OCT2017	31OCT2017	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1116 11161125	Immune system disorders	Allergy to animal	01JAN2015		Y
		Nervous system disorders	Seizure	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Social circumstances	Menopause	01JAN2012	31DEC2012	N
	C4591001 1116 11161126	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2015	31DEC2015	N
			Wrist fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2012		Y
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Elbow operation	01JAN2015	31DEC2015	N
			Shoulder operation	01JAN2010	31DEC2010	N
			Wrist surgery	01JAN2019	31DEC2019	N
	C4591001 1116 11161127	Investigations	Blood cholesterol increased	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1995	31DEC1995	N
	C4591001 1116 11161128	Ear and labyrinth disorders	Deafness	01JAN2006	31DEC2006	N
		Eye disorders	Blepharitis	01JAN2008	31DEC2008	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2008	31DEC2008	N
			Ear operation	01JAN2006	31DEC2006	N
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1116 11161130	Eye disorders	Cataract	01JAN2002	31DEC2007	N	
		Immune system disorders	Seasonal allergy	01JAN1980		Y	
		Injury, poisoning and procedural complications	Meniscus injury	01APR1984	31DEC1984	N	
		Musculoskeletal and connective tissue disorders	Road traffic accident	01APR1984	31DEC1984	N	
			Arthritis	01JAN1980		Y	
			Exostosis	01JAN2006	31DEC2006	N	
			Tendonitis	01MAY2001	31DEC2001	N	
			Tenosynovitis stenosans	01JAN2018		Y	
		Nervous system disorders	Radiculopathy	01JUL1995		Y	
		Skin and subcutaneous tissue disorders	Skin fissures	01APR2009	31AUG2009	N	
					01FEB2014	28FEB2014	N
		Social circumstances	Postmenopause	01JAN2006		Y	
		Surgical and medical procedures	Cataract operation	01JAN2002	31DEC2002	N	
					01JAN2007	31DEC2007	N
				Elbow operation	01MAY2001	31DEC2001	N
				Knee operation	01APR1984	30APR1984	N
				Shoulder operation	01JAN2006	31DEC2006	N
				Spinal operation	01JUL1995	31JUL1995	N
				Tenoplasty	01AUG2009	31DEC2009	N
					01FEB2014	28FEB2014	N
			Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1116 11161131		Cardiac disorders	Palpitations	04SEP2018		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y	
		Vascular disorders	Hypertension	01JAN2018		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161132	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
		Nervous system disorders	Migraine	01JAN1969		Y
			Restless legs syndrome	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1116 11161133	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Nervous system disorders	Nerve compression	01JAN2015		Y
	C4591001 1116 11161134	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JUL2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01AUG2019		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2005	31DEC2005	N
			Abdominal operation	01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1116 11161135	Nervous system disorders	Essential tremor	01JAN2019		Y
	C4591001 1116 11161136	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal corpectomy	01JAN2011	31DEC2011	N
	C4591001 1116 11161137	Cardiac disorders	Coronary artery disease	01MAR2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01MAY2019	31MAY2019	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Coronary artery bypass	01MAR2018	31MAR2018	N
			Spinal operation	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161141	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Spinal nerve stimulator implantation	01JAN2019	31DEC2019	N
	C4591001 1116 11161142	Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc protrusion	01JAN2006	31DEC2006	N
			Pain in extremity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1997	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Surgical and medical procedures	Arteriovenous fistula operation	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Spinal decompression	01FEB2020	29FEB2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal fusion surgery	01JAN2010	31DEC2010	N
			Spinal nerve stimulator implantation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1116 11161144	Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2000	31DEC2000	N
			Limb injury	01JAN1996	31DEC1996	N
			Tendon rupture	01JAN2018	31DEC2018	N
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1987	31DEC1987	N
			Gastric banding	01JAN2000	31DEC2000	N
			Knee operation	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN1996	31DEC1996	N
			Vasectomy	01JAN2018	31DEC2018	N
	C4591001 1116 11161145	Cardiac disorders	Coronary artery disease	01JAN1989	31DEC1989	N
			Myocardial infarction	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2018	N
		Surgical and medical procedures	Blepharoplasty	28AUG2020	28AUG2020	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161146	Blood and lymphatic system disorders	Anaemia	01JAN2017	30JUN2020	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN1990	31DEC1990	N
			Road traffic accident	01DEC1990	31DEC1990	N
			Tendon rupture	01JAN1989	31DEC1989	N
			Upper limb fracture	01JAN1990	31DEC1990	N
		Investigations	Blood cholesterol increased	01JAN1992		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
				01JAN2014	31DEC2014	N
			Tenoplasty	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1116 11161147	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Dry eye	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Metabolism and nutrition disorders	Hyponatraemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1978	31DEC1978	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1996	31DEC1996	N
			Caecectomy	01JAN1995	31DEC1995	N
			Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1978	31DEC1978	N
			Thyroid nodule removal	01JAN2019	31DEC2019	N
			Vascular disorders	Hypertension	01JAN1967	
	C4591001 1116 11161149	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
		Psychiatric disorders	Bipolar disorder	01JAN1995		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2008	31DEC2008	N
	C4591001 1116 11161150	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Foot operation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161151	Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
	C4591001 1116 11161152	Infections and infestations	Sinusitis	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2015		Y
		Social circumstances	Menopause	01JAN2010	31DEC2010	N
	C4591001 1116 11161153	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Vertebral osteophyte	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2018		Y
		Psychiatric disorders	Schizophrenia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2009		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01FEB2019	28FEB2019	N
		Surgical and medical procedures	Caesarean section	03FEB1993	03FEB1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				07MAR1989	07MAR1989	N
	C4591001 1116	Vascular disorders	Hypertension	01JAN2016		Y
	11161155	Infections and infestations	Chronic sinusitis	01JAN2017	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Angioplasty	01DEC2019	31DEC2019	N
			Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1977		Y
	11161156	General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1116	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
	11161161	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1970	31DEC1979	N
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Renal and urinary disorders	Urinary hesitation	01JAN2015		Y
		Surgical and medical procedures	Aortic surgery	01JAN2015	31DEC2015	N
			Implantable defibrillator insertion	01JAN2015	31DEC2015	N
			Shoulder operation	01JAN1979	31DEC1979	N
			Spinal operation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161162	Vascular disorders	Hypertension	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01FEB2020		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Fibromyalgia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01MAR2010	31DEC2010	N
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01MAR2010	31MAR2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161163	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Infections and infestations	Appendicitis	01MAY2017	31MAY2017	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	01JAN2010		Y
		Social circumstances	Menopause	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Appendicectomy	01MAY2017	31MAY2017	N
			Elbow operation	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161165	Gastrointestinal disorders	Dyspepsia	01JAN1991		Y
			Hiatus hernia	01JAN1991		Y
			Oesophageal spasm	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01APR2005	30APR2005	N
		Surgical and medical procedures	Caesarean section	06JUN1978	06JUN1978	N
				08APR1985	08APR1985	N
				08OCT1981	08OCT1981	N
			Female sterilisation	08APR1985	08APR1985	N
			Hip arthroplasty	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161166	Gastrointestinal disorders	Large intestine perforation	01JAN1990	31DEC1990	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Surgical and medical procedures	Prostatectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1116 11161167	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1116 11161168	Cardiac disorders	Tachycardia	01JAN1991		Y
		Gastrointestinal disorders	Diarrhoea	01JUN2019	31AUG2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01OCT2019	31OCT2019	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUN2020		Y
			Polyarthrits	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006	28FEB2006	N
		Surgical and medical procedures	Caesarean section	09JUL1989	09JUL1989	N
			Laparoscopic surgery	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1116 11161169	Infections and infestations	Hepatitis C	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2015	31DEC2015	N
			Hip fracture	01JAN2015	31DEC2015	N
			Upper limb fracture	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Osteoporosis	01JAN2015		Y
		Social circumstances	Menopause	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Bone operation	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2004	31DEC2004	N
			Internal fixation of fracture	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1116 11161170	Renal and urinary disorders	Urinary retention	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161173	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Umbilical hernia	31OCT2019	31OCT2019	N
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2010		Y
		Nervous system disorders	Cluster headache	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN1970		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
			Axillary lymphadenectomy	01MAY1990	31MAY1990	N
			Hip arthroplasty	01DEC2019	31DEC2019	N
			Spinal fusion surgery	01SEP2018	30SEP2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161181	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Synovial cyst	01JAN2010		Y
	C4591001 1116 11161182	Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAR2013	31MAR2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2013		Y
			Post-traumatic stress disorder	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
				01JAN2015	31DEC2015	N
	C4591001 1116 11161183	Social circumstances	Postmenopause	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1116 11161184	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Nervous system disorders	Essential tremor	01JAN1992		Y
		Renal and urinary disorders	Urinary retention	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2009		Y
	C4591001 1116 11161187	Gastrointestinal disorders	Abdominal hernia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2006	31DEC2006	N
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1988	31DEC1988	N
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
			Oesophagogastric fundoplasty	01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2006	31DEC2006	N
	C4591001 1116 11161188	Gastrointestinal disorders	Oesophageal perforation	01JAN1979	31DEC1979	N
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1979	31DEC1979	N
		Investigations	Blood cholesterol increased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Loose body in joint	01JAN1978	31DEC1978	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Chondrectomy	01JAN1978	31DEC1978	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Neck surgery	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161189	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUL2020		Y
			Rheumatic fever	01JAN1956	31DEC1956	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Wrist surgery	01JAN2018	31JAN2018	N
	C4591001 1116 11161190	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
			Herpes virus infection	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161191	Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1967	31DEC1967	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1967	31DEC1967	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Lithotripsy	01JAN2018	31DEC2018	N
	C4591001 1116 11161192	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2008		Y
		Gastrointestinal disorders	Diverticulum	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JUL2020	31JUL2020	N
	C4591001 1116 11161193	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Nausea	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN1999	31DEC1999	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Fracture	01JAN1968	31DEC1968	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc protrusion	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Colectomy	01JAN1999	31DEC1999	N
			Spinal operation	01JAN1971	31DEC1971	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Wrist surgery	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161194	Investigations	Blood cholesterol increased	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1116 11161195	Infections and infestations	Pelvic inflammatory disease	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Caesarean section	01JAN1979	31DEC1979	N
				01JAN1984	31DEC1984	N
				01JAN1985	31DEC1985	N
				01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1116 11161197	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN1990	31DEC1990	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Mammoplasty	01MAR2020	31MAR2020	N
			Rotator cuff repair	01DEC2011	31DEC2011	N
			Scoliosis surgery	01JAN2000	31DEC2000	N
	C4591001 1116 11161198	Cardiac disorders	Sinus node dysfunction	01JAN2010		Y
					31DEC2010	N
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
			Tonsillitis	01JAN1958	31DEC1958	N
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2014	31DEC2014	N
			Osteoarthritis	01JAN2016		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Cardiac pacemaker insertion	01JAN2010	31DEC2010	N
			Cataract operation	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1116 11161199	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Nervous system disorders	Seizure	01JAN1979		Y
		Surgical and medical procedures	Shoulder operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161201	Infections and infestations	Herpes virus infection	01JAN1970		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN1958	31DEC1958	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Nervous system disorders	Generalised tonic-clonic seizure	01JAN2000	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1949		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Shoulder operation	01JAN1958	31DEC1958	N
			Tonsillectomy	01JAN1949	31DEC1949	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1116 11161202	Gastrointestinal disorders	Abdominal hernia	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Oral herpes	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1116 11161207	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2015		Y
		Social circumstances	Menopause	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Caesarean section	01JAN1996	31DEC1996	N
				01JAN2001	31DEC2001	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)		
	C4591001 1116 11161208	Endocrine disorders	Hypothyroidism	01JAN2003	31DEC2003	N		
					01JAN2012		Y	
			Eye disorders	Ocular rosacea	01JUN2020		Y	
			Infections and infestations	Tonsillitis	01JAN1971	31DEC1971	N	
			Social circumstances	Postmenopause	01JAN2010	31DEC2010	N	
			Surgical and medical procedures	Caesarean section	10JUN1982	10JUN1982	N	
						10JUN1997	10JUN1997	N
						17JUL1986	17JUL1986	N
						21NOV1978	21NOV1978	N
		C4591001 1116 11161209	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1971	31DEC1971	N	
					01JAN2012		Y	
			Immune system disorders	Seasonal allergy	01JAN2015		Y	
			Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N	
			Investigations	Blood cholesterol increased	01JAN2008		Y	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign joint neoplasm	01JAN1959	31DEC1959	N	
			Reproductive system and breast disorders	Ovarian cyst	01JAN1999	31DEC1999	N	
			Social circumstances	Postmenopause	01JAN2000	31DEC2000	N	
			Surgical and medical procedures	Oophorectomy	01JAN1999	31DEC1999	N	
						01JAN1950	31DEC1950	N
					01JAN1959	31DEC1959	N	
	C4591001 1116 11161210	Vascular disorders	Hypertension	01JAN2008		Y		
		Cardiac disorders	Arrhythmia	01JAN2012		Y		
			Atrioventricular block	01JAN2012	31DEC2012	N		
			Cardiac failure congestive	01JAN2012		Y		

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Coronary arterial stent insertion	01JAN2012	31DEC2012	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1116 11161212	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
	C4591001 1116 11161213	Congenital, familial and genetic disorders	Heart disease congenital	(b) (6) 1952	31DEC2005	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Atrial septal defect repair	01JAN2003	31DEC2003	N
					01JAN2004	31DEC2004
				01JAN2005	31DEC2005	N
			Caesarean section	05APR1993	05APR1993	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypotension	01JAN2004		Y
	C4591001 1116 11161215	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Tonsillitis	01JAN1975	31DEC1975	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	24JUL1982	17MAR1993	N
		Surgical and medical procedures	Caesarean section	02MAR1984	02MAR1984	N
				24JUL1982	24JUL1982	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	17MAR1993	17MAR1993	N
			Lithotripsy	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161218	Gastrointestinal disorders	Crohn's disease	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Hormone replacement therapy	01JAN2010		Y
			Hysterectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1116 11161219	Cardiac disorders	Coronary artery disease	01OCT2019	31OCT2019	N
			Myocardial infarction	01JAN2011	31DEC2011	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Hepatobiliary disorders	Hepatic cirrhosis	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011	31DEC2011	N
				01OCT2019	31OCT2019	N
		Vascular disorders	Hypertension	01JAN2015	31DEC2015	N
	C4591001 1116 11161221	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign pancreatic neoplasm	01JAN1995	31DEC1995	N
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Surgical and medical procedures	Pancreaticoduodenectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161222	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1973	31DEC1973	N
			Squamous cell breast carcinoma	01JAN2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2020	29FEB2020	N
		Surgical and medical procedures	Breast tumour excision	01JAN1973	31DEC1973	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1976	31DEC1976	N
				01JAN2014	31DEC2014	N
			Cancer surgery	01JAN2019	31DEC2019	N
	C4591001 1116 11161227	Ear and labyrinth disorders	Excessive cerumen production	01JAN2015		Y
		Eye disorders	Dry eye	01JAN2019	31DEC2019	N
		General disorders and administration site conditions	Cyst	18JUL2019	18JUL2019	N
				25JUL2019	25JUL2019	N
		Hepatobiliary disorders	Cholelithiasis	01FEB1993	28FEB1993	N
			Hepatic steatosis	30JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer stage III	08JUN2017	08JUN2017	N
		Nervous system disorders	Headache	01JAN2000		Y
			Neuropathy peripheral	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rash	01FEB2020		Y
		Surgical and medical procedures	Brachytherapy	07DEC2017	07DEC2017	N
			Central venous catheterisation	01AUG2017	30SEP2017	N
			Cholecystectomy	01FEB1993	28FEB1993	N
			Hysterectomy	08JUN2017	08JUN2017	N
			Radiotherapy	23OCT2017	28NOV2017	N
			Transfusion	16FEB2018	16FEB2018	N
				23MAR2018	23MAR2018	N
	C4591001 1116 11161229	Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019	31DEC2019	N
			Trigger finger	01APR2020	31DEC2020	N
				01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
			Tendon sheath incision	01APR2020	31DEC2020	N
				01JAN2019	31DEC2019	N
	C4591001 1116 11161231	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ligament operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161232	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Infections and infestations	Appendicitis	01FEB1995	28FEB1995	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1992	31DEC1992	N
		Psychiatric disorders	Depression	01JAN1979		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	31AUG1990	31AUG1990	N
			Colectomy	01FEB1995	28FEB1995	N
			Hysterectomy	01FEB1995	28FEB1995	N
			Spinal fusion surgery	01JAN1992	31DEC1992	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1116 11161233	Endocrine disorders	Hypothyroidism	01MAR2020		Y
		General disorders and administration site conditions	Pain	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01MAR2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2013		Y
			Insomnia	01JAN2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1995	31DEC1995	N
			Spinal nerve stimulator implantation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1116 11161234	Eye disorders	Cataract	01JAN1995	31DEC1995	N
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1965		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Renal stone removal	01JAN1996	31DEC1996	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161236	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diverticulum	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
	C4591001 1116 11161237	Investigations	Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005	31DEC2005	N
	C4591001 1116 11161238	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
			Spondylitis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Bladder prolapse	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2015	31DEC2015	N
		Social circumstances	Menopause	01JAN1994	31DEC1995	N
			Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Mastectomy	01JAN2005	31DEC2005	N
			Urinary bladder suspension	01JAN2015	31DEC2015	N
	C4591001 1116 11161241	Injury, poisoning and procedural complications	Meniscus injury	01JAN1998	31DEC1998	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1991	31DEC1992	N
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Cystic lung disease	01JAN2004	31DEC2004	N
			Pneumothorax spontaneous	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Meniscus operation	01JAN1998	31DEC1998	N
			Spinal operation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1116 11161243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Hypersensitivity	01JAN1963		Y
			Seasonal allergy	01JAN1963		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Bone disorder	01JAN1998	31DEC1998	N
			Soft tissue disorder	01JAN1998	31DEC1998	N
			Tenosynovitis stenosans	01JAN1997	31DEC1997	N
		Nervous system disorders	Hashimoto's encephalopathy	01JAN2010		Y
			Nerve compression	01JAN1998	31DEC1998	N
			Neuropathy peripheral	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1962	31DEC1962	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161244	Gastrointestinal disorders	Femoral hernia	01JAN2000	31DEC2000	N
			Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JAN1984	31DEC1984	N
			Hiatus hernia	01JAN2000	31DEC2000	N
			Tooth impacted	01JAN1960	31DEC1960	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Colonoscopy	01JUL2020	31JUL2020	N
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2005		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1984	31DEC1984	N
			Hernia repair	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1970	31DEC1970	N
			Wisdom teeth removal	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1116 11161246	Investigations	Blood cholesterol increased	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1116 11161247	Gastrointestinal disorders	Constipation	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1979	31DEC1979	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Intervertebral disc degeneration	01JAN2012		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff syndrome	01JAN2017	31DEC2018	N
				01JAN2018	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Psychiatric disorders	Alcoholism	01JAN2017		Y
			Depression	01JAN2016		Y
			Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN1979	31DEC1979	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1116 11161248	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Holmes-Adie pupil	01JAN1986	31DEC1986	N
		Gastrointestinal disorders	Gastrointestinal disorder	01JAN2006		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1986	31DEC1986	N
			Cholelithiasis	01JAN1986	31DEC1986	N
		Immune system disorders	Hypersensitivity	01JAN1996		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1986	31DEC1986	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1986	31DEC1986	N
		Reproductive system and breast disorders	Amenorrhoea	01JAN1984	31DEC1987	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1975	31DEC1975	N
			Cataract operation	01JAN2017	31JAN2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1986	31DEC1986	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Removal of foreign body	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1116 11161250	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Caesarean section	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161251	General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1960	31DEC1960	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2005		Y
			Varicose vein	01JAN2017		Y
	C4591001 1116 11161253	Cardiac disorders	Tachycardia	18SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Keratotomy	01JAN1981	31DEC1981	N
			Prostatectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1116 11161254	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Nervous system disorders	Migraine	01JAN1965		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1116 11161255	Gastrointestinal disorders	Umbilical hernia	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1116 11161257	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
			Nausea	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Fall	01JAN1975	31DEC1975	N
				01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1975		Y
			Neck pain	01JAN1975		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161262	Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Injury, poisoning and procedural complications	Rib fracture	11JAN1984	11JAN1984	N
			Road traffic accident	11JAN1984	11JAN1984	N
			Scapula fracture	11JAN1984	11JAN1984	N
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161263	Endocrine disorders	Hypothyroidism	01JAN1985	31DEC1985	N
		Investigations	Blood cholesterol increased	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Spinal operation	01JAN1989	31DEC1989	N
	C4591001 1116 11161264	Congenital, familial and genetic disorders	Talipes	01JAN1960	31DEC1960	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
			Umbilical hernia	01JAN1981	31DEC1981	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Accident	01JAN2001	31DEC2001	N
			Lower limb fracture	01JAN1978	31DEC1978	N
				01JAN1982	31DEC1982	N
				01JAN1986	31DEC1986	N
			Rib fracture	01JAN1986	31DEC1986	N
			Road traffic accident	01JAN1986	31DEC1986	N
			Sports injury	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Traumatic liver injury	01JAN1986	31DEC1986	N
			Traumatic lung injury	01JAN1986	31DEC1986	N
			Traumatic renal injury	01JAN1986	31DEC1986	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Compartment syndrome	01JAN1986	31DEC1986	N
			Intervertebral disc degeneration	01JAN2016	31DEC2016	N
			Osteoarthritis	01JAN2015	31DEC2015	N
			Trigger finger	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bone neoplasm	01JAN2014	31DEC2014	N
			Renal cell carcinoma	01JAN2001	31DEC2001	N
		Nervous system disorders	Neuropathy peripheral	01JAN1986		Y
		Psychiatric disorders	Insomnia	01JAN2001		Y
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Carpal tunnel decompression	01JAN2005	31DEC2005	N
			Cataract operation	01JUN2020	30JUN2020	N
			Fasciotomy	01JAN1986	31DEC1986	N
			Hip arthroplasty	01JAN1986	31DEC1986	N
				01JAN2015	31DEC2015	N
			Nasal septal operation	01JAN1972	31DEC1972	N
			Nephrectomy	01JAN2001	31DEC2001	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
				01JAN2016	31DEC2016	N
			Talipes correction	01JAN1960	31DEC1960	N
			Umbilical hernia repair	01JAN1981	31DEC1981	N
			Hypothyroidism	01JAN2003		Y
	C4591001 1116 11161265	Endocrine disorders				

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Mammoplasty	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1116 11161266	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Bipolar disorder	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
				01JAN1987	31DEC1987	N
			Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1116 11161267	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Eye disorders	Dry eye	01JAN2018		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN2014	31DEC2014	N
				01JAN1982	31DEC1982	N
				01JAN1986	31DEC1986	N
				01JAN1990	31DEC1990	N
			Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Hip arthroplasty	01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
			Muscle operation	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1116 11161269	Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN1977	31DEC1977	N
		Social circumstances	Menopause	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Tonsillectomy	01JAN1979	31DEC1979	N
	C4591001 1116 11161270	Injury, poisoning and procedural complications	Clavicle fracture	01JAN1978	31DEC1978	N
			Facial bones fracture	01JAN1978	31DEC1978	N
			Gun shot wound	01JAN1998	31DEC1998	N
			Joint dislocation	01JAN1978	31DEC1978	N
			Road traffic accident	01JAN1978	31DEC1978	N
			Upper limb fracture	01JAN1978	31DEC1978	N
		Investigations	Blood glucose increased	01JAN2018		Y
		Nervous system disorders	Complex regional pain syndrome	01JAN1998		Y
		Psychiatric disorders	Bipolar disorder	01JAN1998		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Eye operation	01JAN1978	31DEC1978	N
			Hip surgery	01JAN2014	31DEC2014	N
			Limb operation	01JAN1978	31DEC1978	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1998	31DEC1998	N
			Sympathectomy	01JAN1999	31DEC1999	N
			Tongue operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161271	Cardiac disorders	Mitral valve prolapse	01JAN1985	31DEC1985	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Blindness unilateral	01JAN1984	31DEC1984	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Psychiatric disorders	Stress	01JAN2010		Y
		Social circumstances	Menopause	01JAN1991	31DEC1992	N
		Surgical and medical procedures	Corneal transplant	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1116 11161272	Cardiac disorders	Myocardial infarction	01OCT2018	31OCT2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990	31DEC1990	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1971		Y
		Nervous system disorders	Neuralgia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT1995	31OCT1995	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1116 11161273	Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Menopause	01JAN2000	31DEC2001	N
	C4591001 1116 11161275	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Loose body in joint	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2009	31DEC2009	N
		Nervous system disorders	Seizure	01JAN2009		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2010	31DEC2011	N
		Surgical and medical procedures	Endometrial ablation	01JAN2009	31DEC2009	N
			Myomectomy	01JAN2009	31DEC2009	N
			Shoulder operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1116 11161278	Nervous system disorders	Neuropathy peripheral	01JUN2020		Y
	C4591001 1116 11161279	Cardiac disorders	Arrhythmia	01MAR2020		Y
		Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Gastrointestinal disorders	Abdominal hernia	01MAR2020	31MAR2020	N
			Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01MAR2020	31MAR2020	N
		Infections and infestations	Infection	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Nerve injury	01JAN2015		Y
		Surgical and medical procedures	Abdominal hernia repair	01MAR2020	31MAR2020	N
			Cholecystectomy	01MAR2020	31MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161280	Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1116 11161281	Endocrine disorders	Hyperparathyroidism	01JAN1975		Y
			Hypothyroidism	01JAN1975		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Dyspepsia	01JAN2016		Y
		General disorders and administration site conditions	Oedema	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1961		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoarthritis	01JAN2014	31DEC2014	N
				01JAN2015		Y
				01JAN2016	31DEC2016	N
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Product issues	Embedded device	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2019		Y
			Hysterectomy	01JAN1975	31DEC1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder arthroplasty	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1116 11161282	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Degenerative bone disease	01JAN2014	31DEC2016	N
			Intervertebral disc degeneration	01JAN2005		Y
			Osteoarthritis	01JAN2011	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2005		Y
			Skin cancer	01JAN2017	31DEC2017	N
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2010		Y
		Surgical and medical procedures	Cochlea implant	01JUN2020		Y
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1949	31DEC1949	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161283	Cardiac disorders	Arrhythmia	01JAN2010		Y
			Myocardial infarction	04AUG2012	04AUG2012	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1976	31DEC1976	N
		Investigations	Blood cholesterol increased	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc compression	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Ovarian adhesion	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Implantable defibrillator insertion	01JAN2014	31DEC2014	N
			Knee operation	01JAN1976	31DEC1976	N
			Medical device battery replacement	01AUG2020	31AUG2020	N
			Stent placement	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1116 11161285	Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Fluid retention	01JUN2020		Y
		Reproductive system and breast disorders	Uterine inflammation	01JAN1968	31DEC1968	N
		Surgical and medical procedures	Colon operation	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1968	31DEC1968	N
	C4591001 1116 11161287	Infections and infestations	Hepatitis C	01JAN2005	31DEC2005	N
			Onychomycosis	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1116 11161289	Endocrine disorders	Hypothyroidism	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Dry eye	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Muscle spasms	01JAN2010		Y
			Osteoporosis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN1984		Y
			Insomnia	01JAN2010		Y
			Schizophrenia	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1971	31DEC1971	N
				01JAN1976	31DEC1976	N
			Female sterilisation	01JAN1976	31DEC1976	N
	C4591001 1116 11161290	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2013		Y
			Osteoarthritis	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Renal and urinary disorders	Urinary hesitation	01JAN2013		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN1995		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161291	Vascular disorders	Thrombosis	01JAN2016	31DEC2016	N
		Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1116 11161294	Psychiatric disorders	Anxiety	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1988	31DEC1988	N
			Wrist fracture	01JAN1988	31DEC1988	N
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Bipolar disorder	01JAN1990		Y
			Depression	01JAN1980		Y
		Renal and urinary disorders	Urinary retention	01JAN2018		Y
	C4591001 1116 11161295	Surgical and medical procedures	Bone operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
			Osteoporosis	01JAN2018		Y
	C4591001 1116 11161296	Psychiatric disorders	Depression	01JAN1995		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1116 11161297	Injury, poisoning and procedural complications	Foot fracture	01JAN1984	31DEC1984	N
			Humerus fracture	01JAN1979	31DEC1979	N
			Ligament sprain	01JAN2018	31DEC2018	N
			Pelvic fracture	01JAN1979	31DEC1979	N
			Tibia fracture	01JAN1997	31DEC1997	N
			Traumatic lung injury	01JAN1979	31DEC1979	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1979	31DEC1979	N
			Spondylitis	01JAN2011		Y
		Nervous system disorders	Seizure	01JAN2011		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2011		Y
			Insomnia	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Surgical and medical procedures	Brain tumour operation	01FEB2011	28FEB2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1116 11161298	Immune system disorders	Allergy to arthropod sting	01JAN2016		Y
			Drug hypersensitivity	01JAN1978		Y
				01JAN2005		Y
				01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rubber sensitivity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1995	01JAN1995	N
		Nervous system disorders	Migraine	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	01JAN1995	N
	C4591001 1116 11161300	Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Myopia	01JAN1992	31DEC1993	N
			Retinal detachment	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2001	31DEC2001	N
			Gastroesophageal reflux disease	01JAN2006		Y
			Oesophageal perforation	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Appendicitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2004		Y
			Depression	01JAN2004		Y
		Surgical and medical procedures	Abdominal panniculectomy	01JAN2006	31DEC2006	N
			Adenotonsillectomy	01JAN1965	31DEC1965	N
			Appendicectomy	01JAN2001	31DEC2001	N
			Cataract operation	01JAN2017	31DEC2017	N
			Gastric banding	01JAN2004	31DEC2004	N
			Gastric banding reversal	01JAN2005	31DEC2005	N
			Hernia repair	01JAN2006	31DEC2006	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Metabolic surgery	01JAN2005	31DEC2005	N
			Oesophageal operation	01JAN2005	31DEC2005	N
			Photorefractive keratectomy	01JAN1993	31DEC1993	N
			Retinopexy	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
	C4591001 1116 11161302	Hepatobiliary disorders	Cholelithiasis	01JAN1975	31DEC1975	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Precancerous cells present	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN1970	31DEC1970	N
			Gallbladder operation	01JAN1975	31DEC1975	N
			Hysterectomy	01JAN1974	31DEC1974	N
	C4591001 1116 11161303	Psychiatric disorders	Depression	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161306	Eye disorders	Glaucoma	01JAN2000		Y
		Investigations	Precancerous cells present	01JAN1995	01JAN1995	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	01JAN1995	N
	C4591001 1116 11161311	Cardiac disorders	Cardiac failure congestive	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hyperthyroidism	01JAN2008		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2017		Y
			Haemorrhoids	01JAN2018		Y
		General disorders and administration site conditions	Chest pain	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2011		Y
			Hypokalaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Back pain	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Bipolar disorder	01JAN2006		Y
			Schizophrenia	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Implantable defibrillator insertion	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1116 11161313	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1116 11161314	Surgical and medical procedures	Hysterectomy	01JAN1998	01JAN1998	N
		Eye disorders	Macular degeneration	01JAN2010		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2016	31DEC2016	N
			Constipation	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
			Osteoporosis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1961	31DEC1961	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			01JAN2017	31DEC2017	N	
	C4591001 1116 11161316		Hysterectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN2016		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholecystitis	01JAN1972	31DEC1972	N
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Cataract operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1972	31DEC1972	N
			Hysterectomy	01JAN1971	31DEC1971	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1116 11161319	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Eye disorders	Eye haemorrhage	01JAN2017	31DEC2017	N
			Macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1980	31DEC1980	N
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1116 11161325	Cardiac disorders	Cardiac failure congestive	01JAN2005		Y
		Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2009	31DEC2009	N
				01JAN2018	31DEC2018	N
			Implantable defibrillator removal	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1116 11161327	Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1116 11161328	Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171001	Ear and labyrinth disorders	Vertigo	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1978		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1982	31DEC1982	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Investigations	Cardiac murmur	(b) (6) 1944		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2014		Y
			Intervertebral disc protrusion	01JAN1998		Y
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
			Benign breast neoplasm	01JAN2010	31DEC2010	N
			Lipoma	01JAN2019	28SEP2020	N
			Uterine leiomyoma	01JAN1970	31DEC1982	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1987	31DEC1988	N
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN1978		Y
			Insomnia	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1950		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
			Carpal tunnel decompression	01JAN1988	31DEC1988	N
			Cholecystectomy	01JAN1982	31DEC1982	N
			Chondroplasty	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Skin neoplasm excision	01JAN2016	31DEC2016	N
		Vascular disorders	Aortic stenosis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171002	Ear and labyrinth disorders	Hypoacusis	01JAN2017		Y
		Gastrointestinal disorders	Diverticulum	27FEB2020		Y
			Large intestine polyp	21FEB2019	21FEB2019	N
				27FEB2020	27FEB2020	N
			Umbilical hernia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Otitis externa	02OCT2018	29OCT2018	N
		Investigations	Blood cholesterol increased	01JAN2004		Y
			Heart rate irregular	01JAN1972		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Renal and urinary disorders	Hydronephrosis	01JAN2018		Y
			Nephrolithiasis	01JAN2000	31DEC2018	N
		Social circumstances	Hearing aid user	01JAN2017		Y
			Tobacco user	01JAN1964		Y
		Surgical and medical procedures	Mole excision	01JUL2020	31JUL2020	N
			Polypectomy	21FEB2019	21FEB2019	N
				27FEB2020	27FEB2020	N
			Renal stone removal	21FEB2019	21FEB2019	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1117 11171003	Eye disorders	Glaucoma	01JAN2017		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1988	31DEC1988	N
			Haemorrhoids	21JUL2020		Y
			Large intestine polyp	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Cardiac murmur	01JAN1948	31DEC1964	N
		Metabolism and nutrition disorders	Obesity	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
			Spinal osteoarthritis	24APR2014		Y
			Synovial cyst	01JAN1980	31DEC1980	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2004		Y
			Skin neoplasm excision	01JAN2010	31DEC2010	N
			Synovial cyst removal	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1117 11171004	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Atrial flutter	01JAN2016	31JAN2016	N
		Gastrointestinal disorders	Colitis	01MAR2002		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2010	31DEC2010	N
			Stress fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01FEB2007	30APR2007	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1970		Y
		Social circumstances	Alcohol use	01JAN1967		Y
		Surgical and medical procedures	Cardiac ablation	01FEB2016	29FEB2016	N
			Cardioversion	01JAN2016	31JAN2016	N
			Cataract operation	01APR2006	30APR2006	N
				01APR2007	30APR2007	N
			Vasectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1117 11171005	Cardiac disorders	Atrial fibrillation	01APR2018	30APR2018	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
			Tinnitus	01JAN2011		Y
		Eye disorders	Cataract	01JAN2013	22SEP2017 30NOV2017	N N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
			Hiatus hernia	01JAN1973		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Gout	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
				01JAN1991	30OCT2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JUL2006	31JUL2006	N
			Urinary retention	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01NOV2017	30NOV2017	N
			Knee arthroplasty	22SEP2017	22SEP2017	N
			Knee arthroplasty	30OCT2018	30OCT2018	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1117 11171006	Ear and labyrinth disorders	Tinnitus	01JAN2014		Y
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2014	31DEC2014	N
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1964		Y
		Injury, poisoning and procedural complications	Accident	01JAN1998	31DEC1998	N
			Ligament rupture	01OCT2019	31DEC2019	N
		Investigations	Colonoscopy	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Vitamin B12 deficiency	01JAN2011	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1998		Y
			Osteoarthritis	01JAN1998		Y
			Pain in extremity	01JAN2018	20JUN2020	N
			Spinal osteoarthritis	01JAN1998		Y
			Trigger finger	01JAN2017	31DEC2017	N
		Psychiatric disorders	Alcoholism	01JAN2012	31DEC2015	N
				01JAN2015	31DEC2015	N
			Anxiety	01JAN1989		Y
		Social circumstances	Ex-tobacco user	01JAN2015	31DEC2015	N
			Hearing aid user	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Arthrodesis	01DEC2019	31DEC2019	N
			Colon operation	01JAN2014	31DEC2014	N
			Knee operation	01JAN1998	31DEC1998	N
			Peripheral nerve decompression	20JUN2020	20JUN2020	N
		Vascular disorders	Raynaud's phenomenon	01JAN2007		Y
	C4591001 1117 11171007	Ear and labyrinth disorders	Vertigo positional	01JAN2013	31DEC2017	N
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Glaucoma	01JAN2017		Y
			Visual impairment	01JAN1958		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
			Hepatitis A	01OCT1971	30NOV1971	N
			Tonsillitis	01JAN1955	31DEC1955	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	10AUG2020		Y
			Scoliosis	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1975	31DEC1975	N
		Psychiatric disorders	Depression	01JAN2010	31DEC2013	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01DEC2019	01OCT2020	N
		Surgical and medical procedures	Appendectomy	01JAN1954	31DEC1954	N
			Cataract operation	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Renal stone removal	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171008	Eye disorders	Visual impairment	01JAN1967		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN1976		Y
			Small intestinal stenosis	01JAN1980	31JAN1980	N
		Immune system disorders	Rubber sensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN1976		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2010		Y
			Tobacco user	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31JAN1980	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Small intestinal resection	01JAN1980	31JAN1980	N
	C4591001 1117 11171009	Immune system disorders	Allergy to chemicals	01JAN1995		Y
			Drug hypersensitivity	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1995	31DEC1995	N
		Social circumstances	Tobacco user	01JAN1975		Y
		Surgical and medical procedures	Knee operation	01JAN1995	31DEC1995	N
			Prostatic operation	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01MAY2016	31MAY2016	N
	C4591001 1117 11171010	Eye disorders	Cataract	01JAN2010	23JUN2020	N
			Myopia	01JAN1954	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Injury, poisoning and procedural complications	Joint injury	01MAR2018	24OCT2018	N
		Investigations	Blood cholesterol increased	01FEB2018		Y
			Vitamin D decreased	24OCT2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Osteopenia	03SEP2014		Y
		Renal and urinary disorders	Urinary incontinence	02MAY2017		Y
		Reproductive system and breast disorders	Uterine prolapse	02MAY2017	12DEC2018	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	23JUN2020	23JUN2020	N
			Hysterectomy	12DEC2018	12DEC2018	N
			Keratotomy	01JAN1998	31DEC1998	N
		Vascular disorders	Varicose vein	01JAN1978		Y
	C4591001 1117 11171012	Gastrointestinal disorders	Constipation	01AUG2019		Y
			Diarrhoea	01AUG2019		Y
		General disorders and administration site conditions	Hernia	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
		Infections and infestations	Pneumonia	22JUN2020	25JUN2020	N
			Tonsillitis	01JAN1958	31DEC1958	N
		Investigations	Cardiac murmur	(b) (6) 1951		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2020		Y
			Vitamin B12 deficiency	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rheumatic fever	01JAN1951	31DEC1951	N
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2018	31DEC2018	N
		Social circumstances	Tobacco user	01JAN1982		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Hernia repair	01JAN2017	31DEC2017	N
			Sebaceous cyst excision	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Aortic arteriosclerosis	26MAR2020		Y
	C4591001 1117 11171013	Gastrointestinal disorders	Oesophageal spasm	01JAN2020		Y
		Investigations	Blood cholesterol increased	01DEC2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2016	N
					31DEC2018	N
			Osteoporosis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1117 11171018	Ear and labyrinth disorders	Hypoacusis	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Eye disorders	Myopia	01JAN1985	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Oral herpes	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2018	31DEC2019	N
			Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Salpingectomy	01JAN1985	31DEC1985	N
			Shoulder arthroplasty	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1117 11171019	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
			Erectile dysfunction	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2018		Y
			Penile prosthesis insertion	01JAN2000		Y
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1117 11171020	Cardiac disorders	Coronary artery disease	01JAN2012		Y
			Myocardial infarction	01JUN2012	30JUN2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2015		Y
			Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
			Diverticulum	01JAN2012		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Intervertebral disc protrusion	01JAN1995		Y
			Osteoporosis	01JAN2014		Y
			Spinal osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1972	31DEC1972	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
			Pulmonary mass	14MAY2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC2000	N
			Menopause	01JAN1990	31DEC1990	N
					31DEC1991	N
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Carpal tunnel decompression	01JAN2005	31DEC2005	N
			Cervicectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171022	Eye disorders	Cataract	01JAN2011	31DEC2011	N
			Dry eye	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Adenoiditis	01JAN1970	31DEC1970	N
			Appendicitis	01JAN1973	31DEC1973	N
			Tonsillitis	01JAN1970	31DEC1970	N
			Upper respiratory tract infection	01NOV2018	31DEC2018	N
		Investigations	Cardiac murmur	01JAN1999		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1997	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1970	31DEC1970	N
			Appendicectomy	01JAN1973	31DEC1973	N
			Cataract operation	01JAN2011	31DEC2011	N
			Endometriosis ablation	01JAN1990	31DEC1997	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1117 11171023	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
			Mitral valve incompetence	01JAN2004	31JAN2004	N
		Eye disorders	Amblyopia	01JAN1976	01AUG1986	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
			Inguinal hernia	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2012		Y
		Nervous system disorders	Restless legs syndrome	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2011		Y
		Surgical and medical procedures	Implantable cardiac monitor insertion	01JAN2014	31DEC2019	N
			Inguinal hernia repair	01JAN1971	31DEC1971	N
			Mitral valve repair	01JAN2004	31JAN2004	N
			Strabismus correction	01AUG1986	01AUG1986	N
			Vasectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1117 11171024	Eye disorders	Cataract	01NOV2019	30NOV2019	N
			Visual impairment	01JAN1952		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
			Iron deficiency	01JAN1966		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	01JAN2015	31DEC2015	N
			Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1947		Y
		Surgical and medical procedures	Cataract operation	01NOV2019	31DEC2019	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1117 11171025	Cardiac disorders	Coronary artery disease	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2002		Y
					31JUL2004	N
			Visual impairment	01JAN1962		Y
		Gastrointestinal disorders	Abdominal hernia	01APR2001	30APR2001	N
			Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
				01JAN1990		Y
				01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUL1991	31JUL1991	N
			Osteoarthritis	01JAN2003	31DEC2005	N
				01JAN2010		Y
		Surgical and medical procedures	Abdominal hernia repair	01APR2001	30APR2001	N
			Carotid endarterectomy	01JAN2020	31JAN2020	N
			Cataract operation	01JUL2004	31JUL2004	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JUL1999	31JUL1999	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1117 11171026	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2014		Y
		Nervous system disorders	Sciatica	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01MAR2015		Y
	C4591001 1117 11171027	Gastrointestinal disorders	Abdominal hernia	01JAN2017	31OCT2017	N
			Dyspepsia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric haemorrhage	01JUL2018	31OCT2018	N
		Injury, poisoning and procedural complications	Meniscus injury	07DEC2019		Y
			Skeletal injury	07DEC2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012		Y
			Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2020		Y
				07DEC2019		Y
			Osteopenia	01JAN2016		Y
		Nervous system disorders	Anosmia	01JAN2000		Y
			Migraine	01JAN1955	31DEC1980	N
		Reproductive system and breast disorders	Mammary duct ectasia	01JAN2011	30NOV2011	N
			Uterine prolapse	01JAN2017	31OCT2017	N
			Vaginal prolapse	01JAN2017	31OCT2017	N
		Social circumstances	Tobacco user	01JAN1965	31DEC1966	N
		Surgical and medical procedures	Colporrhaphy	01OCT2017	31OCT2017	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Mammary ductectomy	01NOV2011	30NOV2011	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1117 11171028	Eye disorders	Visual impairment	01JAN1963		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN1972		Y
			Ex-tobacco user	01JAN1971	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171031	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Palpitations	01JAN2019		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Constipation	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Intraocular pressure increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2015		Y
			Foot deformity	01JAN1985	31DEC1995	N
			Intervertebral disc degeneration	01JAN2016		Y
			Osteoarthritis	01JAN1965	31JAN2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1972	31DEC1972	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1971	31DEC1971	N
			Stress urinary incontinence	01JAN2015		Y
		Surgical and medical procedures	Cardioversion	01JAN2018	31JAN2018	N
			Cataract operation	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Knee arthroplasty	01JAN2018	31JAN2018	N
			Toe operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1117 11171032	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Investigations	Vitamin D decreased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
			Torticollis	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1117 11171033	Eye disorders	Visual impairment	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Infections and infestations	Chronic sinusitis	01DEC2019		Y
			Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2017	30JUN2020	N
			Hand fracture	01JAN2000	31DEC2000	N
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
				26JUN2020	26JUN2020	N
			Blood testosterone decreased	01JAN2018		Y
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1962	31DEC1962	N
			Turbinectomy	04AUG2020	04AUG2020	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1117 11171034	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN1978		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Investigations	Blood pressure increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2013		Y
			Rotator cuff syndrome	01JAN1995	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2013		Y
			Cough	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1968		Y
	C4591001 1117 11171037	Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
		Eye disorders	Cataract	01JUN2020	30JUN2020	N
			Visual impairment	01JAN1958		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01AUG2016		Y
			Insomnia	01JAN2013		Y
			Major depression	01AUG2016		Y
				01MAR1982	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JUN2020	30JUN2020	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1117 11171039	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1972	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Alcohol use	01JAN1982		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
				01JAN1991	31DEC1991	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1117 11171040	Endocrine disorders	Hyperthyroidism	01JAN1997		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Hepatobiliary disorders	Biliary tract disorder	01JAN2013	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2001	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1972		Y
			Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Endometrial ablation	01JAN2007	31DEC2007	N
			Intervertebral disc operation	01JAN2008	31DEC2008	N
	C4591001 1117 11171041	Eye disorders	Cataract	01JAN2017		Y
					31DEC2018	N
		Gastrointestinal disorders	Dental caries	01JAN1975	31DEC1988	N
			Umbilical hernia	01JAN2012	31DEC2012	N
		Infections and infestations	Pneumonia	01JAN1982	31DEC1982	N
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2014	31DEC2014	N
		Investigations	Blood triglycerides increased	01MAR2005		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypercholesterolaemia	01AUG2002		Y
			Obesity	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUL2016	31JUL2016	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1992	31DEC1992	N
				01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Lung disorder	01JAN2010		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1992	31DEC1992	N
				01JAN2017	31DEC2017	N
			Intraocular lens implant	01DEC2017	31DEC2017	N
				01JAN2018	31JAN2018	N
			Rotator cuff repair	01JUL2016	31JUL2016	N
			Tooth repair	01JAN1975	31DEC1988	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01MAR2005		Y
	C4591001 1117 11171042	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Allergy to vaccine	01JAN1955		Y
			Drug hypersensitivity	01JAN2000		Y
			Iodine allergy	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Vitamin D decreased	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2001	31DEC2001	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2000		Y
					31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Oophorectomy	01JAN1996	31DEC1996	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
			Vaginal operation	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	10JUL2020		Y
	C4591001 1117 11171043	Eye disorders	Visual impairment	01JAN1978		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	31DEC2018	N
		Hepatobiliary disorders	Cholecystitis	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01APR2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2014		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
	C4591001 1117 11171046	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Social circumstances	Tobacco user	01JAN1977		Y
		Surgical and medical procedures	Limb operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1117 11171047	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
			Mitral valve prolapse	01JAN1982		Y
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011	26APR2016	N
				01JAN2015	13FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	26APR2016	26APR2016	N
			Knee arthroplasty	13FEB2020	13FEB2020	N
	C4591001 1117 11171048	Eye disorders	Cataract	01JAN2020	31JAN2020	N
		Gastrointestinal disorders	Diverticulum	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1986	31DEC1986	N
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Injury, poisoning and procedural complications	Soft tissue injury	17MAR2019	30APR2019	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypokalaemia	20JUL2020		Y
			Iron deficiency	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2007	N
		Nervous system disorders	Headache	01JAN1966		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2000	31DEC2000	N
			Breast fibrosis	01JAN2015		Y
		Surgical and medical procedures	Breast cyst excision	01JAN2000	31DEC2000	N
			Caesarean section	01JAN1981	31DEC1981	N
				01JAN1985	31DEC1985	N
				01JAN1994	31DEC1994	N
			Cataract operation	01JAN2020	31JAN2020	N
			Cholecystectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1117 11171051	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1991		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	30JUN2020	N
		Social circumstances	Ex-tobacco user	01JAN1977	31DEC1979	N
			Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1117 11171052	Injury, poisoning and procedural complications	Cartilage injury	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Renal and urinary disorders	Haematuria	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN1981	31DEC1981	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1117 11171055	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Infections and infestations	Upper respiratory tract infection	01OCT1958	31OCT1958	N
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
			Restless legs syndrome	01JAN2016		Y
		Renal and urinary disorders	Urinary retention	01DEC2019		Y
		Social circumstances	Ex-tobacco user	01JAN1969	31DEC2007	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2018	31DEC2018	N
			Spinal laminectomy	01NOV2015	30NOV2015	N
			Tracheostomy	01OCT1958	31OCT1958	N
			Tracheostomy tube removal	01OCT1958	31OCT1958	N
	C4591001 1117 11171056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Investigations	Vitamin D decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Influenza immunisation	01JAN2011	31DEC2019	N
	C4591001 1117 11171059	Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
		Eye disorders	Visual impairment	01JAN1960		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N	
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31JUL2019	N	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y	
		Surgical and medical procedures	Inguinal hernia repair	01JAN2010	31DEC2010	N	
			Knee arthroplasty	01JUL2019	31JUL2019	N	
			Tonsillectomy	01JAN1956	31DEC1956	N	
			Varicose vein operation	01JAN2015	31DEC2015	N	
			Vasectomy	01JAN1998	31DEC1998	N	
			Vascular disorders	Varicose vein	01JAN2010		Y
			Eye disorders	Vitreous detachment	01FEB2020		Y
			Gastrointestinal disorders	Colitis microscopic	01APR2019		Y
				Diverticulum	01APR2019		Y
				Gastroesophageal reflux disease	01JAN2013	31DEC2014	N
		Haemorrhoids		01APR2019		Y	
		Hiatus hernia		01JAN2014		Y	
		Immune system disorders		Drug hypersensitivity	01JAN1956		Y
				01JAN1975		Y	
				01JAN2006		Y	
				Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N	
		Injury, poisoning and procedural complications	Chest injury	01JAN2003	31DEC2003	N	
					01SEP2017	30SEP2017	N
				Fall	01OCT2013	31OCT2013	N
				Fibula fracture	01OCT2013	31DEC2013	N
				Rib fracture	01JAN2003	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01SEP2017	31OCT2017	N
			Skeletal injury	01OCT2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01SEP2013	31JAN2014	N
		Nervous system disorders	Headache	01JAN1979		Y
			Migraine	01JAN1986	31DEC2005	N
			Neuropathy peripheral	01JAN2013		Y
				01SEP2013		Y
		Psychiatric disorders	Insomnia	01OCT2018		Y
		Surgical and medical procedures	Brachytherapy	01OCT2013	31DEC2013	N
			Chemotherapy	01OCT2013	31JAN2014	N
			Hip arthroplasty	01FEB2015	28FEB2015	N
			Hysterectomy	01SEP2013	30SEP2013	N
			Mammoplasty	01APR2006	30APR2006	N
			Oophorectomy	01SEP2013	30SEP2013	N
			Salpingo-oophorectomy bilateral	01SEP2013	30SEP2013	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN1998	31DEC2013	N
			Lymphoedema	01JAN2013	31DEC2015	N
			Varicose vein	01JAN1980		Y
	C4591001 1117 11171072	Cardiac disorders	Palpitations	01JAN2018		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1999		Y
		Infections and infestations	Diverticulitis	01JAN2014	31DEC2014	N
			Tonsillitis	01JAN1979	31DEC1979	N
		Investigations	Cardiac murmur	01JAN1968	31DEC1968	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01AUG2012		Y
	C4591001 1117 11171076	Cardiac disorders	Atrial fibrillation	01JAN2014	31DEC2014	N
		Investigations	Cardiac murmur	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cardioversion	01JAN2014	31DEC2014	N
	C4591001 1117 11171079	Cardiac disorders	Mitral valve prolapse	01JAN1981		Y
		Eye disorders	Visual impairment	01JAN1976		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1961		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2019		Y
			Osteoarthritis	01JAN2010		Y
				01JAN2013	31MAR2014	N
				01JAN2017	28FEB2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01OCT2014	31OCT2014	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1967	31DEC2003	N
		Surgical and medical procedures	Hip arthroplasty	01FEB2018	28FEB2018	N
			Hysterectomy	01MAR2014	31MAR2014	N
			Hysterectomy	01OCT2014	31OCT2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1117 11171081	Cardiac disorders	Atrial fibrillation	01OCT2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Infections and infestations	Oral herpes	01JAN1966		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980	30NOV2014	N
				01JAN2017	30NOV2019	N
			Spinal osteoarthritis	01JAN2001		Y
			Spinal stenosis	01JAN2001		Y
		Nervous system disorders	Headache	01JAN1958		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Reproductive system and breast disorders	Uterine prolapse	01AUG2018	05FEB2019	N
			Vaginal prolapse	01JAN2016	05FEB2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01FEB2019	28FEB2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01NOV2014	30NOV2014	N
				01NOV2019	30NOV2019	N
			Spinal fusion surgery	01JUN2018		Y
	C4591001 1117 11171082	Cardiac disorders	Atrial fibrillation	01JAN1996	31DEC1996	N
		Eye disorders	Visual impairment	01JAN1972		Y
		General disorders and administration site conditions	Oedema peripheral	01JUL2019	20JUL2019	N
		Infections and infestations	Chronic sinusitis	01JAN1978		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1979	31DEC1979	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2011	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1117 11171086	Cardiac disorders	Cardiac failure acute	28MAR2019	30APR2019	N
			Cardiac failure congestive	01JAN2017		Y
			Coronary artery disease	01JAN2017		Y
		Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2018		Y
		Eye disorders	Corneal opacity	01JAN2018		Y
			Visual impairment	01JAN2010		Y
		Gastrointestinal disorders	Diverticulum	01FEB2016		Y
			Dysphagia	20DEC2017		Y
			Haemorrhoids	01FEB2016		Y
			Inguinal hernia	01JAN2016	31DEC2016	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Hepatitis C	01JAN1987	31DEC2017	N
			Pneumonia	28MAR2019	30APR2019	N
		Injury, poisoning and procedural complications	Facial bones fracture	01MAR2018	30JUN2018	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	13JUL2020	13JUL2020	N
		Nervous system disorders	Headache	01FEB2020		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
			Post-traumatic stress disorder	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01DEC2018		Y
			Dysphonia	20DEC2017		Y
			Pulmonary hypertension	01JAN2010		Y
		Social circumstances	Substance use	01JAN1968	31DEC2018	N
				01JAN2016	31DEC2019	N
			Tobacco user	01JAN1960		Y
		Surgical and medical procedures	Aortic surgery	19DEC2017	19DEC2017	N
			Carotid artery bypass	18DEC2017	18DEC2017	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Coronary artery bypass	19DEC2017	19DEC2017	N
			Implantable defibrillator insertion	01DEC2018	31DEC2018	N
			Inguinal hernia repair	01JAN2016	31DEC2016	N
			Skin neoplasm excision	13JUL2020	13JUL2020	N
		Vascular disorders	Aortic aneurysm	01DEC2017	19DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171088	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
			Thrombocytopenia	01JUL2001		Y
		Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Coronary artery disease	01JAN2018		Y
			Myocardial infarction	01JAN2001	31DEC2001	N
			Sinus node dysfunction	01JAN2018		Y
		Eye disorders	Cataract	01JAN2019	31JAN2019	N
			Glaucoma	01JAN2019		Y
			Vision blurred	17AUG2020	17AUG2020	N
				31AUG2020	31AUG2020	N
			Visual impairment	01JAN1948		Y
		Gastrointestinal disorders	Colitis	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Gallbladder obstruction	01AUG2018	31AUG2018	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1948		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1962	31DEC1962	N
		Investigations	Prostatic specific antigen increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2014	30APR2014	N
				01APR2015	30APR2015	N
				01APR2016	30APR2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01AUG2018		Y
			Cataract operation	01JAN2019	31JAN2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01AUG2018	31AUG2018	N
			Coronary artery bypass	01JUL2001	31JUL2001	N
			Hip arthroplasty	01APR2016	30APR2016	N
			Knee arthroplasty	01APR2014	30APR2014	N
				01APR2015	30APR2015	N
			Knee operation	01JAN1962	31DEC1962	N
			Lens capsulotomy	17AUG2020	17AUG2020	N
				31AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1117 11171092	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	HLA-B*27 positive	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal stenosis	01JAN2010		Y
			Temporomandibular joint syndrome	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1117 11171097	Cardiac disorders	Acute myocardial infarction	16SEP2015	16SEP2015	N
		Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Cataract	01FEB2019	28FEB2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Sinusitis	01JAN1976		Y
		Investigations	Aspartate aminotransferase increased	02SEP2020		Y
			Biopsy prostate	01JAN2015	31JAN2015	N
			Catheterisation cardiac	16SEP2016	16SEP2016	N
			Haemoglobin increased	02SEP2020		Y
			Prostatic specific antigen increased	01JAN2015	31JAN2015	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Nervous system disorders	Periodic limb movement disorder	01JAN2014		Y
			Shift work disorder	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Renal and urinary disorders	Pollakiuria	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01FEB2019	28FEB2019	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
			Sinus anrostomy	05MAR2015	05MAR2015	N
			Sinus operation	21NOV2014	21NOV2014	N
	C4591001 1117 11171098	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2007		Y
		Eye disorders	Visual impairment	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
			Uterine leiomyoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN2000	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC1985	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
	C4591001 1117 11171104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
			Urinary tract infection	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
			Periarthritis	01JAN1980	31DEC1980	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2016		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1969		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1966		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JUL2020		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Shoulder operation	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Arteriosclerosis	01JAN2016		Y
	C4591001 1117 11171105	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1978		Y
		Injury, poisoning and procedural complications	Muscle strain	22AUG2020		Y
			Tendon rupture	22MAY2019	22MAY2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
			Rotator cuff syndrome	22MAY2019	22MAY2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN1978		Y
		Surgical and medical procedures	Inguinal hernia repair	12MAR2016	12MAR2016	N
			Rotator cuff repair	22MAY2019	22MAY2019	N
			Vasectomy	01JAN2005	31JAN2005	N
	C4591001 1117 11171110	Ear and labyrinth disorders	Deafness	01JAN2013		Y
			Vertigo positional	01JAN2015		Y
			Vestibular disorder	01JAN2018	31DEC2018	N
		Eye disorders	Age-related macular degeneration	01JAN2006		Y
			Cataract	01JAN2015		Y
			Visual impairment	01JAN1990		Y
			Vitreous degeneration	01JAN2014		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2012	31DEC2012	N
			Diverticulum	01JAN2015		Y
			Inguinal hernia	01JAN2008	31DEC2008	N
			Small intestinal obstruction	29OCT2015	29OCT2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2000		Y
			Hypersensitivity	01JAN1964		Y
		Infections and infestations	Pneumonia	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Joint dislocation	01AUG2020	01AUG2020	N
			Ligament rupture	01JAN1990	31DEC1990	N
			Nerve injury	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	30JAN2015	30JAN2015	N
			Weight decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	29OCT2015		Y
		Nervous system disorders	Migraine	01JAN1975		Y
			Subarachnoid haemorrhage	01JAN2002	31JAN2002	N
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2011	31JAN2011	N
				01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
			Joint dislocation reduction	01AUG2020	01AUG2020	N
			Knee arthroplasty	01JAN1996	31DEC1996	N
			Ligament operation	01JAN1990	31DEC1990	N
			Osteotomy	01JAN2000	31DEC2000	N
			Peripheral nerve decompression	01JAN2002	31DEC2002	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1117 11171114	Eye disorders	Visual impairment	01JAN1971		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN1985		Y
		Vascular disorders	Deep vein thrombosis	01JAN2016	31DEC2016	N
			Varicose vein	01JAN2016		Y
	C4591001 1117 11171115	Endocrine disorders	Basedow's disease	01JAN1994	31DEC1994	N
			Hyperparathyroidism	01JAN2009	31DEC2009	N
			Hypothyroidism	01JAN1994		Y
		Immune system disorders	Seasonal allergy	01APR2020		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2009	31DEC2009	N
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
			Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01AUG2020		Y
		Social circumstances	Alcohol use	01JAN1971		Y
			Menopause	01JAN2011		Y
			Tobacco user	01JAN1972	31DEC1976	N
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
			Parathyroidectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1117 11171120	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Retinal detachment	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Intervertebral disc degeneration	01JAN1995		Y
		Social circumstances	Alcohol use	01JAN1977	31DEC2019	N
			Tobacco user	01JAN1977	31DEC2019	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Retinal operation	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1117 11171122	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2012		Y
		Infections and infestations	Urinary tract infection	01JAN1990	31DEC2016	N
		Injury, poisoning and procedural complications	Ankle fracture	11NOV2018	31MAR2019	N
				18NOV2018	31DEC2019	N
			Fibula fracture	11NOV2018	31JAN2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUN2020	30JUN2020	N
			Breast cancer	01FEB2019	31JUL2019	N
			Lipoma	01JUL2020	02NOV2020	N
			Squamous cell carcinoma	01JAN2003	31DEC2003	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010	02NOV2020	N
				01JUN2020	02NOV2020	N
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast conserving surgery	27FEB2019	27FEB2019	N
			Chemotherapy	08APR2019	11JUN2019	N
			Radiotherapy to breast	01JUL2019	31JUL2019	N
			Wisdom teeth removal	01AUG1983	31AUG1983	N
		Vascular disorders	Hypertension	01FEB2019		Y
			Raynaud's phenomenon	01JAN1966		Y
	C4591001 1117 11171123	Cardiac disorders	Supraventricular extrasystoles	01JAN2000		Y
		Eye disorders	Visual impairment	01JAN1986		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1999	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01SEP2019	30SEP2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Social circumstances	Alcohol use	01JAN1971		Y
		Surgical and medical procedures	Appendectomy	01JAN1984	31DEC1984	N
			Intervertebral disc operation	01JAN2014		Y
			Spinal fusion surgery	01JAN2014		Y
	C4591001 1117 11171124	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995	31DEC2015	N
			Oesophageal stenosis	01JAN1985	31DEC1985	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Immune system disorders	Hypersensitivity	01JAN1959		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1993	31DEC1993	N
			Ligament rupture	01JAN1992	31DEC1992	N
			Oesophageal injury	01JAN1985	31DEC1985	N
			Tendon injury	01JAN2004	31DEC2004	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
			Seborrhoeic keratosis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1975		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC2005	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y
			Rhinitis allergic	01JAN1959		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Cancer surgery	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Oesophageal operation	01JAN1985	31DEC1985	N
			Renal stone removal	01JAN1990	31DEC1990	N
				01JAN2005	31DEC2005	N
			Tenoplasty	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1959	31DEC1959	N
			Vasectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1117 11171125	Eye disorders	Visual impairment	01JAN1969		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN1997		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2010	31DEC2010	N
	C4591001 1117 11171133	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Umbilical hernia	01JAN1998		Y
		General disorders and administration site conditions	Surgical failure	01JAN1986	31DEC1986	N
		Investigations	Arthroscopy	01JAN1987	31DEC1987	N
			Blood potassium decreased	01DEC2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1981		Y
			Obesity	01JAN1981		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	02NOV2017	N
				01JAN2017	24MAY2018	N
			Scoliosis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2002		Y
			Peroneal nerve palsy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	02NOV2017	02NOV2017	N
			Knee arthroplasty	24MAY2018	24MAY2018	N
			Spinal decompression	01JAN1984		Y
			Spinal operation	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171135	Vascular disorders	Hypertension	01JAN1981		Y
		Eye disorders	Visual impairment	01JAN2019		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01APR1990	30APR1990	N
	C4591001 1117 11171136		Cholecystectomy	01JAN2008	31DEC2008	N
		Eye disorders	Visual impairment	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN2009		Y
		Immune system disorders	Allergy to animal	01FEB2019		Y
			Dust allergy	01FEB2019		Y
			Mycotic allergy	01FEB2019		Y
			Seasonal allergy	01FEB2019		Y
		Injury, poisoning and procedural complications		01JAN1966		Y
			Colon injury	29SEP2018	29SEP2018	N
			Ligament rupture	01JAN1999	31DEC1999	N
			Meniscus injury	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Vitamin D deficiency	15JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2005	31DEC2015	N
	Psychiatric disorders		Anxiety	01APR2020	31AUG2020	N
		Major depression	01JAN1997		Y	



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1972	31DEC1972	N
		Social circumstances	Alcohol use	01JAN1969		Y
			Menopause	01JAN2007		Y
			Organ donor	27SEP2018	27SEP2018	N
		Surgical and medical procedures	Bunion operation	01JAN2015	31DEC2015	N
			Colon operation	29SEP2018	29SEP2018	N
			Ligament operation	01JAN1999	31DEC1999	N
			Mammoplasty	01JAN1980		Y
			Meniscus operation	01JAN1999	31DEC1999	N
			Nasal septal operation	01JAN1972	31DEC1972	N
	C4591001 1117 11171139	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1995	31DEC1995	N
		Cardiac disorders	Aortic valve stenosis	01MAY2014		Y
			Supraventricular tachycardia	01JAN1995		Y
		Endocrine disorders	Thyroid mass	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Infectious mononucleosis	01JAN1995	31DEC1995	N
		Investigations	Cardiac murmur	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	31MAY2008	N
			Osteopenia	01SEP2019		Y
			Osteoporosis	01SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
		Nervous system disorders	Headache	01JAN2017	31DEC2017	N
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Breast conserving surgery	01JUL2006	31JUL2006	N
			Hip arthroplasty	01MAY2008	31MAY2008	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN2006	31DEC2006	N
			Tooth extraction	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1117 11171141	Blood and lymphatic system disorders	Anaemia	01MAY2020		Y
		Eye disorders	Cataract	01JAN2017	31DEC2018	N
			Visual impairment	01JAN1966		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1989	31DEC1995	N
			Barrett's oesophagus	01JAN2007		Y
			Peptic ulcer	01JAN2007	31DEC2007	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Infections and infestations	Oral herpes	01JAN1970		Y
			Pneumonia	01FEB2018	31DEC2019	N
			Tonsillitis	01APR1977	30APR1977	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Intervertebral disc protrusion	01JAN2016		Y
			Osteoarthritis	01JAN1967		Y
				01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	15JUL1992	31JUL1992	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2019	N
			Neuropathy peripheral	01MAY2020		Y
			Restless legs syndrome	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2018		Y
			Sleep apnoea syndrome	01MAY2020		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1989	31DEC1989	N
				01JAN1995	31DEC1995	N
			Carpal tunnel decompression	01JAN2019	31DEC2019	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	31JUL1992	31JUL1992	N
			Knee operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01APR1977	30APR1977	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1117 11171142	Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Eye disorders	Cataract	01JAN2019		Y
			Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Toothache	01JAN1977	31DEC1977	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
			Seasonal allergy	01JAN1970		Y
		Nervous system disorders	Headache	01JAN1972		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019	31DEC2019	N
		Social circumstances	Menopause	01JAN2010		Y
			Social alcohol drinker	01JAN1974		Y
			Substance use	01JAN1976	31DEC1976	N
			Tobacco user	01JAN1974	31DEC1977	N
	C4591001 1117 11171146	Surgical and medical procedures	Wisdom teeth removal	01JAN1977	31DEC1977	N
		Cardiac disorders	Ventricular enlargement	22JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Hypoacusis	01JAN2012		Y
			Vertigo	01JAN2015		Y
		Eye disorders	Cataract	01JUN2020		Y
			Visual impairment	01JAN1990		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
			Peptic ulcer	01JAN2015	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Cellulitis	31JAN2019	09FEB2019	N
		Investigations	Heart rate irregular	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016	31DEC2016	N
			Muscle spasms	01JAN2010		Y
			Osteoarthritis	01JAN2015		Y
				01JAN2017		Y
			Osteoporosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC2014	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary arterial hypertension	22JAN2018		Y
			Sleep apnoea syndrome	01SEP2018		Y
		Social circumstances	Alcohol use	01JAN1968		Y
			Menopause	01JAN2000		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Aortic aneurysm	22JAN2018		Y
			Arteriosclerosis	22JAN2018		Y
			Deep vein thrombosis	01JAN2019	31DEC2019	N
			Hypertension	01JUN2018		Y
	C4591001 1117 11171147	Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1986	31DEC1986	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Fracture treatment	01JAN1986	31DEC1986	N
			Renal stone removal	01JAN2014	31DEC2014	N
	C4591001 1117 11171148	Cardiac disorders	Atrial flutter	01SEP2016	31OCT2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2008	31DEC2008	N
			Ligament rupture	01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Surgical and medical procedures	Cardiac ablation	01OCT2019	31OCT2019	N
			Chondroplasty	01JAN2008	31DEC2008	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Ligament operation	01JAN1997	31DEC1997	N
	C4591001 1117 11171151	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JUL2020		Y
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Visual impairment	01JAN2012		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		General disorders and administration site conditions	Fatigue	01JAN2010		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1993	31DEC1995	N
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Impetigo	01JAN1950	31DEC1960	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Obesity	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2018	31DEC2018	N
			Lumbar spinal stenosis	01JAN1995		Y
			Neck pain	01JAN2019		Y
			Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2014	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN1980		Y
			Urticaria	01JAN1980		Y
		Surgical and medical procedures	Abdominoplasty	01JAN1993	31DEC1993	N
				01JAN2000	31DEC2000	N
			Cataract operation	01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN2004	31DEC2004	N
			Shoulder arthroplasty	01JAN2015	31JAN2015	N
				01JAN2016	31JAN2016	N
				01JAN2018	31DEC2018	N
	C4591001 1117 11171152	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Injury, poisoning and procedural complications	Ankle fracture	01MAY1989	31MAY1989	N
		Investigations	Biopsy breast	01JUL2018	31JUL2018	N
		Metabolism and nutrition disorders	Food intolerance	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1995		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1985		Y
		Social circumstances	Menopause	01AUG2009		Y
	C4591001 1117 11171153	Surgical and medical procedures	Ankle operation	01MAY1989	31MAY1989	N
		Cardiac disorders	Aortic valve stenosis	01JAN1998		Y
			Atrial flutter	01JAN1998		Y
			Coronary artery disease	01JAN1998		Y
		Eye disorders	Cataract	01JAN2016	31MAY2018	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1998		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Pseudomonas bacteraemia	01JAN2000	31DEC2000	N
			Tinea cruris	01JAN2000		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1967	31DEC1967	N
			Spinal compression fracture	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
			Osteoarthritis	01JAN1990		Y
			Rotator cuff syndrome	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
		Nervous system disorders	Facial paralysis	01JAN1985	31DEC1985	N
				01JAN1989	31DEC1989	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01MAY2018	31MAY2018	N
			Cholecystectomy	01JAN2009	31JAN2009	N
			Shoulder operation	01JAN2009	31DEC2009	N
			Skin neoplasm excision	01JAN2007	31DEC2007	N
				01JAN2008	31DEC2008	N
			Vascular graft	01JAN1998	31DEC1998	N
		Vascular disorders	Aortic stenosis	01JAN1998		Y
			Arterial occlusive disease	01JAN1998	31DEC1998	N
			Hypertension	01JAN1980		Y
	C4591001 1117 11171155	Eye disorders	Cataract	01JAN2008		Y
			Dry eye	01JAN2009		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Osteopenia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1985	31DEC2001	N
			Restless legs syndrome	01JAN2000		Y
			Sciatica	01MAR2015		Y
			Transient ischaemic attack	01DEC2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
				01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01FEB2020		Y
			Dry skin	01JAN2002		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2009	31DEC2009	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Aortic arteriosclerosis	18DEC2015		Y
			Hypertension	01JAN2010		Y
	C4591001 1117 11171157	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171159	Blood and lymphatic system disorders	Lymphadenopathy	01JAN1985	31DEC1985	N
		Eye disorders	Cataract	01OCT2014	01OCT2014	N
			Retinal detachment	03NOV2013	03NOV2013	N
				11SEP2013	11SEP2013	N
				16JAN2014	16JAN2014	N
			Visual impairment	01JAN1970	30JUN2006	N
		Injury, poisoning and procedural complications	Hand fracture	08JUN2020	08JUN2020	N
			Limb injury	01JAN2003	31JAN2003	N
		Investigations	Pelvic laparoscopy	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Bone cyst	01JUL2010	31JUL2010	N
			Foot deformity	01OCT2010	31OCT2010	N
				30OCT2014	30OCT2014	N
			Spinal osteoarthritis	01JAN1970		Y
		Nervous system disorders	Facial paralysis	21JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
			Vulvovaginal dryness	01MAR2020	03SEP2020	N
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Bone cyst excision	01JUL2010	31JUL2010	N
			Bunion operation	01OCT2010	31OCT2010	N
				30OCT2014	30OCT2014	N
			Cataract operation	01OCT2014	01OCT2014	N
			Debridement	01JAN2003	31JAN2003	N
				01JUN2020	30JUN2020	N
			Epidural injection	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1982	31DEC1982	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Joint arthroplasty	02JUL2015	02JUL2015	N
				08JAN2019	08JAN2019	N
			Keratectomy	01JUN2006	31DEC2006	N
			Lymphadenectomy	01JAN1985	31DEC1985	N
			Scleral buckling surgery	16JAN2014	16JAN2014	N
			Vitrectomy	03NOV2013	03NOV2013	N
				11SEP2013	11SEP2013	N
				15JUL2014	15JUL2014	N
	C4591001 1117 11171160	Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Hypersensitivity	01JAN1963		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1997	31DEC1997	N
		Investigations	Blood testosterone decreased	25JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
			Rotator cuff syndrome	01JAN2013		Y
		Reproductive system and breast disorders	Balanoposthitis	01JAN2008	31DEC2017	N
			Benign prostatic hyperplasia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	01JAN2009	31DEC2009	N
		Social circumstances	Alcohol use	01JAN1971		Y
		Surgical and medical procedures	Meniscus removal	01JAN1997	31DEC1997	N
			Precancerous lesion excision	01JAN2009	31DEC2009	N
			Sinus operation	01JAN1998	31DEC1998	N
			Trapeziectomy	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2008		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171162	Eye disorders	Visual impairment	01JAN1960		Y
		Investigations	Continuous glucose monitoring	01JAN2012		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
					30JUN2013	N
				01JAN2015		Y
				01JAN2017		Y
			Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01SEP2019	30SEP2019	N
		Social circumstances	Menopause	01JAN1997		Y
		Surgical and medical procedures	Cancer surgery	01SEP2019	30SEP2019	N
			Drug delivery device placement	01JAN2005		Y
			Knee arthroplasty	01JUN2013	30JUN2013	N
	C4591001 1117 11171163	Eye disorders	Cataract	01APR2016	30APR2018	N
			Glaucoma	01JAN2012		Y
			Macular degeneration	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2011		Y
		Infections and infestations	Tonsillitis	01JAN1941	31DEC1941	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
				01JAN2010	31DEC2010	N
			Osteopenia	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Social circumstances	Alcohol use	01JAN1957		Y
			Menopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01APR2018	31DEC2018	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Mastectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1941	31DEC1941	N
	C4591001 1117 11171164	Eye disorders	Retinal detachment	01JAN1955	31JAN1955	N
			Visual impairment	01JAN1955		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2003	31DEC2003	N
			Diverticulum	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	15MAY2020		Y
			Obesity	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Arthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Renal and urinary disorders	Hydronephrosis	01JAN2016	31DEC2016	N
			Nephrolithiasis	03AUG2020	03AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
			Sleep apnoea syndrome	01JAN2006		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2003	31DEC2003	N
			Appendicectomy	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Eye excision	01JAN1955	31JAN1955	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Knee arthroplasty	25MAY2018	25MAY2018	N
			Lithotripsy	03AUG2020	03AUG2020	N
			Ureteral stent insertion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1117 11171165	Cardiac disorders	Stress cardiomyopathy	15MAY2018	31MAY2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988		Y
			Umbilical hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Rheumatoid factor	01JAN1997	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Vitamin D deficiency	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01NOV2017		Y
			Sjogren's syndrome	01JAN2018		Y
			Spinal osteoarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN1976		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01JAN2006	31DEC2006	N
		Social circumstances	Alcohol use	01JAN2011		Y
			Menopause	01JAN2005		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2006	31DEC2006	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
			Umbilical hernia repair	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171166	Eye disorders	Scintillating scotoma	01JAN1990		Y
			Visual impairment	01JAN1973	31DEC2000	N
		Immune system disorders	Hypersensitivity	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Renal and urinary disorders	Micturition urgency	01JAN2008		Y
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1117 11171167	Cardiac disorders	Coronary artery disease	01JAN2010		Y
			Coronary artery occlusion	01JAN2015	01SEP2018	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Arthropod bite	09SEP2020	16SEP2020	N
		Investigations	Prostatic specific antigen increased	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2001	31DEC2001	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Social circumstances	Social alcohol drinker	01JAN1956		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
			Coronary arterial stent insertion	01SEP2018	01SEP2018	N
			Large intestinal polypectomy	01JAN2015	31DEC2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1117 11171168	Cardiac disorders	Mitral valve incompetence	01JAN2010		Y
		Congenital, familial and genetic disorders	Breast malformation	(b) (6) 1963	(b) (6) 1963	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2020		Y
			Umbilical hernia	01JAN2016	31DEC2016	N
		Hepatobiliary disorders	Cholelithiasis	01OCT2011	31OCT2011	N
		Infections and infestations	Herpes zoster	05JAN2011	05JAN2011	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
				11MAY2017	11MAY2017	N
		Renal and urinary disorders	Nephrolithiasis	01AUG1995	31AUG1995	N
		Social circumstances	Alcohol use	01JAN1983		Y
			Menopause	01JAN2003		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2001	31DEC2001	N
			Cholelithotomy	28OCT2011	28OCT2011	N
			Endometriosis ablation	01JAN1990	31DEC1990	N
				01JAN1992	31DEC1992	N
				01JAN1997	31DEC1997	N
			Female sterilisation	18JUN1996	18JUN1996	N
			Mammoplasty	01JAN1982	31DEC1982	N
				01JAN2017	31DEC2017	N
			Meniscus operation	11MAY2017	11MAY2017	N
				13DEC2010	13DEC2010	N
			Renal stone removal	01AUG1995	01AUG1995	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171173	Gastrointestinal disorders	Inguinal hernia	01MAR2004	31MAY2004	N
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Investigations	Blood triglycerides increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2008		Y
		Surgical and medical procedures	Appendectomy	01JAN1974	31DEC1974	N
			Inguinal hernia repair	01MAY2004	31MAY2004	N
			Knee operation	01JAN2000	31DEC2000	N
			Vasectomy	01FEB1992	29FEB1992	N
	C4591001 1117 11171175	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Musculoskeletal and connective tissue disorders	Compartment syndrome	01JAN1976	31DEC1976	N
			Torticollis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2018	N
			Benign breast neoplasm	01JAN1962	31DEC1962	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1983	31DEC1983	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1981		Y
		Surgical and medical procedures	Appendectomy	01JAN1983	31DEC1983	N
			Breast conserving surgery	01JAN1972	31DEC1972	N
			Coronary arterial stent insertion	01JAN2006	31DEC2006	N
			Fasciotomy	01JAN1976	31DEC1976	N
			Oophorectomy	01JAN1983	31DEC1983	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1117 11171176		Tonsillectomy	01JAN1958	31DEC1958	N
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1964	31DEC1964	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dairy intolerance	01JAN2018		Y
			Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01SEP2018	31MAR2019	N
			Tobacco abuse	01JAN1988	31DEC1998	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN1977		Y
		Surgical and medical procedures	Ankle operation	01JAN2012	31DEC2012	N
		Inguinal hernia repair	01JAN1964	31DEC1964	N	
	C4591001 1117 11171177	Vascular disorders	Hypertension	01JAN2011		Y
		Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Bradycardia	01JUN2014	30JUN2014	N
		Ear and labyrinth disorders	Hypoacusis	01JAN2013		Y
		Endocrine disorders	Thyroid mass	01JAN2019		Y
		Eye disorders	Cataract	01JUN2017	09JUL2018	N
					30JUN2017	N
			Macular degeneration	01JUN2018		Y
		Immune system disorders	Rubber sensitivity	01JUN2014		Y
		Infections and infestations	Hepatitis A	01JAN2000	31DEC2000	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Herpes zoster	01FEB2011	31DEC2016	N
			Malaria	01JAN2004	31DEC2004	N
			Sinusitis	01JAN1946		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1957		Y
			Jaw disorder	01JUN2018	31JUL2018	N
			Rotator cuff syndrome	01OCT2017		Y
			Scoliosis	01JAN1957		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Cerebrovascular accident	01JUL2019	31JUL2019	N
			Post herpetic neuralgia	01FEB2011		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Surgical and medical procedures	Bone lesion excision	16JUL2018	16JUL2018	N
			Cardiac pacemaker insertion	01JUN2014	30JUN2014	N
			Cataract operation	01JUN2017	30JUN2017	N
				09JUL2018	09JUL2018	N
			Lipectomy	01JAN1967	31DEC1967	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1117 11171182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1980	31DEC1980	N
			Joint injury	01JAN1988		Y
			Stab wound	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1988		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Social circumstances	Alcohol use	01JAN1968		Y
			Substance use	01JAN1975		Y
			Tobacco user	01JAN1968		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1117 11171185	Ear and labyrinth disorders	Deafness bilateral	01JAN1993		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Visual impairment	01JAN2000		Y
		Investigations	Arthroscopy	01JAN1989	31DEC1989	N
			Blood cholesterol increased	01JAN2019		Y
			Blood glucose	01MAR2020		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1988		Y
				01JAN2000		Y
		Renal and urinary disorders	Pollakiuria	01JAN2019		Y
		Social circumstances	Hearing aid user	01JAN1993		Y
		Surgical and medical procedures	Cochlea implant	01MAR2016		Y
			Spinal fusion surgery	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1117 11171188	Eye disorders	Visual impairment	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1979	31DEC1979	N
		Immune system disorders	Food allergy	01JAN1973		Y
		Infections and infestations	Hepatitis C	01JAN1987	31DEC1987	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2015	31DEC2015	N
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1981		Y
			Osteoarthritis	01JAN1995	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1982	31DEC1982	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Knee arthroplasty	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1117 11171191	Cardiac disorders	Atrial fibrillation	27JUL2020		Y
		Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 1956	31DEC2003	N
		Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1972		Y
		Infections and infestations	Bronchitis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1972	31DEC1972	N
			Hand fracture	01JAN1971	31DEC1971	N
			Upper limb fracture	01JAN1964	31DEC1964	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wrist fracture	01JAN1964	31DEC1964	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2011		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN1974		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN2003	31DEC2003	N
			Inguinal hernia repair	01JAN2003	31DEC2003	N
			Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1117 11171193	Endocrine disorders	Hypothyroidism	01APR2020		Y
		Eye disorders	Visual impairment	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Foot deformity	01JAN2008	31DEC2012	N
			Intervertebral disc protrusion	01JAN2016		Y
			Osteoarthritis	01JAN2009		Y
					31DEC2013	N
		Psychiatric disorders	Depression	01JAN1970		Y
			Insomnia	01JAN1985		Y
			Post-traumatic stress disorder	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2018	30SEP2019	N
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Bunion operation	01JAN2012	31DEC2012	N
			Hysterectomy	01SEP2019	30SEP2019	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
			Thrombectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Deep vein thrombosis	01JAN1970	31DEC1970	N
			Hypertension	01JAN2010		Y
	C4591001 1117 11171194	Endocrine disorders	Hyperthyroidism	01JAN2013	31DEC2013	N
			Hypothyroidism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1966	31DEC2010	N
		Social circumstances	Menopause	01JAN2010		Y
			Social alcohol drinker	01JAN2015		Y
			Tobacco user	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2001	31DEC2001	N
	C4591001 1117 11171195	Cardiac disorders	Coronary artery disease	01JAN2007		Y
		Eye disorders	Visual impairment	01JAN2005		Y
		Injury, poisoning and procedural complications	Procedural pain	19JUN2020		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	19JUN2020		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Social circumstances	Substance use	01JAN1965		Y
			Tobacco user	01JAN1977	31DEC2007	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2008	31DEC2008	N
			Peripheral artery stent insertion	18JUN2020	18JUN2020	N
		Vascular disorders	Hypertension	01JAN2009		Y
			Peripheral vascular disorder	01JAN2015		Y
			Poor peripheral circulation	01JAN2019	18JUN2020	N
	C4591001 1118 11181004	Immune system disorders	Mycotic allergy	01JAN2008		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181005	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2003		Y
			Osteoporosis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Oophorectomy bilateral	10AUG2000	10AUG2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181006	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2016		Y
			Osteoporosis	01JAN1990		Y
			Rheumatoid arthritis	01JAN2013		Y
		Nervous system disorders	Seizure	01JAN1975		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1994		Y
	C4591001 1118 11181007	Cardiac disorders	Tachycardia	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1118 11181008	Psychiatric disorders	Schizoaffective disorder	01JAN1990		Y
	C4591001 1118 11181011	Nervous system disorders	Migraine	01JUL2011		Y
	C4591001 1118 11181012	Injury, poisoning and procedural complications	Wrist fracture	01JUL2020	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Parkinson's disease	01JAN2005		Y
			Sciatica	01JAN1970		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2008	31DEC2008	N
				01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1118 11181013	Endocrine disorders	Hypothyroidism	21MAR2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15MAY2015		Y
		Vascular disorders	Hypertension	18APR2008		Y
	C4591001 1118 11181015	Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1118 11181020	Gastrointestinal disorders	Hiatus hernia	01JAN2018		Y
		Immune system disorders	Food allergy	01JAN1979		Y
			Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Ligament rupture	01OCT2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
	C4591001 1118 11181022	Cardiac disorders	Ventricular extrasystoles	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1118 11181024	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2004		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1118 11181029	Immune system disorders	Seasonal allergy	01JAN1973		Y
		Infections and infestations	Bronchitis	01JAN1970	31DEC1983	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1983	31DEC1983	N
			Limb traumatic amputation	01JAN1966	31DEC1966	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rib fracture	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970	31DEC1983	N
			Pneumothorax	01JAN1983	31DEC1983	N
			Sleep apnoea syndrome	25FEB2019		Y
		Surgical and medical procedures	Hip arthroplasty	18JAN2019	18JAN2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1118 11181031	Cardiac disorders	Angina pectoris	01JAN2011		Y
			Coronary artery disease	01JAN2011		Y
			Mitral valve prolapse	01JAN2012	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN1967		Y
		Immune system disorders	Allergy to metals	01JAN1980		Y
			Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2013		Y
			Spinal stenosis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1980	31DEC2016	N
		Renal and urinary disorders	Renal failure	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Oophorectomy	01JAN1981	31DEC1981	N
	C4591001 1118 11181036	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN1970		Y
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01NOV1990	05NOV1990	N
				19MAR1986	19MAR1986	N
	C4591001 1118 11181037	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2019		Y
		Psychiatric disorders	Anxiety	01AUG2018		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01DEC2018		Y
		Social circumstances	Postmenopause	01JUL2009		Y
	C4591001 1118 11181038	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Surgical and medical procedures	Knee arthroplasty	01FEB2019	28FEB2019	N
			Meniscus operation	01JAN1984	31DEC1984	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1118 11181039	Gastrointestinal disorders	Constipation	01JAN2018		Y
		Immune system disorders	Hypersensitivity	01JAN1970		Y
		Infections and infestations	Lyme disease	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Pneumonia	01JAN2017	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Facial paralysis	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Ostectomy	01JAN2014	31DEC2014	N
	C4591001 1118 11181041	General disorders and administration site conditions	Oedema peripheral	01DEC2019		Y
		Immune system disorders	Seasonal allergy	01AUG2019		Y
		Metabolism and nutrition disorders	Gout	01DEC2019		Y
			Hypercholesterolaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	16JUL2012		Y
			Muscle spasms	16JUL2020		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1118 11181043	Cardiac disorders	Sinus arrhythmia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N
		Nervous system disorders	Amnesia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2007	N
			Hormone therapy	01JAN2005	31DEC2007	N
		Vascular disorders	Varicose vein	01JAN2012		Y
	C4591001 1118 11181044	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
			Iodine allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1957		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1118 11181045	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2015		Y
	C4591001 1118 11181050	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181051	Gastrointestinal disorders	Colitis ulcerative	01JAN1990		Y
			Gastrooesophageal reflux disease	01JAN2015		Y
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN1999		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Drug abuse	01JAN1999	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1118 11181052	Congenital, familial and genetic disorders	Klippel-Feil syndrome	(b) (6) 1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1118 11181053	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181055	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01DEC2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Transient ischaemic attack	01APR2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
	C4591001 1118 11181056	Vascular disorders	Hypertension	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN1987		Y
				01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
			Osteoporosis	01JAN2016		Y
			Spinal osteoarthritis	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1118 11181057	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1118 11181058	Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2019	31JAN2019	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Splenectomy	01JAN1973	31DEC1973	N
	C4591001 1118 11181065	Investigations	Cardiac murmur	19AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1118 11181066	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1981		Y
		Psychiatric disorders	Anxiety	01JAN1981		Y
			Depression	01JAN1981		Y
		Surgical and medical procedures	Hysterectomy	01JUL2003		Y
	C4591001 1118 11181067	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Infections and infestations	Papilloma viral infection	01MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01MAR2015	31AUG2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Throat cancer	01MAR2015	31AUG2015	N
			Tonsil cancer	01MAR2015	31AUG2015	N
		Surgical and medical procedures	Radiotherapy	01JUN2015	31AUG2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1118 11181068	General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Idiopathic pulmonary fibrosis	01SEP2019		Y
			Pulmonary hypertension	01SEP2019		Y
			Sleep apnoea syndrome	01JAN2003		Y
	C4591001 1118 11181069	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Post-traumatic stress disorder	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Postmenopause	01OCT2017		Y
	C4591001 1118 11181071	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Allergy to vaccine	01JAN2017		Y
			Drug hypersensitivity	01JAN1995		Y
			Hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1118 11181072	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc displacement	01JAN2015		Y
			Neck pain	01JAN2015		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1118 11181073	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1980		Y
		Immune system disorders	Food allergy	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01FEB2020		Y
			Back pain	01FEB2020		Y
			Osteoarthritis	01JAN2010		Y
			Osteopenia	21JUL2020		Y
		Nervous system disorders	Nerve compression	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990		Y
	C4591001 1118 11181074	Immune system disorders	Sarcoidosis	01JAN2010		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Rhinitis	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1990		Y
	C4591001 1118 11181075	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Renal and urinary disorders	Urinary retention	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1118 11181077	Vascular disorders	Hypertension	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Food allergy	01JAN2017		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2009	31DEC2009	N
		Psychiatric disorders	Bipolar disorder	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1118 11181078	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2006		Y
			Intervertebral disc protrusion	23JUL2017		Y
			Osteoarthritis	01OCT2017		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
		Surgical and medical procedures	Female sterilisation	01NOV1990	30NOV1990	N
	C4591001 1118 11181087	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Cataract	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1118 11181088	Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Cardiac disorders	Myocardial infarction	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Gout	01JAN2013		Y
			Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011		Y
			Coronary artery bypass	01DEC2011	31DEC2011	N
			Vascular stent insertion	01JAN2014		Y
			Vasectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1118 11181090	Ear and labyrinth disorders	Hypoacusis	01JAN2007		Y
		Infections and infestations	Herpes zoster	01JAN1964		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Intervertebral disc degeneration	01JAN1990		Y
			Spinal stenosis	01JAN1990		Y
			Spondylitis	01JAN1973		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1118 11181091	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Injury, poisoning and procedural complications	Foot fracture	01JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1991	31DEC1991	N
			Spinal laminectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1118 11181092	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	31DEC2019		Y
		Psychiatric disorders	Nicotine dependence	01JAN1973	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2001	31DEC2001	N
		Vascular disorders	Thrombosis	01JAN1997	31DEC1997	N
	C4591001 1118 11181093	Injury, poisoning and procedural complications	Paranasal sinus injury	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2010	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Prostatectomy	01JAN2015	31DEC2015	N
			Sinus operation	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
			Spinal operation	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Raynaud's phenomenon	(b) (6) 1952		Y
	C4591001 1118 11181094	Ear and labyrinth disorders	Vertigo	01JAN2019		Y
			Vestibular disorder	01JAN2018		Y
		Eye disorders	Eye disorder	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Sciatica	01JAN2014		Y
		Psychiatric disorders	Nicotine dependence	01JAN1972	31DEC1995	N
		Surgical and medical procedures	Spinal laminectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1118 11181095	Eye disorders	Retinal detachment	01MAR2017	30SEP2017	N
			Retinal tear	01MAR2017	30SEP2017	N
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1995		Y
			Myalgia	01JAN1995		Y
	C4591001 1118 11181098	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1118 11181102	Cardiac disorders	Bradycardia	01JAN2000		Y
		Ear and labyrinth disorders	Vertigo	01JUL2020	31JUL2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN1990		Y
		Psychiatric disorders	Nicotine dependence	01JAN1950	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01MAY2018		Y
	C4591001 1118 11181105	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1118 11181113	Immune system disorders	Reaction to food additive	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2013	31DEC2013	N
	C4591001 1118 11181114	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Psychiatric disorders	Insomnia	01SEP1992		Y
		Surgical and medical procedures	Appendicectomy	01AUG2015		Y
			Vasectomy	01APR1994	01APR1994	N
	C4591001 1118 11181118	Cardiac disorders	Myocardial infarction	01SEP1992	01SEP1992	N
				01JAN1980	31DEC1980	N
				01JAN1981	31DEC1981	N
				01JAN2006	31DEC2006	N
				01JAN2012	31DEC2012	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Gastrointestinal disorders	Gastrointestinal disorder	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Polyuria	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Social circumstances	Hearing aid user	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2006	31DEC2006	N
				01JAN2012	31DEC2012	N
			Vasectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Arterial occlusive disease	01JAN2006	31DEC2012	N
			Hypertension	01JAN1980		Y
	C4591001 1118 11181119	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1118 11181120	Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2018		Y
		Psychiatric disorders	Nicotine dependence	01JAN1985	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1118 11181123	Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Cerebrovascular accident	16FEB2016	16FEB2016	N
			Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1118 11181124	Immune system disorders	Drug hypersensitivity	01AUG2016		Y
			Seasonal allergy	01SEP1964		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01AUG2016		Y
			Hypercholesterolaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ear neoplasm malignant	01JAN2015	28JAN2015	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUL1948		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01DEC2017	01DEC2017	N
			Micrographic skin surgery	28JAN2015	28JAN2015	N
		Vascular disorders	Aortic disorder	01NOV2017		Y
			Hypertension	01JAN1995		Y
	C4591001 1118 11181125	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Nicotine dependence	01JAN1965	31DEC1985	N
		Surgical and medical procedures	Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181126	Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1118 11181127	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Onychomycosis	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1118 11181128	Eye disorders	Chalazion	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1118 11181129	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pharyngeal cancer	01SEP2012	31OCT2012	N
		Surgical and medical procedures	Pharyngeal operation	01OCT2012	31OCT2012	N
	C4591001 1118 11181130	Eye disorders	Cataract	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
			Osteoporosis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201002	Infections and infestations	Onychomycosis	01APR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1986		Y
		Surgical and medical procedures	Spinal laminectomy	07FEB2020	07FEB2020	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1120 11201003	Nervous system disorders	Hypersomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1979		Y
	C4591001 1120 11201006	Immune system disorders	Drug hypersensitivity	01JAN1957		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1120 11201007	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1120 11201008	Cardiac disorders	Coronary artery disease	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	05JUL2020	05JUL2020	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JUN2000	30JUN2000	N
			Vasectomy	01JAN1984	31DEC1984	N
	C4591001 1120 11201010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
	C4591001 1120 11201012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201017	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201018	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
			Post-traumatic stress disorder	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1120 11201019	Gastrointestinal disorders	Diverticulum oesophageal	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Diverticulectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1120 11201020	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1996		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1120 11201021	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1120 11201025	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201027	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1989		Y
			Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Hip arthroplasty	23JUN2020	23JUN2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201030	Infections and infestations	Herpes simplex	01JAN1975		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN1985	31DEC1985	N
			Lower limb fracture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Narcolepsy	01JAN1990		Y
		Surgical and medical procedures	Foot operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201032	Ear and labyrinth disorders	Meniere's disease	01JAN2015		Y
		Infections and infestations	Oral herpes	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1120 11201033	Ear and labyrinth disorders	Vertigo	01APR2020		Y
	C4591001 1120 11201035	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1120 11201036	Surgical and medical procedures	Rotator cuff repair	01JAN2018	31DEC2018	N
	C4591001 1120 11201043	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN1992		Y
			Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201047	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1120 11201048	Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
			Rotator cuff repair	01JAN2018	31DEC2018	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201049	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1120 11201050	Vascular disorders	Hypertension	01JAN2006		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015	07NOV2020	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1982	31DEC1982	N
	C4591001 1120 11201051	Vascular disorders	Hypertension	01JAN2017		Y
		Endocrine disorders	Hypergonadism	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Scapholunate dissociation	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000	01NOV2019	N
		Surgical and medical procedures	Skin lesion removal	01JAN2010	31DEC2010	N
			Transurethral prostatectomy	01NOV2019	01NOV2019	N
	C4591001 1120 11201052	Injury, poisoning and procedural complications	Ligament rupture	01JAN2018		Y
	C4591001 1120 11201054	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Transcatheter aortic valve implantation	01JAN2018	31DEC2018	N
		Vascular disorders	Aortic stenosis	01JAN2018		Y
			Hypertension	01JAN2016		Y
	C4591001 1120 11201055	Investigations	Blood testosterone decreased	01JAN2010		Y
			Colonoscopy	27JUL2020	27JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201056	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	31DEC2016	N
			Polyarthritis	01JAN2016		Y
			Trigger finger	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Joint arthroplasty	01JAN2016	31DEC2016	N
			Tenoplasty	01JAN2019	31DEC2019	N
	C4591001 1120 11201057	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1120 11201059	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Cataract	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2001		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1991	31DEC1994	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1120 11201060	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201064	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01APR2014	30APR2014	N
			Spinal operation	01JAN2020	31JAN2020	N
	C4591001 1120 11201066	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
	C4591001 1120 11201067	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
	C4591001 1120 11201069	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201070	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201071	Cardiac disorders	Aortic valve incompetence	01JAN2000	31DEC2000	N
			Coronary artery stenosis	01JAN2008	31DEC2008	N
				01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2008	31DEC2008	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Deep vein thrombosis	01JAN2008	31DEC2008	N
			Hypertension	01JAN2008		Y
	C4591001 1120 11201072	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2019		Y
	C4591001 1120 11201073	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Ear and labyrinth disorders	Vertigo	01JAN2007		Y
		Endocrine disorders	Hyperthyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201074	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Neuralgia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1120 11201080	Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2010	31DEC2014	N
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Spinal operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1120 11201086	Cardiac disorders	Mitral valve prolapse	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1975		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1120 11201087	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1120 11201088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		General disorders and administration site conditions	Pain	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2017		Y
			Knee arthroplasty	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1996		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2019		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1120 11201091	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201092	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2007	N
		Nervous system disorders	Dementia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201093	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1120 11201095	Eye disorders	Macular degeneration	01JAN2018		Y
			Retinal vein occlusion	01JAN2005		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2014	31DEC2014	N
			Gastrointestinal haemorrhage	01JAN2014	31DEC2014	N
			Gastroesophageal reflux disease	01JAN2004		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Hip arthroplasty	01JAN2014	31DEC2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin lesion removal	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1979		Y
		Vascular disorders	Deep vein thrombosis	01JAN2014		Y
			Hypertension	01JAN2000		Y
	C4591001 1120 11201099	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1985		Y
			Hyperlipidaemia	01JAN1997		Y
		Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Spinal operation	01JAN2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1120 11201109	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Essential tremor	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1120 11201114	Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201117	Cardiac disorders	Acute coronary syndrome	01JAN2013		Y
			Myocardial infarction	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2013	31DEC2013	N
	C4591001 1120 11201118	Endocrine disorders	Hyperthyroidism	01JAN2002		Y
		Nervous system disorders	Hypersomnia	01JAN2002		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1120 11201121	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Diastasis recti abdominis	01JAN2016		Y
			Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1120 11201122	Cardiac disorders	Atrial fibrillation	01JAN2017	31DEC2017	N
			Coronary artery occlusion	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201124	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201125	Endocrine disorders	Basedow's disease	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypothyroidism	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
			Thyroidectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201126	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1985		Y
	C4591001 1120 11201127	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1990		Y
	C4591001 1120 11201128	Endocrine disorders	Hyperthyroidism	01JAN2017		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2019	N
			Spinal stenosis	01JAN2019	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2009		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1120 11201129	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1120 11201134	Eye disorders	Dry eye	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201137	Nervous system disorders	Carotid artery stenosis	01JAN2018	25OCT2018	N
		Surgical and medical procedures	Arterial therapeutic procedure	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201138	Immune system disorders	Drug hypersensitivity	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Lens capsulotomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201140	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201141	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1120 11201143	Cardiac disorders	Microvascular coronary artery disease	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2014	N
			Osteoporosis	01JAN1996	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN1974	31DEC1976	Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1976	31DEC1976	N
	C4591001 1120 11201146	Immune system disorders	Food allergy	01JAN2006		Y
		Infections and infestations	Poliomyelitis	01JAN1946		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Social circumstances	Orthosis user	01JAN1946		Y
		Surgical and medical procedures	Prostatectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201147	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1120 11201150	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Eye disorders	Eyelid ptosis	01JAN1955		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1120 11201152	Injury, poisoning and procedural complications	Lower limb fracture	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Deep vein thrombosis	01JAN2018	31DEC2018	N
	C4591001 1120 11201155	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2001	N
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201158	Metabolism and nutrition disorders	Gout	01JAN2005		Y
	C4591001 1120 11201159	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Allergy to vaccine	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1120 11201160	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC2003	N
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1120 11201162	Eye disorders	Ocular hypertension	01JAN2010		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2020	31DEC2020	N
		Vascular disorders	White coat hypertension	01JAN1970		Y
	C4591001 1120 11201163	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Aortic valve replacement	08MAR2020	08MAR2020	N
		Vascular disorders	Arterial stenosis	08MAR2020	08MAR2020	N
	C4591001 1120 11201164	Cardiac disorders	Coronary artery disease	01JAN1989		Y
			Myocardial infarction	01JAN2002	31DEC2002	N
				01JAN2018	31DEC2018	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hyperlipidaemia	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Stent placement	01JAN2002	31DEC2002	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1120 11201167	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1120 11201169	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2005		Y
		Surgical and medical procedures	Hernia repair	01JAN2008	31DEC2008	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201170	Metabolism and nutrition disorders	Hyperlipidaemia	14FEB2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201174	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Spinal operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1120 11201177	Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201183	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201185	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basosquamous carcinoma	01JAN2017	31DEC2018	N
		Nervous system disorders	Thoracic outlet syndrome	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201186	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2003	31DEC2003	N
	C4591001 1120 11201189	Cardiac disorders	Atrial flutter	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Cardioversion	01JAN2019	31DEC2019	N
		Vascular disorders	Deep vein thrombosis	01JAN1972	31DEC1972	N
			Hypertension	01JAN2015		Y
	C4591001 1120 11201192	Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201193	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
			Gout	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN1978		Y
			Hypokalaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1120 11201200	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
			Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Mastectomy	01JAN2014	31DEC2014	N
	C4591001 1120 11201201	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Prostatectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1120 11201206	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1952		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Surgical and medical procedures	Vasectomy	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201208	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Headache	01JAN1970		Y
	C4591001 1120 11201210	Injury, poisoning and procedural complications	Joint injury	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Nervous system disorders	Epilepsy	01JAN1959		Y
			Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
		Surgical and medical procedures	Hip arthroplasty	01JUN2020	30JUN2020	N
	C4591001 1120 11201211	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Psychiatric disorders	Alcoholism	01JAN2015		Y
			Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201212	Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1120 11201213	Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2019		Y
	C4591001 1120 11201214	Endocrine disorders	Goitre	01JAN2014	31DEC2014	N
			Hypoparathyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrointestinal hypomotility	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
			Thyroidectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201215	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Morton's neuralgia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201216	General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
			Limb operation	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201217	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1964		Y
	C4591001 1120	Social circumstances	Postmenopause	01JAN2000		Y
	11201218	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
	11201221					
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1982		Y
		Social circumstances	Postmenopause	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
			Joint arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120	Investigations	Cardiac murmur	01JAN1989		Y
	11201222					
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1120	Eye disorders	Glaucoma	01JAN2015		Y
	11201224					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tendon rupture	01APR2020	30APR2020	N
		Musculoskeletal and connective tissue disorders	Ulnocarpal abutment syndrome	01JAN2019	30APR2020	N
		Surgical and medical procedures	Osteotomy	01APR2020	30APR2020	N
			Tendon operation	01APR2020	30APR2020	N
	C4591001 1120 11201225	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Neck injury	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Neck surgery	01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1120 11201226	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN2015		Y
		Surgical and medical procedures	Toe amputation	01JAN2019	31DEC2019	N
	C4591001 1120 11201227	Eye disorders	Dry eye	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Seizure	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1999		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1991	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
	C4591001 1120 11201228	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201229	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN1964		Y
			Posterior reversible encephalopathy syndrome	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1120 11201242	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	31DEC2013	N
				01JAN1992	31DEC2014	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
	C4591001 1120 11201243	Cardiac disorders	Atrial fibrillation	09JUL2020		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2018		Y
			Vitamin B12 deficiency	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201245	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
			Skin neoplasm excision	20AUG2020	20AUG2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1120 11201246	Injury, poisoning and procedural complications	Spinal cord injury	01MAY2019	31MAY2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN1984	31DEC1984	N
		Nervous system disorders	Post-traumatic neuralgia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201247	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201248	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2020		Y
	C4591001 1120 11201251	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1120 11201253	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Osteopenia	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Night sweats	01JAN2004		Y
	C4591001 1120 11201254	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tongue neoplasm malignant stage unspecified	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1120 11201255	Immune system disorders	Allergy to animal	01JAN1948		Y
			Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1980		Y
		Renal and urinary disorders	Renal disorder	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201256	Eye disorders	Glaucoma	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Oesophageal stenosis	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1120 11201260	Infections and infestations	Genital herpes	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
			Intervertebral disc protrusion	01JAN1988	31DEC1988 31DEC1996	N N
			Osteonecrosis	01JAN1997	31DEC2007	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01JAN1996	31DEC1996	N
			Spinal operation	01JAN1988	31DEC1988	N
				01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201262	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2014		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2020	31JUL2020	N
			Malignant melanoma	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Radiotherapy to skin	01FEB2020	31JUL2020	N
	C4591001 1120 11201264	Infections and infestations	Diverticulitis	01JAN1997	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Colectomy	01JAN2009	31DEC2009	N
			Gastrectomy	01JAN2015	31DEC2015	N
	C4591001 1120 11201269	General disorders and administration site conditions	Peripheral swelling	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201273	Cardiac disorders	Bradycardia	01JAN2019	31DEC2019	N
		Endocrine disorders	Hypogonadism	01JAN2017		Y
			Hypothyroidism	01JAN2010		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201276	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1998		Y
			Seasonal allergy	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1120 11201283	Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1120 11201285	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Mitral valve repair	01JAN1995	31DEC1995	N
				01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201287	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1120 11201290	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201292	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Vitamin B complex deficiency	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tonsillectomy	01JAN1948	31DEC1948	N
	C4591001 1120 11201294	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1120 11201295	Metabolism and nutrition disorders	Obesity	24AUG2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201296	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	30SEP1998	N
		Nervous system disorders	Trigeminal neuralgia	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01SEP1998	30SEP1998	N
	C4591001 1120 11201301	Immune system disorders	Seasonal allergy	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201302	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Shoulder operation	01JAN2015	31DEC2015	N
	C4591001 1120 11201307	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	15MAR2020	15MAR2020	N
			Prostatectomy	24JAN2020	24JAN2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201308	Musculoskeletal and connective tissue disorders	Myalgia	01JAN1996		Y
		Social circumstances	Postmenopause	01FEB1990		Y
		Surgical and medical procedures	Breast reconstruction	01AUG1989	31AUG1989	N
			Hysterectomy	01FEB1990	28FEB1990	N
			Simple mastectomy	01AUG1989	31AUG1989	N
	C4591001 1120 11201310	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
	C4591001 1120 11201313	Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1120 11201316	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Anxiety	01SEP2019		Y
		Reproductive system and breast disorders	Vulvovaginal burning sensation	01JAN2018		Y
	C4591001 1120 11201317	Investigations	Blood magnesium decreased	01SEP2020		Y
			Blood potassium decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1120 11201321	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201327	Reproductive system and breast disorders	Endometriosis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1120 11201328	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1120 11201329	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Surgical and medical procedures	Prostatectomy	01JUL2014	31JUL2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201330	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1962		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31JAN2016	N
				01MAR2015	31MAR2015	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201333	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201335	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1975		Y
			Osteoporosis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1120 11201336	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1120 11201338	Blood and lymphatic system disorders	Lymphadenopathy	16OCT2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1120 11201345	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Amnesia	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201347	Endocrine disorders	Hypogonadism	01JAN2012		Y
	C4591001 1120 11201349	Eye disorders	Glaucoma	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
			Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1120 11201350	Cardiac disorders	Cardiac failure congestive	01JAN1992		Y
			Myocardial infarction	01JAN1992	31DEC1992	N
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Neck pain	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1994		Y
		Surgical and medical procedures	Coronary artery bypass	01DEC1992	31DEC1992	N
			Implantable defibrillator insertion	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1120 11201351	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1983	31DEC1983	N
		Social circumstances	Postmenopause	01JAN1983		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201353	Eye disorders	Glaucoma	01JUL2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Oophorectomy	01JAN2003	31DEC2003	N
	C4591001 1120 11201355	Immune system disorders	Drug hypersensitivity	01JAN1948		Y
			Iodine allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Prostatectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201358	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201359	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Surgical and medical procedures	Nephrectomy	01JAN1979	31DEC1979	N
	C4591001 1120 11201360	Eye disorders	Cataract	01JAN2000	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2014		Y
			Uterine leiomyoma	01JAN1997	31DEC1999	N
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1120 11201361	Endocrine disorders	Hypothyroidism	03SEP2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Nervous system disorders	Headache	01JAN1973		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2019		Y
			Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201362	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1120 11201368	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Nervous system disorders	Small fibre neuropathy	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1120 11201369	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201372	Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
	C4591001 1120 11201374	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1120 11201375	Cardiac disorders	Atrial fibrillation	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2019		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1120 11201377	General disorders and administration site conditions	Pain	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1120 11201378	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1949		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1983	31DEC1983	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1975	31DEC1975	N
			Female sterilisation	01JAN1977	31DEC1977	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201379	General disorders and administration site conditions	Hyperplasia	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1120 11201380	Endocrine disorders	Hypogonadism	01JAN2019		Y
			Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	10SEP2020	10SEP2020	N
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN1995		Y
		Surgical and medical procedures	Nephrectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1120 11201382	Gastrointestinal disorders	Colitis	01JAN2019		Y
			Gastroesophageal reflux disease	15JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1120 11201383	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1120 11201384	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1120 11201387	Gastrointestinal disorders	Diverticulum	01JAN2017		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
		Infections and infestations	Diverticulitis	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01AUG2020		Y
			Obsessive-compulsive disorder	01JAN2000		Y
		Surgical and medical procedures	Colectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1120 11201389	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1120 11201390	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Meniscus operation	01JAN2015	31DEC2015	N
			Urinary bladder suspension	01JAN2018		Y
	C4591001 1120 11201394	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1120 11201399	Vascular disorders	Hypertension	01JAN2000		Y	
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y	
			Constipation		22OCT2020		Y
			Gastrooesophageal reflux disease		01JAN2013		Y
			Pancreatitis chronic		01JAN2013		Y
		Infections and infestations	Tinea pedis		02OCT2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus		01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration		01JAN1991		Y
			Rotator cuff syndrome		01NOV2019		Y
		Psychiatric disorders	Anxiety		01JUL2019		Y
			Depression		01JUL2019		Y
		Surgical and medical procedures	Appendicectomy		01JAN1967	31DEC1967	N
			Bone operation		01JAN1977	31DEC1977	N
			Cardiac operation		01FEB2012	29FEB2012	N
			Cholecystectomy		01JAN2017	31DEC2017	N
		Orchidectomy		01JAN1977	31DEC1977	N	
		Tenotomy		01JAN2005	31DEC2005	N	
				01JAN2014	31DEC2014	N	
	C4591001 1120 11201400	Endocrine disorders	Hypothyroidism	01JAN1970		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y	
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2020		Y	
		Social circumstances	Postmenopause	01JAN2000		Y	
		Vascular disorders	Hypertension	01JAN2003		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201403	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Cardiac murmur	01JAN2014	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1972		Y
			Insomnia	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Surgical and medical procedures	Mitral valve repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201408	Blood and lymphatic system disorders	Anaemia	01FEB2020		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Renal and urinary disorders	Nephrogenic diabetes insipidus	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01APR2019		Y
			Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1120 11201410	Cardiac disorders	Atrial fibrillation	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1954		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1954		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31DEC2019	N
			Meniscus operation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wrist surgery	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201411	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Hip fracture	11MAY2020	12MAY2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hip arthroplasty	12MAR2020	12MAY2020	N
			Hysterectomy	01JAN1977	31DEC1977	N
			Nephrectomy	01JAN1999	31DEC1999	N
	C4591001 1120 11201412	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2011	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Social circumstances	Ex-tobacco user	01OCT2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
			Spinal operation	01JAN2005	31DEC2005	N
	C4591001 1120 11201413	Immune system disorders	Seasonal allergy	01JAN1958		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201414	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1953		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Vascular disorders	Deep vein thrombosis	01JAN2019		Y
			Hypertension	01JAN2016		Y
	C4591001 1120 11201415	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201419	Eye disorders	Amblyopia	01JAN1975		Y
		Surgical and medical procedures	Inguinal hernia repair	01MAR2017	31MAR2017	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2006	31DEC2010	N
	C4591001 1120 11201421	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Surgical and medical procedures	Gastric bypass	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1120 11201422	Immune system disorders	Drug hypersensitivity	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
			Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Penile prosthesis insertion	01JAN2009	31DEC2009	N
			Prostatectomy	01JAN2007	31DEC2007	N
			Spinal operation	01DEC2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1120 11201423	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1120 11201424	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1994	31DEC1994	N
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hormone replacement therapy	01JAN2010		Y
	C4591001 1120 11201426	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1120 11201428	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1120 11201432	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2008		Y
			Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Vascular disorders	Hypertension	14FEB2020		Y
	C4591001 1120 11201434	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1120 11201435	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Hormone replacement therapy	01JAN1989		Y
			Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1120 11201436	Cardiac disorders	Angina pectoris	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	08SEP2020		Y
		Surgical and medical procedures	Coronary artery bypass	10AUG2020	10AUG2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1121 11211007	Reproductive system and breast disorders	Uterine prolapse	01JAN1993	31DEC1994	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1121 11211011	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2016		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1121 11211016	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2009	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01DEC2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1121 11211017	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1999	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1121 11211019	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1121 11211021	Psychiatric disorders	Depression	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1121 11211031	Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1121 11211032	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1121 11211037	Psychiatric disorders	Anxiety	03JAN2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2002	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1121 11211040	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Vascular disorders	Hypertension	27AUG2014		Y
	C4591001 1121 11211042	Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1121 11211043	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1121 11211045	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1121 11211046	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1121 11211047	Metabolism and nutrition disorders	Gout	01JAN2005		Y
	C4591001 1121 11211049	Social circumstances	Postmenopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1121 11211051	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1121 11211055	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1121 11211056	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1121 11211058	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1121 11211062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Postmenopause	01NOV2006		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1121 11211063	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1121 11211071	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1121 11211072	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1121 11211073	Reproductive system and breast disorders	Adenomyosis	01JAN1997	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1121 11211074	Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1121 11211075	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1121 11211077	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1121 11211079	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
	C4591001 1121 11211083	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1121 11211086	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1121 11211088	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1121 11211090	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
	C4591001 1121 11211092	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
	C4591001 1121 11211098	Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1121 11211101	Nervous system disorders	Migraine	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1999	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1121 11211102	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1121 11211103	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1121 11211104	Reproductive system and breast disorders	Menorrhagia	01JAN2013	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1121 11211107	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
			Type 2 diabetes mellitus	01JAN2007		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1121 11211119	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1121 11211122	Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1122 11221002	Cardiac disorders	Mitral valve prolapse	18MAY2006		Y
		Ear and labyrinth disorders	Deafness neurosensory	18AUG2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05MAY2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18MAY2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	16JUL2012		Y
				28JUL2008		Y
		Nervous system disorders	Lumbar radiculopathy	10AUG2009		Y
		Vascular disorders	Essential hypertension	18MAY2006		Y
	C4591001 1122 11221007	Infections and infestations	Diverticulitis	01JAN2007		Y
		Injury, poisoning and procedural complications	Joint injury	25FEB2008	01MAY2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	19FEB2004		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2004		Y
		Vascular disorders	Hypertension	01NOV2015		Y
	C4591001 1122 11221010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1122 11221011	Ear and labyrinth disorders	Deafness unilateral	21FEB2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15JUN2016		Y
			Obesity	16SEP2015		Y
			Type 2 diabetes mellitus	16SEP2015		Y
		Nervous system disorders	Carpal tunnel syndrome	15JUN2016		Y
			Cerebral infarction	12FEB2019		Y
		Vascular disorders	Hypertension	16SEP2015		Y
	C4591001 1122 11221013	Investigations	Weight decreased	01JAN2006		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01DEC2010		Y
			Hyperlipidaemia	01JAN1990		Y
		Nervous system disorders	Hypogeusia	01JAN2017		Y
			Hyposmia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1122 11221015	Reproductive system and breast disorders	Benign prostatic hyperplasia	07DEC2017		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	07DEC2017		Y
	C4591001 1122 11221017	Blood and lymphatic system disorders	Anaemia	01OCT2018		Y
		Cardiac disorders	Coronary artery disease	01OCT2018		Y
		Ear and labyrinth disorders	Deafness neurosensory	06FEB2013		Y
		Endocrine disorders	Hypothyroidism	29JAN2013		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01OCT2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Oesophageal carcinoma stage 0	01JAN2008	31DEC2009	N
		Renal and urinary disorders	Proteinuria	01OCT2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Chemotherapy	01JAN2008	31DEC2008	N
			Oesophagectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Essential hypertension	01OCT2018		Y
	C4591001 1122 11221018	Eye disorders	Oscillopsia	01JAN2011		Y
		Gastrointestinal disorders	Colitis ischaemic	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
			Vertebral foraminal stenosis	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eye naevus	01JAN2018		Y
		Nervous system disorders	Transient ischaemic attack	01DEC2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1122 11221019	Endocrine disorders	Hyperparathyroidism primary	01JAN2004	31MAY2005	N
			Hyperthyroidism	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Appendix cancer	01NOV2004	30NOV2004	N
		Nervous system disorders	Morton's neuralgia	01JAN2010		Y
			Restless legs syndrome	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
	C4591001 1122 11221020	General disorders and administration site conditions	Oedema peripheral	09SEP2020		Y
		Investigations	Colonoscopy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1985		Y
		Surgical and medical procedures	Polypectomy	01JAN2012	31DEC2012	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1122 11221021	Metabolism and nutrition disorders	Hyperlipidaemia	01APR2017		Y
		Surgical and medical procedures	Prostatectomy	06JUN2005	06JUN2005	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1122 11221029	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1122 11221034†	Eye disorders	Retinal tear	27JUL2015	14SEP2018	N
		Gastrointestinal disorders	Large intestine polyp	17JUN2015	31DEC2015	N
		Infections and infestations	Hepatitis C	13OCT2015		Y
			Periodontitis	27OCT2011		Y
		Investigations	HIV test positive	05AUG2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2018		Y
			Spinal osteoarthritis	19MAR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	13OCT2015	31DEC2017	N
		Nervous system disorders	Radiculopathy	19MAR2018		Y
		Renal and urinary disorders	Hypertonic bladder	07FEB2017	31DEC2018	N
				12FEB2017		Y
			Incontinence	07FEB2017	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	14AUG2013		Y
		Vascular disorders	Essential hypertension	13OCT2015		Y
	C4591001 1122 11221039	Metabolism and nutrition disorders	Hyperlipidaemia	01APR2019		Y
	C4591001 1122 11221043	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1122 11221044	Cardiac disorders	Cardiac disorder	05JAN2017		Y
			Cardiac failure chronic	05JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05JAN2017		Y
			Type 2 diabetes mellitus	05JAN2017		Y
			Vitamin B12 deficiency	22JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
		Psychiatric disorders	Adjustment disorder	17DEC2019		Y
			Alcohol abuse	05JAN2017		Y
		Vascular disorders	Hypertension	05JAN2017		Y
	C4591001 1122 11221049	Injury, poisoning and procedural complications	Tendon rupture	01JUN2020	04FEB2021	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1122 11221050	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2014		Y
		Infections and infestations	Chronic hepatitis C	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1122 11221055	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
			Coronary artery disease	01JAN2005		Y
		Ear and labyrinth disorders	Deafness neurosensory	01JAN2016		Y
		Gastrointestinal disorders	Gastrointestinal disorder	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1122 11221057	Eye disorders	Cataract	29JAN2018	31JUL2020	N
		Infections and infestations	Acute sinusitis	01OCT2020		Y
			Bronchitis	18JAN2018	31JUL2020	N
		Psychiatric disorders	Depression	29JAN2018		Y
			Nicotine dependence	01JAN1970		Y
	C4591001 1122 11221058	Skin and subcutaneous tissue disorders	Actinic keratosis	14FEB2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
			Pain in extremity	29SEP2020		Y
	C4591001 1122 11221060	Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1123 11231006	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1123 11231008	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1123 11231010	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	01JAN2017		Y
		Endocrine disorders	Hyperaldosteronism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JUL2020		Y
			Muscle rupture	01JAN2017	31MAY2017	N
		Investigations	Blood testosterone decreased	01JAN2010		Y
			Cardiac murmur	01JAN1958		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN1984		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01MAY2017	31MAY2017	N
			Implantable defibrillator replacement	01MAY2017	31MAY2017	N
			Muscle operation	01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231011	Cardiac disorders	Mitral valve prolapse	(b) (6) 1953		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1972	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1123 11231012	Immune system disorders	Drug hypersensitivity	01JAN1967		Y
			Seasonal allergy	01JAN1993		Y
		Injury, poisoning and procedural complications	Muscle rupture	01OCT2019		Y
		Social circumstances	Menopause	01JAN2011		Y
	C4591001 1123 11231013	General disorders and administration site conditions	Adverse drug reaction	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2009		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1123 11231014	Immune system disorders	Contrast media allergy	01JAN1982		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1972		Y
			Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1996		Y
			Insomnia	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1991		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231015	Cardiac disorders	Coronary artery disease	01JAN2012		Y
			Supraventricular tachycardia	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1984	31DEC1984	N
		Renal and urinary disorders	Focal segmental glomerulosclerosis	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1123 11231016	Immune system disorders	Seasonal allergy	01JAN1997		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JUN2018	31DEC2018	N
		Surgical and medical procedures	Ligament operation	10DEC2018	10DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1123 11231017	Injury, poisoning and procedural complications	Tendon rupture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Polyuria	01JAN2014		Y
		Surgical and medical procedures	Tenoplasty	01JAN2015	31DEC2015	N
	C4591001 1123 11231018	Endocrine disorders	Hypothyroidism	01JAN2003		Y
	C4591001 1123 11231021	Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1123 11231023	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Intestinal perforation	22JUL2015	22JUL2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Surgical and medical procedures	Colectomy	22JUL2015	22JUL2015	N
	C4591001 1123 11231025	Endocrine disorders	Hypothyroidism	01APR2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JUN2020		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01OCT2018		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1123 11231036	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1123 11231037	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
	C4591001 1123 11231039	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1123 11231040	Ear and labyrinth disorders	Meniere's disease	01JAN1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Renal and urinary disorders	Pollakiuria	01JAN2010		Y
	C4591001 1123 11231047	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2006		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1123 11231049	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2019		Y
	C4591001 1123 11231050	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Injury, poisoning and procedural complications	Patella fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N
	C4591001 1123 11231053	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1123 11231054	Psychiatric disorders	Anxiety	01NOV2019		Y
		Renal and urinary disorders	Urinary incontinence	01MAY2020		Y
		Vascular disorders	Hypertension	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231056	Gastrointestinal disorders	Haemorrhoids	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1956		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1123 11231058	Ear and labyrinth disorders	Deafness	01DEC2019		Y
		Immune system disorders	Allergy to plants	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
	C4591001 1123 11231061	Immune system disorders	Seasonal allergy	01JAN1966		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2000		Y
	C4591001 1123 11231063	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1123 11231065	Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1993		Y
	C4591001 1123 11231066	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2009		Y
		Investigations	Colonoscopy	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31JAN2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
			Prostatomegaly	01JAN2018		Y
		Surgical and medical procedures	Colectomy	01JAN2016	31JAN2016	N
	C4591001 1123 11231070	Surgical and medical procedures	Hysterectomy	01JUN2018	30JUN2018	N
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1123 11231071	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1123 11231079	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
	C4591001 1123 11231080	Endocrine disorders	Hypothyroidism	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1123 11231087	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1123 11231089	Congenital, familial and genetic disorders	Spine malformation	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1123 11231093	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2018		Y
	C4591001 1123 11231096	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1123 11231097	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1123 11231103	Gastrointestinal disorders	Abdominal pain	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1123 11231107	General disorders and administration site conditions	Pain	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1123 11231110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1123 11231111	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1981		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JUN1981	30JUN1981	N
		Nervous system disorders	Trigeminal neuralgia	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Surgical and medical procedures	Cranial nerve decompression	01JAN1997	31DEC1997	N
			Thyroidectomy	01JUN1981	30JUN1981	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1123 11231113	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231126	Cardiac disorders	Atrial fibrillation	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2007		Y
	C4591001 1123 11231129	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
				01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1123 11231131	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231133	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Lipoma excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1123 11231139	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1123 11231140	Nervous system disorders	Headache	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1123 11231141	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1123 11231146	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1123 11231147	Endocrine disorders	Hypothyroidism	01JAN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1985		Y
	C4591001 1123 11231148	Endocrine disorders	Hypothyroidism	01MAY2019		Y
			Thyroid mass	01APR2019	31MAY2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Anal incontinence	01JAN2008		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
				01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Thyroidectomy	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1123 11231149	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Injury, poisoning and procedural complications	Cataract traumatic	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Cataract operation	01JAN1971	31DEC1971	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1123 11231158	Immune system disorders	Allergy to animal	01JAN1970		Y
			Allergy to arthropod sting	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1970		Y
	C4591001 1123 11231166	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01MAY1994	30JUN1994	N
		Surgical and medical procedures	Hysterectomy	01JUN1994	30JUN1994	N
	C4591001 1123 11231167	Social circumstances	Postmenopause	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231169	Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1123 11231180	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2020		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231181	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
			Vena cava filter insertion	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231182	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231185	Immune system disorders	Drug hypersensitivity	01APR2019		Y
				01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2018	18APR2019	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Bartholin's cyst	01SEP2019	13NOV2019	N
		Surgical and medical procedures	Cyst drainage	13NOV2019	13NOV2019	N
			Knee arthroplasty	18APR2019	18APR2019	N
	C4591001 1123 11231186	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231192	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231193	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	21MAY2020	N
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	21MAY2020	21MAY2020	N
	C4591001 1123 11231196	Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1123 11231198	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01JAN2010	05DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31JAN2001	N
		Surgical and medical procedures	Hysterectomy	01JAN2001	31JAN2001	N
			Joint arthroplasty	05DEC2016	05DEC2016	N
	C4591001 1123 11231203	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1992	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1123 11231205	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1123 11231206	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1123 11231211	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Hirsutism	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1123 11231214	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
		Nervous system disorders	Neuralgia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1123 11231219	Congenital, familial and genetic disorders	Congenital absence of vertebra	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to metals	01JAN2010		Y
			Drug hypersensitivity	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2020	31JAN2020	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
	C4591001 1123 11231224	Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1123 11231225	Endocrine disorders	Hypogonadism	01JAN2018		Y
			Hypothyroidism	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01MAR1963		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1123 11231226	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010	31DEC2017	N
			Neck pain	01JAN2010	31DEC2017	N
		Reproductive system and breast disorders	Mastoptosis	01JAN2010	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231231	Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Social circumstances	Menopause	01JUL2018		Y
	C4591001 1123 11231241	Cardiac disorders	Coronary artery disease	01OCT2019		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUL2019		Y
	C4591001 1123 11231242	Endocrine disorders	Hypothyroidism	01JAN2000		Y
			Thyroid mass	01JAN2000	31DEC2000	N
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2000	31DEC2000	N
	C4591001 1123 11231244	Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1123 11231250	Infections and infestations	Herpes simplex	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
	C4591001 1123 11231254	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01MAY2019		Y
			Osteonecrosis	01MAR2013	30JUN2013	N
			Osteoporosis	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01OCT2017	31OCT2017	N
			Cubital tunnel syndrome	01OCT2017	31OCT2017	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
			Hip arthroplasty	01JUN2013	30JUN2013	N
			Neck surgery	01FEB2020	29FEB2020	N
			Pelvic operation	01MAY2019	31MAY2019	N
			Peripheral nerve decompression	01OCT2017	31OCT2017	N
			Spinal fusion surgery	01APR2015	30APR2015	N
				01DEC2019	31DEC2019	N
				01MAY2019	31MAY2019	N
			Urinary bladder suspension	01JAN2011	31DEC2011	N
	C4591001 1123 11231255	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Toe amputation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1123 11231256	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Progesterone decreased	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)		
	C4591001 1123 11231257	Vascular disorders	Hypertension	01JAN2015		Y		
		Endocrine disorders	Hypothyroidism	01JAN2000		Y		
		Eye disorders	Macular degeneration	01JAN1990		Y		
		Gastrointestinal disorders	Dry mouth	01FEB2019		Y		
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y		
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tongue neoplasm malignant stage unspecified	01MAY2017	28FEB2019	N		
		Nervous system disorders	Facial nerve disorder	01FEB2019		Y		
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N		
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2019		Y		
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y		
	C4591001 1123 11231259	Surgical and medical procedures	Glossectomy	01DEC2018	31DEC2018	N		
				Renal stone removal	01JAN2018	31DEC2018	N	
		Immune system disorders	Seasonal allergy	01JAN2000		Y		
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration		01JAN2000		Y	
						01NOV2019		Y
					Osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1995		Y		
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y		
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y		
		C4591001 1123 11231270	Cardiac disorders	Coronary artery disease	01JAN2019		Y	
	Metabolism and nutrition disorders		Hyperlipidaemia	01MAY2019		Y		



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2000		Y
		Surgical and medical procedures	Coronary artery bypass	01MAY2019	31MAY2019	N
			Vasectomy	01JAN1995		Y
	C4591001 1123 11231271	Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Gastrointestinal disorders	Abdominal pain	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2007		Y
			Rectal spasm	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Spondylitis	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1960		Y
	C4591001 1123 11231273	Eye disorders	Dry eye	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231274	Endocrine disorders	Hypothyroidism	01OCT2018		Y
			Thyroid mass	01MAY2016	31MAY2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma	01MAY1990	31MAY2016	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Thyroid operation	01MAY2018	31MAY2018	N
			Thyroidectomy	01OCT2018	31OCT2018	N
	C4591001 1123 11231277	Endocrine disorders	Hypogonadism	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1123 11231278	Eye disorders	Cataract	01JAN1955		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2004	31DEC2004	N
			Prostate cancer	01JAN2002	31DEC2009	N
			Tonsil cancer	01JAN2010	31DEC2010	N
	C4591001 1123 11231279	Renal and urinary disorders	Urinary incontinence	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1965		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN1975		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2003	31DEC2005	N
	C4591001 1123 11231282	Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
	C4591001 1123 11231284	Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1123 11231285	Vascular disorders	Hypertension	01JAN2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2005		Y
	C4591001 1123 11231288	Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	05OCT2005	N
		Surgical and medical procedures	Hysterectomy	05OCT2005	05OCT2005	N
	C4591001 1123 11231296	Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231297	Infections and infestations	Herpes simplex	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC1992	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Oophorectomy bilateral	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1123 11231310	Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2015	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Colostomy	01JAN2016	31DEC2016	N
			Intestinal resection	01JAN2015	31DEC2015	N
			Oophorectomy bilateral	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1123 11231314	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Hyperthermia malignant	01JAN1973		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2014		Y
	C4591001 1123 11231315	General disorders and administration site conditions	Drug intolerance	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Maxillofacial operation	29OCT2019	29OCT2019	N
	C4591001 1123 11231316	Endocrine disorders	Hypogonadism	01MAR2019		Y
		Eye disorders	Retinal detachment	01JAN2008	31DEC2008	N
		Investigations	Intraocular pressure increased	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Scleral buckling surgery	01JAN2008	31DEC2008	N
	C4591001 1123 11231318	Eye disorders	Glaucoma	01JAN2014		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2010		Y
			Vitamin D deficiency	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1123 11231319	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1983		Y
		Surgical and medical procedures	Appendectomy	01JAN2005	31DEC2005	N
			Lower oesophageal sphincter magnetic augmentation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1123 11231331	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31DEC2012	N
		Nervous system disorders	Essential tremor	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2007	31DEC2007	N
		Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Joint arthroplasty	01JAN2009	31DEC2009	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1123 11231332	Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1123 11231333	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1123 11231335	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1990		Y
		Social circumstances	Menopause	01JAN2011		Y
	C4591001 1123 11231340	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN2016	31DEC2016	N
			Osteoporosis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
			Spinal fusion surgery	01JAN2016	31DEC2016	N
	C4591001 1123 11231341	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019		Y
		Nervous system disorders	Cerebrovascular disorder	01JAN2018		Y
			Dementia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1123 11231342	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Scoliosis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1123 11231344	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01SEP2018	30SEP2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN1994	31DEC1996	N
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Rotator cuff repair	01SEP2018	30SEP2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1123 11231345	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Urinary bladder suspension	01JAN2012	31DEC2012	N
	C4591001 1123 11231347	Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
	C4591001 1123 11231348	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
	C4591001 1123 11231349	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01APR2017		Y
		Social circumstances	Postmenopause	01AUG2009		Y
	C4591001 1123 11231354	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1962		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Knee arthroplasty	19JAN2017	19JAN2017	N
			Tenoplasty	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2015	31DEC2015	N
	C4591001 1123 11231355	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Wrist surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1123 11231356	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2009		Y
	C4591001 1123 11231367	Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1123 11231368	Endocrine disorders	Hyperparathyroidism	01DEC2019		Y
			Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rubber sensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Blepharoplasty	01APR2018	30APR2018	N
			Parathyroidectomy	01MAY2020	31MAY2020	N
	C4591001 1123 11231371	Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1123 11231373	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1123 11231374	Cardiac disorders	Myocardial infarction	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Coronary artery bypass	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Arteriosclerosis	01JAN2005	31DEC2005	N
			Hypertension	01JAN1987		Y
	C4591001 1123 11231376	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Obesity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1981	31DEC2015	N
				01JAN2010	31DEC2016	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2016	31DEC2016	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1123 11231378	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1123 11231379	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Rubber sensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
			Rotator cuff syndrome	01JAN2019	31JAN2019	N
		Nervous system disorders	Restless legs syndrome	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1123 11231380	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1123 11231385	Immune system disorders	Seasonal allergy	01JAN1963		Y
	C4591001 1123 11231388	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN1945		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1123 11231390	Vascular disorders	Hypertension	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Investigations	Biopsy prostate	01MAR2020	31MAR2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01FEB2020	31JUL2020	N
	C4591001 1123 11231391	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012	31DEC2016	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1123 11231393	Cardiac disorders	Ventricular extrasystoles	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Hypersensitivity	01JAN2018		Y
			Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
	C4591001 1123 11231394	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2015	31DEC2015	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN1991	31DEC1991	N
	C4591001 1123 11231400	Nervous system disorders	Headache	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1123 11231401	Eye disorders	Cataract	01JAN2018	31DEC2019	N
			Glaucoma	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Trabeculectomy	01JAN2012	31DEC2012	N
	C4591001 1123 11231402	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2005		Y
	C4591001 1123 11231406	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
			Hiatus hernia	01SEP2020		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019	31JUL2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2018		Y
			Rubber sensitivity	01JAN1997		Y
			Seasonal allergy	01JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	29FEB2004	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01FEB2004	29FEB2004	N
	C4591001 1124 11241002	Infections and infestations	Adenoiditis	01JAN1964	31DEC1964	N
			Tonsillitis	01JAN1964	31DEC1964	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1964	31DEC1964	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1124 11241004	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Alcoholism	01JAN2005	31DEC2010	N
			Anxiety	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1124 11241006	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2019		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1996	31DEC1996	N
				01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip squamous cell carcinoma	01JAN2003	31DEC2003	N
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
			Sciatica	01JUN2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2007	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1996	31DEC1996	N
				01JAN2019	31DEC2019	N
			Caesarean section	01JAN1990	31DEC1990	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2003	31DEC2003	N
			Uterine dilation and curettage	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1124 11241007	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1124 11241009	Musculoskeletal and connective tissue disorders	Osteoarthritis	14NOV2019		Y
		Social circumstances	Postmenopause	14SEP1998		Y
	C4591001 1124 11241011	Immune system disorders	Seasonal allergy	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1969		Y
			Spinal osteoarthritis	01JAN1969		Y
		Surgical and medical procedures	Vasectomy	01JAN1968	31DEC1968	N
	C4591001 1124 11241013	Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2012		Y
		Surgical and medical procedures	Tooth extraction	01JUL2020	31JUL2020	N
	C4591001 1124 11241014	Injury, poisoning and procedural complications	Injury corneal	01JAN1984	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01DEC2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Corneal transplant	01JAN1984	31DEC1984	N
			Rotator cuff repair	01DEC2019	31DEC2019	N
			Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1124 11241015	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Neck pain	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Uterine operation	01JAN1965	31DEC1965	N
	C4591001 1124 11241016	Eye disorders	Cataract	01JAN2005		Y
				01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1124 11241021	Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1124 11241023	Cardiac disorders	Angina pectoris	01JAN1998	31DEC2011	N
			Coronary artery disease	01JAN1998		Y
			Myocardial infarction	01JAN2011	31DEC2011	N
		Investigations	Blood cholesterol increased	01JAN1998		Y
			Blood triglycerides increased	01JAN1998		Y
		Metabolism and nutrition disorders	Iron deficiency	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1124 11241029	Gastrointestinal disorders	Umbilical hernia	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign gastrointestinal neoplasm	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Benign tumour excision	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Incisional hernia repair	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N
		Vascular disorders	Deep vein thrombosis	01JAN2017	31DEC2017	N
			Hypertension	01JAN2015		Y
	C4591001 1124 11241031	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1986		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2008	31DEC2008	N
	C4591001 1124 11241033	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Oesophageal haemorrhage	01JAN2018	31DEC2018	N
		Infections and infestations	Osteomyelitis	01JAN2016	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Foot operation	01JAN2016	31DEC2016	N
			Haemostasis	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Mastectomy	01JAN2011	31DEC2011	N
			Oophorectomy bilateral	01JAN2011	31DEC2011	N
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
	C4591001 1124 11241034	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Biopsy breast normal	01JAN1991	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2001	31DEC2001	N
			Osteoporosis	01JAN2003		Y
			Osteosclerosis	01JAN1977	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2019	31DEC2019	N
			Uterine leiomyoma	01JAN1997	31DEC1997	N
		Nervous system disorders	Migraine	01JAN1970	31DEC2017	N
		Renal and urinary disorders	Urinary incontinence	01JAN2004	31DEC2008	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1991		Y
		Surgical and medical procedures	Bladder operation	01JAN2008	31DEC2008	N
			Bunion operation	01JAN2001	31DEC2001	N
			Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Stapedectomy	01JAN1971	31DEC1971	N
				01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241035	Cardiac disorders	Myocardial infarction	01JAN1996	31DEC1996	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Diverticulitis	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Knee arthroplasty	11MAR2019	11MAR2019	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1124 11241037	Immune system disorders	Seasonal allergy	01JAN2001		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
			Blood triglycerides increased	01JAN2001		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1124 11241040	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241044	Investigations	Cardiac murmur	01SEP2019		Y
	C4591001 1124 11241045	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1124 11241046	Cardiac disorders	Supraventricular tachycardia	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	01JUL2019	31JUL2019	N
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN2016		Y
			Osteopenia	01JAN1979		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2012	31DEC2012	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2012	31DEC2012	N
	C4591001 1124 11241048	Cardiac disorders	Coronary artery disease	01JAN2015		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JUN2020		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
			Blood triglycerides increased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2015		Y
			Osteoporosis	01JAN2015		Y
			Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2018		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2005	31DEC2005	N
			Hypertonic bladder	01JAN2010		Y
			Nephrolithiasis	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2013	31DEC2013	N
			Coronary arterial stent insertion	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Varicose vein operation	01JAN2000	31DEC2000	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241051	Eye disorders	Cataract	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN1988		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1960	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1124 11241056	Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
			Prostatomegaly	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal operation	01JAN2019	31DEC2019	N
			Tenodesis	01JAN2019	31DEC2019	N
			Vasectomy	01JAN2003	31DEC2003	N
			Vertebroplasty	01JAN2018	31DEC2018	N
	C4591001 1124 11241062	Skin and subcutaneous tissue disorders	Actinic keratosis	01NOV2019		Y
		Surgical and medical procedures	Vasectomy	01MAR1999	31MAR1999	N
	C4591001 1124 11241063	Eye disorders	Cataract	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1124 11241064	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Metabolism and nutrition disorders	Overweight	01JAN1966		Y
	C4591001 1124 11241070	Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN2007		Y
			Obesity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
		Reproductive system and breast disorders	Menstruation irregular	01JAN2001	31DEC2020	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1124 11241073	Immune system disorders	Seasonal allergy	01JAN2020		Y
		Infections and infestations	Herpes simplex	01JAN2015		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb injury	01JAN1995	31DEC1995	N
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2012	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
			Nephrolithiasis	01JAN2017		Y
		Surgical and medical procedures	Knee operation	01JAN1999	31DEC1999	N
			Shoulder operation	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1124 11241074	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1974		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1124 11241079	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
			Blood triglycerides increased	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN2003		Y
			Bipolar disorder	01JAN2003		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2003		Y
			Insomnia	01JAN2003		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01DEC2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1124 11241080	Cardiac disorders	Atrial flutter	01AUG2018		Y
		Congenital, familial and genetic disorders	Heart disease congenital	01JAN1954		Y
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
				01JAN2018		Y
			Seasonal allergy	01JAN1964		Y
		Infections and infestations	Helicobacter infection	01JAN1974	31DEC1998	N
		Investigations	Laparoscopy	01JAN1985	31DEC1985	N
		Nervous system disorders	Migraine	01JAN1962		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1985	31DEC1985	N
		Social circumstances	Postmenopause	01MAR2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
			Female sterilisation	01JAN1992	31DEC1992	N
	C4591001 1124 11241082	Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2001		Y
			Sleep apnoea syndrome	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee operation	01JAN2009	31DEC2009	N
			Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1124 11241085	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1981	31DEC1981	N
			Varicose vein operation	01JAN2005	31DEC2005	N
		Vascular disorders	Varicose vein	01JAN2005	31DEC2005	N
	C4591001 1124 11241088	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1990	31DEC1991	N
		Infections and infestations	Diverticulitis	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2008	31DEC2008	N
			Osteopenia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1124 11241089	Surgical and medical procedures	Bunion operation	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2005	31DEC2005	N
			Tendon injury	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Neck surgery	01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241091	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1940		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
			Blood triglycerides increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1940		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nephrolithiasis	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1124 11241098	Infections and infestations	Chronic sinusitis	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Surgical and medical procedures	Sinus operation	01JAN1995	31DEC1995	N
	C4591001 1124 11241101	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
			Fibromyalgia	01JAN2016		Y
			Osteoarthritis	01JAN1991		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Sciatica	01JAN1991		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1124 11241107	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1124 11241110	Blood and lymphatic system disorders	Anaemia	01JAN1990	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2009		Y
			Inguinal hernia	01JAN1964	31DEC1964	N
				01JAN1967	31DEC1967	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Meniscus injury	01MAY2017	31MAY2017	N
		Investigations	Cardiac murmur	01JAN1984		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2006	31DEC2012	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1990		Y
			Menopausal symptoms	01JAN2012		Y
			Menorrhagia	01JAN2000	31DEC2017	N
			Menstruation irregular	01JAN1970	31DEC2018	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
			Inguinal hernia repair	01JAN1964	31DEC1964	N
				01JAN1967	31DEC1967	N
			Meniscus operation	01MAY2017	31MAY2017	N
			Uterine dilation and curettage	01JAN2018	31JAN2018	N
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
	C4591001 1124 11241114					
		Gastrointestinal disorders	Abdominal pain	01JAN2005	31DEC2005	N
			Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Overweight	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Cataract operation	01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN1998	31JAN1998	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
	C4591001 1124 11241115	Cardiac disorders	Cardiac failure congestive	01JAN2000		Y
			Coronary artery disease	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN1990		Y
			Cardiac murmur	01JAN2000		Y
			Heart rate irregular	01JAN2000		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN1990		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2001	31DEC2001	N
			Cataract operation	01JAN2005	31DEC2005	N
			Coronary artery surgery	01JAN2000	31DEC2000	N
	C4591001 1124 11241116	Eye disorders	Cataract	01JAN2015		Y
			Glaucoma	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
	C4591001 1124 11241117	Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1983	31DEC1983	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2002	31DEC2019	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01MAY2011		Y
		Surgical and medical procedures	Appendicectomy	01JAN2016	31DEC2016	N
			Caesarean section	01JAN1998	31DEC1998	N
				01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
				01JAN2002	31DEC2002	N
			Carpal tunnel decompression	01JAN2002	31DEC2002	N
				01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN1983	31DEC1983	N
			Female sterilisation	01JUL2002	31JUL2002	N
	C4591001 1124 11241119	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1980	31DEC1980	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
			Blood testosterone decreased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Blood triglycerides increased	01JAN1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
				01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000	31DEC2016	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN1984		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y
		Surgical and medical procedures	Knee operation	01JAN1980	31DEC1980	N
				01JAN2006	31DEC2006	N
	C4591001 1124 11241121	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Thyroidectomy	01JAN2000	31DEC2000	N
	C4591001 1124 11241123	Infections and infestations	Appendicitis	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2007	31DEC2007	N
			Meniscus operation	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1999	31DEC1999	N
	C4591001 1124 11241124	Immune system disorders	Seasonal allergy	01JAN1983		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Investigations	Cardiac murmur	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Sciatica	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992	31DEC2000	N
		Surgical and medical procedures	Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1124 11241126	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01MAR2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Hip fracture	04MAR2019	04MAR2019	N
		Psychiatric disorders	Anxiety disorder	01APR2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	24AUG2020		Y
		Social circumstances	Postmenopause	01OCT2011		Y
		Surgical and medical procedures	Hip surgery	04MAR2019	04MAR2019	N
	C4591001 1124 11241128	Gastrointestinal disorders	Crohn's disease	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1124 11241130	Gastrointestinal disorders	Colitis microscopic	01MAY2020		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241131	Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2010		Y
		Nervous system disorders	Trigger finger	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Nerve compression	01JAN2009		Y
			Asthma	01JAN1990	31DEC2010	N
		Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
			Spinal laminectomy	01JAN2013	31DEC2013	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1124 11241132	Gastrointestinal disorders	Umbilical hernia	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1956		Y
		Surgical and medical procedures	Dental implantation	01JAN2020	31JAN2020	N
			Orthognathic surgery	01JAN1974	31DEC1974	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Umbilical hernia repair	01JAN1958	31DEC1958	N
	C4591001 1124 11241133	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2008		Y
			Seasonal allergy	01JAN2011		Y
		Investigations	Heart rate irregular	01JAN1974	31DEC1974	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2017	31DEC2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Spinal laminectomy	05DEC2019	05DEC2019	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1124 11241134	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1976		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
			Osteoarthritis	01JAN2000		Y
				01JAN2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1124 11241135	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1999	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2011		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN1981		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y
		Nervous system disorders	Migraine	01JAN1967		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1993	31DEC2004	N
		Surgical and medical procedures	Caesarean section	01JAN1988	31DEC1988	N
				01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastric bypass	01JAN2004	31DEC2004	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Knee operation	01JAN1995	31DEC1995	N
				01JAN2019	31DEC2019	N
	C4591001 1124 11241136	Cardiac disorders	Cardiac failure congestive	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
			Heart rate irregular	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241138	Gastrointestinal disorders	Pancreatitis	01JAN1983	31DEC1983	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1983	31DEC1983	N
			Cholecystectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1124 11241139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Inguinal hernia	01JAN1993	31DEC1993	N
		Immune system disorders	Drug hypersensitivity	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
		Psychiatric disorders	Anxiety disorder	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1124 11241140	Gastrointestinal disorders	Abdominal hernia	01JAN2017	31DEC2017	N
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
			Tendon injury	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1973		Y
			Osteoarthritis	01JAN2015		Y
			Plantar fasciitis	01JAN1994	31DEC1994	N
		Psychiatric disorders	Anxiety disorder	01JAN2019		Y
			Attention deficit hyperactivity disorder	01JAN2012		Y
			Insomnia	01JAN1973		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2017	31DEC2017	N
			Fascia release	01JAN1994	31DEC1994	N
			Removal of foreign body	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
			Tenoplasty	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241143	Injury, poisoning and procedural complications	Meniscus injury	01JAN1986	31DEC1986	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoporosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	01JAN2016		Y
			Thyroid cancer	01JAN1977	31DEC1977	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Chemotherapy	01JAN2016	29FEB2020	N
			Meniscus operation	01JAN1986	31DEC1986	N
			Stem cell transplant	01JAN2016	31DEC2016	N
			Thyroid operation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1124 11241144	Infections and infestations	Pneumonia	01JAN2012	31DEC2012	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1124 11241145	Eye disorders	Cataract	01JAN2010	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Pneumonia	01JAN2016	31DEC2016	N
			Tonsillitis	01JAN1947	31DEC1947	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Alcoholism	01JAN1965	31DEC1975	N
			Depression	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN1990		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2000		Y
			Menopausal symptoms	01JAN1992	31DEC1994	N
			Menorrhagia	01JAN1960	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
			Psoriasis	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Hypertension	01JAN2016		Y
	C4591001 1124 11241146	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01AUG2019	31AUG2019	N
			Ovarian cancer	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Skin neoplasm excision	01AUG2019	31AUG2019	N
	C4591001 1124 11241147	Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2016	31DEC2016	N
		Investigations	Liver function test increased	01JAN2018		Y
			Platelet count decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2014		Y
		Surgical and medical procedures	Shoulder arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1124 11241148	Blood and lymphatic system disorders	Anaemia	01MAY2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Food allergy	01JAN1970		Y
			Iodine allergy	01JAN1970		Y
		Infections and infestations	Herpes simplex	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2006	31DEC2006	N
			Malignant melanoma	01JAN2005	31DEC2005	N
			Squamous cell carcinoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	30APR2018	N
		Psychiatric disorders	Anxiety disorder	01JAN2000		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1980		Y
		Social circumstances	Postmenopause	01OCT2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01APR2018	30APR2018	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
	C4591001 1124 11241150	Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Sciatica	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1968	31DEC1968	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241151	Cardiac disorders	Myocardial infarction	01JAN1999	31DEC1999	N
		Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2013		Y
	C4591001 1124 11241154	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Herpes simplex	01JAN1984		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1999	31DEC1999	N
	C4591001 1124 11241155	Eye disorders	Cataract	01JAN2016	31DEC2017	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Muscle injury	01JAN1995	31DEC1995	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Nervous system disorders	Carotid artery thrombosis	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cerebrovascular accident	01JAN2019	31DEC2019	N
		Psychiatric disorders	Alcoholism	01JAN1990	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Cataract operation	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Muscle reattachment	01JAN1995	31DEC1995	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1124 11241156	Blood and lymphatic system disorders	Anaemia	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2018	31DEC2018	N
		Immune system disorders	Contrast media allergy	01JAN1973		Y
		Infections and infestations	Central nervous system viral infection	01JAN1971	31DEC1972	N
			Urinary tract infection	01JAN1968	31DEC1985	N
		Injury, poisoning and procedural complications	Nasal injury	01JAN1974	31DEC1974	N
		Investigations	Biopsy breast normal	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1986	31DEC1987	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1974	31DEC1974	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Bunion operation	01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN1974	31DEC1974	N
		Vascular disorders	Raynaud's phenomenon	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241157	Blood and lymphatic system disorders	Anaemia	01JAN1980	31DEC1980	N
		Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
				01JAN1970		Y
			Seasonal allergy	01JAN2000		Y
			Sunscreen sensitivity	01JAN1980		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Blood triglycerides increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1985	31DEC1985	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Incisional hernia repair	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1124 11241158	Gastrointestinal disorders	Large intestine polyp	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Vasectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1124 11241159	Vascular disorders	Hypertension	01JAN2010		Y	
		Cardiac disorders	Angina pectoris	01JAN2007		Y	
				Coronary artery disease	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y	
				Spinal stenosis	01JAN1990		Y
		Renal and urinary disorders	Dysuria	01JAN2000		Y	
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000	31DEC2000	N	
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2005	31DEC2005	N	
			Spinal laminectomy	01JAN2017	31DEC2017	N	
			Transurethral prostatectomy	01JAN2000	31DEC2000	N	
	C4591001 1124 11241160	Vascular disorders	Hypertension	01JAN2000		Y	
		Endocrine disorders	Hypothyroidism	01JAN2015		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y	
			Seasonal allergy	01JAN2017		Y	
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y	
			Osteopenia	01JAN2015		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2002	31DEC2002	N	
		Nervous system disorders	Migraine	01JAN1984		Y	
			Sciatica	01JAN2017		Y	
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N	
	Reproductive system and breast disorders	Menopausal symptoms	01JAN2015	31DEC2017	N		
		Menorrhagia	01JAN2012	31DEC2013	N		
	Social circumstances	Postmenopause	01JAN2016		Y		

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Colectomy	01JAN2002	31DEC2002	N
	C4591001 1124 11241161	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1124 11241162	Congenital, familial and genetic disorders	Hydrocele	01JAN2020	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hydrocele operation	01JAN2020	31JAN2020	N
			Intervertebral disc operation	01JAN2019	31DEC2019	N
			Nasal polypectomy	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
	C4591001 1124 11241164	Cardiac disorders	Supraventricular tachycardia	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1987		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1995		Y
		Surgical and medical procedures	Carotid artery stent insertion	01JAN2012	31DEC2012	N
			Vascular stent insertion	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1985		Y
			Peripheral vascular disorder	01JAN2012		Y
	C4591001 1124 11241165	Blood and lymphatic system disorders	Anaemia	01JAN1999	31DEC2015	N
		Endocrine disorders	Thyroid disorder	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2015		Y
		Nervous system disorders	Autoimmune encephalopathy	01JAN2007	31DEC2007	N
			Carpal tunnel syndrome	01JAN1999	31DEC2006	N
			Sciatica	01JAN2007		Y
			Seizure	01JAN2008	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
			Rosacea	01JAN1995	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1999	31DEC1999	N
				01JAN2006	31DEC2006	N
			Knee arthroplasty	01JAN2018		Y
			Nephrectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1124 11241166	Congenital, familial and genetic disorders	Factor XII deficiency	01JAN1994		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1952	31DEC1952	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241169	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31JUL2009	N
		Social circumstances	Postmenopause	01NOV2017		Y
		Surgical and medical procedures	Spinal fusion surgery	01JUL2009	31JUL2009	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1124 11241171	Endocrine disorders	Thyroid disorder	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1124 11241172	Cardiac disorders	Mitral valve prolapse	01JAN1957		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Pneumonia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Limb injury	01JAN1995	31DEC1995	N
		Investigations	Cardiac murmur	01JAN1957		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN1970		Y
			Migraine	01JAN1970		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ovarian cyst	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Limb operation	01JAN1995	31DEC1995	N
			Ovarian cystectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1124 11241173	General disorders and administration site conditions	Cyst	01JAN1999	31DEC1999	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017	31DEC2018	N
				01JAN2020		Y
		Surgical and medical procedures	Arthrodesis	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN2010	31DEC2010	N
			Spinal operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1124 11241175	Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
	C4591001 1124 11241177	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Malignant melanoma	01JAN2002	31DEC2002	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Dysuria	01JAN2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2002	31DEC2002	N
				01JAN2018	31DEC2018	N
			Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1124 11241181	Investigations	Blood cholesterol increased	01JAN2006		Y
			Blood testosterone decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1124 11241182	Injury, poisoning and procedural complications	Limb injury	01JAN1987	31DEC1987	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
			Blood triglycerides increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2018		Y
		Surgical and medical procedures	Limb operation	01JAN1987	31DEC1987	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
	C4591001 1124 11241191	Cardiac disorders	Coronary artery disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1984		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1124 11241192	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Spondylitis	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1983	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
	C4591001 1124 11241193	Cardiac disorders	Ventricular extrasystoles	01JAN2019	31DEC2019	N
		Infections and infestations	Lyme disease	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Gout	01JAN2016	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Intervertebral disc protrusion	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
			Tenoplasty	01JAN2010	31DEC2010	N
		Eye disorders	Cataract	01JAN2012	31DEC2018	N
	C4591001 1124 11241201					
		Gastrointestinal disorders	Small intestinal obstruction	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1970	31DEC1980	N
		Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Cataract operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1124 11241203	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Endocrine disorders	Thyroid mass	01JAN2017		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2019	31DEC2019	N
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Surgical and medical procedures	Shoulder operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1124 11241204	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
				01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1124 11241205	Cardiac disorders	Supraventricular tachycardia	01JAN1998		Y
		Infections and infestations	Pneumonia	01JAN1998	31DEC1998	N
				01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1998	31DEC1998	N
			Joint injury	01JAN1965	31DEC1965	N
		Investigations	Blood cholesterol increased	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Lung neoplasm malignant	01JAN2001	31DEC2001	N
			Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Nervous system disorders	Sciatica	01JAN2015		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Cancer surgery	01JAN2019	31DEC2019	N
			Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Lung lobectomy	01JAN2001	31DEC2001	N
			Open reduction of fracture	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Tenoplasty	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1124 11241206	Eye disorders	Cataract	01JAN2017	31DEC2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2002		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
				01MAR2020	31MAR2020	N
			Female sterilisation	01JAN1994	31DEC1994	N
	C4591001 1124 11241209	Blood and lymphatic system disorders	Anaemia	01JUN2016	30JUN2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Congenital, familial and genetic disorders	Gastrointestinal arteriovenous malformation	01JUN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1124 11241210	Eye disorders	Cataract	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	20FEB2020	20FEB2020	N
		Surgical and medical procedures	Lithotripsy	01JAN2015	31DEC2015	N
			Wisdom teeth removal	01JAN1964	31DEC1964	N
		Vascular disorders	Thrombosis	01FEB2020	29FEB2020	N
	C4591001 1124 11241211	Cardiac disorders	Supraventricular tachycardia	01JAN2018		Y
		Eye disorders	Cataract	01JAN2016	31DEC2017	N
		Gastrointestinal disorders	Hiatus hernia	01JAN2020		Y
			Inguinal hernia	01JAN1947	31DEC1947	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1952	31DEC1952	N
			Poliomyelitis	01JAN1950	31DEC1950	N
			Tonsillitis	01JAN1947	31DEC1947	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
				01JAN2011	31DEC2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
			Back pain	01JAN2017		Y
			Bursitis	15AUG2020		Y
			Finger deformity	01JAN2013	31DEC2013	N
			Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1947	31DEC1947	N
			Appendicectomy	01JAN1952	31DEC1952	N
			Breast conserving surgery	01JAN2013	31DEC2013	N
			Cataract operation	01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN1947	31DEC1947	N
			Limb operation	01JAN2013	31DEC2013	N
			Meniscus operation	01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Uterine dilation and curettage	01JAN1971	31DEC1971	N
				01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1988	31DEC2002	N
	C4591001 1124 11241215	Eye disorders	Cataract	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Arthroscopy	01JAN2020	31JAN2020	N
			Biopsy prostate	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Gout	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Overweight	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2010	31DEC2010	N
		Nervous system disorders	Piriformis syndrome	01JAN2005		Y
		Renal and urinary disorders	Dysuria	01JAN2005		Y
			Nephrolithiasis	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2005	31DEC2005	N
			Transurethral bladder resection	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1124 11241220	Injury, poisoning and procedural complications	Joint injury	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1124 11241221	Immune system disorders	Allergy to arthropod sting	01JAN1957		Y
			Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Obesity	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1980		Y
		Nervous system disorders	Sciatica	01JAN1990		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2009		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1124 11241229	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1999		Y
			Back pain	01JAN1999		Y
			Intervertebral disc protrusion	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Psychiatric disorders	Alcoholism	01JAN1972	31DEC2016	N
			Anxiety disorder	01JAN2000		Y
			Bipolar disorder	01JAN1999		Y
			Depression	01JAN1999		Y
			Drug abuse	01JAN1989	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1124 11241230	Social circumstances	Postmenopause	01APR2018		Y
	C4591001 1124 11241231	Cardiac disorders	Cardiac failure congestive	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1125 11251001	Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
	C4591001 1125 11251002	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1968		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1125 11251012	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1125 11251016	Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Hypercholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1125 11251018	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1125 11251035	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Nausea	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Fibromyalgia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hot flush	01JAN2019		Y
			Hypertension	01JAN2005		Y
	C4591001 1125 11251037	Endocrine disorders	Hypothyroidism	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Oedema peripheral	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypokalaemia	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	15DEC2015	15DEC2015	N
		Psychiatric disorders	Depression	01JAN2012		Y
		Reproductive system and breast disorders	Cystocele	15DEC2015	15DEC2015	N
		Surgical and medical procedures	Cystocele repair	15DEC2015	15DEC2015	N
			Hysterectomy	15DEC2015	15DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251041	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
				01JAN1995		Y
			Reaction to food additive	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251047	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1125 11251048	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
			Uterine leiomyoma	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Micrographic skin surgery	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy bilateral	01JAN2004	31DEC2004	N
			Salpingectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Essential hypertension	01JAN2004		Y
	C4591001 1125 11251054	Endocrine disorders	Hypothyroidism	01JAN2010		Y
			Thyroiditis subacute	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1125 11251055	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1962		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Neurectomy	01JAN2016	31DEC2016	N
	C4591001 1125 11251056	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2000		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hot flush	01JAN1998		Y
	C4591001 1125 11251057	Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1125 11251063	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Obesity	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1975	31DEC1977	N
		Social circumstances	Postmenopause	01JAN1977		Y
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
	C4591001 1125 11251064	Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Obesity	01JAN1990		Y
	C4591001 1125 11251065	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1125 11251066	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
	C4591001 1125 11251068	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Investigations	Catheterisation cardiac	27SEP2013	27SEP2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Aortic aneurysm repair	02OCT2013	02OCT2013	N
			Aortic valve replacement	02OCT2013	02OCT2013	N
			Coronary artery bypass	02OCT2013	02OCT2013	N
		Vascular disorders	Aortic aneurysm	02OCT2013	02OCT2013	N
	C4591001 1125 11251069	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2016		Y
	C4591001 1125 11251070	Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Cardiac disorders	Coronary artery disease	01JAN1959		Y
		Congenital, familial and genetic disorders	Congenital pulmonary valve disorder	01JAN1940		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Investigations	Biopsy breast	14MAY2007	14MAY2007	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2007	01MAY2007	N
			Pulmonary valve repair	01JAN1959	31DEC1959	N
			Venous operation	21JUL2010	21JUL2010	N
		Vascular disorders	Hypertension	01JAN1965		Y
			Varicose vein	01JAN2008		Y
	C4591001 1125 11251071	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN2019		Y
		Reproductive system and breast disorders	Endometrial hypoplasia	01JAN1994	31DEC1994	N
		Social circumstances	Postmenopause	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251072	Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Cardiac disorders	Aortic valve stenosis	01JAN2005	31DEC2005	N
			Coronary artery disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2015		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2005	31DEC2005	N
			Coronary artery bypass	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251073	Endocrine disorders	Hypothyroidism	01AUG2004		Y
		Gastrointestinal disorders	Femoral hernia	01MAR1994	30APR1994	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	28OCT2019	28OCT2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
		Surgical and medical procedures	Endometriosis ablation	28OCT2019	28OCT2019	N
			Femoral hernia repair	01APR1994	30APR1994	N
			Hysterectomy	01MAY2001	31MAY2001	N
		Salpingo-oophorectomy bilateral	28OCT2019	31OCT2019	N	
		Umbilical hernia repair	28OCT2019	28OCT2019	N	
	Vascular disorders	Hypertension	01JAN1995		Y	
	C4591001 1125 11251076	Social circumstances	Postmenopause	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251077	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1125 11251079	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		General disorders and administration site conditions	Oedema	01JAN2018		Y
		Infections and infestations	Sepsis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypokalaemia	01JAN2019		Y
			Obesity	01JAN2002		Y
		Renal and urinary disorders	Acute kidney injury	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1125 11251082	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Investigations	Cardiac murmur functional	01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2014		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1125 11251083	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1977		Y
			Multiple sclerosis	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN1993		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
	C4591001 1125 11251084	Social circumstances	Postmenopause	01JAN1995		Y
		Cardiac disorders	Myocardial infarction	01JAN2002	31DEC2002	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Coronary arterial stent insertion	01JAN2002	31DEC2002	N
				01JAN2018	31DEC2018	N
	C4591001 1125 11251085	Vascular disorders	Essential hypertension	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01MAR2020		Y
		Metabolism and nutrition disorders	Gout	01OCT2019		Y
			Type 2 diabetes mellitus	01JUL2019		Y
	C4591001 1125 11251088	General disorders and administration site conditions	Oedema peripheral	01FEB2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1125 11251089	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Eye disorders	Cataract	01JAN2019		Y
					20JAN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	20JAN2020	20JAN2020	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1125 11251092	Cardiac disorders	Atrial fibrillation	01DEC2019		Y
			Atrial flutter	01DEC2019		Y
			Cardiac failure chronic	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Catheterisation cardiac	01DEC2019	31DEC2019	N
				01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	01DEC2019		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251093	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2013		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1991	31DEC1991	N
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1125 11251100	Injury, poisoning and procedural complications	Joint dislocation	01JAN1990		Y
	C4591001 1125 11251103	Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1125 11251104	Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Thoracic outlet syndrome	01JAN2017	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Rib excision	01JAN2018	31DEC2018	N
	C4591001 1125 11251107	Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251110	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1125 11251113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	31DEC2017	N
			Exostosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251114	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1125 11251115	Ear and labyrinth disorders	Vertigo positional	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251118	Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1125 11251120	Cardiac disorders	Ventricular arrhythmia	01JAN2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hyperlipidaemia	01JAN2008		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nephrolithiasis	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1125 11251121	Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1125 11251123	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251125	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1125 11251129	Gastrointestinal disorders	Gastrooesophageal reflux disease	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2015		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN2018	31DEC2018	N
		Investigations	Endoscopy	10JUL2020	10JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2018	31DEC2018	N
				01FEB2019	28FEB2019	N
			Tonsillectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1125 11251130	Congenital, familial and genetic disorders	Factor II mutation	01JUN2014		Y
		Endocrine disorders	Hypothyroidism	01APR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01OCT2013	31OCT2013	N
	C4591001 1125 11251133	Surgical and medical procedures	Hysterectomy	01OCT2013	31OCT2013	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Arthroscopy	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Surgical and medical procedures	Carpal tunnel decompression	01AUG2019	31AUG2019	N
				01JUL2019	31JUL2019	N
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1125 11251137	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1125 11251141	Endocrine disorders	Hypothyroidism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251143	Cardiac disorders	Atrial fibrillation	01JAN2018	31DEC2018	N
		Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Epididymal cyst	01JAN2015	31AUG2020	N
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
			Epididymal cyst removal	01AUG2020	31AUG2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1125 11251145	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hypercholesterolaemia	01JAN2008		Y
			Hypokalaemia	01JAN2015		Y
			Obesity	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1125 11251147	Immune system disorders	Drug hypersensitivity	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2005		Y
		Nervous system disorders	Essential tremor	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN1990		Y
			Tobacco user	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1125 11251154	Cardiac disorders	Angina pectoris	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01FEB2000		Y
	C4591001 1125 11251161	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Investigations	Endoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Arterial stent insertion	01OCT2013	31OCT2013	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hot flush	01JAN2000		Y
			Hypertension	01JAN2002		Y
			Subclavian artery occlusion	01OCT2013	31OCT2013	N
	C4591001 1125 11251163	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
	C4591001 1125 11251165	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01MAY2019	31MAY2019	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1125 11251171	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Colonoscopy	01AUG2020	31AUG2020	N
			Oesophagogastroduodenoscopy	01AUG2020	31AUG2020	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1125 11251185	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1125 11251186	Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2020		Y
			Insomnia	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1125 11251187	Immune system disorders	Drug hypersensitivity	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2017		Y
		Psychiatric disorders	Anxiety	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1125 11251189	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1990	31DEC1994	N
		Social circumstances	Postmenopause	01JAN1994		Y
	C4591001 1125 11251190	Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Cardiac disorders	Bradycardia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1125 11251191	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1125 11251192	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1125 11251196	General disorders and administration site conditions	Oedema peripheral	01JAN1979		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1974		Y
	C4591001 1125 11251199	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1125 11251204	Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1125 11251206	Immune system disorders	Seasonal allergy	01JAN1992		Y
	C4591001 1125 11251209	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Tendon rupture	01SEP2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Nervous system disorders	Cerebrovascular accident	01FEB2016	29FEB2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1125 11251210	Social circumstances	Postmenopause	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251211	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251220	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Nervous system disorders	Parkinson's disease	01DEC2012		Y
	C4591001 1125 11251222	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
				01JAN2004		Y
			Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JUN2020	31AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251223	Immune system disorders	Seasonal allergy	01JAN2009		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2009	31DEC2009	N
			Vocal cord polyp	01JAN1985	31DEC1985	N
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
			Nasal polypectomy	01JAN2009	31DEC2009	N
			Vocal cord polypectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1125 11251224	Cardiac disorders	Atrial flutter	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Iron deficiency	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Nervous system disorders	Restless legs syndrome	01JAN2006		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1977	31DEC1978	N
		Social circumstances	Postmenopause	01JAN1978		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1125 11251225	Injury, poisoning and procedural complications	Ligament rupture	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2008		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2006	31DEC2006	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Ligament operation	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1125 11251226	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1955		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1125 11251227	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Gout	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1990		Y
			Raynaud's phenomenon	01JAN2018		Y
	C4591001 1125 11251228	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Injury, poisoning and procedural complications	Uterine rupture	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN2005		Y
			Seizure	01JAN2008		Y
			Spasmodic dysphonia	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Angioplasty	29SEP2015	29SEP2015	N
			Cataract operation	10FEB2016	10FEB2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				22MAR2016	22MAR2016	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Lens capsulotomy	10DEC2017	10DEC2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1125 11251229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1990	N
			Menorrhagia	01JAN1990	31DEC1990	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1125 11251230	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01OCT2020		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1974	31DEC1974	N
		Nervous system disorders	Restless legs syndrome	01FEB2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN1974	31DEC1974	N
	C4591001 1125 11251231	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Oestrogen deficiency	01JAN2003		Y
		Immune system disorders	Seasonal allergy	01APR2020		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1125 11251232	Immune system disorders	Allergy to vaccine	01JAN1954		Y
			Drug hypersensitivity	01JAN1954		Y
				01JAN2012		Y
			Seasonal allergy	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JUN2020	28AUG2020	N
		Social circumstances	Postmenopause	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2020	31JAN2020	N
			Lipoma excision	28AUG2020	28AUG2020	N
	C4591001 1125 11251234	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1125 11251236	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1996		Y
		Infections and infestations	Chronic sinusitis	01JAN1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1988		Y
		Psychiatric disorders	Insomnia	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1126 11261001	Immune system disorders	Drug hypersensitivity	16JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22FEB2011		Y
			Vitamin D deficiency	05JUL2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	22FEB2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				30MAR2007		Y
			Osteoporosis	30NOV2018		Y
			Synovial cyst	23APR2015	06NOV2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	21MAR2013		Y
	C4591001 1126 11261003	Gastrointestinal disorders	Hiatus hernia	03SEP2015		Y
			Proctitis ulcerative	01MAR2000		Y
	C4591001 1126 11261004	Cardiac disorders	Coronary artery disease	09JUN2008		Y
		Eye disorders	Cataract	12MAY2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal cancer	06DEC2017	29JAN2018	N
		Reproductive system and breast disorders	Seborrhoeic keratosis	27MAR2019		Y
			Erectile dysfunction	03DEC2008		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary granuloma	27DEC2017		Y
			Reflux laryngitis	28NOV2018		Y
		Vascular disorders	Aortic aneurysm	28NOV2018		Y
			Hypertension	12MAY2008		Y
	C4591001 1126 11261007	Metabolism and nutrition disorders	Glucose tolerance impaired	05OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05MAY1999		Y
			Sleep apnoea syndrome	20OCT2014		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	04OCT2007		Y
	C4591001 1126 11261008	Immune system disorders	Drug hypersensitivity	06FEB2004		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	10AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	12JUN2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	19JAN2015		Y
	C4591001 1126 11261015	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectal cancer	29SEP2008	09JUL2009	N
	C4591001 1126 11261016	Infections and infestations	Hepatitis C	16DEC1997	17DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	05FEB1999		Y
		Vascular disorders	Hypertension	05FEB1999		Y
	C4591001 1126 11261020	Cardiac disorders	Coronary artery disease	29FEB2016		Y
		Immune system disorders	Drug hypersensitivity	03FEB2009		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1126 11261023	Nervous system disorders	Migraine	13FEB2018		Y
	C4591001 1126 11261026	Immune system disorders	Drug hypersensitivity	21AUG2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	21AUG2018		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	17OCT2018		Y
			Osteoarthritis	28SEP2015		Y
			Osteopenia	20OCT2017		Y
		Skin and subcutaneous tissue disorders	Skin mass	20AUG2016		Y
		Vascular disorders	Hypertension	19MAR2014		Y
	C4591001 1126 11261027	Cardiac disorders	Atrial fibrillation	01JAN1996		Y
		Endocrine disorders	Hypothyroidism	24MAR2014		Y
		Immune system disorders	Drug hypersensitivity	24MAR2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29MAY2019		Y
			Obesity	11MAR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	05MAR2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	24MAR2014		Y
	C4591001 1126 11261031	Immune system disorders	Drug hypersensitivity	15DEC2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	25OCT2001		Y
		Vascular disorders	Hypertension	22APR2005		Y
	C4591001 1126 11261032	Metabolism and nutrition disorders	Hyperlipidaemia	04APR2001		Y
	C4591001 1126 11261036	Cardiac disorders	Atrial fibrillation	24JUN2017		Y
		Endocrine disorders	Hypothyroidism	14JUN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	05JAN2018		Y
		Immune system disorders	Drug hypersensitivity	12APR2007		Y
				12AUG2016		Y
				18JUL2018		Y
				22MAR2020		Y
				24MAR2017		Y
				30OCT2019		Y
			Food allergy	13APR2016		Y
		Infections and infestations	Diverticulitis	15APR2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16OCT2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	03JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	16MAY2007	30NOV2007	N
			Squamous cell carcinoma of the tongue	05MAY2016	01FEB2018	N
		Nervous system disorders	Dizziness	10JUN2017		Y
			Seizure	08JUN2009		Y
		Renal and urinary disorders	Lower urinary tract symptoms	12OCT2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	20MAY2016		Y
		Vascular disorders	Deep vein thrombosis	16JUL2019		Y
	C4591001 1126 11261038	Endocrine disorders	Goitre	26SEP2018		Y
			Hypothyroidism	11APR2011		Y
		Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	17SEP2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	16OCT2012	05OCT2015	N
		Surgical and medical procedures	Breast conserving surgery	13NOV2012	13NOV2012	N
	C4591001 1126 11261042	Hepatobiliary disorders	Hepatic cyst	04DEC2018		Y
		Reproductive system and breast disorders	Cervical dysplasia	08JAN2015		Y
		Social circumstances	Menopause	01JAN2010	31DEC2010	N
	C4591001 1126 11261049	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	22OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	11SEP2015	18SEP2015	N
		Skin and subcutaneous tissue disorders	Purpura senile	22NOV2019		Y
		Social circumstances	Menopause	03SEP2013		Y
		Surgical and medical procedures	Lipoma excision	18SEP2015	18SEP2015	N
	C4591001 1126 11261050	Gastrointestinal disorders	Diverticulum intestinal	24APR2012		Y
			Inguinal hernia	05DEC2016	08DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	22APR2004		Y
			Type 2 diabetes mellitus	26JUL2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	08JUN2007		Y
		Renal and urinary disorders	Chronic kidney disease	20JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19FEB2003		Y
			Sleep apnoea syndrome	02FEB2011		Y
		Surgical and medical procedures	Inguinal hernia repair	08DEC2016	08DEC2016	N
		Vascular disorders	Aortic arteriosclerosis	04NOV2015		Y
			Peripheral artery aneurysm	13JUN2014		Y
	C4591001 1126 11261051	Infections and infestations	Rhinitis	30AUG2013		Y
		Injury, poisoning and procedural complications	Iatrogenic injury	19OCT2018	19OCT2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30AUG2013		Y
			Nasal septum deviation	08JUN2018	19OCT2018	N
			Nasal turbinate hypertrophy	18JUN2018	04DEC2019	N
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Rhinoplasty	19OCT2018	19OCT2018	N
	C4591001 1126 11261052	Gastrointestinal disorders	Gastroesophageal reflux disease	16JUL2007		Y
		Infections and infestations	Rhinitis	13DEC2007		Y
		Injury, poisoning and procedural complications	Joint dislocation	13JUL2017	13JUL2017	N
		Investigations	Biopsy vulva	07MAY2019	07MAY2019	N
		Metabolism and nutrition disorders	Obesity	19JAN2013		Y
		Reproductive system and breast disorders	Vulvar dysplasia	07MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	19MAY2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pulmonary granuloma	21MAY2018		Y
		Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Joint arthroplasty	13JUL2017	13JUL2017	N
	C4591001 1126 11261057	Gastrointestinal disorders	Diverticulum	26FEB2018		Y
			Gastroesophageal reflux disease	11JUN2016		Y
		Immune system disorders	Drug hypersensitivity	14MAY2018		Y
			Food allergy	11JUN2013		Y
				19NOV2018		Y
			Rubber sensitivity	19NOV2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	08JUL2008		Y
			Obesity	11JUN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10JAN2008		Y
		Nervous system disorders	Migraine with aura	08SEP2017		Y
		Psychiatric disorders	Major depression	13MAR2015		Y
		Renal and urinary disorders	Urge incontinence	26OCT2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	11JUN2014		Y
			Rhinitis allergic	08JUL2008		Y
			Sleep apnoea syndrome	24JUL2013		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	15APR2019		Y
		Social circumstances	Menopause	01JAN2005	31DEC2005	N
		Vascular disorders	Aortic arteriosclerosis	06DEC2016		Y
			Hypertension	05FEB2020		Y
	C4591001 1126 11261058	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	28JUN2016		Y
		Metabolism and nutrition disorders	Obesity	29MAR2011		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	05NOV2013	05NOV2013	N
			Diffuse large B-cell lymphoma	08NOV2017	01JUL2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	16MAY2012		Y
			Sleep apnoea syndrome	02OCT2015		Y
		Vascular disorders	Aortic arteriosclerosis	10MAY2019		Y
			Hypertension	29DEC2012		Y
	C4591001 1126 11261059	Gastrointestinal disorders	Gastroesophageal reflux disease	06JUL2020		Y
		Hepatobiliary disorders	Cholelithiasis	01OCT2014	22OCT2014	N
		Immune system disorders	Allergy to animal	03AUG2012		Y
			Drug hypersensitivity	04MAY2012		Y
				19NOV2014		Y
			Food allergy	01DEC2008		Y
	C4591001 1126 11261065	Surgical and medical procedures	Cholecystectomy	22OCT2014	22OCT2014	N
		Immune system disorders	Drug hypersensitivity	20MAR2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	15JAN2019		Y
		Vascular disorders	Aortic arteriosclerosis	22MAY2018		Y
	C4591001 1126 11261066	Cardiac disorders	Atrial fibrillation	11SEP2012		Y
			Ventricular extrasystoles	18NOV2009		Y
		Immune system disorders	Drug hypersensitivity	04AUG2008		Y
				06JUN2000		Y
		Metabolism and nutrition disorders	Obesity	18JUL1997		Y
			Type 2 diabetes mellitus	11DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	11AUG2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	22SEP2009		Y
		Vascular disorders	Hypertension	23APR2007		Y
	C4591001 1126 11261067	Skin and subcutaneous tissue disorders	Androgenetic alopecia	28JUN2013		Y
	C4591001 1126 11261069	Cardiac disorders	Supraventricular tachycardia	11DEC2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05DEC2006		Y
		Respiratory, thoracic and mediastinal disorders	Cough	09OCT2019		Y
		Vascular disorders	Aortic arteriosclerosis	15NOV2019		Y
	C4591001 1126 11261070	Eye disorders	Myopic chorioretinal degeneration	02DEC2016		Y
		Metabolism and nutrition disorders	Gout	13OCT1988		Y
			Hyperlipidaemia	13OCT1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	09DEC2005	27MAR2019	N
		Psychiatric disorders	Depression	17NOV2015		Y
		Renal and urinary disorders	Chronic kidney disease	06JUN2006		Y
			Glomerulonephritis membranous	06JUN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11NOV2014		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	09DEC2005		Y
		Surgical and medical procedures	Corneal transplant	21MAR2014	21MAR2014	N
			Keratoplasty	09JUL2009		Y
				20NOV2014		Y
				27MAR2013	27MAR2013	N
			Retinopexy	02DEC2019	02DEC2019	N
		Vascular disorders	Hypertension	13OCT1988		Y
	C4591001 1126 11261071	Endocrine disorders	Hypothyroidism	15JUN2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Dry eye	17FEB2010		Y
		Gastrointestinal disorders	Colitis ulcerative	22JUL2015		Y
			Gastrooesophageal reflux disease	24SEP2009		Y
			Irritable bowel syndrome	31MAR2000		Y
		Immune system disorders	Drug hypersensitivity	13OCT2002		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	09MAR2011		Y
			Hyperlipidaemia	15APR2008		Y
		Nervous system disorders	Migraine	15APR2008		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	12SEP2012		Y
			Major depression	25MAR2016		Y
	C4591001 1126 11261072	Metabolism and nutrition disorders	Hyperlipidaemia	10DEC2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	02SEP2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	04MAR2008		Y
	C4591001 1126 11261073	Skin and subcutaneous tissue disorders	Actinic keratosis	01FEB2006	04SEP2008	N
		Gastrointestinal disorders	Diverticulum intestinal	31JUL2008		Y
		Immune system disorders	Allergy to metals	25JUL2012		Y
			Drug hypersensitivity	28AUG2008		Y
				30JUN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	09JUN2008		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	29JUN2009		Y
			Rosacea	08OCT2012		Y
		Social circumstances	Menopause	01JAN1993	31DEC1993	N
		Vascular disorders	Aortic arteriosclerosis	30NOV2016		Y
			Peripheral venous disease	20AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261077	Blood and lymphatic system disorders	Thrombocytopenia	10OCT2018		Y
		Ear and labyrinth disorders	Deafness bilateral	26AUG2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	22OCT2019		Y
		Vascular disorders	Aortic arteriosclerosis	31MAY2019		Y
	C4591001 1126 11261079	Immune system disorders	Food allergy	06NOV2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23DEC2011	16SEP2016	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	16DEC2012		Y
	C4591001 1126 11261084	Cardiac disorders	Left ventricular hypertrophy	21DEC2015		Y
		Endocrine disorders	Hypogonadism male	19APR2013		Y
			Hypothyroidism	20JUL2001		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16OCT2015		Y
			Intestinal pseudo-obstruction	21AUG2015	17JUN2017	N
			Large intestine perforation	29AUG2015	29AUG2015	N
		Hepatobiliary disorders	Cholelithiasis	31JAN2017	15AUG2017	N
		Immune system disorders	Drug hypersensitivity	01MAY2018		Y
				31MAR2009		Y
		Infections and infestations	Clostridium difficile infection	08DEC2015	27NOV2016	N
		Metabolism and nutrition disorders	Obesity	30MAY2003		Y
			Type 2 diabetes mellitus	20JUL2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998	31JUL1999	N
				11AUG2006	18AUG2015	N
			Spinal osteoarthritis	14JAN2014		Y
			Spondylolysis	16APR2009		Y
		Psychiatric disorders	Anxiety	12OCT2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	12OCT2015		Y
			Insomnia	19APR2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13DEC2011		Y
			Sleep apnoea syndrome	29NOV2016		Y
		Surgical and medical procedures	Cholecystectomy	15AUG2017	15AUG2017	N
			Colectomy total	27MAY2017	27MAY2017	N
			Hip arthroplasty	01JUL1999	31JUL1999	N
			Ileostomy	18AUG2015	18AUG2015	N
			Ileostomy closure	29AUG2015	13DEC2015	N
		Vascular disorders	Deep vein thrombosis	13DEC2013	13DEC2013	N
	C4591001 1126 11261087	Gastrointestinal disorders	Gastroesophageal reflux disease	20NOV2016		Y
		Vascular disorders	Hypertension	29JUL2014		Y
	C4591001 1126 11261088	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Choroid melanoma	29JAN2002	31DEC2002	N
			Follicle centre lymphoma, follicular grade I, II, III	11AUG2015	03FEB2016	N
			Prostate cancer	07DEC2004	15MAR2005	N
			Squamous cell carcinoma	15APR2013	24APR2013	N
		Surgical and medical procedures	Ear operation	15APR2013	15APR2013	N
			Skin graft	15APR2013	15APR2013	N
		Vascular disorders	Hypertension	07JAN2015		Y
	C4591001 1126 11261089	Immune system disorders	Allergy to animal	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	12AUG2003	N
		Nervous system disorders	Migraine	14JUL2008		Y
		Psychiatric disorders	Anxiety	14SEP2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19JUN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	14OCT2008		Y
	C4591001 1126 11261090	Surgical and medical procedures	Hysterectomy	12AUG2003	12AUG2003	N
		Immune system disorders	Drug hypersensitivity	02JUN2015		Y
				06JUL2020		Y
		Injury, poisoning and procedural complications	Fall	01JAN2001	31DEC2001	N
			Joint injury	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Vitamin D deficiency	03OCT2010	01JUN2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05JUL2011		Y
			Osteoporosis	18JUN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	17APR2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	05NOV2014		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2006	31DEC2006	N
			Knee arthroplasty	15JUL2011	15JUL2011	N
	C4591001 1126 11261091	Gastrointestinal disorders	Diverticulum intestinal	07JAN2013		Y
			Gastroesophageal reflux disease	28SEP2004		Y
		Immune system disorders	Food allergy	30JUL2019		Y
			Rubber sensitivity	08SEP2010		Y
		Infections and infestations	Chronic sinusitis	29MAY2007		Y
		Nervous system disorders	Cervical radiculopathy	30APR2010		Y
		Renal and urinary disorders	Nephrolithiasis	28FEB2019	28FEB2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Lithotripsy	28FEB2019	28FEB2019	N
		Vascular disorders	Hypertension	14JUL2003		Y
	C4591001 1126 11261094	Eye disorders	Retinal disorder	08MAY2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	07SEP2018		Y
			Osteopenia	10SEP2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive breast carcinoma	01JAN2003	31DEC2003	N
		Nervous system disorders	Migraine	28APR2010		Y
			Neuropathy peripheral	25SEP2019		Y
		Psychiatric disorders	Insomnia	07SEP2018		Y
		Skin and subcutaneous tissue disorders	Acne	07SEP2018		Y
		Surgical and medical procedures	Simple mastectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Lymphoedema	04APR2012		Y
	C4591001 1126 11261095	Gastrointestinal disorders	Diverticulum intestinal	12MAR2003		Y
			Leukoplakia oral	07FEB2020		Y
		General disorders and administration site conditions	Pain	10JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	13NOV2006		Y
			Osteoarthritis	01JAN2007		Y
				19NOV2007	13FEB2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	30JAN2012	17APR2012	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	23DEC2016		Y
		Surgical and medical procedures	Knee arthroplasty	13FEB2018	13FEB2018	N
			Prostatectomy	17APR2012	17APR2012	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1126 11261096	Gastrointestinal disorders	Diverticulum intestinal	12DEC2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26AUG2004		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	22JUL2004		Y
		Skin and subcutaneous tissue disorders	Rosacea	08MAR2008		Y
		Vascular disorders	Hypertension	13MAY2002		Y
	C4591001 1126 11261097	Gastrointestinal disorders	Gastrooesophageal reflux disease	06AUG2013		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	04FEB2010	24FEB2010	N
		Surgical and medical procedures	Dupuytren's contracture operation	24FEB2010	24FEB2010	N
			Skin graft	24FEB2010	24FEB2010	N
		Vascular disorders	Hypertension	25JUN2007		Y
	C4591001 1126 11261098	Metabolism and nutrition disorders	Hyperlipidaemia	10AUG2004		Y
			Type 2 diabetes mellitus	06APR2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10JUL2012		Y
		Surgical and medical procedures	Osteotomy	19JUL2012	19JUL2012	N
		Vascular disorders	Aortic arteriosclerosis	06JUN2013		Y
	C4591001 1126 11261100	Immune system disorders	Drug hypersensitivity	26APR2006		Y
			Iodine allergy	06OCT2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	27APR2020		Y
			Type 2 diabetes mellitus	26DEC2018		Y
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1126 11261102	Blood and lymphatic system disorders	Iron deficiency anaemia	03OCT2016		Y
		Endocrine disorders	Thyroid mass	18JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Abdominal pain	09JUL2020	10SEP2020	N
			Gastroesophageal reflux disease	24JUL2007		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	28APR2006	N
		Immune system disorders	Food allergy	30SEP2016		Y
		Infections and infestations	Gastroenteritis	11JUL2020	03SEP2020	N
		Injury, poisoning and procedural complications	Femur fracture	11SEP2018	11SEP2018	N
			Spinal compression fracture	18APR2012	18APR2012	N
		Investigations	Biopsy thyroid gland	18JAN2012	18JAN2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	25MAR2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	25APR2012		Y
			Lumbar spinal stenosis	15MAY2017		Y
			Osteoarthritis	30NOV2010	02AUG2018	N
			Osteoporosis	31MAR2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	18OCT2017	28NOV2017	N
				24SEP2008	14MAR2012	N
		Nervous system disorders	Restless legs syndrome	20NOV2017		Y
		Psychiatric disorders	Anxiety	17JAN2020		Y
			Depression	28FEB2012		Y
		Renal and urinary disorders	Chronic kidney disease	10MAY2019		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2000	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	18FEB2014		Y
		Surgical and medical procedures	Bone operation	11SEP2018	11SEP2018	N
			Breast conserving surgery	01JAN2008	31DEC2008	N
				28NOV2017	28NOV2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	07OCT2016	07OCT2016	N
				30SEP2016	30SEP2016	N
			Cholecystectomy	28APR2006	28APR2006	N
			Hip arthroplasty	02AUG2018	02AUG2018	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Aortic arteriosclerosis	28APR2017		Y
			Hypertension	18JAN2006		Y
	C4591001 1126 11261106	Gastrointestinal disorders	Diverticulum intestinal	22OCT2010		Y
		Hepatobiliary disorders	Cholelithiasis	11JAN2011	28FEB2011	N
		Metabolism and nutrition disorders	Obesity	01JAN2000	28FEB2011	N
		Musculoskeletal and connective tissue disorders	Back pain	05NOV2019		Y
		Surgical and medical procedures	Cholecystectomy	28FEB2011	28FEB2011	N
			Gastric bypass	28FEB2011	28FEB2011	N
	C4591001 1126 11261107	Ear and labyrinth disorders	Deafness bilateral	29MAR2019		Y
		Immune system disorders	Drug hypersensitivity	22FEB2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	22NOV2007		Y
	C4591001 1126 11261108	Immune system disorders	Drug hypersensitivity	15SEP2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23APR2018		Y
		Vascular disorders	Hypertension	01APR2018		Y
	C4591001 1126 11261110	Endocrine disorders	Hypothyroidism	06MAY2006		Y
		Nervous system disorders	Migraine with aura	05MAR2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	19NOV2008		Y
		Social circumstances	Menopause	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261112	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis allergic	01JAN1965		Y
	C4591001 1126 11261117	Cardiac disorders	Arteriosclerosis coronary artery	08MAY2017		Y
			Supraventricular tachycardia	10AUG2010		Y
		Gastrointestinal disorders	Encapsulating peritoneal sclerosis	18DEC2015	06AUG2018	N
		Immune system disorders	Drug hypersensitivity	18NOV2016		Y
				21OCT2004		Y
				28JUN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	19MAR2019		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN1992	31DEC1992	N
		Nervous system disorders	Migraine with aura	07DEC2009		Y
		Psychiatric disorders	Insomnia	04MAR2009		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	22OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	02MAR2006		Y
			Sleep apnoea syndrome	22FEB2011		Y
		Vascular disorders	Aortic arteriosclerosis	01AUG2013		Y
			Hypertension	22MAR2018		Y
	C4591001 1126 11261118	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Essential tremor	13MAY2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2012		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2009	31DEC2009	N
	C4591001 1126 11261119	Gastrointestinal disorders	Gastroesophageal reflux disease	06NOV2006		Y
		Investigations	Biopsy	09APR2008	09APR2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	07DEC2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	19OCT2015	N
				01JAN2015	05NOV2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2008	09APR2008	N
		Surgical and medical procedures	Knee arthroplasty	05NOV2019	05NOV2019	N
				19OCT2015	19OCT2015	N
		Vascular disorders	Aortic arteriosclerosis	25MAR2019		Y
			Hypertension	07DEC2005		Y
	C4591001 1126 11261120	Infections and infestations	Herpes simplex	22FEB2017		Y
	C4591001 1126 11261123	Eye disorders	Open angle glaucoma	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	31DEC2008		Y
			Seasonal allergy	01JAN1970		Y
		Investigations	Tuberculin test positive	24JUN2009	31DEC2010	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	04DEC2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	09OCT2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	19NOV2014		Y
			Seborrhoeic keratosis	07DEC2016		Y
		Nervous system disorders	Cervical radiculopathy	04NOV2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261125	Skin and subcutaneous tissue disorders	Idiopathic guttate hypomelanosis	04NOV2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05JAN2009		Y
		Immune system disorders	Drug hypersensitivity	27JAN2012		Y
		Infections and infestations	Herpes zoster	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	03AUG2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic squamous cell carcinoma	11OCT2011	01MAY2012	N
			Squamous cell carcinoma of the tongue	11OCT2011	01MAY2012	N
		Nervous system disorders	Carpal tunnel syndrome	06MAR2017		Y
		Respiratory, thoracic and mediastinal disorders	Dysphonia	26AUG2020		Y
		Surgical and medical procedures	Neck dissection	11NOV2011	11NOV2011	N
	C4591001 1126 11261127	Vascular disorders	Hypertension	11NOV2011		Y
		Cardiac disorders	Supraventricular tachycardia	23SEP2013		Y
		Endocrine disorders	Goitre	06AUG2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Prostatic specific antigen increased	25JUL2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	07DEC2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Surgical and medical procedures	Vasectomy	01JAN1976	31DEC1976	N
		C4591001 1126 11261129	Immune system disorders	Drug hypersensitivity	01JAN2000	
	Metabolism and nutrition disorders		Obesity	01JAN2000	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	25FEB2016		Y
		Psychiatric disorders	Depression	17FEB2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	29MAR2019		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2005	31DEC2005	N
	C4591001 1126 11261130	Investigations	Biopsy prostate normal	01JUL2011	01JUL2011	N
			Prostatic specific antigen increased	23NOV2010	27DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	13JAN2006	05JUN2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	20APR2010	30APR2010	N
		Psychiatric disorders	Major depression	22APR2019		Y
		Surgical and medical procedures	Skin lesion removal	30APR2010	30APR2010	N
	C4591001 1126 11261132	Endocrine disorders	Thyroid mass	01JAN1978	31DEC1978	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	11MAY2007		Y
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	12AUG2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10APR2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	12DEC2017		Y
			Osteoporosis	30JUL2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	14DEC2009	14DEC2009	N
		Social circumstances	Menopause	01JAN1991		Y
		Surgical and medical procedures	Skin lesion removal	14DEC2009	14DEC2009	N
			Thyroidectomy	01JAN1970	31DEC1978	N
	C4591001 1126 11261133	Eye disorders	Normal tension glaucoma	02AUG2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	04APR2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261136	Hepatobiliary disorders	Bile duct stone	06JUN2017		Y
		Metabolism and nutrition disorders	Obesity	04MAY2015		Y
		Vascular disorders	Aortic arteriosclerosis	18DEC2013		Y
	C4591001 1126 11261137	Cardiac disorders	Atrial fibrillation	30NOV2012		Y
		Endocrine disorders	Hypothyroidism	15FEB2011		Y
		Gastrointestinal disorders	Diarrhoea	25SEP2009		Y
			Gastroesophageal reflux disease	07FEB2007		Y
			Irritable bowel syndrome	30NOV2011		Y
		General disorders and administration site conditions	Oedema peripheral	26JUN1998		Y
			Pain	31AUG2009		Y
		Immune system disorders	Drug hypersensitivity	04JAN2005		Y
				15JAN2015		Y
				16JUL1998		Y
				16NOV1998		Y
				23SEP2001		Y
			Food allergy	01AUG2011		Y
				26FEB2018		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	29OCT2015	31DEC2016	N
		Metabolism and nutrition disorders	Gout	09JAN2018		Y
			Obesity	13FEB2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	30MAR2016		Y
			Cervical spinal stenosis	02AUG2011		Y
			Osteoarthritis	01MAY2013		Y
				15AUG2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				17APR2007		Y
			Osteoporosis	22FEB2016		Y
			Plantar fasciitis	30MAR2006		Y
			Sacroiliac joint dysfunction	02JUN2011		Y
			Spinal stenosis	28OCT2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	24JAN2006		Y
		Nervous system disorders	Carotid artery disease	20MAR2015		Y
			Migraine	01JAN1982	31DEC2012	N
			Post herpetic neuralgia	24OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma-chronic obstructive pulmonary disease overlap syndrome	25JUN2014		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	02FEB2006		Y
			Purpura senile	14OCT2019		Y
		Social circumstances	Menopause	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Anticoagulant therapy	01JAN2013		Y
		Vascular disorders	Aortic arteriosclerosis	22AUG2016		Y
			Hypertension	04APR2014		Y
	C4591001 1126 11261138	Metabolism and nutrition disorders	Hyperlipidaemia	04MAY2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01NOV2004	11JUN2010	N
		Psychiatric disorders	Major depression	31MAY2019		Y
	C4591001 1126 11261139	Endocrine disorders	Hypothyroidism	03DEC2008		Y
		Immune system disorders	Drug hypersensitivity	08NOV2013		Y
				21OCT2003		Y
			Food allergy	13NOV2013		Y
		Nervous system disorders	Restless legs syndrome	18JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	31OCT2005		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Mitral valve repair	13NOV2013	13NOV2013	N
	C4591001 1126 11261140	Immune system disorders	Drug hypersensitivity	13JUN2020		Y
	C4591001 1126 11261146	Gastrointestinal disorders	Gastroesophageal reflux disease	06AUG2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	03FEB2010		Y
			Facet joint syndrome	25AUG2009		Y
			Intervertebral disc degeneration	25AUG2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	02OCT2015		Y
			Prostate cancer	04JAN2017	17MAR2017	N
		Nervous system disorders	Spondylitic myelopathy	30JAN2009		Y
	C4591001 1126 11261147	Gastrointestinal disorders	Diverticulum intestinal	12JUL2008		Y
		Injury, poisoning and procedural complications	Tendon rupture	29NOV2019	02DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	04JUN2004		Y
		Nervous system disorders	Essential tremor	04OCT2018		Y
		Surgical and medical procedures	Tenoplasty	02DEC2019	02DEC2019	N
		Vascular disorders	Hypertension	04JUN2004		Y
	C4591001 1126 11261152	Cardiac disorders	Atrial fibrillation	27SEP2019		Y
		Hepatobiliary disorders	Hepatic steatosis	14AUG2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	09DEC2015		Y
			Obesity	20JUN2018		Y
			Type 2 diabetes mellitus	09DEC2015		Y
		Social circumstances	Menopause	01NOV2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	06APR2007		Y
	C4591001 1126 11261153	Congenital, familial and genetic disorders	Congenital jaw malformation	01JAN2000	16DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	02OCT2007		Y
		Investigations	Hysteroscopy	28AUG2020	28AUG2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	11OCT2013	07JAN2014	N
			Meningioma	01APR2016	04JAN2019	N
		Psychiatric disorders	Major depression	24SEP2015		Y
		Reproductive system and breast disorders	Uterine haemorrhage	03AUG2020	25AUG2020	N
			Uterine polyp	03AUG2020	28AUG2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04FEB2019		Y
		Surgical and medical procedures	Breast reconstruction	28AUG2019	28AUG2019	N
			Mastectomy	07JAN2014	07JAN2014	N
			Meningioma surgery	04JAN2019	04JAN2019	N
			Osteotomy	16DEC2019	16DEC2019	N
			Uterine dilation and curettage	28AUG2020	28AUG2020	N
	C4591001 1126 11261154	Immune system disorders	Drug hypersensitivity	06OCT2017		Y
		Reproductive system and breast disorders	Cystocele	01JAN2010		Y
			Rectocele	01JAN2010		Y
		Social circumstances	Menopause	13JUL2014		Y
		Surgical and medical procedures	Vaginal pessary insertion	14SEP2017		Y
	C4591001 1126 11261155	Metabolism and nutrition disorders	Hyperlipidaemia	31JUL2006		Y
		Psychiatric disorders	Major depression	31JUL2006		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1126 11261156	Cardiac disorders	Angina pectoris	12JAN2018		Y
			Coronary artery disease	23SEP2015		Y
			Left ventricular hypertrophy	16FEB2010		Y
		Eye disorders	Dry eye	07DEC2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	24NOV1999		Y
		General disorders and administration site conditions	Oedema peripheral	09JUN2006		Y
		Immune system disorders	Drug hypersensitivity	08JUN2009		Y
				20APR2004		Y
				24JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	17NOV2009		Y
		Nervous system disorders	Neuropathy peripheral	14FEB2017		Y
		Renal and urinary disorders	Chronic kidney disease	06FEB2012		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary granuloma	12SEP2019		Y
			Rhinitis allergic	22NOV2000		Y
			Sleep apnoea syndrome	01DEC2015		Y
		Surgical and medical procedures	Aortic valve replacement	23SEP2015	23SEP2015	N
			Hysterectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Aortic arteriosclerosis	14FEB2014		Y
			Hypertension	06FEB2012		Y
	C4591001 1126 11261159	Cardiac disorders	Palpitations	01JAN2000	31DEC2010	N
		Congenital, familial and genetic disorders	Thalassaemia beta	(b) (6) 1953		Y
		Ear and labyrinth disorders	Motion sickness	03APR2013		Y
			Vertigo	01JAN1990	31DEC2007	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	07AUG2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	18APR2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	18APR2006		Y
			Hyperlipidaemia	17JUL2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2008		Y
		Renal and urinary disorders	Stress urinary incontinence	28JUL2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	14APR2017		Y
	C4591001 1126 11261160	Eye disorders	Conjunctivitis allergic	10OCT2016		Y
			Meibomian gland dysfunction	10OCT2016		Y
		Gastrointestinal disorders	Diverticulum intestinal	09OCT2002		Y
			Gastrooesophageal reflux disease	14AUG2007		Y
		Immune system disorders	Drug hypersensitivity	19JUL2004		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Muscle strain	08JUN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	06APR2006		Y
			Hyperlipidaemia	06APR2006		Y
			Vitamin D deficiency	08JUN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	29MAY2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	14MAY2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	05AUG2016		Y
		Vascular disorders	Hypertension	05MAY2012		Y
	C4591001 1126 11261162	Cardiac disorders	Ventricular tachycardia	25MAY2006		Y
		Congenital, familial and genetic disorders	Congenital scoliosis	25MAY2006		Y
		Immune system disorders	Drug hypersensitivity	12SEP2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	05MAY2006		Y
		Reproductive system and breast disorders	Erectile dysfunction	06JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	02OCT2019		Y
	C4591001 1126 11261163	Eye disorders	Cataract	30OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03FEB2004		Y
	C4591001 1126 11261164	Cardiac disorders	Atrial fibrillation	08JUN2014		Y
			Coronary artery disease	08JUN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	07NOV2012		Y
			Hyperlipidaemia	14FEB2003		Y
			Vitamin D deficiency	12MAY2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06NOV2019		Y
		Vascular disorders	Aortic arteriosclerosis	21MAY2014		Y
			Hypertension	24JAN2000		Y
	C4591001 1126 11261165	Infections and infestations	Oral herpes	18JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	22JAN2015		Y
			Obesity	26FEB2015		Y
			Type 2 diabetes mellitus	22JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	24APR2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	14OCT2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	20JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	26FEB2016		Y
	C4591001 1126 11261167	Ear and labyrinth disorders	Deafness bilateral	07OCT2004		Y
		Gastrointestinal disorders	Diverticulum	06APR2016		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	01JAN2008	31DEC2008	N
			Post concussion syndrome	11DEC2008		Y
		Investigations	High density lipoprotein decreased	24FEB2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	06DEC2006		Y
			Hyperlipidaemia	03FEB2003		Y
		Nervous system disorders	Essential tremor	30JAN2006		Y
		Psychiatric disorders	Major depression	08OCT2015	19FEB2016	N
		Reproductive system and breast disorders	Organic erectile dysfunction	16JAN2008		Y
	C4591001 1126 11261168	Musculoskeletal and connective tissue disorders	Osteoporosis	02NOV2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	06DEC2013		Y
		Vascular disorders	Hypertension	06SEP2002		Y
	C4591001 1126 11261169	Vascular disorders	Aortic arteriosclerosis	28APR2020		Y
	C4591001 1126 11261174	Eye disorders	Myopia	01JAN1956		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				27JUL2017		Y
				27NOV2011		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	18JUL2011		Y
		Psychiatric disorders	Major depression	07AUG2015	24MAY2017	N
		Skin and subcutaneous tissue disorders	Purpura	10MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	12JUN2006		Y
	C4591001 1126 11261175	Congenital, familial and genetic disorders	Congenital spondylolisthesis	30JUN2008		Y
		Ear and labyrinth disorders	Tinnitus	26JUN2009		Y
		Endocrine disorders	Hypothyroidism	09JUN2005		Y
		Gastrointestinal disorders	Chronic gastritis	18SEP2018		Y
		General disorders and administration site conditions	Pain	17OCT2008		Y
		Immune system disorders	Allergy to metals	10AUG2012		Y
			Drug hypersensitivity	11FEB1999		Y
				28SEP2012		Y
		Infections and infestations	Hepatitis B	01JAN2000	30APR2010	N
			Hepatitis C	01JAN2000	30APR2010	N
		Musculoskeletal and connective tissue disorders	Arthropathy	24SEP2018		Y
			Spondyloarthropathy	18FEB2009		Y
		Nervous system disorders	Migraine	26APR2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	28OCT2015		Y
			Rhinitis allergic	26APR2007		Y
		Social circumstances	Menopause	01JAN2000		Y
		Vascular disorders	Aortic arteriosclerosis	07JUN2019		Y
	C4591001 1126 11261176	Cardiac disorders	Atrial fibrillation	20APR2000		Y
		Vascular disorders	Hypertension	22APR2015		Y
	C4591001 1126 11261179	Metabolism and nutrition disorders	Glucose tolerance impaired	07DEC2009		Y
			Hyperlipidaemia	04FEB2011		Y
			Vitamin D deficiency	04FEB2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	15APR2019		Y
			Osteoarthritis	05MAY2015		Y
			Patellofemoral pain syndrome	14NOV2005		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2010	31OCT2010	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	24JUN2005		Y
			Sleep apnoea syndrome	01DEC2015		Y
		Vascular disorders	Hypertension	07JAN2004		Y
	C4591001 1126 11261180	Gastrointestinal disorders	Abdominal hernia	22NOV2019	07FEB2020	N
			Inguinal hernia	22NOV2019	07FEB2020	N
		Surgical and medical procedures	Abdominal hernia repair	07FEB2020	07FEB2020	N
			Inguinal hernia repair	07FEB2020	07FEB2020	N
	C4591001 1126 11261181	Gastrointestinal disorders	Gastroesophageal reflux disease	24JUL2009		Y
		Immune system disorders	Allergy to arthropod sting	08AUG2013		Y
			Drug hypersensitivity	04AUG2008		Y
				31JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	09JUL2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06FEB2020		Y
			Rhinitis allergic	11AUG2009		Y
		Social circumstances	Menopause	01JAN1997		Y
	C4591001 1126 11261188	Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	11JAN2018		Y
			Gout	01JAN2014		Y
			Hyperlipidaemia	11JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	08MAY2019		Y
	C4591001 1127 11271001	Vascular disorders	Hypertension	01JAN2005		Y
		Eye disorders	Astigmatism	01JAN1957		Y
			Hypermetropia	01JAN1992		Y
			Myopia	01JAN1992		Y
		Gastrointestinal disorders	Pancreatic cyst	01AUG2019	31AUG2019	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN1996		Y
			Insomnia	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1127 11271002	Surgical and medical procedures	Pancreaticoduodenectomy	01AUG2019	31AUG2019	N
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Eye disorders	Myopia	01JAN1964		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Sinusitis	01JAN1972		Y
			Upper respiratory tract infection	01JAN1978		Y
			Urinary tract infection	01JAN1978		Y
		Investigations	Cardiac murmur	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271003	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1957		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Spinal stenosis	01JAN1970	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Bipolar disorder	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Scab	04APR2020		Y
	C4591001 1127 11271005	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Astigmatism	01JAN2000		Y
		Immune system disorders	Rubber sensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1980	05MAY2020	N
			Tendon rupture	01JAN2017	31MAY2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271006	Cardiac disorders	Palpitations	01JAN2010		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2014		Y
			Ear pain	15JUL2020	29JUL2020	N
		Eye disorders	Astigmatism	01JAN1978		Y
			Cataract	01JAN2018		Y
			Hypermetropia	01JAN1978		Y
			Myopia	01JAN1978		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN1975		Y
		Infections and infestations	Onychomycosis	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Spinal osteoarthritis	01JAN2018	06MAY2020	N
			Temporomandibular joint syndrome	15JUL2020	29JUL2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Skin lesion removal	01JAN2000	31DEC2000	N
			Spinal laminectomy	06MAY2020	06MAY2020	N
	C4591001 1127 11271007	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Astigmatism	23JUN2020		Y
			Cataract	14FEB2020		Y
			Presbyopia	01JAN1977		Y
			Retinal tear	01JAN2020	14FEB2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01JAN2017		Y
			Rotator cuff syndrome	01APR2016	31OCT2016	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Post-traumatic stress disorder	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1127 11271008	Ear and labyrinth disorders	Tinnitus	01JAN2016	31MAY2020	N
		Eye disorders	Myopia	01JAN1983		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1982		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988		Y
			Chronic obstructive pulmonary disease	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1127 11271009	Cardiac disorders	Atrial fibrillation	01JAN1998		Y
			Mitral valve prolapse	01JAN1998		Y
		Eye disorders	Astigmatism	01JAN1954		Y
			Dry eye	09JUL2018		Y
			Presbyopia	01JAN1952		Y
		General disorders and administration site conditions	Malaise	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JUL1997		Y
			Seasonal allergy	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Femur fracture	06APR2017	06APR2017	N
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JUN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	06NOV2010		Y
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	24JUN1997	17JUL1997	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01FEB2016		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Fracture treatment	06APR2017	06APR2017	N
			Hysterectomy	01JAN1985	01JAN1985	N
			Lymphadenectomy	17JUL1997	17JUL1997	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1127 11271010	Blood and lymphatic system disorders	Anaemia	01JAN2009		Y
		Eye disorders	Astigmatism	01JAN1984		Y
			Hypermetropia	01JAN1984		Y
			Myopia	01JAN1984		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271012	Cardiac disorders	Coronary artery disease	01OCT2019		Y
		Eye disorders	Dry eye	01JAN2018		Y
			Myopia	01JAN1955		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01OCT2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT2019	01OCT2019	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1127 11271018	Eye disorders	Astigmatism	01JAN1968		Y
			Myopia	01JAN1968		Y
		Gastrointestinal disorders	Constipation	15FEB2019		Y
			Gastroesophageal reflux disease	01JAN2012		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Urinary tract infection	01MAY2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1968		Y
			Migraine	01JAN1968		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1127 11271019	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN1984		Y
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1960		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN1986		Y
			Raynaud's phenomenon	01JAN2016		Y
	C4591001 1127 11271020	Eye disorders	Astigmatism	01JAN1960		Y
			Hypermetropia	01JAN1980		Y
			Myopia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
	C4591001 1127 11271023	Ear and labyrinth disorders	Deafness bilateral	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Myopia	01JAN1962		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Bronchitis	01JAN1960		Y
			Urinary tract infection	01JAN1951		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2002	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1127 11271031	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
			Meniere's disease	01JAN1980		Y
			Tinnitus	01JAN1980		Y
		Eye disorders	Myopia	01JAN1959		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Umbilical hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
			Osteoarthritis	01JAN2009		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Umbilical hernia repair	01JAN2016	31DEC2016	N
	C4591001 1127 11271034	Blood and lymphatic system disorders	Anaemia macrocytic	01JAN2017		Y
		Eye disorders	Dry eye	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
			Gastrooesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Microangiopathy	01JAN2018		Y
	C4591001 1127 11271035	Eye disorders	Hypermetropia	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1127 11271038	Eye disorders	Myopia	01JAN1967		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Allergy to animal	01JAN1962		Y
		Infections and infestations	Chronic sinusitis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
			Rhinitis allergic	01JAN1963		Y
	C4591001 1127 11271039	Ear and labyrinth disorders	Deafness unilateral	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Cardiac murmur	01JAN1949		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2010		Y
				01JAN2018	31DEC2018	N
		Nervous system disorders	Tension headache	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Arthrodesis	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1127 11271041	Eye disorders	Astigmatism	01JAN2003		Y
			Dry eye	01JAN2010		Y
			Hypermetropia	01JAN2003		Y
			Myopia	01JAN2003		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN2014		Y
			Seasonal allergy	01JAN2014		Y
		Infections and infestations	Oral herpes	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteopenia	01JUL2020		Y
			Spondylolisthesis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasm	01JAN1984		Y
			Uterine leiomyoma	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1127 11271042	Eye disorders	Myopia	01JAN1976		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2002	31DEC2002	N
	C4591001 1127 11271045	Eye disorders	Presbyopia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Tooth infection	01MAY2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Cardioversion	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271046	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Seasonal allergy	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1985		Y
	C4591001 1127 11271049	Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1127 11271050	Eye disorders	Dry eye	01MAY2020		Y
			Myopia	01JAN2006		Y
			Presbyopia	01JAN2006		Y
		Gastrointestinal disorders	Constipation	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN2012		Y
		General disorders and administration site conditions	Atrophy	01JAN2014		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
			Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271051	Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01APR2015	30JUN2015	N
			Seborrhoeic keratosis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01JUN2015	30JUN2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1127 11271053	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2019		Y
		Immune system disorders	Drug hypersensitivity	01APR2002		Y
			Seasonal allergy	01APR1990		Y
		Infections and infestations	Oral herpes	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
			Type 2 diabetes mellitus	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01DEC1989	30SEP2017	N
			Scoliosis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JUN2019		Y
			Uterine leiomyoma	01JUN2014	30SEP2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
			Sciatica	01JAN2016		Y
		Psychiatric disorders	Autism spectrum disorder	01NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01APR1997		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01SEP2015	31DEC2015	N
			Knee arthroplasty	01SEP2017	30SEP2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1127 11271054	Eye disorders	Astigmatism	01JAN1964		Y
			Hypermetropia	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Iodine allergy	01JAN1990		Y
			Rubber sensitivity	01JAN1991		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoarthritis	01JAN2015		Y
			Plantar fasciitis	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN1984		Y
	C4591001 1127 11271055	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
				01JAN1993		Y
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1962		Y
		Infections and infestations	Sinusitis	01JAN1982		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1127 11271056	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Haemorrhoids	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1955		Y
	C4591001 1127 11271058	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1127 11271060	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1984	31DEC1984	N
	C4591001 1127 11271061	Ear and labyrinth disorders	Deafness unilateral	01JAN2002		Y
			Inner ear disorder	01JAN2002		Y
			Tinnitus	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2000		Y
	C4591001 1127 11271062	Injury, poisoning and procedural complications	Meniscus injury	01FEB2020	21JUL2020	N
		Surgical and medical procedures	Meniscus operation	21JUL2020	21JUL2020	N
			Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1127 11271064	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN1985		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1127 11271065	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1127 11271067	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
			Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1956		Y
			Nasal septum deviation	01JAN1976		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1127 11271071	Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1127 11271074	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
			Large intestine polyp	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Bronchitis	01JAN2005		Y
			Sinusitis	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Bipolar disorder	01JAN2000		Y
			Insomnia	01JAN2015		Y
			Obsessive-compulsive disorder	01JAN1997		Y
			Post-traumatic stress disorder	01JAN2000		Y
			Schizophrenia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
			Cough	01JAN2015		Y
		Social circumstances	Denture wearer	01JAN2017		Y
			Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271075	Ear and labyrinth disorders	Meniere's disease	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2009		Y
			Neck pain	01JAN2009		Y
			Spinal osteoarthritis	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1127 11271081	Investigations	Prostatic specific antigen increased	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1127 11271082	Endocrine disorders	Hypothyroidism	01JAN2000	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
			Depression	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1127 11271083	Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Umbilical hernia	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1987		Y
		Infections and infestations	Bronchitis	01JAN1995		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Conjunctivitis	31JUL2020	05AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1127 11271088	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Presbyopia	01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1988		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Meniscus operation	01JAN2018	31DEC2018	N
	C4591001 1127 11271089	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
				01JAN1966		Y
			Food allergy	01JAN1970		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Bladder spasm	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
	C4591001 1127 11271090	Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Eye disorders	Myopia	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	23JUL2019		Y
			Insomnia	23JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1954		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1127 11271092	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1127 11271093	Cardiac disorders	Mitral valve prolapse	01JAN1980		Y
		Endocrine disorders	Oestrogen deficiency	01JAN2016		Y
		Eye disorders	Presbyopia	01JAN1963		Y
		Immune system disorders	Seasonal allergy	01JAN1953		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
			Oophorectomy bilateral	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1127 11271094	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN1998		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1127 11271095	Cardiac disorders	Atrial tachycardia	01JAN2000		Y
		Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2019		Y
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
			Schizoaffective disorder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1127 11271098	Eye disorders	Presbyopia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Acoustic neuroma removal	01JAN1995	31DEC1995	N
	C4591001 1127 11271100	Immune system disorders	Seasonal allergy	01MAR1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
		Nervous system disorders	Headache	01JAN1990		Y
	C4591001 1127 11271104	Ear and labyrinth disorders	Deafness bilateral	01JAN2013		Y
			Tinnitus	01JAN1963		Y
		Eye disorders	Myopia	01JAN1957		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1127 11271108	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2016		Y
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Investigations	Blood uric acid increased	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lactose intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1992		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
			Rosacea	01JAN1973		Y
		Vascular disorders	Hypertension	01JAN2012		Y
		Eye disorders	Dry eye	01JAN2016		Y
	C4591001 1127 11271110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Seizure	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1127 11271111	Eye disorders	Presbyopia	01JAN1959		Y
	C4591001 1127 11271114	Immune system disorders	Seasonal allergy	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2012		Y
	C4591001 1128 11281003	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281004	Cardiac disorders	Angina pectoris	25JUN2019	26JUN2019	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2000	31DEC2000	N
			Dyspepsia	01JAN2010		Y
			Inguinal hernia	01JAN1956	31DEC1956	N
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Investigations	Biopsy salivary gland	01JAN2000	31DEC2000	N
			Blood cholesterol increased	26APR2019		Y
			Blood triglycerides increased	01JAN2000		Y
			Cardiac murmur	31JUL2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
			Osteoarthritis	01NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1982	31DEC1982	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2000	31DEC2000	N
			Inguinal hernia repair	01JAN1956	31DEC1956	N
			Orchidectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Aortic stenosis	01JUN2014		Y
			Hypertension	01JAN2016		Y
	C4591001 1128 11281006	Immune system disorders	Multiple allergies	01JAN2005		Y
		Infections and infestations	Oral herpes	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JUL2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1128 11281007	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1128 11281008	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281009	Cardiac disorders	Angina pectoris	01JAN2017		Y
			Myocardial infarction	01JAN2017	01JAN2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1996		Y
			Vitamin D deficiency	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	17NOV2014		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Nicotine dependence	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2016		Y
		Surgical and medical procedures	Coronary arterial stent insertion	17JAN2017	17JAN2017	N
			Hip arthroplasty	17NOV2014	17NOV2014	N
			Vasectomy	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1128 11281010	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1983	31DEC1983	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
			Oophorectomy bilateral	01JAN1983	31DEC1983	N
	C4591001 1128 11281011	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1128 11281013	Injury, poisoning and procedural complications	Ligament rupture	01JAN2003	31DEC2003	N
		Investigations	Arthroscopy	28OCT2019	28OCT2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Surgical and medical procedures	Ligament operation	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1128 11281014	Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
			Tonsillitis	01JAN1953	31DEC1953	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Vitamin D decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01DEC2017		Y
			Muscle fatigue	01JAN2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Prostatectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Vasectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypotension	01AUG2019		Y
	C4591001 1128 11281015	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Macular degeneration	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1945	31DEC1945	N
		Musculoskeletal and connective tissue disorders	Musculoskeletal pain	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1982	31DEC1987	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1945	31DEC1945	N
		Vascular disorders	Hypertension	01JAN1973		Y
	C4591001 1128 11281016	Congenital, familial and genetic disorders	Hydrocele	01JAN1968	31DEC1968	N
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
			Inguinal hernia	01JAN1968	31DEC1968	N
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hydrocele operation	01JAN1968	31DEC1968	N
			Inguinal hernia repair	01JAN1968	31DEC1968	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281019	Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1964	31DEC1964	N
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2016	31DEC2018	N
	C4591001 1128 11281022	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Back pain	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2004	31DEC2004	N
	C4591001 1128 11281027	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1128 11281032	Eye disorders	Glaucoma	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2000		Y
	C4591001 1128 11281033	Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1966	31DEC1966	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Mastectomy	01JAN1998	31DEC1998	N
			Ovarian cystectomy	01JAN1966	31DEC1966	N
	C4591001 1128 11281034	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2016		Y
		Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Investigations	Blood cholesterol increased	01FEB2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Haemostasis	01JAN1990	31DEC1990	N
			Thoracotomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1128 11281036	Infections and infestations	Tonsillitis	01JAN1973	31DEC1973	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1974		Y
			Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Rectocele	30JUL2020		Y
		Surgical and medical procedures	Caesarean section	27FEB1979	27FEB1979	N
			Tonsillectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1128 11281037	Gastrointestinal disorders	Faeces soft	01JAN2017		Y
		General disorders and administration site conditions	Asthenia	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1974	31DEC1974	N
			Urinary tract infection	01JAN2017		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01APR2016		Y
			Obesity	01JAN2006	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Abdominoplasty	01JAN2016	31DEC2016	N
			Gastric bypass	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1128 11281039	Cardiac disorders	Arrhythmia	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1128 11281040	Gastrointestinal disorders	Umbilical hernia	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1128 11281041	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1990	31DEC1990	N
		Psychiatric disorders	Insomnia	01DEC2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Mastectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1128 11281043	Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1128 11281044	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
			Tenolysis	01JAN1997	31DEC1997	N
				01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281046	Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01MAR2019	31MAR2019	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1128 11281048	Eye disorders	Cataract	01JAN2012	31DEC2017	N
		Hepatobiliary disorders	Cholecystitis	01MAY2017	31MAY2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Gastrectomy	01JAN2019	31DEC2019	N
	C4591001 1128 11281051	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
			Obesity	01JAN1976	30SEP2018	N
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
			Rhinitis allergic	01JAN2019		Y
			Sleep apnoea syndrome	01JAN1994	31DEC1999	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Gastric bypass	01DEC2017	31DEC2017	N
			Uvulopalatopharyngoplasty	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1128 11281052	Gastrointestinal disorders	Eosinophilic oesophagitis	01JAN2016		Y
			Gastrooesophageal reflux disease	01JAN2006		Y
			Pancreatic cyst	01JAN2016		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Osteochondroma	01JAN1982	31DEC1982	N
		Nervous system disorders	Myoclonus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2002		Y
			Urinary retention	01JAN2016		Y
		Reproductive system and breast disorders	Peyronie's disease	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN1965		Y
			Rhinitis allergic	01JAN1995		Y
			Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1982	31DEC1982	N
			Meniscus operation	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1128 11281053	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1128 11281056	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Spinal column injury	01JAN1976		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1993	31DEC1993	N
		Nervous system disorders	Epilepsy	01JAN2005		Y
			Migraine	01JAN1976		Y
			Neuropathy peripheral	01JAN1976		Y
		Social circumstances	Postmenopause	01JUL2013		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1128 11281058	Blood and lymphatic system disorders	Anaemia	01JUN2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1128 11281059	Infections and infestations	Herpes simplex	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1128 11281060	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2002		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281063	Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hyperlipidaemia	01JAN2018		Y
	C4591001 1128 11281066	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31JAN2017	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
		Surgical and medical procedures	Prostatectomy	01JAN2017	31JAN2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1128 11281068	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2018		Y
			Osteoarthritis	01JAN2014	31DEC2014	N
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2006	31MAR2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Hysterectomy	01MAR2008	31MAR2008	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Ligament operation	01JAN2014	31DEC2014	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
	C4591001 1128 11281072	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2004	31DEC2014	N
			Myalgia	01JAN2000		Y
			Osteoarthritis	01JAN2018	31DEC2018	N
			Spinal osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1971		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Spinal operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281075	Congenital, familial and genetic disorders	Vitello-intestinal duct remnant	01JAN1966	31DEC1966	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Infections and infestations	Diverticulitis	01JAN1966	31DEC1966	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Surgical and medical procedures	Small intestinal resection	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1128 11281076	Eye disorders	Glaucoma	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2015	31DEC2015	N
			Trabeculectomy	01JAN2018	31DEC2018	N
	C4591001 1128 11281079	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Depression	01FEB2020		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1984	31DEC1984	N
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
	C4591001 1128 11281081	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2018		Y
		Infections and infestations	Ear infection	01JAN1961	31DEC1961	N
		Investigations	Carbon dioxide increased	01OCT2018	31OCT2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1980	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01OCT2018		Y
			Chronic obstructive pulmonary disease	01MAR2019		Y
			Pulmonary thrombosis	01JAN1983	31DEC1983	N
			Rhinitis allergic	01JAN2009		Y
			Sleep apnoea syndrome	01FEB2019		Y
		Surgical and medical procedures	Hysterectomy	01DEC1990	31DEC1990	N
			Tympanoplasty	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1128 11281082	Hepatobiliary disorders	Cholecystitis	01JAN1994	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
			Osteoarthritis	01JAN2000	17MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Knee arthroplasty	17MAR2020	17MAR2020	N
	C4591001 1128 11281084	Eye disorders	Cataract	01JAN2018	30APR2018	N
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1984	31MAY2001	N
		Social circumstances	Postmenopause	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01APR2018	30APR2018	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Knee arthroplasty	02MAY2001	02MAY2001	N
			Tonsillectomy	01JAN1954	31DEC1954	N
	C4591001 1128 11281085	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Gastrointestinal disorders	Gastritis	01JAN2017		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
			Hepatic steatosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2000	31DEC2000	N
			Uterine leiomyoma	01JAN1984	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
			Caesarean section	01JAN1980	31DEC1980	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1128 11281087	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1992	31DEC1992	N
	C4591001 1128 11281088	Cardiac disorders	Ventricular extrasystoles	01JAN2009		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1990		Y
			Tinnitus	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1128 11281089	Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Intestinal cyst	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Face lift	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Fracture treatment	01JAN1993	31DEC1993	N
			Intestinal operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1128 11281090	Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Oophorectomy bilateral	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281091	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1979		Y
			Osteoarthritis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1128 11281097	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma stage I	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1128 11281099	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1978	31DEC2007	N
			Vulvovaginal dryness	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN2007	31JAN2007	N
	C4591001 1128 11281100	Eye disorders	Dry eye	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	19MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1128 11281104	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Craniofacial fracture	01JAN1998	31DEC1998	N
			Ligament rupture	01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01NOV1980	30NOV1980	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1980	31DEC1980	N
			Myalgia	01JAN1975		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Inguinal hernia repair	01JAN1988	31DEC1988	N
				01JAN1993	31DEC1993	N
			Ligament operation	01JAN2016	31DEC2016	N
			Oesophageal operation	01DEC2019	31DEC2019	N
			Plastic surgery to the face	01JAN1998	31DEC1998	N
	C4591001 1128 11281105	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Vitamin D deficiency	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1992	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1128 11281106	Endocrine disorders	Hypothyroidism	01JAN1996		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2015	31MAY2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Hepatobiliary disorders	Cholecystitis	01MAY1985	31MAY1985	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN1994		Y
				01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Fibromyalgia	01JAN2000		Y
			Intervertebral disc protrusion	01JAN1990	15AUG2004	N
			Osteopenia	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	31MAR1997	N
		Psychiatric disorders	Nicotine dependence	01JAN1962		Y
		Renal and urinary disorders	Pollakiuria	01AUG2018		Y
			Renal failure	10NOV2015	10NOV2015	N
		Reproductive system and breast disorders	Menorrhagia	01NOV1989	15APR1990	N
		Surgical and medical procedures	Breast reconstruction	01JUN1997	30JUN1997	N
			Cataract operation	01MAY2019	31MAY2019	N
				01NOV2019	30NOV2019	N
			Cholecystectomy	01MAY1985	31MAY1985	N
			Female sterilisation	01MAR1984	31MAR1984	N
			Hysterectomy	15APR1990	15APR1990	N
			Mastectomy	01MAR1997	31MAR1997	N
			Medical device removal	01AUG2018	31AUG2018	N
			Spinal fusion surgery	15AUG2004	15AUG2004	N
			Spinal nerve stimulator implantation	01JUN2009	30JUN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281108	Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01SEP2011	30SEP2011	N
		Surgical and medical procedures	Rotator cuff repair	01SEP2011	30SEP2011	N
			Tonsillectomy	01JAN1954	31DEC1954	N
	C4591001 1128 11281109	Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
	C4591001 1128 11281110	Eye disorders	Glaucoma	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1128 11281111	Cardiac disorders	Palpitations	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1967	31DEC1967	N
		Surgical and medical procedures	Adenoidectomy	01JAN1967	31DEC1967	N
	C4591001 1128 11281121	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1973	31DEC1989	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Menorrhagia	01AUG2000	31AUG2010	N
		Social circumstances	Postmenopause	01AUG2010		Y
		Surgical and medical procedures	Chondroplasty	01JAN1989	31DEC1989	N
			Endometrial ablation	01AUG2010	31AUG2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1979	31DEC1979	N
	C4591001 1128 11281122	Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
		Hepatobiliary disorders	Cholecystitis	01JAN1987	31DEC1987	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1961	31DEC1961	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01APR2020		Y
			Prostatic hypoplasia	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
			Cholecystectomy	01JAN1987	31DEC1987	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1128 11281127	Eye disorders	Optic atrophy	01JAN2009		Y
		Surgical and medical procedures	Vasectomy	01JAN1975	31DEC1975	N
	C4591001 1128 11281130	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1128 11281131	Surgical and medical procedures	Vasectomy	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281133	Eye disorders	Cataract	01JUN2020		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01APR2019	30APR2019	N
				01JAN1997	31DEC2000	N
			Myalgia	01JAN2015		Y
		Surgical and medical procedures	Intervertebral disc operation	01APR2019	30APR2019	N
				01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1128 11281138	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Oropharyngeal cancer	01JAN2018	24OCT2018	N
		Surgical and medical procedures	Lymphadenectomy	14AUG2018	14AUG2018	N
			Tonsillectomy	14AUG2018	14AUG2018	N
	C4591001 1128 11281139	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Tonsillitis	01NOV1984	30NOV1984	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Adenoidectomy	01NOV1984	30NOV1984	N
			Carpal tunnel decompression	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01NOV1984	30NOV1984	N
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1128 11281140	Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
				01JAN2008	31DEC2008	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
				01JAN2008	31DEC2008	N
	C4591001 1128 11281141	Cardiac disorders	Atrial fibrillation	01JAN2008		Y
			Coronary artery disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN2008		Y
			Hyperlipidaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Nervous system disorders	Cerebral haemorrhage	01APR2012	30APR2012	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2018		Y
			Mitral valve repair	01FEB2019	28FEB2019	N
			Penile prosthesis insertion	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1128 11281142	Injury, poisoning and procedural complications	Splenic rupture	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1978		Y
		Surgical and medical procedures	Splenectomy	01JAN1963	31DEC1963	N
	C4591001 1128 11281148	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
		Surgical and medical procedures	Joint arthroplasty	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
			Shoulder arthroplasty	01JAN2012	31DEC2012	N
				01JAN2020	31JAN2020	N
			Spinal fusion surgery	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JUL2000		Y
	C4591001 1128 11281149	Eye disorders	Glaucoma	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
			Spondylitis	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2000		Y
	C4591001 1128 11281150	General disorders and administration site conditions	Pain	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01FEB2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
	C4591001 1128 11281158	Surgical and medical procedures	Vasectomy	01JAN1976	31DEC1976	N
		Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Haemorrhoids	01JAN1956	31DEC1962	N
		Infections and infestations	Tonsillitis	01JAN1945	31DEC1945	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1945	31DEC1945	N
			Cardiac pacemaker insertion	01JAN2016	31DEC2016	N
			Cataract operation	01JAN2013	31DEC2013	N
			Haemorrhoid operation	01JAN1962	31DEC1962	N
			Lung lobectomy	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1945	31DEC1945	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1128 11281160	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Injury, poisoning and procedural complications	Wrist fracture	01DEC2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01NOV1994	30NOV1994	N
			Joint arthroplasty	01DEC2010	31DEC2010	N
			Mammoplasty	01JAN1999	31DEC1999	N
	C4591001 1128 11281161	Eye disorders	Cataract	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glaucoma	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1962	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Endometrial ablation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1128 11281163	Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1128 11281166	Social circumstances	Postmenopause	01JAN1988		Y
	C4591001 1128 11281172	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1128 11281179	Cardiac disorders	Supraventricular tachycardia	01JAN1964	31DEC2000	N
		Eye disorders	Vitreous floaters	01JAN2018	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Respiratory, thoracic and mediastinal disorders	Nasal cyst	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2000	31DEC2000	N
			Sinus operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1964	31DEC1964	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2002	31DEC2002	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	17SEP1977	17SEP1977	N
			Carpal tunnel decompression	01JAN2002	31DEC2002	N
			Uterine dilation and curettage	01JAN1978	31DEC1978	N
	C4591001 1128 11281185	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01DEC1975		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1128 11281186	Hepatobiliary disorders	Cholecystitis	01JAN1992	31DEC1992	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1985		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1987	31DEC1990	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1975		Y
		Surgical and medical procedures	Caesarean section	05OCT1982	05OCT1982	N
			Cholecystectomy	01JAN1992	31DEC1992	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1128 11281189	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Obesity	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Reproductive system and breast disorders	Breast cyst	01JAN1993	31JAN1993	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2002	31DEC2012	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1993	31JAN1993	N
			Nasal septal operation	01JAN2012	31DEC2012	N
	C4591001 1128 11281191	Immune system disorders	Seasonal allergy	01JAN1992		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1980	31DEC2012	N
				01JAN2000	31DEC2019	N
		Surgical and medical procedures	Fracture treatment	01JAN2013	31DEC2013	N
			Hip arthroplasty	01OCT2019	31OCT2019	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1128 11281192	Eye disorders	Cataract	01JAN2006	31DEC2006	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Injury, poisoning and procedural complications	Humerus fracture	01FEB2020	29FEB2020	N
			Pelvic fracture	01JAN2015	31DEC2015	N
			Ulnar nerve injury	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wrist fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Obesity	01JAN1977	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2000	31DEC2000	N
			Urinary incontinence	01JAN1998		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1977	31DEC1981	N
		Surgical and medical procedures	Cataract operation	01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN1989	31DEC1989	N
			Gastric bypass	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1981	31DEC1981	N
			Keratomileusis	01JAN1998	31DEC1998	N
			Medical device battery replacement	01JAN2019	31DEC2019	N
			Peripheral nerve decompression	01JAN2005	31DEC2005	N
			Urinary bladder suspension	01JAN2000	31DEC2000	N
			Urinary control neurostimulator implantation	01JAN2013	31DEC2013	N
	C4591001 1128 11281193	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
			Osteopenia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1128 11281194	Surgical and medical procedures	Caesarean section	13DEC1982	13DEC1982	N
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1978	31DEC1978	N
		Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
			Tonsillitis	01JAN1943	31DEC1943	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin B12 deficiency	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Artificial urinary sphincter implant	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Haemorrhoid operation	01JAN1978	31DEC1978	N
			Tonsillectomy	01JAN1943	31DEC1943	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1128 11281203	Nervous system disorders	Sciatica	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1128 11281205	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1128 11281206	Gastrointestinal disorders	Gastrooesophageal reflux disease	01NOV2019		Y
		Infections and infestations	Urinary tract infection	19AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281207	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01APR2019		Y
			Diabetic ulcer	01FEB2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1128 11281211	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Hyperuricaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1128 11281212	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2013	31DEC2013	N
			Prostate cancer	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Colectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1128 11281213	Gastrointestinal disorders	Precancerous lesion of digestive tract	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Bipolar disorder	01JAN1990		Y
			Depression	01JAN1990		Y
			Insomnia	01JAN1969		Y
			Mania	01JAN1990		Y
		Surgical and medical procedures	Polypectomy	01JAN2014	31DEC2014	N
			Skin graft	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1128 11281214	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Hepatobiliary disorders	Cholelithiasis	01FEB2020	29FEB2020	N
		Infections and infestations	Urinary tract infection	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1996	31DEC1996	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	08JUN1984	08JUN1984	N
				14MAY1982	14MAY1982	N
			Cholecystectomy	01FEB2020	29FEB2020	N
			Spinal laminectomy	01JAN1996	31DEC1996	N
	C4591001 1128 11281215	Gastrointestinal disorders	Coeliac disease	01FEB2020		Y
			Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1990		Y
			Vitamin D deficiency	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1980		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1986		Y
		Social circumstances	Postmenopause	01AUG2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1128 11281221	Investigations	Diagnostic procedure	01JUL2007	31JUL2007	N
		Musculoskeletal and connective tissue disorders	Exostosis	01MAY2016	31MAY2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JUL2007	31JUL2007	N
		Surgical and medical procedures	Bone operation	01MAY2016	31MAY2016	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1128 11281223	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
			Tonsillitis	01JAN1956	31DEC1956	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1128 11281226	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
			Chronic sinusitis	01JAN1985		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2008	31DEC2008	N
			Ligament rupture	01JAN2013	31DEC2013	N
			Muscle rupture	01JAN2010	31DEC2010	N
			Nerve injury	01JAN2001	31DEC2001	N
			Tendon rupture	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood testosterone decreased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012	31DEC2014	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2020	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N
			Limb operation	01JAN2014	31DEC2014	N
			Lower oesophageal sphincter magnetic augmentation	01JAN2017	31DEC2017	N
			Muscle operation	01JAN2010	31DEC2010	N
			Peripheral nerve decompression	01JAN2001	31DEC2001	N
			Shoulder operation	01JAN2014		Y
			Sinus operation	01JAN2019	31DEC2019	N
			Tendon operation	01JAN2008	31DEC2008	N
			Vasectomy	01JAN1984	31DEC1984	N
			Wrist surgery	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1128 11281229	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Hypokalaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01NOV2013		Y
		Vascular disorders	Thrombosis	01JAN2016		Y
	C4591001 1128 11281233	Eye disorders	Myopia	01JAN1994		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Heart rate increased	01JAN2008		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2008		Y
			Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Keratotomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1128 11281234	Immune system disorders	Seasonal allergy	01JAN1972		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2004	31DEC2014	N
		Investigations	Precancerous cells present	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Foot operation	01JAN2004	31DEC2014	N
			Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1128 11281236	Cardiac disorders	Myocardial infarction	06APR2013	06APR2013	N
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01APR2013		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
			Psoriasis	01JAN2014		Y
		Social circumstances	Organ donor	01JAN1991	31JAN1991	N
		Surgical and medical procedures	Coronary arterial stent insertion	06APR2013	06APR2013	N
				08APR2013	08APR2013	N
		Vascular disorders	Hypertension	01APR2013		Y
	C4591001 1128 11281237	Infections and infestations	Appendicitis	01JAN2016	31DEC2016	N
		Investigations	Biopsy prostate	11MAR2020	11MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cardiac murmur	01JAN1954	31DEC1968	N
			Prostatic specific antigen increased	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1955		Y
			Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN2016	31DEC2016	N
	C4591001 1128 11281238	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2010	31MAR2010	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	04DEC2001	04DEC2001	N
			Limb operation	01OCT1960	31OCT1960	N
			Skin neoplasm excision	01MAR2010	31MAR2010	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1128 11281242	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1128 11281250	Social circumstances	Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281251	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
	C4591001 1128 11281253	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seasonal allergy Uterine leiomyoma	01JAN2000 01JAN2002	31DEC2007	Y N
	C4591001 1128 11281256	Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Investigations	Arthroscopy	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01AUG2018	31AUG2018	N
				01JUN2018	30JUN2018	N
			Knee arthroplasty	01JAN1998	31DEC1998	N
				01JAN2017	31DEC2017	N
			Knee operation	01JAN1965	31DEC1965	N
				01JAN2016	31DEC2016	N
			Nasal septal operation	01OCT2017	31OCT2017	N
			Ptosis repair	01JAN2019	31JAN2019	N
			Scar excision	01JAN2018	31DEC2018	N
				01JAN2019	31JAN2019	N
				01JAN2020	31DEC2020	N
			Vasectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN1982		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281258	Injury, poisoning and procedural complications	Ligament rupture	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2015		Y
		Surgical and medical procedures	Ligament operation	01JAN2005	31DEC2005	N
			Liposuction	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2005	31DEC2005	N
			Vasectomy reversal	01DEC2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1128 11281259	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281260	Infections and infestations	Tonsillitis	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01FEB2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN2002	31DEC2002	N
			Umbilical hernia repair	01JAN2018	31DEC2018	N
	C4591001 1128 11281264	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Salivary gland cyst	01JAN1983	31DEC1983	N
		Immune system disorders	Drug hypersensitivity	01FEB2020		Y
				01SEP1979		Y
		Infections and infestations	Diverticulitis	01JAN2015		Y
			Tonsillitis	01JAN1959	31DEC1960	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN1973	31DEC1974	N
		Pregnancy, puerperium and perinatal conditions	Cephalo-pelvic disproportion	01SEP1979	18JAN1985	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1993	31DEC1998	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01FEB2019	29FEB2020	N
		Surgical and medical procedures	Caesarean section	01JUN1982	01JUN1982	N
				01SEP1979	01SEP1979	N
				18JAN1985	18JAN1985	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Limb operation	01FEB2020	29FEB2020	N
			Parotidectomy	01JAN1983	31DEC1983	N
			Synovial cyst removal	01JAN1974	31DEC1974	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1128 11281266	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1984		Y
		Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1128 11281270	Cardiac disorders	Mitral valve prolapse	01JAN2010		Y
		Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2010	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		General disorders and administration site conditions	Granuloma	01FEB2010	28FEB2010	N
		Immune system disorders	Sarcoidosis	01JAN2010		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Chronic sinusitis	01JAN1964		Y
			Cystitis	01JAN1990	31DEC2000	N
			Herpes zoster	01SEP2017	30NOV2017	N
			Tonsillitis	01JAN1967	31DEC1967	N
			Upper respiratory tract infection	01JAN1965	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
			Osteopenia	01MAY2020		Y
			Undifferentiated connective tissue disease	01DEC2010		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Renal and urinary disorders	Urethral polyp	01JAN2015		Y
		Reproductive system and breast disorders	Cervical polyp	01FEB2001	28FEB2001	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2000	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2000	31DEC2005	N
		Surgical and medical procedures	Cervical polypectomy	01FEB2001	28FEB2001	N
			Corneal operation	01JAN2012	31DEC2012	N
			Limb operation	01FEB2010	28FEB2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal septal operation	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1128 11281271	Surgical and medical procedures	Vasectomy	01JAN1990		Y
	C4591001 1128 11281273	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
			Myalgia	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN2002	28FEB2002	N
		Social circumstances	Postmenopause	01MAR2017		Y
		Surgical and medical procedures	Caesarean section	24OCT1994	24OCT1994	N
				28FEB2002	28FEB2002	N
			Salpingectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01NOV2012		Y
	C4591001 1128 11281277	Eye disorders	Exfoliation syndrome	01JAN2009	31DEC2019	N
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Injury, poisoning and procedural complications	Limb crushing injury	01JAN1959	31DEC1959	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Finger repair operation	01JAN1959	31DEC1959	N
			Intraocular lens implant	01NOV2019	30NOV2019	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1128 11281278	Gastrointestinal disorders	Dyspepsia	01JAN1980		Y
			Large intestine polyp	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01MAY2015	28MAY2015	N
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
			Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Aortic aneurysm	01JAN2016		Y
			Aortic arteriosclerosis	01JAN2016		Y
			Hypertension	01JAN2008		Y
	C4591001 1128 11281280	Eye disorders	Blindness unilateral	(b) (6) 1962		Y
		Gastrointestinal disorders	Varices oesophageal	01JAN1968	31DEC1979	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Injury, poisoning and procedural complications	Splenic injury	01JAN1968	31DEC1968	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Portal shunt procedure	01JAN1979	31DEC1979	N
			Splenectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1128 11281284	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
			Urinary tract infection	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1986		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2000	31DEC2000	N
			Appendectomy	01JAN1970	31DEC1970	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Knee arthroplasty	01DEC2018	31DEC2018	N
	C4591001 1128 11281293	Gastrointestinal disorders	Inguinal hernia	01JAN1957	31DEC1957	N
		Infections and infestations	Tonsillitis	01JAN1947	31DEC1947	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1998	31DEC1998	N
		Investigations	Blood testosterone decreased	01JUN2000		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JUN2000	30JUN2000	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1990		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1957	31DEC1957	N
			Meniscus operation	01JAN1998	31DEC1998	N
			Pituitary tumour removal	01JUN2000	30JUN2000	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Vasectomy	01JAN1975	31DEC1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281295	Cardiac disorders	Cardiac failure congestive	05NOV2018		Y
			Coronary artery disease	01JAN2016		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1985		Y
		Hepatobiliary disorders	Cholelithiasis	07DEC1985	07DEC1985	N
		Immune system disorders	Contrast media allergy	05NOV2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Caesarean section	04DEC1985	04DEC1985	N
			Cholecystectomy	07DEC1985	07DEC1985	N
			Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1974	31DEC1974	N
			Tooth extraction	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1128 11281296	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2005		Y
			Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Hysterectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1128 11281298	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1128 11281303	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Nervous system disorders	Nerve compression	01JAN1989	30JUN2017	N
		Renal and urinary disorders	Hypertonic bladder	01MAR2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01MAR2019		Y
			Prostatomegaly	01JAN2014		Y
	C4591001 1128 11281307	Surgical and medical procedures	Spinal laminectomy	01JUN2017	30JUN2017	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2003		Y
			Irritable bowel syndrome	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Cardiac murmur	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1981		Y
		Psychiatric disorders	Depression	01JAN1985		Y
			Insomnia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Raynaud's phenomenon	01JAN1976		Y
	C4591001 1128 11281308	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
				01JAN2018		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01AUG2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281313	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Large intestine polyp	01AUG2020	20AUG2020	N
			Nausea	01JAN2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Infections and infestations	Diverticulitis	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2014		Y
				01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1989	31DEC1989	N
			Uterine cancer	01JAN1988	31DEC1988	N
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
			Large intestinal polypectomy	20AUG2020	20AUG2020	N
			Thyroidectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1128 11281314	Hepatobiliary disorders	Cholecystitis	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1968	31DEC1968	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1987	31DEC1987	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1991	31DEC1991	N
			Migraine	01JAN1977		Y
		Psychiatric disorders	Bipolar disorder	01JAN2019		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1968		Y
		Surgical and medical procedures	Appendectomy	01JAN1968	31DEC1968	N
			Carpal tunnel decompression	01JAN1991	31DEC1991	N
			Cataract operation	01JAN2016	31DEC2016	N
			Cholecystectomy	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Knee operation	01JAN1987	31DEC1987	N
				01JAN1996	31DEC1996	N
	C4591001 1128 11281315	Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007	31DEC2013	N
					31DEC2020	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2020	31JAN2020	N
	C4591001 1128 11281316	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
			Herpes simplex	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1982	31DEC1982	N
			Hepatic rupture	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Reproductive system and breast disorders	Prostatic hypoplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
			Nasal septal operation	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1128 11281318	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960	31DEC2015	N
			Rhinitis allergic	01JAN1960		Y
	C4591001 1128 11281320	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		General disorders and administration site conditions	Pain	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
			Osteomyelitis	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Ligament sprain	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Osteoporosis	01JAN2017		Y
			Trigger finger	01JAN2000	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
			Cubital tunnel syndrome	01JAN1999	31DEC1999	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Ankle operation	01JAN1998	31DEC1998	N
			Appendectomy	01JAN1970	31DEC1970	N
			Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Debridement	01JAN2017	31DEC2017	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Peripheral nerve decompression	01JAN1999	31DEC1999	N
			Renal stone removal	01JAN2007	31DEC2007	N
			Tendon sheath incision	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1128 11281321	Cardiac disorders	Myocardial infarction	11OCT2018	11OCT2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	11OCT2018	11OCT2018	N
				19DEC2018	19DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281322	Cardiac disorders	Coronary artery occlusion	01JAN2018	31JAN2018	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1982		Y
			Meniere's disease	01JAN1980		Y
		Endocrine disorders	Hypogonadism	01JAN2018		Y
		Eye disorders	Cataract	01JAN1996	31DEC1996	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1972		Y
		Surgical and medical procedures	Cataract operation	01JAN1996	31DEC1996	N
			Coronary arterial stent insertion	01JAN2018	31JAN2018	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281325	Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2016	N
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1128 11281329	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1128 11281330	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN1984		Y
			Spondylitis	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Knee operation	01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1128 11281333	Cardiac disorders	Aortic valve prolapse	01JAN1950		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Arthritis bacterial	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1999	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	31DEC2009	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN1997	31DEC1997	N
			Shoulder arthroplasty	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1128 11281335	Blood and lymphatic system disorders	Anaemia	01JAN1976		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017		Y
			Myalgia	01JAN2017		Y
			Osteoarthritis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2013	N
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
				01JAN2017		Y
			Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Female sterilisation	01FEB1987	28FEB1987	N
			Gastric bypass	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Mastectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1128 11281336	Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
			Myalgia	01JUN2020		Y
		Nervous system disorders	Neuralgia	01JAN2015		Y
		Surgical and medical procedures	Foot operation	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Intervertebral disc operation	01JAN2002	31DEC2002	N
				01JAN2004	31DEC2004	N
			Shoulder arthroplasty	01JAN2015	31DEC2015	N
			Therapeutic nerve ablation	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281340	Gastrointestinal disorders	Anal fistula	01JAN2014	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Surgical and medical procedures	Anal fistula repair	01DEC2015	31DEC2015	N
		Vascular disorders	Hypertension	01NOV2015		Y
	C4591001 1128 11281344	Gastrointestinal disorders	Umbilical hernia	01JAN1998	31JAN1998	N
		Infections and infestations	Chronic sinusitis	01JAN1969		Y
			Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1977	31DEC1977	N
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Exostosis	01JAN1996	31DEC1998	N
				01JAN1997	31DEC1997	N
			Muscle spasms	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JUL1998	31AUG1998	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1997	31DEC1997	N
			Lipoma excision	01AUG1998	31AUG1998	N
			Meniscus operation	01JAN1977	31DEC1977	N
			Shoulder operation	01DEC1998	31DEC1998	N
			Sinus operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1962	31DEC1962	N
			Umbilical hernia repair	01JAN1998	31JAN1998	N
			Vasectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281346	Cardiac disorders	Arrhythmia	01NOV2019	30NOV2019	N
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1953		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01NOV2019		Y
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1128 11281348	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1128 11281349	General disorders and administration site conditions	Oedema peripheral	01JAN2009		Y
		Hepatobiliary disorders	Hepatic cirrhosis	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Investigations	Cardiac murmur	01JAN1949		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1128 11281350	Endocrine disorders	Hypothyroidism	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
			Upper limb fracture	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Fracture treatment	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Meniscus operation	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1128 11281351	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN1985		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01OCT2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
	C4591001 1128 11281353	Cardiac disorders	Cardiomyopathy	01JAN2011		Y
		Congenital, familial and genetic disorders	Stargardt's disease	01JAN1979		Y
		Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1128 11281354	Ear and labyrinth disorders	Deafness bilateral	01JAN1965		Y
		Endocrine disorders	Goitre	01JAN1997		Y
			Hypothyroidism	01JAN1997		Y
		Investigations	Cardiac murmur	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01DEC1992	31DEC1992	N
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
			Oophorectomy	01DEC1992	31DEC1992	N
	C4591001 1128 11281356	Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01DEC2001	01DEC2001	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1128 11281360	Endocrine disorders	Hyperthyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Hernia	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Hernia repair	01JAN2014	31DEC2014	N
			Phlebectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
			Peripheral vascular disorder	01JAN2010	31DEC2018	N
	C4591001 1128 11281362	Injury, poisoning and procedural complications	Gun shot wound	01JAN1966	31DEC1966	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	17MAY2017		Y
			Muscle spasms	01MAY2017		Y
			Myalgia	01JAN2017		Y
		Nervous system disorders	Migraine	01MAY2017		Y
		Psychiatric disorders	Nicotine dependence	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2018		Y
		Surgical and medical procedures	Pharyngeal operation	01MAY2017		Y
			Spinal decompression	01MAY2017	31MAY2017	N
	C4591001 1128 11281365	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nausea	01FEB2020		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2007		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
				01JAN2013		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01FEB2020		Y
		Social circumstances	Physical assault	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Cholecystectomy	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1128 11281370	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Irritable bowel syndrome	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1968		Y
			Intervertebral disc degeneration	01JAN1968	19JUN2019	N
		Psychiatric disorders	Depression	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Spinal fusion surgery	19JUN2019	19JUN2019	N
		Vascular disorders	Hypertension	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281371	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1128 11281372	Cardiac disorders	Bradycardia	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc degeneration	01JAN2005		Y
			Muscle spasms	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	01JAN1991	31DEC1991	N
		Nervous system disorders	Headache	01SEP1991		Y
			Seizure	01JAN1991		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Depression	01JAN2013		Y
		Surgical and medical procedures	Brain tumour operation	01OCT1991	31OCT1991	N
			Cardiac pacemaker insertion	01JAN2018	31DEC2018	N
			Shoulder operation	01JAN2008		Y
			Vagal nerve stimulator implantation	01JAN2008		Y
	C4591001 1128 11281374	Blood and lymphatic system disorders	Lymphoid tissue hyperplasia	01JAN2013	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Iritis	01JAN1956		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Vitamin D deficiency	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1960	31DEC1960	N
			Cholecystectomy	01JAN1970	31DEC1970	N
			Female sterilisation	01JAN1970	31DEC1970	N
			Lymphoid tissue operation	01JAN2014	31DEC2014	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1128 11281375	Immune system disorders	Seasonal allergy	01JAN1971		Y
		Injury, poisoning and procedural complications	Limb fracture	01JAN2012	31DEC2012	N
		Investigations	Blood testosterone decreased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1999	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1128 11281376	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Small intestinal obstruction	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Meniscus injury	01MAR2020		Y
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2010		Y
			Rotator cuff syndrome	01JAN2002	31DEC2004	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2005	31DEC2005	N
			Spinal stenosis	01JAN2010		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
			Small intestine operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1128 11281377	Injury, poisoning and procedural complications	Concussion	19SEP2019	19SEP2019	N
			Road traffic accident	19SEP2019	19SEP2019	N
		Investigations	Cardiac murmur	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Skin hypopigmentation	(b) (6) 1952		Y
		Surgical and medical procedures	Intraocular lens implant	01APR2019	30APR2019	N
	C4591001 1128 11281378	Hepatobiliary disorders	Cholelithiasis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Nerve injury	01SEP1994	30SEP1994	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990	31DEC1994	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1960		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1981	31DEC1981	N
			Spinal operation	01SEP1994	30SEP1994	N
	C4591001 1128 11281379	Endocrine disorders	Hypothyroidism	01JAN1971		Y
		Eye disorders	Astigmatism	01JAN1958	31DEC1994	N
			Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Cyclic vomiting syndrome	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Keratotomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1128 11281380	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
		Investigations	Blood potassium decreased	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1983		Y
					31DEC1988	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1997	N
		Nervous system disorders	Diabetic neuropathy	01JAN1995		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01JAN1988	31DEC1988	N
			Oophorectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1128 11281381	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1128 11281382	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2007	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Intervertebral disc degeneration	01JAN2002	31AUG2018	N
			Muscle spasms	01JAN2019		Y
			Osteoarthritis	01JAN2006	31DEC2017	N
		Nervous system disorders	Dementia	01JAN2016		Y
			Neuralgia	01JAN2019		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
			Sleep disorder	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2006	31DEC2006	N
				01JAN2017	31DEC2017	N
			Spinal fusion surgery	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1128 11281383	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
			Pain in extremity	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1129 11291002	Blood and lymphatic system disorders	Anaemia	01JAN2003	31DEC2009	N
		Eye disorders	Myopia	01JAN1966		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1999	31DEC1999	N
		Investigations	Endoscopy gastrointestinal	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Overweight	01JAN1976		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2017	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983	31DEC1986	N
			Sleep apnoea syndrome	01MAR2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
			Myomectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1129 11291003	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2004	31DEC2004	N
				01JAN2012	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN1981		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2000	31DEC2014	N
			Osteoarthritis	01JAN2010		Y
			Plantar fasciitis	01JAN2017	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Seizure	01JAN1979		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011	31DEC2017	N
		Surgical and medical procedures	Bone lesion excision	01JAN2014	31DEC2014	N
			Inguinal hernia repair	01JAN2004	31DEC2004	N
				01JAN2012	31DEC2012	N
			Keratomileusis	01JAN2003	31DEC2003	N
			Vasectomy	01JAN1983	31DEC1983	N
	C4591001 1129 11291004	Eye disorders	Hypermetropia	01JAN2012		Y
		Infections and infestations	Rhinitis	01JAN2000		Y
		Investigations	Heart rate irregular	01JAN2018	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2000	31DEC2000	N
		Psychiatric disorders	Insomnia	01JAN1985		Y
		Reproductive system and breast disorders	Menopausal symptoms	25SEP2019		Y
			Menorrhagia	01JAN2014	31DEC2014	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2014	31DEC2014	N
			Mammoplasty	01JAN2017	31DEC2017	N
	C4591001 1129 11291007	Blood and lymphatic system disorders	Anaemia	01JAN2014	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Congenital, familial and genetic disorders	Gilbert's syndrome	(b) (6) 1952		Y
		Eye disorders	Cataract	01JAN2015		Y
			Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
			Proctitis	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2017		Y
		Infections and infestations	Urinary tract infection	01JAN1978	31DEC1978	N
		Injury, poisoning and procedural complications	Radius fracture	01JAN2009	31DEC2009	N
			Skeletal injury	01JAN2017	31DEC2017	N
			Spinal compression fracture	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	09JAN2020	N
		Nervous system disorders	Hypoxic-ischaemic encephalopathy	01JAN2013	31DEC2013	N
		Renal and urinary disorders	Micturition disorder	01JAN2007		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2020		Y
			Prostatomegaly	01JAN2007	31JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Surgery	01JAN1956	31DEC1956	N
			Varicocele repair	01JAN1979	31DEC1979	N
	C4591001 1129 11291008	Blood and lymphatic system disorders	Leukopenia	01NOV2019		Y
		Cardiac disorders	Mitral valve prolapse	01JAN2007		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypermetropia	01JAN1985		Y
			Myopia	01JAN1950		Y
			Myopic chorioretinal degeneration	01JAN2009		Y
			Retinal scar	01JAN2009		Y
		Gastrointestinal disorders	Constipation	01JAN1967		Y
		Immune system disorders	Hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2017		Y
		Investigations	Cardiac murmur	01JAN2007		Y
			Electrocardiogram abnormal	01JAN2006		Y
			Stool analysis abnormal	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1994		Y
			Osteoporosis	01JAN1995		Y
			Synovial cyst	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2000	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2017		Y
		Social circumstances	Ex-tobacco user	01JAN1967	31DEC1976	N
		Surgical and medical procedures	Bunion operation	01JAN1994	31DEC2015	N
			Synovial cyst removal	01JAN2013		Y
	C4591001 1129 11291009	Congenital, familial and genetic disorders	Thalassaemia alpha	01JAN1964		Y
		Eye disorders	Myopia	01JAN1978		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
			Blood triglycerides increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
			Micturition disorder	01MAY2020		Y
			Nephrolithiasis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
		Social circumstances	Ex-tobacco user	01JAN1982	31DEC2010	N
		Surgical and medical procedures	Jaw operation	01JAN1986		Y
			Lithotomy position	01JAN2016		Y
			Renal stone removal	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291011	Blood and lymphatic system disorders	Anaemia	01JAN1959	31DEC2006	N
		Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2000		Y
		Ear and labyrinth disorders	Vertigo	01JAN2018		Y
		Eye disorders	Astigmatism	01JAN1944		Y
			Cataract	01JAN1944		Y
			Myopia	01JAN1944		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
			Dyspepsia	01JAN1956		Y
		General disorders and administration site conditions	Fatigue	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Peripheral swelling	01FEB2020	31MAY2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				01JAN2016		Y
			Seasonal allergy	01JAN2017		Y
		Infections and infestations	Postoperative wound infection	01JAN2016	31DEC2018	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017		Y
		Investigations	Staphylococcus test positive	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1964		Y
			Osteoarthritis	01JAN2010		Y
				01SEP2010		Y
			Scoliosis	01JAN1964		Y
			Spinal osteoarthritis	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2004	31DEC2006	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1959	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1949	31DEC1949	N
			Female sterilisation	01JAN1977	31DEC1977	N
			Gallbladder operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Spinal operation	01JAN1985	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendon sheath incision	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1949	31DEC1949	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1129 11291012	Eye disorders	Cataract	01JAN2001	31DEC2002	N
			Hypermetropia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
			Prostatomegaly	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1970	31DEC2000	N
		Surgical and medical procedures	Lens extraction	01JAN2002	31DEC2002	N
	C4591001 1129 11291013	Gastrointestinal disorders	Large intestine polyp	01JUN2018	31JUL2018	N
		General disorders and administration site conditions	Hernia	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN1990	31DEC2009	N
		Injury, poisoning and procedural complications	Nerve injury	01SEP2019		Y
			Tendon injury	01JAN1997	31DEC1997	N
		Investigations	Blood cholesterol increased	01FEB2020		Y
			Blood triglycerides increased	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Intervertebral disc compression	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960	31DEC1965	N
		Surgical and medical procedures	Polypectomy	01JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291015	Gastrointestinal disorders	Haemorrhoids	01SEP2019		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Onychomycosis	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2000		Y
			Libido decreased	01JAN2015		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2020		Y
	C4591001 1129 11291016	Ear and labyrinth disorders	Cerumen impaction	01JAN2019	31DEC2019	N
		Eye disorders	Cataract	01JAN2000		Y
			Glaucoma	01JAN2000		Y
			Myopia	01JAN1960		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Hernia	01JAN1990	31DEC1990	N
		Immune system disorders	Food allergy	01JAN1956		Y
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN2017	31DEC2017	N
			Blood triglycerides increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Hernia repair	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291018	Eye disorders	Cataract	01JAN2015		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2005	31DEC2005	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2002		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN1985	31DEC1985	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
			Blood triglycerides increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
			Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC1992	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rosacea	01JAN1995		Y
		Social circumstances	Ex-tobacco user	01JAN2010	31DEC2015	N
		Surgical and medical procedures	Limb operation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1129 11291021	Eye disorders	Eyelid ptosis	01JAN2013	31DEC2013	N
			Myopia	01JAN1965		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		General disorders and administration site conditions	Hernia	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Reaction to food additive	01JAN1987		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN2017		Y
			Tobacco user	01JAN1976		Y
		Surgical and medical procedures	Eyelid operation	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN2000	31DEC2000	N
			Gallbladder operation	01JAN2014	31DEC2014	N
			Hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1129 11291022	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
			Vertigo	01MAY2020		Y
		Eye disorders	Cataract	01JAN2017		Y
			Hypermetropia	01JUL2020		Y
				17JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN1990	31DEC1990	N
			Onychomycosis	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2019		Y
			Osteoporosis	01JAN2010		Y
		Nervous system disorders	Amnesia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Libido decreased	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
			Prostatomegaly	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2005		Y
		Social circumstances	Tobacco user	01JAN1964	31DEC1964	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291023	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Ear infection	01JAN1990	31DEC1990	N
			Tooth abscess	01JAN2020	31JAN2020	N
		Investigations	Blood cholesterol increased	01MAR2018		Y
			Blood triglycerides increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2020		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01FEB2020		Y
		Social circumstances	Tobacco user	01JAN1975		Y
		Surgical and medical procedures	Ear operation	01JAN1990	31DEC1990	N
		Vascular disorders	Thrombophlebitis	01MAY2020		Y
	C4591001 1129 11291024	Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010	31DEC2018	N
			Dyspepsia	01JAN2000		Y
			Inguinal hernia	01JAN2014	31DEC2014	N
		General disorders and administration site conditions	Hernia	01JAN2014	31DEC2014	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013	31DEC2016	N
			Bladder cancer	01JAN2010	31DEC2015	N
			Squamous cell carcinoma of skin	01JAN2013	31DEC2016	N
		Renal and urinary disorders	Micturition disorder	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Colectomy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291026	Congenital, familial and genetic disorders	Talipes	(b) (6) 1955	31DEC2004	N
		Eye disorders	Hypermetropia	01JAN1968		Y
			Myopia	01JAN1968		Y
		Gastrointestinal disorders	Constipation	01JAN2001		Y
			Diverticulum	01JAN2010		Y
			Gastric ulcer	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2011		Y
			Haemorrhoids	01JAN2020		Y
			Large intestine polyp	01JAN2013	31DEC2013	N
		Infections and infestations	Fungal skin infection	01JAN2015	31DEC2016	N
			Onychomycosis	01JAN2015	31DEC2016	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2013	31DEC2013	N
			Foot fracture	01JAN2013	31DEC2013	N
			Head injury	01JAN2005	31DEC2005	N
			Ligament sprain	01JAN2013	31DEC2013	N
			Muscle rupture	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
			Tendon rupture	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
			Blood triglycerides increased	01JAN2011		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2013		Y
			Foot deformity	01JAN1955	31DEC1955	N
			Intervertebral disc degeneration	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Muscle spasms	01JAN2013		Y
			Osteoarthritis	01JAN1999		Y
			Scoliosis	01JAN2008		Y
			Spinal stenosis	01JAN2010		Y
			Spondylolisthesis	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
			Seborrhoeic keratosis	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN1984		Y
			Neuropathy peripheral	01JAN2013		Y
			Sciatica	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Bipolar disorder	01JAN2006		Y
			Insomnia	01JAN2008		Y
			Libido decreased	01JAN2013		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
			Nephrolithiasis	01JAN2015	31DEC2017	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
			Rosacea	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Arthrodesis	01JAN2006	31DEC2006	N
			Bone lesion excision	01JAN2005	31DEC2005	N
			Bunion operation	01JAN2004	31DEC2004	N
			Chondroplasty	01JAN2016	31DEC2016	N
			Lipoma excision	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal operation	01JAN2012	31DEC2012	N
			Neurectomy	01JAN2013	31DEC2013	N
			Ostectomy	01JAN2004		Y
			Spinal fusion surgery	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Tenotomy	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1129 11291027	Cardiac disorders	Bradycardia	01JAN2014		Y
		Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Eye disorders	Cataract	01JAN1980	31DEC2005	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
			Blood triglycerides increased	01JAN2001		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Nervous system disorders	Tremor	01JAN1975		Y
		Psychiatric disorders	Libido decreased	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2003		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2014		Y
			Gallbladder operation	01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1129 11291028	Cardiac disorders	Angina pectoris	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Tinnitus	01JAN1989		Y
			Vertigo	01JAN2016		Y
		Eye disorders	Cataract	01JUL2018	31JUL2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Hiatus hernia	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1949	31DEC1949	N
		Investigations	Blood cholesterol increased	01JAN1988		Y
			Blood triglycerides increased	01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Foot deformity	01JAN1994	31DEC1999	N
			Osteopenia	01JAN2010		Y
			Osteoporosis	01JAN2019		Y
		Nervous system disorders	Amnesia	01JAN2005		Y
			Diabetic neuropathy	01JAN2017		Y
			Transient ischaemic attack	01APR2001	30APR2001	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01APR1968	31DEC1971	N
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Bunion operation	01JAN1999	31DEC1999	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31JAN2010	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Renal stone removal	01JAN1971	31DEC1971	N
			Toe operation	01JAN1994	31DEC1999	N
			Tonsillectomy	01JAN1949	31DEC1949	N
	C4591001 1129 11291031	Ear and labyrinth disorders	Deafness	01JAN1990		Y
		Eye disorders	Cataract	01JAN2015		Y
			Glaucoma	01JAN2019		Y
			Hypermetropia	01JAN1995		Y
			Myopia	01JAN1985		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN1962		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast fibroma	01JAN1961		Y
		Nervous system disorders	Headache	01JAN1962		Y
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	01JAN2005		Y
		Social circumstances	Tobacco user	01JAN1961	31DEC1985	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291032	Eye disorders	Cataract	01JAN2017	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN1963	31DEC1963	N
			Tibia fracture	01JAN1963	31DEC1963	N
		Investigations	Arthroscopy	01JAN1999	31DEC1999	N
			Blood cholesterol increased	01JAN2016		Y
			Electrocardiogram abnormal	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Overweight	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2007	31DEC2010	N
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN1970		Y
		Renal and urinary disorders	Nephrolithiasis	01FEB2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960	31DEC1982	N
		Social circumstances	Tobacco user	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01DEC2019	31DEC2019	N
			Knee arthroplasty	01JAN2002	31DEC2002	N
			Shoulder arthroplasty	01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2015	31DEC2015	N
			Spinal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1129 11291033	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2016		Y
			Middle insomnia	01JAN2005		Y
		Social circumstances	Tobacco user	01JAN1982	31DEC2005	N
		Surgical and medical procedures	Vasectomy	01JAN1999	31DEC1999	N
	C4591001 1129 11291034	Congenital, familial and genetic disorders	Familial polycythaemia	01JAN1938		Y
		Ear and labyrinth disorders	Vertigo	01JAN2014		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN1956		Y
		Infections and infestations	Onychomycosis	01JAN1954		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	29OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
			Squamous cell carcinoma of skin	01JAN2009	31DEC2009	N
		Nervous system disorders	Sciatica	01JAN2016	31JAN2020	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1983		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291035	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Large intestine polyp	01JAN2019	31DEC2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2000	31DEC2000	N
			Tonsillitis	01JAN1954	31DEC1956	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1966	31DEC1986	N
		Surgical and medical procedures	Appendectomy	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1956	31DEC1956	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
			Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1129 11291036	Cardiac disorders	Bradycardia	01JAN2013	31DEC2013	N
			Coronary artery disease	01JAN2013	31DEC2013	N
			Mitral valve incompetence	10JUL2018		Y
			Tricuspid valve incompetence	10JUL2018		Y
		Eye disorders	Hypermetropia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
			Heart rate irregular	01JAN2013		Y
		Metabolism and nutrition disorders	Overweight	11JUL2018		Y
			Type 2 diabetes mellitus	01OCT2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Diabetic neuropathy	01JUN2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2013	31DEC2013	N
			Coronary arterial stent insertion	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1129 11291037	Eye disorders	Hypermetropia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018	31DEC2019	N
			Large intestine polyp	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1987		Y
		Infections and infestations	Appendicitis	01JAN1985	31JAN1985	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2011	31JAN2011	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of prostate	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	24APR2017		Y
		Social circumstances	Tobacco user	01JAN1979	31DEC2012	N
		Surgical and medical procedures	Appendicectomy	01JAN1985	31JAN1985	N
			Knee operation	01JAN2011	01JAN2011	N
	C4591001 1129 11291038	Eye disorders	Hypermetropia	01JAN2006		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2015	31DEC2015	N
		Immune system disorders	Perfume sensitivity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb crushing injury	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
			Blood triglycerides increased	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1975		Y
		Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1129 11291039	Cardiac disorders	Palpitations	01JAN2014		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Eye disorders	Cataract	01JAN2013	31DEC2013	N
				01JAN2019	31DEC2019	N
			Hypermetropia	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1989	31DEC1992	N
			Gastroesophageal reflux disease	01JAN1989	31DEC1992	N
			Large intestine polyp	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
			Hepatitis A	01JAN1951	31DEC1951	N
			Histoplasmosis	01JAN1957	31DEC1957	N
			Pneumonia	01JAN1945	31DEC1945	N
				01JAN1948	31DEC1948	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1956		Y
			Actinic keratosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hyperkeratosis	01JAN1970		Y
			Appendicectomy	01JAN1956		Y
			Limb operation	01JAN2015	31DEC2015	N
			Spinal laminectomy	01JAN1993	31DEC1993	N
		Vascular disorders		01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Hot flush	01JAN1995		Y
		Blood and lymphatic system disorders	Hypertension	01JAN2009		Y
	C4591001 1129 11291043		Anaemia	01MAR2017	31AUG2017	N
		Ear and labyrinth disorders	Deafness	01JAN1970		Y
		Eye disorders	Cataract	01MAR2017		Y
			Hypermetropia	01JAN1958		Y
		Gastrointestinal disorders	Diarrhoea	01AUG1966		Y
			Gastric ulcer	01MAY2015	31MAY2015	N
		Hepatobiliary disorders	Gastrooesophageal reflux disease	01MAR2010		Y
			Large intestine polyp	01AUG2015	30NOV2015	N
			Hepatomegaly	01JAN1966		Y
		Infections and infestations	Plasmodium falciparum infection	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Foreign body	01JAN1966		Y
			Head injury	01JAN1956	31DEC1956	N
			Ligament rupture	01AUG2010	31AUG2010	N
			Muscle rupture	01APR1996	31DEC1996	N
				01MAY2006	31MAY2016	N
			Skeletal injury	01JAN1950	31DEC1950	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Heart rate irregular	01APR2010		Y
			White blood cell count increased	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
			Insomnia	01JAN1970		Y
			Libido decreased	01SEP1999		Y
			Post-traumatic stress disorder	01JAN1999		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01APR1999		Y
			Prostatomegaly	01JAN1966		Y
		Social circumstances	Tobacco user	01JAN1955	13DEC1978	N
		Surgical and medical procedures	Toe operation	01OCT2014	31OCT2014	N
		Vascular disorders	Hypertension	01APR2010		Y
	C4591001 1129 11291044	Blood and lymphatic system disorders	Anaemia	02FEB2020		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Genital herpes	01JAN1987		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Foot deformity	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN1970		Y
		Nervous system disorders	Seizure	01JAN2006	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Renal and urinary disorders	Pollakiuria	01JAN2000		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC2007	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	15JUN2017	15JUN2017	N
			Bunion operation	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN1987		Y
			Hysterectomy	01JAN2007	31DEC2007	N
			Knee arthroplasty	01DEC2019	31DEC2019	N
				01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1129 11291046	Eye disorders	Cataract	01JAN2019		Y
			Hypermetropia	01JAN1962		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2003	31DEC2004	N
			Diarrhoea	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Food allergy	01JAN1971		Y
			Seasonal allergy	01JAN1989		Y
		Infections and infestations	Appendicitis	01JAN2002	31DEC2002	N
			Tonsillitis	01JAN1953	31DEC1953	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercalcaemia	01APR2018	31AUG2018	N
			Hyperlipidaemia	01JAN2000		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	31DEC2017	N
			Osteoarthritis	01JAN2019		Y
			Synovial cyst	01JAN2016	31DEC2016	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2019	N
			Restless legs syndrome	01JAN2000		Y
			Sciatica	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
			Micturition disorder	01JAN2014		Y
			Stress urinary incontinence	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1987		Y
				01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2016		Y
			Pulmonary embolism	01JAN2016	31DEC2018	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1989		Y
		Social circumstances	Tobacco user	01JAN1969	31DEC1971	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2001	31DEC2004	N
			Adenoidectomy	01JAN1971	31DEC1971	N
			Carpal tunnel decompression	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1984		Y
			Hysterectomy	01JAN1989	31DEC1989	N
			Meniscus operation	01JAN2005	31DEC2005	N
			Meniscus removal	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1953		Y
		Vascular disorders	Deep vein thrombosis	01JAN2016	31DEC2018	N
			Hypertension	01JAN1995		Y
	C4591001 1129 11291049	Blood and lymphatic system disorders	Anaemia	01JAN2020		Y
		Eye disorders	Hypermetropia	01JAN2009		Y
			Myopia	01JAN2009		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1979	31DEC1995	N
			Haemorrhoids	01JAN1986	31DEC1986	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1984		Y
				01JAN2016		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1980	31DEC1980	N
		Investigations	Intraocular pressure increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Paraesthesia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2003		Y
			Chronic respiratory disease	01JAN2003		Y
		Social circumstances	Tobacco user	01JAN1971		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Haemorrhoid operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1129 11291050	Immune system disorders	Hypersensitivity	01JAN2017		Y
		Investigations	Blood testosterone decreased	01JUL2019		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin D deficiency	01JUN2017		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01FEB2020		Y
		Nervous system disorders	Headache	01JAN1980		Y
		Psychiatric disorders	Agitation	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
	C4591001 1129 11291051	Eye disorders	Cataract	01MAR2020	03JUN2020	N
			Dacryostenosis acquired	01NOV2017	31DEC2017	N
		Gastrointestinal disorders	Irritable bowel syndrome	06FEB2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
					23JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Vaginal polyp	01AUG2017	30SEP2017	N
		Surgical and medical procedures	Cataract operation	03JUN2020	03JUN2020	N
			Lacrimal duct procedure	01NOV2017	30NOV2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291052	Eye disorders	Cataract	01JAN2010	31DEC2018	N
			Myopia	01JAN1966		Y
		General disorders and administration site conditions	Hernia	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1980	31DEC1981	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Renal and urinary disorders	Renal failure	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Bone operation	01JAN1981	31DEC1981	N
			Inguinal hernia repair	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1129 11291053	Eye disorders	Myopia	01JAN1967		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN1985		Y
				01JAN1990		Y
				01JAN1993		Y
				01JAN2005		Y
			Seasonal allergy	01JAN1999		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1961		Y
				01JAN1976		Y
			Meniscus injury	01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Biopsy breast	01JAN1984	31DEC1984	N
				01JAN2009		Y
				01JAN2011		Y
		Metabolism and nutrition disorders	Overweight	01JAN2000	31DEC2010	N
			Vitamin D deficiency	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Osteoarthritis	01JAN2010		Y
			Scoliosis	01JAN2014		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1999	31DEC1999	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1972	31DEC1979	N
			Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Meniscus operation	01JAN2007		Y
				01JAN2013		Y
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1129 11291057	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Coronary artery disease	01JAN2008		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2003		Y
			Myopia	01JAN2003		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Hepatitis A	01JAN1965	31DEC1965	N
			Infectious mononucleosis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Hypertriglyceridaemia	01JAN2008		Y
			Vitamin D deficiency	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Nervous system disorders	Amnesia	01JAN2015		Y
			Headache	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
			Prostatomegaly	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
			Emphysema	01JAN2003		Y
			Nasal septum deviation	01JAN1967	31DEC2012	N
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2019	31DEC2019	N
		Social circumstances	Tobacco user	01JAN1964	31DEC2003	N
		Surgical and medical procedures	Aortic stent insertion	01JAN2014		Y
			Coronary arterial stent insertion	01JAN2008		Y
			Nasal septal operation	01JAN2012	31DEC2012	N
	C4591001 1129 11291059	Eye disorders	Cataract	01JAN1990	31DEC1999	N
			Hypermetropia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1960		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1960		Y
				01JAN1970		Y
		Immune system disorders	Large intestine polyp	01JAN2018	31DEC2018	N
			Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Investigations	Catheterisation cardiac	27JAN2020	27JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1992		Y
			Vitamin B12 deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC2019	N
				01JAN2019	31DEC2019	N
		Psychiatric disorders	Headache	01JAN1960		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
			Libido decreased	01JAN2016		Y
		Renal and urinary disorders	Micturition disorder	01JAN2013		Y
			Nocturia	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
			Prostatomegaly	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1950		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Acne	01JAN1960	31DEC1965	N
			Eczema	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN1990	31DEC1999	N
			Coronary arterial stent insertion	27JAN2020	27JAN2020	N
			Haemorrhoid operation	01JAN1980	31DEC1980	N
				01JAN1995	31DEC1995	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Shoulder arthroplasty	01JAN1997	31DEC1997	N
				01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Transurethral prostatectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291060	Ear and labyrinth disorders	Deafness	01JAN1976		Y
		Eye disorders	Cataract	01JAN2012	31DEC2018	N
			Retinal tear	01JAN2007	31DEC2007	N
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998		Y
			Facial paralysis	01AUG2018	31DEC2019	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2005		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2003	31DEC2003	N
			Cataract operation	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Knee operation	01JAN1982	31DEC1982	N
			Meniscus operation	01JAN1982	31DEC1982	N
			Vitrectomy	01JAN2018	31DEC2018	N
	C4591001 1129 11291062	Blood and lymphatic system disorders	Anaemia	01JAN2017	31DEC2018	N
		Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2015		Y
			Gastric ulcer	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Rib fracture	01AUG2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	06JAN2020		Y
			Vitamin B12 deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2018	31JUL2018	N
		Reproductive system and breast disorders	Prostatomegaly	03JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1970	31DEC2018	N
		Vascular disorders	Hypertension	01OCT2019		Y
			Varicose vein	01JAN1970		Y
	C4591001 1129 11291065	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Ear and labyrinth disorders	Deafness	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Endocrine disorders	Hypothyroidism	01JAN2015		Y	
		Eye disorders	Cataract	01JAN1998	31DEC1998	N	
				01JAN2002	31DEC2002	N	
			Glaucoma	01JAN2017		Y	
			Myopia	01JAN1967		Y	
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1968		Y	
				Large intestine polyp	01JAN2008	31DEC2008	N
			Umbilical hernia	01JAN2010	31DEC2010	N	
	Injury, poisoning and procedural complications		Femur fracture	01JAN2018	31DEC2018	N	
			Jaw fracture	01JAN1970	31DEC1970	N	
					01JAN2004	31DEC2004	N
				Meniscus injury	01JAN2018	31DEC2018	N
			Spinal compression fracture	01JAN2004	31DEC2004	N	
	Metabolism and nutrition disorders		Hypercholesterolaemia	01JAN2014		Y	
				Hypertriglyceridaemia	01JAN2014		Y
	Musculoskeletal and connective tissue disorders		Back pain	01JAN1995	31DEC1995	N	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Basal cell carcinoma	01JAN1986		Y	
				Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
	Psychiatric disorders		Depression	01JAN1973		Y	
				Insomnia	01JAN1982		Y
	Respiratory, thoracic and mediastinal disorders		Sleep apnoea syndrome	01JAN2014		Y	
	Surgical and medical procedures		Cataract operation	01JAN1998	31DEC1998	N	
					01JAN2002	31DEC2002	N
				Coronary arterial stent insertion	01JAN2014	31DEC2014	N
				Fracture treatment	01JAN1970	31DEC1970	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc operation	01JAN1970	31DEC1970	N
			Stem cell therapy	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2010	31DEC2010	N
			Vitrectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291066	Eye disorders	Myopia	01JAN1966		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
			Gastroesophageal reflux disease	01JAN2012		Y
			Hiatus hernia	01JAN2015		Y
			Large intestine polyp	01JAN2004	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN1982		Y
			Food allergy	01JAN1973		Y
				01JAN1980		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Pneumonia	01JAN2018	31DEC2018	N
			Urinary tract infection	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1973	31DEC1973	N
			Concussion	01JAN1985	31DEC1985	N
			Foot fracture	01JAN2011	31DEC2011	N
		Investigations	Arthroscopy	01JAN2003	31DEC2003	N
				01JAN2007	31DEC2007	N
			Laparoscopy	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
			Osteoarthritis	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2008		Y
			Trigger finger	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometriosis	01JAN2013		Y
		Surgical and medical procedures	Tendon sheath incision	01JAN2018	31DEC2018	N
	C4591001 1129 11291067	Eye disorders	Hypermetropia	01JAN2015		Y
			Myopia	01JAN1975		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1984		Y
			Lactose intolerance	01JAN1985		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	20JUN2020	30JUN2020	N
		Nervous system disorders	Cerebrovascular accident	01JAN2017	31DEC2017	N
		Psychiatric disorders	Libido decreased	01JAN2015		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2007	31DEC2007	N
	C4591001 1129 11291068	Blood and lymphatic system disorders	Anaemia	01MAR2020		Y
		Cardiac disorders	Coronary artery disease	01JUL2015		Y
		Endocrine disorders	Hypothyroidism	01JUL2007		Y
		Eye disorders	Hypermetropia	01JAN1956		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JUN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Catheterisation cardiac	01JUL2015	31JUL2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertriglyceridaemia	01APR2020		Y
			Vitamin B12 deficiency	01MAY2008		Y
			Vitamin D deficiency	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Social circumstances	Tobacco user	01JAN1980	31DEC2014	N
		Surgical and medical procedures	Arterial stent insertion	01JAN2018	31DEC2018	N
			Coronary arterial stent insertion	01JUL2015	31JUL2015	N
			Female sterilisation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JUL2015		Y
			Peripheral arterial occlusive disease	01JUN2018		Y
	C4591001 1129 11291074	Cardiac disorders	Atrial fibrillation	01JAN2018	31DEC2018	N
			Coronary artery disease	01JAN2013	31DEC2013	N
			Mitral valve disease	01JAN2013	31DEC2013	N
		Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Myopia	(b) (6) 1936		Y
		Gastrointestinal disorders	Diverticulum	01JAN2018	31DEC2018	N
			Short-bowel syndrome	18MAY2020		Y
		General disorders and administration site conditions	Gait disturbance	14JAN2020		Y
			Oedema peripheral	14JAN2020	29FEB2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Clostridium difficile infection	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1950		Y
			Hypertriglyceridaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscular weakness	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2017	N
		Nervous system disorders	Amnesia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Cough variant asthma	01MAY2020		Y
		Skin and subcutaneous tissue disorders	Seborrhoea	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1960	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Colectomy	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Intraocular lens implant	01JAN2010	31DEC2010	N
			Mitral valve replacement	01JAN2012	31DEC2012	N
			Vena cava filter insertion	01JUN2018	31DEC2019	N
		Vascular disorders	Deep vein thrombosis	01JUN2018	30JUN2018	N
			Vena cava thrombosis	01JAN2018	31DEC2018	N
	C4591001 1129 11291075	Cardiac disorders	Ventricular extrasystoles	01JAN1998		Y
		Eye disorders	Cataract	01JAN2015	08DEC2015 22DEC2015	N N
			Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01MAR2020		Y
		Infections and infestations	Herpes virus infection	01JAN2015		Y
			Lyme disease	01JAN2012	31DEC2012	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN2017	31DEC2017	N
			Iliotibial band syndrome	01FEB2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2010		Y
			Exostosis	01JAN2016	31DEC2016	N
				01MAR2016	31MAR2016	N
			Muscle spasms	01JAN2008		Y
			Osteoarthritis	01JAN1980		Y
				01JAN2000	31JUL2018	N
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1989		Y
			Depression	01OCT2011	29FEB2012	N
			Insomnia	01JAN1989		Y
		Surgical and medical procedures	Cataract operation	08DEC2015	08DEC2015	N
				22DEC2015	22DEC2015	N
			Knee arthroplasty	01JUL2018	31JUL2018	N
		Vascular disorders	Hot flush	01JAN1990		Y
			Orthostatic hypotension	01JAN2019		Y
			Peripheral vascular disorder	01JAN2019		Y
	C4591001 1129 11291076	Blood and lymphatic system disorders	Anaemia	01OCT2016	31DEC2018	N
		Cardiac disorders	Angina pectoris	01JAN2010	31DEC2010	N
			Atrial fibrillation	01MAY2017	30JUN2017	N
			Coronary artery disease	01JAN2010		Y
		Eye disorders	Cataract	01JAN2001	31DEC2003	N
			Myopia	01JAN1954		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Retinal tear	01JAN1998	31DEC1998	N
		General disorders and administration site conditions	Hernia	01JUN2006	31DEC2009	N
		Immune system disorders	Oedema peripheral	01MAY2017	30JUN2017	N
			Allergy to arthropod bite	01JAN1987		Y
			Food allergy	01JAN2001		Y
			Seasonal allergy	01JAN1952		Y
				01JAN2002		Y
		Infections and infestations	Urinary tract infection	02OCT2017	16OCT2017	N
		Metabolism and nutrition disorders	Gout	01JAN1972	31DEC1979	N
			Hypercholesterolaemia	01JAN2010		Y
			Overweight	01JAN1978	31DEC1985	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine with aura	01JAN1996		Y
		Psychiatric disorders	Libido decreased	28NOV2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1945	31DEC1982	N
		Social circumstances	Tobacco user	01JAN1966	31DEC1986	N
		Surgical and medical procedures	Cardiac pacemaker insertion	01AUG2010	31AUG2010	N
			Cataract operation	01JAN2003	31DEC2003	N
			Coronary artery bypass	01JUN2000	30JUN2000	N
			Hernia repair	01JAN2009	31DEC2009	N
			Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291077	Ear and labyrinth disorders	Deafness	01JAN2005		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
			Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1959	31DEC1959	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Mammoplasty	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291078	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
			Coronary artery disease	01JAN1986	31DEC1986	N
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Large intestine polyp	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Rubber sensitivity	01JAN1969		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1982		Y
			Hypercholesterolaemia	01JAN1986		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Cataract operation	01JAN2010	31DEC2010	N
			Coronary arterial stent insertion	01JAN1989	31DEC1989	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
			Peripheral nerve transposition	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
	C4591001 1129 11291080	Gastrointestinal disorders	Constipation	01JAN2010		Y
			Dyspepsia	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN1979		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Fibromyalgia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Renal and urinary disorders	Pollakiuria	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
	C4591001 1129 11291081	Endocrine disorders	Goitre	01JAN2005		Y
		Eye disorders	Myopia	01JAN1975		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Onychomycosis	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
			Perthes disease	01JAN1966	31DEC1969	N
	C4591001 1129 11291083	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Infections and infestations	Urinary tract infection	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1963	31DEC1963	N
				01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Pollakiuria	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Knee operation	01JAN1992	31DEC1992	N
			Nasal septal operation	01JAN2012	31DEC2012	N
	C4591001 1129 11291084	Eye disorders	Cataract	01JAN2009		Y
					31DEC2014	N
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
			Urinary tract infection	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Scapula fracture	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2008	31DEC2008	N
			Osteopenia	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV2004	31JAN2005	N
			Uterine leiomyoma	01JAN1976	31DEC1976	N
		Nervous system disorders	Headache	01JAN1990		Y
			Subarachnoid haemorrhage	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1954	31DEC1954	N
			Breast conserving surgery	01JAN2005	31DEC2005	N
			Cataract operation	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1976	31DEC1976	N
			Knee operation	01JAN2008	31DEC2008	N
	C4591001 1129 11291085	Blood and lymphatic system disorders	Thrombocytopenia	01JAN2011		Y
		Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2018	31DEC2018	N
			Tibia fracture	01JAN2017	31DEC2017	N
		Investigations	Catheterisation cardiac	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Overweight	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Non-Hodgkin's lymphoma	01JAN2007	31DEC2009	N
			Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Headache	01JAN1976		Y
			Migraine	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1982	31DEC1990	N
		Surgical and medical procedures	Cancer surgery	01JAN2014	31DEC2014	N
			Cardiac ablation	01JAN2019	31DEC2019	N
			Cardiac pacemaker insertion	01JAN2018		Y
			Rotator cuff repair	01JAN2004	31DEC2004	N
				01JAN2007	31DEC2007	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1129 11291086	Eye disorders	Cataract	01JAN2010		Y
			Hypermetropia	01JAN1995		Y
			Maculopathy	01JAN2019		Y
			Myopia	01JAN1962		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
			Gastroesophageal reflux disease	01JAN1985		Y
			Large intestine polyp	01JAN2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Rhinitis	01JAN2010		Y
			Sinusitis	01JAN2010		Y
			Tonsillitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Vitamin D deficiency	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1979	31DEC2017	N
			Squamous cell carcinoma of skin	01JAN2010	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013		Y
			Transient ischaemic attack	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010		Y
		Surgical and medical procedures	Stem cell transplant	01OCT2018	31OCT2018	N
			Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1129 11291087	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Eye disorders	Cataract	01JAN2014	31DEC2015	N
		Gastrointestinal disorders	Constipation	01JAN1995	31DEC2017	N
			Diarrhoea	01JAN1995	31DEC2017	N
			Diverticulum	01JAN2012		Y
			Dyspepsia	01JAN1955		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2000	31DEC2000	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1996	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
				01JAN1990		Y
			Food allergy	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Fungal infection	01JAN2000	31DEC2017	N
			Urinary tract infection	01JAN1972	31DEC1975	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN1994		Y
			Overweight	01JAN1990	31DEC2019	N
			Vitamin B12 deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2008	31DEC2014	N
			Muscle spasms	01JAN2017		Y
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN1996	30SEP2019	N
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Depression	01JAN1967		Y
			Insomnia	01JAN1996		Y
			Libido decreased	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1976	31DEC1976	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1955		Y
			Rosacea	01JAN1955	31DEC2017	N
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2018	31DEC2018	N
			Large intestinal polypectomy	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
			Metabolic surgery	01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN1976	31DEC1976	N
			Skin neoplasm excision	01SEP2019	30SEP2019	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
			Urethral dilation procedure	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1129 11291090	Eye disorders	Hypermetropia	01JAN1963		Y
			Myopia	01JAN1963		Y
		Gastrointestinal disorders	Constipation	01JAN1962		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Hypertriglyceridaemia	01JAN1990		Y
			Overweight	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Muscle spasms	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291091	Eye disorders	Hypermetropia	01JAN2005		Y
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Spinal decompression	01JAN1985	31DEC1985	N
				01JAN1995	31DEC1995	N
				01JAN2015	31DEC2015	N
	C4591001 1129 11291093	Endocrine disorders	Hypothyroidism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Foot deformity	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Bunion operation	01JAN2009	31DEC2009	N
			Meniscus operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1129 11291094	Cardiac disorders	Angina pectoris	01JAN2000		Y
			Arrhythmia	01JAN1975		Y
			Supraventricular tachycardia	01JAN1975		Y
		Ear and labyrinth disorders	Vertigo	01JUN2020	15JUN2020	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Cataract	01JAN2016		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Fungal skin infection	19DEC2017		Y
		Metabolism and nutrition disorders	Overweight	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
			Osteoarthritis	01JAN2008		Y
			Trigger finger	01JAN2017		Y
		Renal and urinary disorders	Nephropathy	01JAN1995		Y
			Renal disorder	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN2006	31DEC2006	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01DEC2006	31DEC2006	N
			Knee arthroplasty	01APR2018	30APR2018	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1129 11291095	Gastrointestinal disorders	Constipation	01JAN1975		Y
			Diarrhoea	01JAN1975		Y
			Gastroesophageal reflux disease	01JAN1980		Y
			Irritable bowel syndrome	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Metabolism and nutrition disorders	Overweight	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
			Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2009		Y
			Scoliosis	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	30JUN2020	N
		Nervous system disorders	Sciatica	01JAN2010	31DEC2019	N
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1970		Y
			Libido decreased	01JAN1984		Y
		Renal and urinary disorders	Pollakiuria	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1980		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Face lift	01JAN2015	31DEC2015	N
			Gastric bypass	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Mammoplasty	01JAN2012	31DEC2012	N
			Rectocele repair	01JAN2007	31DEC2007	N
			Skin neoplasm excision	01JUN2020	31DEC2020	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Myopia	01JAN1970	31DEC2006	N
	C4591001 1129 11291099	Eye disorders				
		Injury, poisoning and procedural complications	Ligament rupture	01MAY2014	31MAY2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Vitamin D deficiency	01JAN2014	31DEC2017	N
		Nervous system disorders	Headache	01JAN1958		Y
		Surgical and medical procedures	Keratomileusis	01JAN2006	31DEC2006	N
			Ligament operation	01MAY2014	31MAY2014	N
			Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1129 11291100	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Glaucoma	01APR2020		Y
			Hypermetropia	01JAN2005		Y
			Myopia	01JAN1998		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2010	31DEC2010	N
		Immune system disorders	Food allergy	01JAN1964		Y
			Seasonal allergy	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Iridotomy	01JUN2020	30JUN2020	N
			Mammoplasty	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1129 11291101	Eye disorders	Hypermetropia	01JAN2012		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Rotator cuff syndrome	01JAN1990	31DEC1990	N
				01JAN2018	31DEC2018	N
		Nervous system disorders	Amnesia	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2016		Y
		Surgical and medical procedures	Meniscus operation	01JAN1990	31DEC1990	N
			Rotator cuff repair	01JAN1990	31DEC1990	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1129 11291102	Eye disorders	Cataract	01JAN2017	30APR2019	N
			Hypermetropia	01APR2019		Y
		Gastrointestinal disorders	Constipation	01JAN1970		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2010		Y
		Infections and infestations	Rectal abscess	01JAN1971	31DEC1971	N
			Urinary tract infection	01JAN2012		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012		Y
			Hypercholesterolaemia	01JAN1990		Y
			Hypertriglyceridaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Polymyalgia rheumatica	01JAN2013	31DEC2015	N
		Nervous system disorders	Dizziness	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Depression	01JAN1970		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2015		Y
		Surgical and medical procedures	Abscess drainage	01JAN1971	31DEC1971	N
			Cataract operation	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291103	Cardiac disorders	Ventricular extrasystoles	01JAN1990		Y
		Ear and labyrinth disorders	Tinnitus	01JAN1991		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN1957		Y
		Gastrointestinal disorders	Diverticulum	01JAN1995		Y
			Gastroesophageal reflux disease	01JAN1995		Y
			Irritable bowel syndrome	01JAN1992		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Urinary tract infection	01JAN2009	31DEC2013	N
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Sciatica	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN1999		Y
			Insomnia	01JAN2009		Y
			Libido decreased	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
			Prostatomegaly	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Hypoxia	01JAN1991		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	15MAY1952	15MAY1952	N
			Aneurysm repair	01DEC2015	31DEC2015	N
			Cardiac ablation	11DEC2015	11DEC2015	N
				15MAY2009	21MAY2009	N
			Cardioversion	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN1998	31DEC1998	N
				01JAN1999	31DEC1999	N
			Lesion excision	08AUG2008	08AUG2008	N
			Nasal septal operation	26AUG2015	26AUG2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Penile prosthesis insertion	23MAY2017	23MAY2017	N
			Skin lesion removal	14FEB2013	14FEB2013	N
			Tonsillectomy	15MAY1952	15MAY1952	N
			Turbinectomy	26AUG2015	26AUG2015	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1129 11291105	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN2018		Y
			Myopia	01JAN1973		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Injury, poisoning and procedural complications	Avulsion fracture	01JAN1980	31DEC1980	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2018	31DEC2018	N
			Neoplasm of appendix	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1129 11291107	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Eye disorders	Hypermetropia	01JAN1967	31DEC2009	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01SEP2015	30NOV2015	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01MAR2010	31MAR2010	N
			Uterine leiomyoma	01JAN1998	31DEC2015	N
		Nervous system disorders	Sciatica	01JAN2018		Y
		Surgical and medical procedures	Abdominoplasty	01NOV2017	30NOV2017	N
			Caesarean section	01JAN1986	31DEC1986	N
				01JAN1994	31DEC1994	N
			Hysterectomy	01JAN2015	31DEC2015	N
				01JUN2015	30JUN2015	N
			Keratomileusis	01JAN2009	31DEC2009	N
			Parathyroidectomy	01MAR2010	31MAR2010	N
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1129 11291108	Eye disorders	Astigmatism	01JAN1995		Y
			Retinal detachment	01JAN1975	31DEC1975	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1965	31DEC1971	N
		Social circumstances	Tobacco user	01JAN1968	31DEC1979	N
		Surgical and medical procedures	Aortic aneurysm repair	01JUN2018	30JUN2018	N
			Retinopexy	01JAN1975	31DEC1975	N
		Vascular disorders	Aortic aneurysm	01JAN2018	30JUN2018	N
			Hypertension	01JAN1996		Y
	C4591001 1129 11291109	Blood and lymphatic system disorders	Thrombocytopenia	01JAN2013	31DEC2017	N
		Eye disorders	Myopia	01JAN1969		Y
		Immune system disorders	Hypersensitivity	01JAN1974	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1974	31DEC1976	N
		Investigations	Cardiac murmur	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	31DEC2017	N
		Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1129 11291110	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2014	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1990	31DEC2000	N
	C4591001 1129 11291111	Blood and lymphatic system disorders	Anaemia	01JAN1990	31DEC1990	N
		Endocrine disorders	Basedow's disease	01JAN2000	31DEC2001	N
			Hypothyroidism	01JAN2001		Y
		Eye disorders	Cataract	01JAN2000		Y
					31DEC2018	N
		Gastrointestinal disorders	Constipation	01JAN1980		Y
			Diverticulum	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Investigations	Ejection fraction decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2010	31DEC2010	N
			Uterine leiomyoma	01JAN2003		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tremor	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01JAN2008		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980		Y
			Polycystic ovaries	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2001		Y
		Social circumstances	Tobacco user	01JAN1970	31DEC1980	N
		Surgical and medical procedures	Cancer surgery	01JAN2010	31DEC2010	N
			Cataract operation	01JAN2018	31DEC2018	N
			Radiotherapy to thyroid	01JAN2000	31DEC2000	N
		Ear and labyrinth disorders	Deafness	01JAN2015		Y
			Hypermetropia	01JAN2000		Y
		Eye disorders	Inguinal hernia	01JAN1980	31DEC1980	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
			Seasonal allergy	01JAN2010		Y
		Immune system disorders	Staphylococcal infection	01JAN2017	31DEC2017	N
		Infections and infestations	Facial bones fracture	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Hypercholesterolaemia	01JAN2019		Y
		Metabolism and nutrition disorders	Intervertebral disc degeneration	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2017	N
			Spinal stenosis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1990	31DEC1990	N
			Sciatica	01JAN2016	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Tobacco user	01JAN1963	31DEC1975	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN1980	31DEC1980	N
			Intervertebral disc operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1129 11291113	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Myopia	01JAN1975		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1965		Y
				01JAN1980		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2007		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2015		Y
			Retrognathia	01JAN1959		Y
			Scoliosis	01JAN1959		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1977		Y
			Sleep apnoea syndrome	25SEP2018		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1977	31DEC1977	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1129 11291114	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Eye disorders	Cataract	01JAN2015	31DEC2016	N
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
			Dyspepsia	01JAN2014		Y
			Gastric ulcer	01JAN2010	31DEC2010	N
			Gastrooesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Rubber sensitivity	01JAN1969		Y
			Seasonal allergy	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteoarthritis	01JAN2000		Y
			Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUN2020	30JUN2020	N
				01MAR2020	31MAR2020	N
			Breast cancer	01JAN2007	31DEC2007	N
			Squamous cell carcinoma	01MAR2020	31MAR2020	N
			Uterine leiomyoma	01JAN1978	31DEC1980	N
		Renal and urinary disorders	Bladder prolapse	01JAN2009		Y
		Social circumstances	Tobacco user	01JAN1959	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Blepharoplasty	01JAN2015	31DEC2015	N
			Breast conserving surgery	01JAN2007	31DEC2007	N
			Cancer surgery	01MAR2020	31MAR2020	N
			Cataract operation	01DEC2016	31DEC2016	N
			Hysterectomy	01JAN1980	31DEC1980	N
			Skin neoplasm excision	01JUN2020	30JUN2020	N
				01MAR2020	31MAR2020	N
	C4591001 1129 11291115	Blood and lymphatic system disorders	Anaemia	01JAN1970	31DEC1985	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN1961		Y
		Gastrointestinal disorders	Periodontal disease	01JAN2014		Y
		Immune system disorders	Food allergy	01JAN1970		Y
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
			Urinary tract infection	01JAN1970	31DEC1970	N
		Investigations	Cardiac murmur	01JAN1990		Y
			Hepatitis C antibody positive	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
			Periarthritis	01JAN1990	31DEC1995	N
			Tenosynovitis stenosans	01JAN2007	31DEC2007	N
			Trigger finger	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1985	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1970		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC2002	N
		Surgical and medical procedures	Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1129 11291116	Eye disorders	Hypermetropia	01JAN2001		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1979		Y
			Large intestine polyp	01JUL2016	31JUL2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2016	31DEC2016	N
		Investigations	Biopsy testes	01JAN1990	31DEC1990	N
			Blood testosterone decreased	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoid cystic carcinoma	01JAN1992	31DEC1992	N
			Extragenital primary seminoma (pure)	01JAN1992	31DEC1992	N
			Lip and/or oral cavity cancer	01JAN1992	31DEC1992	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1995		Y
		Surgical and medical procedures	Incisional hernia repair	01JAN2016	31DEC2016	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Patellectomy	01JAN1992	31DEC1992	N
			Sternotomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291118	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Ear and labyrinth disorders	Deafness	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN1965		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1985	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
			Herpes simplex	01JAN2005		Y
			Tonsillitis	01JAN1967	31DEC1967	N
		Investigations	Heart rate irregular	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Osteoarthritis	01JAN2010		Y
			Sjogren's syndrome	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2018	N
			Squamous cell carcinoma of skin	01JAN2010	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2014	31DEC2014	N
			Diabetic neuropathy	01JAN2010		Y
			Headache	01JAN1956		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
			Libido decreased	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1961	31DEC1973	N
		Surgical and medical procedures	Adenoidectomy	01JAN1967	31DEC1967	N
			Appendicectomy	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN1985	31DEC1985	N
			Sinus operation	01JAN1980	31DEC1980	N
				01JAN1993	31DEC1993	N
				01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN1990		Y
			Poor peripheral circulation	01JAN2010		Y
	C4591001 1129 11291119	Cardiac disorders	Atrial fibrillation	01JUL2019	31OCT2019	N
			Supraventricular tachycardia	01DEC2017	31JUL2019	N
		Eye disorders	Hypermetropia	01JAN1977		Y
			Myopia	01JAN1977		Y
		Gastrointestinal disorders	Large intestine polyp	17NOV2017	17NOV2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Infections and infestations	Tonsillitis streptococcal	01JAN1982	31DEC1982	N
		Investigations	Biopsy breast	01JAN1990	31DEC1990	N
				01JAN2000	31DEC2000	N
				01JAN2015	31DEC2015	N
			Biopsy lung	07OCT2011	07OCT2011	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2010		Y
			Spinal osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Sciatica	12SEP2016	31MAR2017	N
		Psychiatric disorders	Anxiety	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cardiac ablation	09JUL2019	09JUL2019	N
				15OCT2019	15OCT2019	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Pulmonary resection	07OCT2011	07OCT2011	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1982	31DEC1982	N
	C4591001 1129 11291121	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Urinary tract infection	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Overweight	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Fallopian tube obstruction	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1129 11291122	Ear and labyrinth disorders	Vertigo	01JAN2013	31DEC2013	N
		Eye disorders	Cataract	01APR2019	30APR2019	N
			Hypermetropia	01MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Large intestine polyp	01JAN2013	31DEC2013	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Allergy to animal	01JAN1979		Y
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01APR2019	30APR2019	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1129 11291123	Blood and lymphatic system disorders	Splenic lesion	01JAN2015		Y
		Ear and labyrinth disorders	Deafness	01JAN2017		Y
			Vertigo	01JAN2019	31DEC2019	N
		Eye disorders	Conjunctival haemorrhage	01JAN2014	31DEC2014	N
			Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y
		Investigations	Biopsy prostate	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Biopsy skin	01JAN2017	31DEC2017	N
			Liver function test abnormal	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2005		Y
			Overweight	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
			Squamous cell carcinoma of skin	01JAN2017	31DEC2017	N
		Nervous system disorders	Headache	01JAN2000		Y
			Parkinson's disease	01JAN2018		Y
			Tremor	01JAN2014		Y
		Psychiatric disorders	Libido decreased	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Tobacco user	01JAN1965	31DEC1990	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291125	Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Hypermetropia	01JAN1994		Y
		Gastrointestinal disorders	Diverticulum	07JUL2020	07JUL2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Diverticulitis	01JAN2008	31DEC2008	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Upper limb fracture	01FEB2020	30JUN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2008	31DEC2008	N
		Nervous system disorders	Tremor	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Colectomy	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1129 11291126	Ear and labyrinth disorders	Deafness	01JAN1995		Y
		Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Hiatus hernia	13MAY2020		Y
			Inguinal hernia	14OCT2013	17NOV2013	N
			Irritable bowel syndrome	01JAN2012		Y
			Large intestine polyp	01OCT1995	31OCT1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2012		Y
		Injury, poisoning and procedural complications	Spinal compression fracture	01JUN2019		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin B12 deficiency	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Intervertebral disc degeneration	01JAN1980		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN1990	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Libido decreased	01JAN1990		Y
		Renal and urinary disorders	Renal cyst	13MAY2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	07MAY2019		Y
			Pleural calcification	07MAY2019		Y
		Surgical and medical procedures	Face lift	01JAN1998	31DEC1998	N
			Inguinal hernia repair	17NOV2013	17NOV2013	N
			Neck lift	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1129 11291127	Blood and lymphatic system disorders	Anaemia	01MAR2020		Y
		Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Eye disorders	Myopia	01JAN2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
			Haemorrhoids	01MAY2020		Y
			Large intestine polyp	18MAY2020	18MAY2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Infections and infestations	Diverticulitis	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN1990		Y
	C4591001 1129 11291128	Immune system disorders	Seasonal allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Vitamin B12 deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
	C4591001 1129 11291130	Eye disorders	Cataract	01JAN2000	30APR2019	N
			Hypermetropia	01APR2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2000	31DEC2000	N
		Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
			Tonsillitis	01JAN1943	31DEC1943	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN1968	31DEC1998	N
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Cataract operation	01APR2019	30APR2019	N
			Tonsillectomy	01JAN1943	31DEC1943	N
	C4591001 1129 11291131	Eye disorders	Hypermetropia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
			Gastroesophageal reflux disease	01JAN1995		Y
			Irritable bowel syndrome	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Pilonidal cyst	01JAN1978	31DEC1978	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Dysmenorrhoea	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Allergic cough	01JAN1990		Y
		Social circumstances	Tobacco user	01JAN1972	31DEC1991	N
		Surgical and medical procedures	Endometrial ablation	01JAN2000	31DEC2000	N
			Knee operation	01JAN1995	31DEC1995	N
			Mammoplasty	01JAN1999	31DEC1999	N
			Pilonidal sinus repair	01JAN1978	31DEC1978	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1129 11291132	Ear and labyrinth disorders	Deafness	01JAN1979		Y
		Eye disorders	Myopia	01JAN1997		Y
		Gastrointestinal disorders	Diverticulum	01JAN1999	31DEC2000	N
		Immune system disorders	Allergy to animal	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN1980		Y
		Social circumstances	Tobacco user	01JAN1975	30APR2018	N
		Surgical and medical procedures	Colectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291133	Ear and labyrinth disorders	Deafness	01JAN2003		Y
		Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Ear operation	01JAN2003		Y
			Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1129 11291134	Ear and labyrinth disorders	Cerumen impaction	01JAN1950		Y
		Eye disorders	Cataract	01JAN1985		Y
			Macular degeneration	01JAN2014		Y
			Myopia	01JAN1948		Y
			Retinal detachment	10FEB2010		Y
		Gastrointestinal disorders	Diarrhoea	01JAN1960		Y
			Diverticulum	01JAN1993		Y
			Dyspepsia	01JAN1960		Y
			Inguinal hernia	01JAN2015		Y
			Large intestine polyp	01JAN1993	31DEC1993	N
		Immune system disorders	Seasonal allergy	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1985	31DEC1985	N
			Clavicle fracture	01JAN1943	31DEC1943	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2012	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
			Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Prostatectomy	01JAN2012	31DEC2012	N
	C4591001 1129 11291136	Eye disorders	Myopia	01JAN1956		Y
		Gastrointestinal disorders	Diarrhoea	01JUN2018		Y
		Infections and infestations	Onychomycosis	01JAN2005		Y
			Urinary tract infection	01JUN2019		Y
		Injury, poisoning and procedural complications	Subdural haematoma	26JUL2019	18JUN2020	N
		Metabolism and nutrition disorders	Overweight	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005	31DEC2010	N
			Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2017	N
			Uterine leiomyoma	01JAN1987	31DEC1989	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
			Seizure	26JUL2019	26JUL2019	N
			Subarachnoid haemorrhage	01MAR2019	30APR2019	N
		Renal and urinary disorders	Bladder prolapse	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Tobacco user	01JAN1968	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bladder repair	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1129 11291137	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Allergy to animal	01JAN2005		Y
			Seasonal allergy	01JAN2005		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Hypertriglyceridaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
				01JUN2020		Y
			Foot deformity	01JAN1980	31DEC1990	N
			Osteopenia	01JAN2012		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019		Y
		Surgical and medical procedures	Bunion operation	01JAN1990	31DEC1990	N
			Fracture treatment	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1129 11291138	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JAN2002		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Iritis	22NOV2010	22NOV2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ocular ischaemic syndrome	01JAN2018		Y
			Open angle glaucoma	01JAN2018		Y
			Retinal detachment	12APR2012	31DEC2014	N
		General disorders and administration site conditions	Therapy responder	29OCT2018		Y
		Hepatobiliary disorders	Hepatic steatosis	11FEB2003		Y
		Immune system disorders	Allergic oedema	01JAN2017		Y
			Drug hypersensitivity	01JAN1958		Y
				01JAN1973		Y
				01JAN2017		Y
			Food allergy	01JAN1953		Y
				01JAN1975		Y
			Seasonal allergy	01JAN2003		Y
		Infections and infestations	Encephalitis	01JAN2002	31DEC2002	N
			Fungal skin infection	28SEP2016	31DEC2016	N
			Lyme disease	08AUG2011	31DEC2011	N
			Meningitis viral	01JAN2002	31DEC2002	N
			Tropical ulcer	15JUL2019	31DEC2019	N
			Upper respiratory tract infection	27JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Iliotibial band syndrome	01JAN2000		Y
			Wrist fracture	01JAN1965	31DEC1965	N
		Investigations	Arthroscopy	01JAN1985	31DEC1985	N
				01JAN1993	31DEC1993	N
				21NOV2005	21NOV2005	N
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Ligament disorder	26JUL2017		Y
			Osteoarthritis	01JAN1998		Y
			Temporomandibular joint syndrome	26JUL2004		Y
		Nervous system disorders	Diabetic neuropathy	27OCT2009		Y
			Hemiplegia	01JAN2002		Y
			Spasmodic dysphonia	04AUG2003		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961	31DEC2016	N
			Sleep apnoea syndrome	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Surgical and medical procedures	Bone cyst excision	01JAN1979	31DEC1979	N
			Bone operation	14JUN2017	14JUN2017	N
			Cataract operation	01JAN2018	31DEC2018	N
			Elbow operation	30JAN2019	30JAN2019	N
			Eye laser surgery	19NOV2014	19NOV2014	N
			Fascia release	07JUL2015	07JUL2015	N
			Injection	17APR2020	17APR2020	N
			Knee arthroplasty	10OCT2014	10OCT2014	N
				15AUG2013	15AUG2013	N
				20AUG2019	20AUG2019	N
			Knee operation	01JAN2000	31DEC2000	N
				13MAY2010	13MAY2010	N
			Ligament operation	01JUL1996	31JUL1996	N
			Skin neoplasm excision	13NOV2015	13NOV2015	N
			Spinal fusion surgery	01JAN2018	31DEC2018	N
			Spinal laminectomy	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tenotomy	05APR2006	05AUG2006	N
				20JUL2009	20JUL2009	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1129 11291139	Endocrine disorders	Hyperthyroidism	01MAY1996	31MAY1996	N
			Hypothyroidism	01DEC1996		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
			Vitreous detachment	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Coeliac disease	01JAN2017		Y
			Constipation	01JAN2010		Y
			Duodenal ulcer	01JAN1970	31MAY1970	N
			Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Cyst	01JAN2012	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01SEP1986		Y
			Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN2006	31DEC2006	N
			Infectious mononucleosis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Arthropod bite	01JUN2020	04JUN2020	N
			Contusion	01JAN1969	31DEC1969	N
		Investigations	Cardiac murmur	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2009	31DEC2009	N
				01JAN2012	31DEC2012	N
			Osteoarthritis	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoporosis	01JAN2016		Y
			Spinal stenosis	01JAN2018		Y
		Nervous system disorders	Piriformis syndrome	01OCT2017		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2002		Y
		Reproductive system and breast disorders	Bartholin's cyst	01JUN2008	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	03MAR2006		Y
	C4591001 1129 11291140	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Cardiac disorders	Aortic valve sclerosis	06APR2017		Y
			Aortic valve stenosis	16MAY2018		Y
			Mitral valve prolapse	06APR2017		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Myopia	01JAN1985		Y
		Gastrointestinal disorders	Constipation	01JAN1990		Y
			Gastroesophageal reflux disease	01JAN2010		Y
			Haemorrhoids	01JUL2012		Y
			Inguinal hernia	01JAN1999	31DEC2000	N
		Injury, poisoning and procedural complications	Decompression sickness	01AUG2019	31DEC2019	N
			Meniscus injury	01MAY2012	31JUL2012	N
		Investigations	Cardiac murmur	01JAN2017		Y
			Catheterisation cardiac	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Vitamin B12 deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2013	31JAN2014	N
			Muscular weakness	01AUG2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01MAR2020		Y
			Spinal stenosis	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2017	N
			Squamous cell carcinoma of skin	01JAN2005	31DEC2019	N
		Nervous system disorders	Carotid artery stenosis	27JUN2018		Y
			Lumbar radiculopathy	01MAR2020	01JUN2020	N
			Sciatica	01JAN2009	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
			Prostatomegaly	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2014	31DEC2014	N
			Cataract operation	01JAN2016	31DEC2016	N
			Haemorrhoid operation	01JAN2005	31DEC2005	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Meniscus operation	01JUL2012	31JUL2012	N
		Vascular disorders	Hypertension	27JUN2018		Y
	C4591001 1129 11291146	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JUN2014	30JUN2014	N
		Surgical and medical procedures	Hysterectomy	01DEC2014	31DEC2014	N
	C4591001 1129 11291147	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Large intestine polyp	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Overweight	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1129 11291149	Cardiac disorders	Cardiac failure	01JAN2007		Y
			Cardiomyopathy	01JAN2007		Y
			Palpitations	01JAN2007		Y
		Eye disorders	Hypermetropia	01JAN1965		Y
			Myopia	01JAN1965		Y
		Gastrointestinal disorders	Oral lichen planus	01JAN2005		Y
		General disorders and administration site conditions	Chest pain	01JAN2016	31DEC2016	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1980	31DEC1980	N
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1978	31DEC1978	N
			Ligament rupture	01JAN2010	31DEC2010	N
		Investigations	Catheterisation cardiac	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2007		Y
			Vitamin B12 deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2018		Y
			Osteopenia	01JAN2009		Y
			Rotator cuff syndrome	01OCT2017	31OCT2017	N
		Psychiatric disorders	Libido decreased	01JAN2007		Y
		Renal and urinary disorders	Micturition urgency	01JAN2007		Y
		Reproductive system and breast disorders	Adnexal torsion	01JAN1960	31DEC1960	N
		Respiratory, thoracic and mediastinal disorders	Organising pneumonia	01JAN2001	31DEC2001	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2007		Y
			Seborrhoeic dermatitis	01JAN2005		Y
		Social circumstances	Tobacco user	01JAN1969	31DEC1993	N
		Surgical and medical procedures	Cholecystectomy	01JAN1980	31DEC1980	N
			Ligament operation	01JAN2010	31DEC2010	N
			Rotator cuff repair	01OCT2017	31OCT2017	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Aortic aneurysm	01JAN2016		Y
			Hypertension	01JAN2000		Y
	C4591001 1129 11291150	Cardiac disorders	Bradycardia	01JAN1990		Y
		Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Constipation	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Seizure	01JAN1967		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Pterygium operation	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1949	31DEC1949	N
		Vascular disorders	White coat hypertension	01JAN1990		Y
	C4591001 1129 11291151	Eye disorders	Myopia	01JAN1971	31DEC2000	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Reproductive system and breast disorders	Uterine prolapse	01DEC2005	31DEC2005	N
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Oophorectomy bilateral	01DEC2005	31DEC2005	N
	C4591001 1129 11291152	Eye disorders	Cataract	01JAN1999	31DEC2007	N
			Dry eye	01JAN2007		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Infections and infestations	Fungal skin infection	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1989		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1972	31DEC1999	N
			Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1970	31DEC1972	N
		Nervous system disorders	Amnesia	01JAN2017		Y
			Diabetic neuropathy	01JAN2001		Y
			Sciatica	01JAN1999		Y
		Psychiatric disorders	Libido decreased	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	06NOV1972	06NOV1972	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc operation	01AUG1999	31AUG1999	N
			Intraocular lens implant	01JAN2007	31DEC2007	N
			Spinal fusion surgery	01AUG1996	31AUG1996	N
		Vascular disorders	Hypertension	01JAN1972		Y
	C4591001 1129 11291154	Eye disorders	Glaucoma	01FEB2018		Y
			Myopia	01JAN2012		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
			Knee operation	01JAN2009	31DEC2009	N
	C4591001 1129 11291155	Cardiac disorders	Myocardial infarction	01JAN2000	31DEC2000	N
			Pericarditis	01JAN2008	31DEC2008	N
		Eye disorders	Hypermetropia	01JAN2002		Y
		General disorders and administration site conditions	Oedema peripheral	07AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Investigations	Catheterisation cardiac	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Overweight	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2000	31DEC2000	N
				01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
			Coronary artery bypass	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291158	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2002		Y
		Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Diverticulum	01JAN2007		Y
			Gastroesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN1995		Y
			Large intestine polyp	01JAN2007	31DEC2013	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1946		Y
			Milk allergy	01JAN1980		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Poliomyelitis	01JAN1946	31DEC1946	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1945	31DEC1948	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2019	N
			Colon cancer	01JAN2013	31DEC2013	N
			Squamous cell carcinoma of skin	01JAN2000	31DEC2019	N
		Nervous system disorders	Vocal cord paralysis	01JAN1946		Y
		Renal and urinary disorders	Pollakiuria	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Nasal septum deviation	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Colectomy	01JAN2013	31DEC2013	N
			Hernia repair	01JAN2002	31DEC2002	N
				01JAN2012	31DEC2012	N
			Micrographic skin surgery	01JAN2000	31DEC2000	N
				01JAN2019	31DEC2019	N
			Nasal septal operation	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1129 11291159	Cardiac disorders	Bradycardia	01JAN2018		Y
		Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Eye disorders	Dry eye	01JAN2015		Y
			Hypermetropia	01JAN1969		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Large intestine polyp	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2008		Y
		Infections and infestations	Fungal skin infection	01JAN2016		Y
		Injury, poisoning and procedural complications	Urethral stricture traumatic	01JAN1976	31DEC1976	N
		Investigations	Tuberculin test positive	01JUL2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
			Overweight	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin B6 deficiency	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1976		Y
			Intervertebral disc degeneration	01APR2017		Y
			Muscle spasms	01JAN1977		Y
			Osteoarthritis	01JAN2019		Y
			Osteoporosis	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2018		Y
			Restless legs syndrome	01JAN1976		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2019		Y
		Renal and urinary disorders	Bladder spasm	01JAN1976		Y
			Nephrolithiasis	01JAN2017	31JUL2017	N
			Pollakiuria	01JAN1976		Y
			Renal cyst	01DEC2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
			Prostatomegaly	01JAN1976		Y
		Surgical and medical procedures	Inguinal hernia repair	01NOV2017	30NOV2017	N
			Renal stone removal	01JAN2017	31JAN2017	N
				01JUL2017	31JUL2017	N
				01JUN2017	30JUN2017	N
			Urethral operation	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1129 11291160	Ear and labyrinth disorders	Deafness	01JAN2011		Y
		Eye disorders	Myopia	01JAN1966		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2015	N
				01JAN2015	31DEC2016	N
			Large intestine polyp	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Libido decreased	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1129 11291161	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
		Eye disorders	Cataract	01JAN2018		Y
			Hypermetropia	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Respiratory fume inhalation disorder	01JAN1965		Y
		Investigations	Catheterisation cardiac	01JAN2011	31DEC2011	N
				01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
			Vitamin B12 deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Spinal osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN1965	31DEC1972	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
	C4591001 1129 11291162	Blood and lymphatic system disorders	Anaemia	01JAN2013		Y
		Cardiac disorders	Angina pectoris	01JAN2016	31DEC2016	N
			Cardiac disorder	01OCT2014	31OCT2014	N
			Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31DEC2014	N
		Eye disorders	Cataract	01JAN2018		Y
			Hypermetropia	01JAN2016		Y
			Myopia	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1985		Y
			Gastric ulcer	01JAN1969	31DEC1969	N
			Gastrooesophageal reflux disease	01JAN1985		Y
			Impaired gastric emptying	01JAN2010		Y
		General disorders and administration site conditions	Calcinosis	01JAN1985		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2013		Y
			Seasonal allergy	01JAN1974		Y
		Infections and infestations	Clostridium difficile infection	01JAN2013	31DEC2013	N
			Urinary tract infection	01JAN1975	31DEC1975	N
				01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Post procedural diarrhoea	01JAN2013		Y
		Investigations	Catheterisation cardiac	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Hypokalaemia	01JAN2013		Y
			Vitamin B12 deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	CREST syndrome	01JAN1984		Y
			Scleroderma	01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1986	31DEC1986	N
		Reproductive system and breast disorders	Endometriosis	01JAN1970	31DEC1988	N
		Social circumstances	Tobacco user	01JAN1979	31DEC1985	N
		Surgical and medical procedures	Appendectomy	01OCT2013	31OCT2013	N
			Calcific deposits removal	01JAN1989	31DEC1989	N
				01JAN1990	31DEC1990	N
			Cholecystectomy	01OCT2013	31OCT2013	N
			Colostomy	01JUL2013	31JUL2013	N
			Colostomy closure	01OCT2013	31OCT2013	N
			Coronary arterial stent insertion	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Intestinal resection	01JUL2013	31JUL2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291166	Ear and labyrinth disorders	Deafness	01JAN2017		Y
		Eye disorders	Astigmatism	01JAN1955		Y
			Cataract	01JAN2017		Y
					31DEC2017	N
			Hypermetropia	01JAN1965		Y
			Myopia	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Diarrhoea	01DEC2019	31MAR2020	N
			Hiatus hernia	01JAN2017		Y
			Oesophageal stenosis	01MAR2020	30APR2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1950		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
	C4591001 1129 11291167	Cardiac disorders	Angina pectoris	01JAN2019		Y
			Coronary artery disease	01OCT2019		Y
			Palpitations	01JAN2018		Y
		Eye disorders	Cataract	01JAN2017	31JAN2018	N
			Visual impairment	01JAN1985		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1970	31DEC1980	N
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Infections and infestations	Acute sinusitis	07AUG2020	10AUG2020	N
			Appendicitis	01JAN1951	31DEC1951	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
		Investigations	Catheterisation cardiac	01OCT2019	31OCT2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Vitamin B12 deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUN2020	31AUG2020	N
		Nervous system disorders	Transient ischaemic attack	01JAN2018	31DEC2018	N
			Tremor	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JUN2019	30JUN2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Prostatomegaly	01JAN2018		Y
			Appendicectomy	01JAN1951	31DEC1951	N
			Cataract operation	01JAN2018	31JAN2018	N
			Coronary arterial stent insertion	01OCT2019	31OCT2019	N
			Meniscus operation	01JAN2008	31DEC2008	N
	C4591001 1129 11291170	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Cataract	01MAR2020		Y
			Dry eye	01JAN2010		Y
			Retinal tear	01JAN2008	31DEC2008	N
		Gastrointestinal disorders	Large intestine polyp	01JAN2000	31DEC2000	N
				01JAN2015	31DEC2015	N
				01JUN2020	30JUN2020	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2017		Y
				01JAN2005		Y
		Infections and infestations	Bronchitis	01JAN2010	31DEC2010	N
			Ear infection	01AUG2020	31AUG2020	N
			Oral herpes	01JAN1980		Y
		Investigations	Laparoscopy	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Tendonitis	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1978		Y
		Skin and subcutaneous tissue disorders	Rash	18AUG2020	19AUG2020	N
		Surgical and medical procedures	Keratomileusis	01JAN2008	31DEC2008	N
	C4591001 1129 11291172	Eye disorders	Cataract	01JAN2006	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip squamous cell carcinoma	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1977	31DEC1977	N
				01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291173	Eye disorders	Cataract	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1129 11291174	Cardiac disorders	Mitral valve prolapse	(b) (6) 1950		Y
			Ventricular extrasystoles	01JAN2012		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Cataract	01JAN2013	31DEC2014	N
			Myopia	01JAN1962		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
				01JAN2012		Y
			Seasonal allergy	01JAN1962		Y
		Infections and infestations	Diverticulitis	01JAN2007	31DEC2008	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2018	31DEC2018	N
		Investigations	Catheterisation cardiac	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Overweight	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
			Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Fracture treatment	01JAN2018	31DEC2018	N
			Mitral valve repair	01JAN2012	31DEC2012	N
	C4591001 1129 11291175	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2005		Y
			Hypermetropia	01JAN1995		Y
		Gastrointestinal disorders	Diverticulum	01JAN1993	31DEC1993	N
			Dyspepsia	01JAN2015		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2017		Y
		Immune system disorders	Allergy to animal	01JAN1952		Y
			Allergy to plants	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN2005		Y
				01JAN2017		Y
		Injury, poisoning and procedural complications	Fibula fracture	01JAN1987	31DEC1987	N
			Tibia fracture	01JAN1987	31DEC1987	N
		Investigations	Cardiac murmur	01JAN2014		Y
		Metabolism and nutrition disorders	Overweight	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
			Intervertebral disc degeneration	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01MAR2014	31MAR2014	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Fracture treatment	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Lymphadenectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2017		Y
			Lymphoedema	01JAN2017		Y
	C4591001 1129 11291176	Cardiac disorders	Atrial fibrillation	01JAN2013	31DEC2013	N
		Ear and labyrinth disorders	Deafness	01JAN2000		Y
			Vertigo	01JAN2016		Y
		Endocrine disorders	Goitre	01JAN1994		Y
		Eye disorders	Cataract	01JAN2018		Y
			Eyelid cyst	01JAN2019	11SEP2020	N
			Hypermetropia	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2011		Y
		Gastrointestinal disorders	Colitis microscopic	01JAN2020		Y
			Diarrhoea	01JAN2020		Y
			Diverticulum	01JAN2002		Y
			Large intestine polyp	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Hypersensitivity	01JAN1994		Y
			Mycotic allergy	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Intraocular pressure increased	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Hypertriglyceridaemia	01JAN2000		Y
			Overweight	01JAN1986		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN1996		Y
				01JAN2016		Y
			Osteoarthritis	01JAN2012		Y
				01JAN2017		Y
			Osteoporosis	01JAN2018		Y
			Vertebral osteophyte	01JAN1996		Y
		Nervous system disorders	Sciatica	01JAN2016		Y
		Renal and urinary disorders	Micturition urgency	01JAN2016		Y
		Reproductive system and breast disorders	Breast hyperplasia	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Tobacco user	01JAN1969	31DEC1973	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2014	31DEC2014	N
			Eyelid cyst removal	11SEP2020	11SEP2020	N
			Female sterilisation	01JAN2001	31DEC2001	N
			Meniscus operation	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Venous operation	01JAN2013	31DEC2013	N
	C4591001 1129 11291177	Blood and lymphatic system disorders	Anaemia	01JAN1957	31DEC1970	N
		Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
			Myopia	01JAN1955	31DEC2016	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Large intestine polyp	01JAN2001		Y
		General disorders and administration site conditions	Oedema	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1953	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
				01NOV2019	30NOV2019	N
		Nervous system disorders	Migraine	01JAN1968	31DEC1980	N
		Psychiatric disorders	Depression	01JAN1996	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Dry skin	01MAR2020		Y
		Social circumstances	Tobacco user	01JAN1969	31JAN1978	N
		Surgical and medical procedures	Appendicectomy	01JAN1972	31DEC1972	N
			Cataract operation	01JAN2016	31DEC2016	N
			Ovarian cystectomy	01JAN1972	31DEC1972	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1984	31DEC1984	N
			Varicose vein operation	01JAN1980	31DEC1980	N
	C4591001 1129 11291179	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Cataract	01JAN2017		Y
			Hypermetropia	01JAN1988		Y
			Myopia	01JAN1988		Y
		Gastrointestinal disorders	Diverticulum	01JAN1988		Y
		General disorders and administration site conditions	Oedema	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1961		Y
			Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01MAR2006		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1962	31DEC1962	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Oophorectomy bilateral	01JAN1987	31DEC1987	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1952	31DEC1952	N
			Urinary bladder suspension	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1129 11291180	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
			Optic neuropathy	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Diverticulum	01JAN2014		Y
			Dyspepsia	01JAN2010		Y
			Large intestine polyp	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y
				01JAN2005		Y
		Infections and infestations	Clostridium difficile infection	01JAN2015	31DEC2015	N
			Gastroenteritis	01FEB2019	31DEC2019	N
			Urinary tract infection	01JAN1973		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Hypertriglyceridaemia	01JAN2017		Y
			Type 1 diabetes mellitus	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin B12 deficiency	01JAN2012		Y
			Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
			Trigger finger	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2020	31MAR2020	N
			Headache	01JAN1966		Y
			Migraine	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
			White coat hypertension	01JAN2015		Y
	C4591001 1129 11291183	Cardiac disorders	Atrial fibrillation	01JAN2003		Y
		Eye disorders	Hypermetropia	01JAN2018		Y
			Myopia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Cardiac murmur	01JAN2003		Y
		Metabolism and nutrition disorders	Overweight	01JAN2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2003	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2016	31DEC2016	N
			Heart valve replacement	01JAN2003	31DEC2003	N
			Varicose vein operation	01JAN2019	31DEC2019	N
	C4591001 1129 11291184	Gastrointestinal disorders	Large intestine polyp	01JAN2002	31DEC2002	N
			Pancreatitis	01JAN2001	31DEC2001	N
				01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Renal and urinary disorders	Pollakiuria	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1972	31DEC1989	N
		Surgical and medical procedures	Meniscus operation	01JAN2014	31DEC2014	N
	C4591001 1129 11291186	Ear and labyrinth disorders	Vertigo	01JAN2008	31DEC2008	N
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1989	31DEC1995	N
		Surgical and medical procedures	Caesarean section	01SEP1996	30SEP1996	N
	C4591001 1129 11291188	Blood and lymphatic system disorders	Anaemia	01JAN1990	31DEC1990	N
		Eye disorders	Hypermetropia	01JAN1965		Y
			Myopia	01JAN1965		Y
		Gastrointestinal disorders	Constipation	01JAN1962		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Chronic sinusitis	01JAN1980	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillitis	01JAN1973	31DEC1973	N
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2020		Y
			Hypercholesterolaemia	01JAN1982		Y
			Overweight	01JAN2008		Y
			Vitamin B12 deficiency	01JAN2010		Y
			Vitamin D deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1985	31DEC1985	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1993	31DEC1993	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
					31DEC2015	N
		Psychiatric disorders	Depression	01JAN2013		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN1990	31DEC2017	N
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Bladder repair	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Breast conserving surgery	01JAN2012		Y
			Bunion operation	01JAN1985	31DEC1985	N
			Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Mammoplasty	01JAN1998	31DEC1998	N
			Sinus operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291191	Ear and labyrinth disorders	Deafness	01NOV2018		Y
		Eye disorders	Hypermetropia	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01OCT2018		Y
			Gastroesophageal reflux disease	01OCT2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Immune system disorders	Food allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Fibromyalgia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	15MAR2019	27MAR2019	N
			Lipoma	01MAY2020	14MAY2020	N
		Reproductive system and breast disorders	Endometriosis	15MAR2019	27MAR2019	N
		Social circumstances	Tobacco user	01JAN1968	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Hysterectomy	27MAR2019	27MAR2019	N
			Lipoma excision	14MAY2020	14MAY2020	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1129 11291194	Eye disorders	Hypermetropia	01JAN1993		Y
			Myopia	01JAN1993		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc protrusion	01MAR2019	31MAR2019	N
		Social circumstances	Tobacco user	01JAN1974	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291195	Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
		Eye disorders	Macular degeneration	01JUN2019		Y
			Myopia	01JAN1966		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteopenia	01AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01AUG2019	31AUG2019	N
	C4591001 1129 11291198	Surgical and medical procedures	Knee arthroplasty	01JUL2018	31JUL2018	N
			Sinus operation	01JAN2012	31DEC2012	N
		Vascular disorders	Thrombosis	01DEC2017	31MAR2018	N
		Eye disorders	Glaucoma	01JAN2019		Y
			Presbyopia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
			Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
		Micrographic skin surgery	01JAN2015	31DEC2015	N	
			01JAN2017	31DEC2017	N	
	Vascular disorders	Hypertension	01JAN2019		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291199	Ear and labyrinth disorders	Deafness	01JAN2010		Y
			Tinnitus	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2012		Y
			Myopia	01JAN2009		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
				01JAN1994		Y
			Seasonal allergy	01JAN1976		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2009	31DEC2009	N
				01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2009		Y
			Tobacco user	01JAN1986	31DEC1994	N
		Surgical and medical procedures	Abdominoplasty	01JAN2011	31DEC2011	N
			Appendicectomy	01JAN1982	31DEC1982	N
			Gastric banding	01JAN2011	31DEC2011	N
			Mammoplasty	01JAN2011	31DEC2011	N
			Rhinoplasty	01JAN2008	31DEC2008	N
	C4591001 1129 11291200	Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1990		Y
		Renal and urinary disorders	Pollakiuria	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1986	31DEC1986	N
			Micrographic skin surgery	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1129 11291203	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Cataract	01JAN2017		Y
			Hypermetropia	01JAN2017		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Infections and infestations	Pilonidal cyst	01JAN1990	31DEC1990	N
		Investigations	Catheterisation cardiac	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Squamous cell carcinoma of skin	01JAN2005	31DEC2005	N
		Nervous system disorders	Transient ischaemic attack	01JAN2008	31DEC2008	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Renal and urinary disorders	Pollakiuria	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01SEP2020		Y
		Social circumstances	Tobacco user	01JAN1972		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
			Micrographic skin surgery	01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
	C4591001 1129 11291204	Eye disorders	Macular degeneration	17NOV2016		Y
		Gastrointestinal disorders	Anal fissure	01JAN1996	31DEC1996	N
			Colitis microscopic	01JUN2017		Y
			Large intestine polyp	01JAN2012	31DEC2012	N
				01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
			Seasonal allergy	01JAN1979		Y
		Injury, poisoning and procedural complications	Fracture	01JAN1971	31DEC1971	N
			Radius fracture	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN1989		Y
			Osteoarthritis	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2005		Y
			Osteoporosis	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1974	31DEC1979	N
		Surgical and medical procedures	Anal fissure excision	01JAN1996	31DEC1996	N
			Caesarean section	01JAN1990	31DEC1990	N
			Closed fracture manipulation	01JAN1971	31DEC1971	N
			Open reduction of fracture	01JAN1971	31DEC1971	N
	C4591001 1129 11291205	Cardiac disorders	Bundle branch block left	01MAY2020		Y
		Eye disorders	Hypermetropia	01JAN1975		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2007		Y
			Gastroesophageal reflux disease	01JAN2007		Y
			Large intestine polyp	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Overweight	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Osteoarthritis	01JAN2004		Y
			Osteopenia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lobular breast carcinoma in situ	01JAN2000	31DEC2000	N
			Metaplastic breast carcinoma	01JAN2012	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	31DEC2004	N
		Psychiatric disorders	Depression	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
			Breast reconstruction	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1986	31DEC1986	N
			Fracture treatment	01JAN2012	31DEC2012	N
			Mastectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1129 11291206	Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Eye disorders	Myopia	01JAN1973		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Onychomycosis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	31DEC2000	N
			Musculoskeletal chest pain	01JAN1990		Y
			Osteoarthritis	01JAN1986		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1990		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Keratomileusis	01JAN2007	31DEC2007	N
			Tenoplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1129 11291207	Eye disorders	Hypermetropia	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1978		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Investigations	Biopsy prostate	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1129 11291214	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JUN2019		Y
		Eye disorders	Cataract	01JAN2017	31DEC2019	N
			Hypermetropia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Investigations	Endoscopy	01JAN2015	31JAN2015	N
			Oesophagogastroduodenoscopy	01JAN2015	31JAN2015	N
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Oesophageal carcinoma	01JAN2015	10JUN2015	N
		Nervous system disorders	Carotid artery disease	01SEP2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Carotid artery stent insertion	01NOV2019	30NOV2019	N
			Cataract operation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291215	Eye disorders	Tonsillectomy	01JAN1962	31DEC1962	N
			Astigmatism	01JAN1962		Y
			Hypermetropia	01JAN2013		Y
			Myopia	01JAN1962		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN1995		Y
			Large intestine polyp	01JAN2000	31DEC2004	N
		Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
			Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Hepatitis A	01JAN1980	31DEC1980	N
			Pharyngitis streptococcal	01JAN1972	31DEC1972	N
			Urinary tract infection	01JAN2001		Y
		Injury, poisoning and procedural complications	Skeletal injury	01DEC2018	31JAN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colorectal cancer	01JAN2004	31DEC2004	N
			Malignant melanoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Headache	01JAN1965		Y
			Migraine	01JAN1965		Y
			Sciatica	01JAN2015		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1980		Y
					31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291217	Surgical and medical procedures	Large intestine operation	01JAN2004	31DEC2004	N
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Borderline glaucoma	01JAN1980		Y
			Hypermetropia	01JAN1961		Y
			Myopia	01JAN1961		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2012	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1976	31DEC1976	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1975		Y
				01JAN2005		Y
				Seasonal allergy	01JAN1960	
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
			Tonsillitis	01JAN1955	31DEC1955	N
			Urinary tract infection	01JAN2000	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin B12 deficiency	01JAN2016		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
				Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004
			Uterine leiomyoma	01JAN1996	31DEC2006	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN1980	31DEC1996	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1970		Y
			Lichen planus	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Breast conserving surgery	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cheilectomy	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN1976	31DEC1976	N
			Female sterilisation	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Thyroidectomy	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1955	31DEC1955	N
			Urinary bladder suspension	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291218	Ear and labyrinth disorders	Deafness unilateral	01FEB2019		Y
		Endocrine disorders	Hypothyroidism	01FEB2019		Y
		Eye disorders	Myopia	01JAN1966		Y
		Gastrointestinal disorders	Constipation	01FEB2019		Y
			Inguinal hernia	01JAN1957	31DEC1957	N
		Infections and infestations	Hepatitis A	01JAN1994	31DEC1994	N
			Tonsillitis	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01FEB2019	28FEB2019	N
			Papillary thyroid cancer	01JAN2015	31DEC2015	N
			Schwannoma	01FEB2019	28FEB2019	N
		Surgical and medical procedures	Craniotomy	01FEB2019	28FEB2019	N
			Inguinal hernia repair	01JAN1957	31DEC1957	N
			Thyroidectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1129 11291219	Eye disorders	Glaucoma	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1956	31DEC1956	N
		Investigations	Heart rate irregular	01JAN2015	31DEC2016	N
		Metabolism and nutrition disorders	Overweight	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Squamous cell carcinoma	01JUL2020	31JUL2020	N
		Renal and urinary disorders	Micturition disorder	01JAN2010		Y
			Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Arthrodesis	01JAN1993	31DEC1993	N
			Toe operation	01JAN2016	31DEC2016	N
	C4591001 1129 11291221	Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN1972		Y
		Gastrointestinal disorders	Diverticulum	01JAN2018		Y
			Large intestine polyp	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
			Chronic sinusitis	01JAN2017	31DEC2019	N
			Gastroenteritis salmonella	01MAY2019	31MAY2019	N
			Tonsillitis	01JAN1957	31DEC1957	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
			Hypertriglyceridaemia	01JAN2001		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
			Intervertebral disc protrusion	01JAN2004	31DEC2004	N
				01JAN2012	31DEC2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
			Squamous cell carcinoma of skin	01JAN2015	31DEC2015	N
		Nervous system disorders	Restless legs syndrome	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01NOV2019	30NOV2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1997	31DEC1997	N
			Sleep apnoea syndrome	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2010		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2016	31DEC2016	N
			Appendicectomy	01JAN1982	31DEC1982	N
			Arthrodesis	01JAN2006	31DEC2006	N
			Fracture reduction	01JAN1974	31DEC1974	N
			Intervertebral disc operation	01JAN2004	31DEC2004	N
				01JAN2012	31DEC2012	N
			Nasal septal operation	01JAN1997	31DEC1997	N
			Rhinoplasty	01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1957	31DEC1957	N
			Uvulectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1129 11291222	Endocrine disorders	Thyroid mass	01JAN1980	31DEC1980	N
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Infections and infestations	Tonsillitis	01JAN1982	31DEC1982	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
			Squamous cell carcinoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC1990	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN1990	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1948	31DEC1948	N
			Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Nasal operation	01JAN1985	31DEC1985	N
			Prostatic operation	01JAN2005	31DEC2005	N
			Renal stone removal	01JAN1990	31DEC1990	N
			Thyroidectomy	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1982	31DEC1982	N
		Eye disorders	Myopia	01JAN1989		Y
	C4591001 1129 11291225	Injury, poisoning and procedural complications	Muscle rupture	01JAN2014	31DEC2014	N
			Tendon rupture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Overweight	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Intervertebral disc protrusion	01JAN2016	31DEC2016	N
			Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Neurogenic bladder	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Social circumstances	Tobacco user	01JAN1967	31DEC1977	N	
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N	
			Knee arthroplasty	01JAN2003	31DEC2003	N	
				01JAN2006	31DEC2006	N	
			Muscle operation	01JAN2014	31DEC2014	N	
			Spinal fusion surgery	01JAN2013	31DEC2013	N	
				01JAN2017	31DEC2017	N	
				01JAN2003	31DEC2003	N	
			Ear and labyrinth disorders	Vertigo	01JAN2014	31DEC2016	N
	C4591001 1129 11291226		Eye disorders	Cataract	01JAN2020	30SEP2020	N
				Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Myopia	01JAN2005		Y	
			Constipation	01JAN1971		Y	
			Dyspepsia	01JAN2011		Y	
			Large intestine polyp	01JAN2001	31DEC2001	N	
				01JAN2006	31DEC2006	N	
			01JAN2011	31DEC2011	N		
			01JAN2018	31DEC2018	N		
			01JAN2019	31DEC2019	N		
		Immune system disorders	Seasonal allergy	01JAN2015		Y	
		Metabolism and nutrition disorders	Overweight	01JAN2016		Y	
		Musculoskeletal and connective tissue disorders	Muscle spasms	01OCT2019		Y	
			Osteoarthritis	01JAN2016		Y	
			Osteoporosis	01JAN2016		Y	
		Nervous system disorders	Headache	01JAN1970		Y	
		Psychiatric disorders	Anxiety	01JAN2018		Y	
			Insomnia	01JAN2016		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Vaginal prolapse	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cataract operation	30SEP2020	30SEP2020	N
			Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1129 11291227	Eye disorders	Glaucoma	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN1980		Y
			Food allergy	01JAN1975		Y
		Infections and infestations	Urinary tract infection	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Overweight	01JAN2015		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2000	31DEC2019	N
		Nervous system disorders	Sciatica	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Parathyroid gland operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291230	Eye disorders	Hypermetropia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Sciatica	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1129 11291231	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Overweight	01JAN2018		Y
			Vitamin D deficiency	01AUG2020		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
	C4591001 1129 11291232	Eye disorders	Hypermetropia	01JAN1990		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1978	31DEC2002	N
		Surgical and medical procedures	Bunion operation	01JAN1999	31DEC1999	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Hip arthroplasty	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
	C4591001 1129 11291233	Gastrointestinal disorders	Gastric ulcer	01AUG2020		Y
		Investigations	Blood testosterone decreased	01APR2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Heart rate irregular	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JUN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01DEC2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01AUG2019	31AUG2019	N
			Renal stone removal	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1129 11291234	Ear and labyrinth disorders	Deafness bilateral	01JAN2009		Y
		Eye disorders	Cataract	01JAN2006	31DEC2017	N
			Hypermetropia	01JAN2017		Y
			Myopia	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN2005		Y
			Diarrhoea	01JAN2005		Y
			Dyspepsia	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2005		Y
			Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1995		Y
			Vitamin B12 deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Muscle spasms	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN1995		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Psychiatric disorders	Libido decreased	01JAN1995		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1954	31DEC1994	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Uterine dilation and curettage	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1129 11291236	Eye disorders	Myopia	01JAN1990		Y
		Infections and infestations	Hepatitis B	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
			Prostatomegaly	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1965	31DEC1975	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2000	31DEC2000	N
			Inguinal hernia repair	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1129 11291237	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
			Mitral valve prolapse	01JAN2005	31DEC2005	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Sciatica	01JAN1981		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
			Prostatomegaly	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1964	31DEC1973	N
		Surgical and medical procedures	Cardioversion	18AUG2020	31DEC2020	N
			Mitral valve repair	01JAN2005	31DEC2005	N
	C4591001 1129 11291239	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Infections and infestations	Fungal infection	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN1980		Y
			Tobacco user	01JAN1960	31DEC2008	N
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01DEC2010	31DEC2010	N
			Hip arthroplasty	01OCT2011	31OCT2011	N
	C4591001 1129 11291240	Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN1963		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Investigations	Laparoscopy	01JAN1977	31DEC1977	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01FEB2020		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1975	31DEC2016	N
		Renal and urinary disorders	Cystitis interstitial	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1987		Y
			Dermal cyst	01AUG2019	31AUG2019	N
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1986	31JAN1986	N
			Sebaceous cyst excision	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1129 11291241	Eye disorders	Astigmatism	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2002	31DEC2002	N
				01JAN2006	31DEC2006	N
				01JAN2009	31DEC2009	N
	C4591001 1129 11291242	Cardiac disorders	Angina pectoris	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN1975		Y
			Myopia	01JAN1975		Y
		Gastrointestinal disorders	Constipation	01JAN2004		Y
			Diarrhoea	01JAN2004		Y
			Dyspepsia	01JAN2004		Y
			Gastroesophageal reflux disease	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01JAN2004		Y
		Hepatobiliary disorders	Hepatic cyst	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Hypertriglyceridaemia	01JAN2004		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Renal and urinary disorders	Renal disorder	01JAN2014		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2010		Y
			Ovarian cyst	01JAN2009	31DEC2009	N
		Skin and subcutaneous tissue disorders	Granuloma skin	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1980		Y
		Surgical and medical procedures	Breast operation	01JAN2009	31DEC2009	N
			Endometrial ablation	01JAN2007	31DEC2007	N
			Oophorectomy bilateral	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1129 11291243	Eye disorders	Hypermetropia	01JAN1993		Y
			Myopia	01JAN1970	31DEC1990	N
		Gastrointestinal disorders	Large intestine polyp	08SEP2020	08SEP2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2002		Y
		Infections and infestations	Urinary tract infection	01JAN1970	31DEC1990	N
		Investigations	Precancerous cells present	01JAN1986	31DEC1986	N
		Musculoskeletal and connective tissue disorders	Osteopenia	09JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1966		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
			Keratomileusis	01JAN1990	31DEC1990	N
		Vascular disorders	Hot flush	01JAN2011		Y
	C4591001 1129 11291246	Eye disorders	Hypermetropia	01JAN1998		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1981	31DEC1984	N
			Large intestine polyp	01JAN2011	31DEC2011	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
				01JAN1990		Y
			Food allergy	01JAN2015		Y
			Milk allergy	01JAN1979		Y
			Rubber sensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Overweight	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC2002	N
		Reproductive system and breast disorders	Endometriosis	01JAN1996	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1970		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Ligament operation	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291247	Eye disorders	Tonsillectomy	01JAN1961	31DEC1961	N
			Hypermetropia	01JAN2011		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1961	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN1990		Y
		C4591001 1129 11291248	Cardiac disorders	Supraventricular extrasystoles	01JAN2018	
	Eye disorders		Myopia	01JAN1954		Y
	Gastrointestinal disorders		Dyspepsia	01JAN2000		Y
			Large intestine polyp	01JAN2011	31DEC2011	N
	Immune system disorders		Drug hypersensitivity	01JAN1970		Y
	Infections and infestations		Urinary tract infection	01JAN2019	31DEC2019	N
	Metabolism and nutrition disorders		Hypercholesterolaemia	01JAN2005		Y
			Hypertriglyceridaemia	01JAN2005		Y
			Overweight	01JAN1951		Y
			Type 2 diabetes mellitus	01JAN2007		Y
	Social circumstances		Tobacco user	01JAN1965	31DEC2016	N
	Surgical and medical procedures		Gastrectomy	01JAN2012		Y
						31DEC2012
		Knee arthroplasty	01JAN2007	31DEC2007	N	
			01JAN2009	31DEC2009	N	
	Vascular disorders	Hypertension	01JAN1995		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291250	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Hepatitis A	01JAN1961	31DEC1961	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Polycythaemia vera	01JAN2008		Y
			Squamous cell carcinoma of skin	01SEP2019	30SEP2019	N
		Nervous system disorders	Carotid artery disease	01JAN1999		Y
			Carpal tunnel syndrome	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Micrographic skin surgery	01SEP2019	30SEP2019	N
			Spinal decompression	01JAN2005	31DEC2005	N
	C4591001 1129 11291251	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Cataract	01JAN2016	31DEC2019	N
			Hypermetropia	01JAN2016		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN1949		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1986	31DEC1986	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Paranasal sinus benign neoplasm	01JAN2004	31DEC2004	N
			Uterine leiomyoma	01JAN1980	31DEC1989	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1965	31DEC1969	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Ligament operation	01JAN1986	31DEC1986	N
			Sinus operation	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1129 11291254†	Eye disorders	Hypermetropia	01JAN1959		Y
			Myopia	01JAN1959		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2012		Y
		Infections and infestations	Herpes zoster	01JUL2008	31AUG2008	N
		Investigations	HIV test positive	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Overweight	01JAN1993		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2006		Y
			Post herpetic neuralgia	01JAN2009		Y
			Transient ischaemic attack	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2009		Y
			Hypertonic bladder	01JAN2008		Y
		Surgical and medical procedures	Carotid artery stent insertion	01JAN2006	31DEC2006	N
			Hip arthroplasty	01JAN2005	31DEC2005	N
			Shoulder arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1130 11301003	Eye disorders	Eyelid ptosis	22JAN2013		Y
		Immune system disorders	Seasonal allergy	07APR2000		Y
		Psychiatric disorders	Psychogenic erectile dysfunction	08JAN2001		Y
		Vascular disorders	Varicose vein	01JAN1978		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1130 11301004	Gastrointestinal disorders	Diverticulum	01OCT1999		Y
			Enterovesical fistula	06MAR2018	01JUN2018	N
		Investigations	Colonoscopy abnormal	15MAY2015		Y
		Metabolism and nutrition disorders	Obesity	29NOV2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	02APR2020		Y
		Nervous system disorders	Migraine with aura	01OCT1999		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	19MAY2019		Y
		Surgical and medical procedures	Colectomy	01JUN2018	01JUN2018	N
			Glaucoma drainage device placement	17JAN2011	17JAN2011	N
			Keratoplasty	09FEB2016	09FEB2016	N
				23MAR2016	23MAR2016	N
			Sigmoidectomy	01JUN2018	01JUN2018	N
		Vascular disorders	Essential hypertension	01OCT1999		Y
	C4591001 1130 11301005	Cardiac disorders	Atrial fibrillation	01SEP2007		Y
			Coronary artery disease	10SEP2001		Y
			Ischaemic cardiomyopathy	28NOV2012		Y
			Myocardial infarction	18MAY2007	18MAY2007	N
		Gastrointestinal disorders	Gastrointestinal haemorrhage	23OCT2010	23OCT2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	09DEC1997		Y
			Obesity	23APR2014		Y
			Type 2 diabetes mellitus	26APR2017		Y
		Renal and urinary disorders	Chronic kidney disease	13FEB2015		Y
			Nephrolithiasis	08MAR1999		Y
		Respiratory, thoracic and mediastinal disorders	Chronic respiratory failure	20OCT2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	11DEC2014		Y
		Surgical and medical procedures	Implantable defibrillator insertion	01AUG2007	01AUG2007	N
			Skin neoplasm excision	23FEB2015	24APR2015	N
		Vascular disorders	Aortic aneurysm	28JAN2013		Y
			Aortic arteriosclerosis	12FEB2015		Y
			Essential hypertension	02DEC1997		Y
	C4591001 1130 11301006	Congenital, familial and genetic disorders	Corneal dystrophy	16MAY2019		Y
		Ear and labyrinth disorders	Deafness neurosensory	01OCT2004		Y
		Eye disorders	Glaucoma	07MAR2017		Y
		Gastrointestinal disorders	Anal incontinence	15JUL1998		Y
		Metabolism and nutrition disorders	Obesity	25AUG2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	05SEP2017		Y
		Renal and urinary disorders	Urinary incontinence	28DEC1999		Y
		Surgical and medical procedures	Intraocular lens implant	28NOV2018		Y
			Radiotherapy	07FEB2018	26FEB2018	N
	C4591001 1130 11301007	Gastrointestinal disorders	Gastroesophageal reflux disease	22OCT2009		Y
		Metabolism and nutrition disorders	Gout	08JUL2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15JAN2018		Y
			Facet joint syndrome	09JUN2016		Y
			Spinal osteoarthritis	15JAN2018		Y
			Spondyloarthropathy	17JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	01JAN1999	31DEC2000	N
			Renal cancer	01JAN2016	16SEP2016	N
		Renal and urinary disorders	Chronic kidney disease	06SEP2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mixed incontinence	29JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	22JAN2008		Y
			Sleep apnoea syndrome	13JAN2020		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	31OCT2007		Y
		Surgical and medical procedures	Breast conserving surgery	21JUL1999	21JUL1999	N
			Chemotherapy	01JAN1999	31DEC1999	N
			Lymphadenectomy	21JUL1999	21JUL1999	N
			Nephrectomy	16SEP2016	16SEP2016	N
			Radiotherapy to breast	01JAN1999	31DEC1999	N
		Vascular disorders	Essential hypertension	05DEC2016		Y
	C4591001 1130 11301009	Blood and lymphatic system disorders	Lymphadenopathy	21AUG2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	25APR2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13SEP2016		Y
	C4591001 1130 11301010	Eye disorders	Hyalosis asteroid	10APR2018		Y
			Macular oedema	10APR2018		Y
			Retinopathy proliferative	10APR2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	04JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04JAN2019		Y
			Type 2 diabetes mellitus	21OCT2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	20MAR2019	31DEC2019	N
			Eye naevus	10APR2018		Y
			Rectal cancer	24AUG2018	31DEC2019	N
		Renal and urinary disorders	Chronic kidney disease	21JUL2020		Y
		Surgical and medical procedures	Radiotherapy	16OCT2018	29NOV2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Essential hypertension	04JAN2019		Y
	C4591001 1130 11301011	Gastrointestinal disorders	Gastroesophageal reflux disease	14MAR2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26OCT2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	22SEP2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	22SEP2016		Y
			Prostatitis	11JAN2011		Y
	C4591001 1130 11301012	Metabolism and nutrition disorders	Hyperlipidaemia	18JUN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	09NOV2017	19DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	28SEP2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	29SEP2017		Y
		Skin and subcutaneous tissue disorders	Alopecia	18JUN2008		Y
			Mechanical urticaria	22AUG2008		Y
		Surgical and medical procedures	Cryotherapy	19DEC2007	19DEC2007	N
	C4591001 1130 11301013	Eye disorders	Cataract	19OCT2017		Y
			Dry age-related macular degeneration	19OCT2017		Y
			Dry eye	29MAY2020		Y
		Gastrointestinal disorders	Barrett's oesophagus	09JUL2010		Y
			Gastroesophageal reflux disease	23JUN1999		Y
		General disorders and administration site conditions	Xerosis	02APR1997		Y
		Musculoskeletal and connective tissue disorders	Sjogren's syndrome	18NOV1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Autonomic neuropathy	01JAN2013		Y
			Migraine without aura	17SEP2002		Y
		Psychiatric disorders	Insomnia	06JAN2014		Y
		Renal and urinary disorders	Urinary incontinence	14FEB2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	14JUL2010		Y
		Vascular disorders	Aortic arteriosclerosis	15AUG2019		Y
	C4591001 1130 11301017	Infections and infestations	Rhinitis	26JUN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12SEP2011		Y
			Obesity	14OCT2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	21OCT2014		Y
		Surgical and medical procedures	Anticoagulant therapy	13SEP2011		Y
		Vascular disorders	Deep vein thrombosis	01NOV2003		Y
			Essential hypertension	12SEP2011		Y
			Post thrombotic syndrome	14SEP2011		Y
	C4591001 1130 11301018	Congenital, familial and genetic disorders	Patent ductus arteriosus	06DEC1997	31MAR1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	30SEP2005		Y
			Obesity	16SEP2005		Y
			Vitamin D deficiency	24NOV2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	19JAN2010		Y
		Psychiatric disorders	Major depression	01DEC2004		Y
		Social circumstances	Postmenopause	20AUG2015		Y
		Vascular disorders	Essential hypertension	06OCT2009		Y
	C4591001 1130 11301019	Endocrine disorders	Hypothyroidism	20SEP2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	20MAR2008		Y
			Vitamin B12 deficiency	13MAY2008		Y
		Nervous system disorders	Relapsing multiple sclerosis	15SEP1995		Y
		Psychiatric disorders	Major depression	15SEP1995		Y
	C4591001 1130 11301020	Infections and infestations	Onychomycosis	26JAN2009		Y
		Metabolism and nutrition disorders	Obesity	27APR2018		Y
			Type 2 diabetes mellitus	03FEB2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	16AUG2012		Y
			Pain in extremity	21FEB2020		Y
		Nervous system disorders	Facial paralysis	27DEC1999		Y
			Horner's syndrome	23OCT2019		Y
			Polyneuropathy	13MAR2009		Y
		Psychiatric disorders	Major depression	19SEP2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	25JAN2007		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	27MAR1999		Y
		Vascular disorders	Essential hypertension	19SEP2014		Y
	C4591001 1130 11301022	Eye disorders	Maculopathy	06SEP2018		Y
		Gastrointestinal disorders	Diverticulum intestinal	11APR2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29APR2006		Y
		Musculoskeletal and connective tissue disorders	Arthritis	12OCT2008		Y
			Osteoarthritis	12OCT2008		Y
				22JUN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	16AUG2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	12MAY2015		Y
		Surgical and medical procedures	Intraocular lens implant	06SEP2018		Y
		Vascular disorders	Essential hypertension	27MAR1995		Y
	C4591001 1130 11301023	Cardiac disorders	Myocardial infarction	27OCT1998	27OCT1998	N
			Ventricular fibrillation	27OCT1998	27OCT1998	N
		Ear and labyrinth disorders	Deafness neurosensory	15JUL2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15OCT2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18DEC2009		Y
		Surgical and medical procedures	Coronary arterial stent insertion	27OCT1998		Y
		Vascular disorders	Essential hypertension	01OCT2019		Y
	C4591001 1130 11301024	Cardiac disorders	Coronary artery disease	11AUG2003		Y
			Myocardial infarction	21JUL2003	21JUL2003	N
		Immune system disorders	Drug hypersensitivity	28NOV2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	12APR2011		Y
			Hypercholesterolaemia	01FEB2005		Y
			Type 2 diabetes mellitus	30MAR2011		Y
		Renal and urinary disorders	Chronic kidney disease	07JUL2014		Y
		Vascular disorders	Essential hypertension	18JAN2001		Y
	C4591001 1130 11301025	Endocrine disorders	Hypothyroidism	25DEC2012	30DEC2016	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	09APR2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	25SEP2012		Y
			Vitamin B12 deficiency	02SEP2015		Y
			Vitamin D deficiency	25SEP2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Major depression	25SEP2012		Y
		Surgical and medical procedures	Cholecystectomy	24SEP2012	24SEP2012	N
		Vascular disorders	Aortic arteriosclerosis	15APR2018		Y
			Essential hypertension	28JAN2019		Y
	C4591001 1130 11301027	Ear and labyrinth disorders	Tinnitus	02FEB2007		Y
		Infections and infestations	Cellulitis	25AUG2020	02SEP2020	N
			Gastroenteritis	17JUN2020	21JUN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	05NOV1999		Y
		Renal and urinary disorders	Acute kidney injury	17JUN2020	17JUN2020	N
			Chronic kidney disease	11NOV2011		Y
			Proteinuria	29NOV1995		Y
	C4591001 1130 11301029	Vascular disorders	Aortic arteriosclerosis	17JUN2020		Y
		Ear and labyrinth disorders	Deafness neurosensory	15APR2016		Y
		Endocrine disorders	Hypothyroidism	24SEP2008		Y
		Gastrointestinal disorders	Diverticulum intestinal	20JAN2012	07FEB2013	N
			Gastroesophageal reflux disease	17MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16MAY2006		Y
			Obesity	20NOV2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiofibroma	01JAN1968	31DEC1970	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	28APR2012		Y
		Surgical and medical procedures	Sigmoidectomy	07FEB2013	07FEB2013	N
			Sinus operation	01JAN1970	31DEC1970	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1130 11301030	Cardiac disorders	Ventricular extrasystoles	10FEB2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Retinopathy proliferative	07MAY2008		Y
		Gastrointestinal disorders	Barrett's oesophagus	02SEP2015	31AUG2018	N
		Immune system disorders	Seasonal allergy	30NOV2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	20SEP1995		Y
			Obesity	15JUL2013		Y
			Type 2 diabetes mellitus	30SEP2004		Y
		Nervous system disorders	Carpal tunnel syndrome	13APR2006		Y
			Cervical radiculopathy	13SEP2007		Y
			Diabetic neuropathy	09FEB2007		Y
			Facial paralysis	17OCT2007		Y
			Hemiplegia	26OCT2009		Y
			Ischaemic stroke	26OCT2009	26OCT2009	N
		Renal and urinary disorders	Diabetic nephropathy	30SEP2004		Y
			Microalbuminuria	11AUG2009		Y
			Proteinuria	17JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	15MAR1996		Y
		Skin and subcutaneous tissue disorders	Necrobiosis lipidica diabetorum	28AUG2014	31DEC2017	N
		Vascular disorders	Essential hypertension	22DEC2005		Y
			Lymphoedema	17AUG2009		Y
	C4591001 1130 11301031	Endocrine disorders	Hypothyroidism	14AUG2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	24MAR1995		Y
		Infections and infestations	Chronic sinusitis	02MAR2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	26APR2016		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	30JUL2019		Y
			Osteoarthritis	25FEB2000		Y
			Osteoporosis	25APR2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	26NOV2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	05FEB2002	05FEB2002	N
			Breast cancer	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
		Nervous system disorders	Neuropathy peripheral	17DEC2009		Y
		Skin and subcutaneous tissue disorders	Rosacea	17NOV2000		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
			Skin neoplasm excision	05FEB2002	05FEB2002	N
		Vascular disorders	Aortic arteriosclerosis	09NOV2019		Y
	C4591001 1130 11301034	Nervous system disorders	Intracranial aneurysm	30JUL2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995		Y
		Vascular disorders	Essential hypertension	01JAN2011		Y
	C4591001 1130 11301035	Congenital, familial and genetic disorders	Corneal dystrophy	21JAN2013		Y
		Ear and labyrinth disorders	Tinnitus	12AUG1998		Y
		Gastrointestinal disorders	Diverticulum intestinal	15SEP2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	14MAR2005		Y
	C4591001 1130 11301036	Musculoskeletal and connective tissue disorders	Osteoporosis	23MAR2011		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	11JUL2018		Y
	C4591001 1130 11301037	Metabolism and nutrition disorders	Hyperlipidaemia	21JAN2008		Y
			Type 2 diabetes mellitus	07JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12AUG2020		Y
		Vascular disorders	Essential hypertension	01DEC2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1130 11301038	Congenital, familial and genetic disorders	Type V hyperlipidaemia	05FEB2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	16JAN2015		Y
			Inguinal hernia	03SEP2018	19OCT2018	N
		Infections and infestations	Genital herpes simplex	06FEB2013		Y
		Psychiatric disorders	Bipolar II disorder	01JAN2001		Y
			Post-traumatic stress disorder	16MAY2013		Y
		Surgical and medical procedures	Gastric bypass	01JAN2004		Y
			Inguinal hernia repair	19OCT2018	19OCT2018	N
	C4591001 1130 11301039	Cardiac disorders	Atrial fibrillation	15JUN2020		Y
		Gastrointestinal disorders	Colitis microscopic	28AUG2020		Y
		Infections and infestations	Urinary tract infection	01JUN2017		Y
		Injury, poisoning and procedural complications	Meniscus injury	07JUN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	07AUG2019		Y
		Renal and urinary disorders	Chronic kidney disease	28NOV2006		Y
		Surgical and medical procedures	Hysterectomy	11DEC2007	11DEC2007	N
		Vascular disorders	Essential hypertension	07APR1998		Y
	C4591001 1130 11301040	Eye disorders	Cataract	20DEC2019		Y
		Nervous system disorders	Restless legs syndrome	03AUG2020		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1974	31DEC1974	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1130 11301041	Infections and infestations	Urinary tract infection	01JAN1974		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	13DEC2013		Y
		Nervous system disorders	Migraine	14NOV2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Atrophic vulvovaginitis	11MAR2010		Y
	C4591001 1130 11301042	Vascular disorders	Essential hypertension	13DEC2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	13OCT2015		Y
		Hepatobiliary disorders	Hepatic fibrosis	22MAY2019		Y
			Non-alcoholic steatohepatitis	15NOV2017		Y
			Nonalcoholic fatty liver disease	05OCT2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	28JAN2010		Y
			Obesity	15NOV2017		Y
			Type 2 diabetes mellitus	27FEB2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	17JUL2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01AUG2012		Y
		Psychiatric disorders	Major depression	28JUL2011		Y
		Renal and urinary disorders	Haematuria	16JUL2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	17JUL2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JUL2008		Y
		Surgical and medical procedures	Cholecystectomy	08APR2008	08APR2008	N
	C4591001 1130 11301048	Cardiac disorders	Bundle branch block right	02OCT2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Genital herpes simplex	05NOV2015		Y
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Persistent depressive disorder	01JAN1987		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	02OCT2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
			Mammoplasty	01JAN2010	31DEC2010	N
			Nasal septal operation	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Turbinectomy	01JAN1989	31DEC1989	N
	C4591001 1130 11301050	Blood and lymphatic system disorders	Macrocytosis	30DEC2014		Y
		Cardiac disorders	Angina pectoris	09NOV2001		Y
			Coronary artery disease	09NOV2001		Y
		Ear and labyrinth disorders	Deafness neurosensory	09JAN2015		Y
		Gastrointestinal disorders	Diverticulum intestinal	08AUG2019		Y
		Infections and infestations	Genital herpes simplex	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07APR2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	20AUG2013		Y
		Nervous system disorders	Lumbar radiculopathy	20AUG2013		Y
			Neuropathy peripheral	26AUG2014		Y
		Psychiatric disorders	Anxiety disorder	09NOV2001		Y
			Obsessive-compulsive disorder	19JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Snoring	10JAN2016		Y
	C4591001 1130 11301053	Surgical and medical procedures	Large intestinal polypectomy	08AUG2019	08AUG2019	N
		Endocrine disorders	Basedow's disease	27NOV2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	21SEP2013		Y
			Obesity	21SEP2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06NOV2018		Y
		Nervous system disorders	Cerebrovascular accident	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hemiplegia	01JAN1997		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998		Y
		Vascular disorders	Essential hypertension	21SEP2013		Y
	C4591001 1130 11301055	Eye disorders	Dermatochalasis	14NOV2007		Y
		Infections and infestations	Urinary tract infection	15JUN2009	31DEC2012	N
		Injury, poisoning and procedural complications	Epicondylitis	12MAR2020		Y
		Nervous system disorders	Migraine without aura	03APR1997		Y
		Psychiatric disorders	Major depression	08APR2005		Y
		Renal and urinary disorders	Nephrolithiasis	15DEC2008	15DEC2008	N
	C4591001 1130 11301057	Surgical and medical procedures	Hysterectomy	13OCT2012	13OCT2012	N
		Ear and labyrinth disorders	Deafness	01JAN2017		Y
			Tinnitus	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1993	31DEC1993	N
		Vascular disorders	Deep vein thrombosis	01JAN1993	31DEC1993	N
				01JAN1997	31DEC1997	N
	C4591001 1130 11301060	Congenital, familial and genetic disorders	Corneal dystrophy	15JUL2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Eye naevus	05JUL2018		Y
			Prostate cancer	06JUN2018		Y
		Psychiatric disorders	Generalised anxiety disorder	02APR2018		Y
			Major depression	12JAN2011		Y
			Obsessive-compulsive disorder	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	17DEC2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	26APR2019		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1985		Y
		Surgical and medical procedures	Cataract operation	21NOV2019	21NOV2019	N
			Hernia repair	01JAN2003	31DEC2003	N
			Inguinal hernia repair	01JAN2004	31DEC2004	N
			Intraocular lens implant	03JAN2017		Y
			Leukocytosis	19AUG2020		Y
	C4591001 1130 11301061	Blood and lymphatic system disorders				
		Gastrointestinal disorders	Diverticulum intestinal	18JUL2005		Y
			Gastrointestinal haemorrhage	18NOV2018	19NOV2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	23SEP2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	30MAR2005	30MAR2005	N
		Nervous system disorders	Migraine with aura	16AUG2013		Y
		Social circumstances	Tobacco user	01JAN1980	31OCT2015	N
		Vascular disorders	Aortic arteriosclerosis	30MAY2017		Y
	C4591001 1130 11301062	Cardiac disorders	Aortic valve stenosis	06MAY2016		Y
		Ear and labyrinth disorders	Deafness	01JAN2005		Y
			Tinnitus	01JAN1990		Y
		Eye disorders	Dry age-related macular degeneration	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13APR2016		Y
			Hypokalaemia	04NOV2006		Y
			Obesity	28APR2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	13APR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	15APR2016		Y
			Urinary retention	03FEB2017		Y
		Social circumstances	Tobacco user	01JAN1966	09AUG2020	N
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
		Vascular disorders	Essential hypertension	13APR2016		Y
	C4591001 1130 11301065	Blood and lymphatic system disorders	Leukocytosis	15APR2020	09JUN2020	N
			Thrombocytosis	15APR2020		Y
		Endocrine disorders	Hypothyroidism	15APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15APR2020		Y
			Iron deficiency	16APR2020		Y
		Nervous system disorders	Migraine without aura	01JAN1973		Y
		Psychiatric disorders	Major depression	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	15FEB2017	16FEB2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1130 11301066	Eye disorders	Cataract	18MAY2018		Y
			Myopic chorioretinal degeneration	18MAY2018		Y
		Immune system disorders	Seasonal allergy	01JUL2011		Y
		Metabolism and nutrition disorders	Obesity	08MAY2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	08MAY2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1130 11301067	Infections and infestations	Oral herpes	01JAN2012		Y
		Investigations	Colonoscopy	01JAN2017	31DEC2017	N
		Nervous system disorders	Restless legs syndrome	01JAN2014		Y
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2017	31DEC2017	N
			Retinopexy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1130 11301070	Cardiac disorders	Atrial fibrillation	05AUG2014		Y
		Eye disorders	Open angle glaucoma	09DEC2013		Y
		Infections and infestations	Hepatitis C	29JUN2012	16JUN2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	16JUL2007		Y
			Type 2 diabetes mellitus	29OCT1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	11MAY2009	29DEC2015	N
		Surgical and medical procedures	Prostate cryoablation	02SEP2009	02SEP2009	N
			Radiotherapy to prostate	26OCT2015	29DEC2015	N
		Vascular disorders	Essential hypertension	08NOV1996		Y
	C4591001 1130 11301071	Cardiac disorders	Atrial fibrillation	10FEB2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2003		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1958		Y
		Surgical and medical procedures	Vasectomy	01JAN1974	31DEC1974	N
	C4591001 1130 11301076	Metabolism and nutrition disorders	Hypercholesterolaemia	03MAY2012		Y
			Obesity	11MAR2013		Y
			Type 2 diabetes mellitus	18APR2012		Y
	C4591001 1130 11301080	Metabolism and nutrition disorders	Hyperlipidaemia	17APR2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	17APR2015		Y
			Spinal osteoarthritis	02FEB2015		Y
		Surgical and medical procedures	Cataract operation	19DEC2018	19DEC2018	N
	C4591001 1130 11301095	Gastrointestinal disorders	Gastroesophageal reflux disease	12JUL2010		Y
			Hiatus hernia	28JUL2006		Y
			Pancreatic pseudocyst	22SEP2008	12JUL2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pancreatitis	28JUL2006	16AUG2006	N
		Infections and infestations	Pneumonia bacterial	08NOV2016	13APR2017	N
			Sepsis	08NOV2016	13APR2017	N
		Metabolism and nutrition disorders	Diabetic dyslipidaemia	28JUL2006		Y
			Vitamin D deficiency	05JUN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	16MAR2016	16MAR2016	N
			Colon adenoma	16MAR2016	16MAR2016	N
			Squamous cell carcinoma of skin	19JUN2009	19JUN2009	N
		Nervous system disorders	Migraine with aura	12JUL2010		Y
			Neuropathy peripheral	21JUL2010		Y
			Transient ischaemic attack	16JUL2014		Y
		Psychiatric disorders	Major depression	22SEP2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07NOV2016		Y
		Surgical and medical procedures	Cholecystectomy	28JUL2006	28JUL2006	N
			Gastric bypass	28JUL2006	28JUL2006	N
			Pancreatectomy	28JUL2006	28JUL2006	N
		Vascular disorders	Aortic arteriosclerosis	02SEP2016		Y
			Essential hypertension	22SEP2008		Y
	C4591001 1130 11301096	Ear and labyrinth disorders	Deafness neurosensory	03MAR2014		Y
		Eye disorders	Optic ischaemic neuropathy	01OCT2013		Y
		Immune system disorders	Allergy to arthropod sting	17JAN2014		Y
		Infections and infestations	Herpes simplex	18DEC2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	08OCT2018		Y
			Pain in extremity	04APR2018		Y
			Psoriatic arthropathy	09MAY2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	06APR2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	23FEB2000		Y
	C4591001 1130 11301098	Eye disorders	Macular fibrosis	09JUL2019		Y
			Vitreous detachment	03JUN2019		Y
		Gastrointestinal disorders	Gastric ulcer	05MAR2019	23APR2019	N
			Haemorrhoids	02APR1999	20AUG2019	N
		Musculoskeletal and connective tissue disorders	Osteochondrosis	01JAN1969		Y
		Nervous system disorders	Carpal tunnel syndrome	07AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	27MAR2013		Y
			Rhinitis allergic	27MAR2013		Y
		Social circumstances	Menopause	23AUG2006	05MAR2009	N
			Postmenopause	05MAR2009		Y
		Surgical and medical procedures	Intraocular lens implant	03JUN2019		Y
	C4591001 1131 11311001	Cardiac disorders	Myocardial ischaemia	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1972	31DEC1972	N
		Investigations	Blood cholesterol increased	01JAN2011		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013		Y
		Social circumstances	Corrective lens user	01JAN1972		Y
			Ex-tobacco user	01JAN1976	31DEC1983	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2011		Y
			Renal stone removal	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Small intestine operation	01JAN1972	31DEC1972	N
			Transfusion	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1131 11311003	Nervous system disorders	Headache	01JAN1970		Y
			Migraine	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1131 11311005	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1131 11311007	Cardiac disorders	Bradycardia	01AUG2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1986	31DEC1986	N
			Plantar fasciitis	01JAN2017	31DEC2018	N
			Tendonitis	01APR2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1986	31DEC1986	N
			Keratomileusis	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1131 11311008	Immune system disorders	Seasonal allergy	01JAN1966		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1968	31DEC1968	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1974		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1961	31DEC1961	N
			Cancer surgery	01JAN2015	31DEC2015	N
			Lip operation	01JAN1968	31DEC1968	N
			Tonsillectomy	01JAN1961	31DEC1961	N
	C4591001 1131 11311009	Blood and lymphatic system disorders	Blood loss anaemia	01JAN1995	31DEC1995	N
			Iron deficiency anaemia	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Genital herpes simplex	01JAN1990		Y
		Injury, poisoning and procedural complications	Anaemia postoperative	01JAN2004		Y
			Post procedural complication	01JAN2003	31DEC2003	N
		Investigations	Cardiac murmur	01JAN1956		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Skin and subcutaneous tissue disorders	Dermatitis	01FEB2020		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Bunion operation	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Gastric bypass	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Knee operation	01JAN2000	31DEC2000	N
			Ligament operation	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
			Toe operation	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311010	Ear and labyrinth disorders	Hypoacusis	01JAN1990		Y
			Tinnitus	01JAN1990	31DEC1990	N
		Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN2015		Y
		Gastrointestinal disorders	Small intestine ulcer	01JAN1980	31DEC1982	N
				01JAN1981	31DEC1981	N
				01JAN1982	31DEC1982	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Investigations	Blood glucose increased	01JUN2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999		Y
					31DEC1999	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2011	31DEC2018	N
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Social circumstances	Blood donor	01JAN2000	31DEC2018	N
		Surgical and medical procedures	Cataract operation	01DEC2019	31DEC2019	N
			Dental implantation	01JAN2019	31DEC2019	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Small intestine operation	01JAN1982	31DEC1982	N
	C4591001 1131 11311012	Cardiac disorders	Atrial fibrillation	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Palpitations	01JAN2017		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1980		Y
			Dyspepsia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2004		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Denture wearer	01JAN2005		Y
			Hearing aid user	01JAN1995		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN1980	31DEC1980	N
			Cataract operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1131 11311013	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2012		Y
		Social circumstances	Blood donor	01JAN2019	31DEC2019	N
			Corrective lens user	01JAN2010		Y
			Hearing aid user	01JAN2020		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1947	31DEC1947	N
			Appendectomy	01JAN1964	31DEC1964	N
			Arthrodesis	01JAN2019	31DEC2019	N
			Cataract operation	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1970	31DEC1970	N
			Vertebroplasty	01JAN2017	31DEC2017	N
	C4591001 1131 11311014	Cardiac disorders	Cardiac failure chronic	01JAN2000		Y
			Cardiomyopathy	01JAN2010		Y
			Mitral valve incompetence	01JAN1998		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1998		Y
		Ear and labyrinth disorders	Vertigo	01JAN2014		Y
		Eye disorders	Hypermetropia	01JAN1950		Y
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
			Osteopenia	31JUL2013		Y
			Spinal osteoarthritis	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2015		Y
			Prostate cancer	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Dental prosthesis placement	01JAN2017	31DEC2017	N
			Prostatectomy	01JAN2008	31DEC2008	N
	C4591001 1131 11311019	Eye disorders	Glaucoma	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Spinal osteoarthritis	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1996	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN1987		Y
			Depression	01JAN1987		Y
		Surgical and medical procedures	Caesarean section	01JAN1974	31DEC1974	N
			Carpal tunnel decompression	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN1975	31DEC1975	N
			Hysterectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1131 11311021	Eye disorders	Hypermetropia	01JAN1982		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1973	31DEC1973	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1973	31DEC1980	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1982		Y
			Denture wearer	01JAN1974		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1953	31DEC1953	N
			Transfusion	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2014	31DEC2015	N
	C4591001 1131 11311022	Eye disorders	Hypermetropia	01JAN1958		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1969	31DEC1969	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN1958		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1966	31DEC1966	N
			Fracture treatment	01JAN1969	31DEC1969	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1131 11311023	Cardiac disorders	Ventricular extrasystoles	01JAN2017		Y
			Ventricular tachycardia	01JAN2017	31DEC2017	N
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Myopia	01JAN1963		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Nervous system disorders	Syncope	01JAN2017	31DEC2017	N
			Tension headache	01JAN1964		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Renal stone removal	01JAN2013	31DEC2013	N
			Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1131 11311025	Cardiac disorders	Coronary artery disease	01JAN2005	31DEC2010	N
		Ear and labyrinth disorders	Vertigo	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Tendonitis	01JAN2013		Y
		Nervous system disorders	Post herpetic neuralgia	01JAN2003	31DEC2003	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Insomnia	01JAN2011		Y
			Panic disorder	01JAN1987	31DEC1990	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1976		Y
		Social circumstances	Blood donor	01MAR2020		Y
			Corrective lens user	01JAN1990		Y
			Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN1997	31DEC1997	N
			Caesarean section	01JAN1995	31DEC1995	N
	C4591001 1131 11311027	Eye disorders	Myopia	01JAN1968		Y
		Infections and infestations	Herpes zoster	01JAN1987	31DEC1987	N
		Investigations	Biopsy breast	13FEB2018	13FEB2018	N
		Psychiatric disorders	Insomnia	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast calcifications	01JAN2018	13FEB2018	N
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1978	31DEC1978	N
			Caesarean section	01JAN1986	31DEC1986	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1131 11311028	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2015		Y
		Eye disorders	Myopia	01JAN1962		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1986	31DEC1990	N
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN1986	31DEC1986	N
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2015		Y
			Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1986	31DEC2000	N
		Nervous system disorders	Headache	01JAN1996		Y
			Migraine	01JAN1996		Y
		Psychiatric disorders	Depression	01MAR2020		Y
			Insomnia	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
			Stress urinary incontinence	01JAN1990		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1962		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc operation	01JAN1996	31DEC1996	N
				01JAN1998	31DEC1998	N
			Joint arthroplasty	01JAN2010	31DEC2010	N
			Urinary bladder suspension	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1131 11311029	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y
		Investigations	Prostatic specific antigen increased	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2009		Y
		Social circumstances	Blood donor	01JAN1974		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1963	31DEC1963	N
			Dupuytren's contracture operation	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
				01JAN2018	31DEC2018	N
			Joint dislocation reduction	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1131 11311030	Eye disorders	Hypermetropia	01JAN1962		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1962		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1965	31DEC1965	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1131 11311033	Eye disorders	Cataract	01JAN2017		Y
			Myopia	01JAN1958		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
			Melanoma recurrent	01OCT2018	31OCT2018	N
		Renal and urinary disorders	Urge incontinence	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1951		Y
		Social circumstances	Corrective lens user	01JAN1958		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Steroid therapy	01JUL2020		Y
	C4591001 1131 11311034	Endocrine disorders	Hypothyroidism	01JAN2005	31DEC2005	N
		Eye disorders	Hypermetropia	01JAN1964		Y
			Myopia	01JAN1964		Y
		Immune system disorders	Seasonal allergy	01JAN1958		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2010	01JAN2020	N
			Overweight	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
			Trigger finger	01JAN2019	31DEC2020	N
		Psychiatric disorders	Depression	01JAN2013	31DEC2015	N
		Reproductive system and breast disorders	Uterine polyp	01JAN2018	31DEC2018	N
		Social circumstances	Blood donor	01JAN2017		Y
			Corrective lens user	01JAN1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Tendon sheath incision	09JAN2020	09JAN2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1131 11311036	Cardiac disorders	Mitral valve prolapse	01JAN1985		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2017		Y
		Eye disorders	Hypermetropia	01JAN1969		Y
			Retinal tear	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
		General disorders and administration site conditions	Pain	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Lyme disease	01JAN2015	31DEC2017	N
			Tonsillitis	01JAN1964	31DEC1964	N
		Psychiatric disorders	Depression	01JAN1980		Y
			Insomnia	01JAN2000		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Bladder repair	01DEC2018	31DEC2018	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01DEC2018	31DEC2018	N
			Retinal operation	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1131 11311037	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Eye disorders	Cataract	01JUL2020		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN1999	31DEC1999	N
		Immune system disorders	Seasonal allergy	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
			Vitamin D deficiency	01FEB2020		Y
		Nervous system disorders	Syncope	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2000	31DEC2000	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Muscle operation	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
			Vasectomy	01DEC1998	31DEC1998	N
	C4591001 1131 11311039	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2010	N
		Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Irritable bowel syndrome	01JAN2010		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2011	31DEC2011	N
		Investigations	Heart rate irregular	01JAN1995		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
			Haemorrhoid operation	01JAN2008	31DEC2008	N
			Rhinoplasty	01JAN1966	31DEC1966	N
			Shoulder arthroplasty	01JAN2010	31DEC2010	N
			Transfusion	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311040	Vascular disorders	Hypertension	01JAN2012		Y
		Eye disorders	Hypermetropia	01JAN2008		Y
			Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989	31DEC2016	N
		Infections and infestations	Kidney infection	01JAN1964	31DEC1967	N
		Injury, poisoning and procedural complications	Laryngeal injury	01JAN2016	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005		Y
			Osteoarthritis	01JAN2010		Y
			Periarthritis	01JAN2013	31DEC2016	N
				01JAN2017	31DEC2020	N
		Nervous system disorders	Headache	01JAN1971	31DEC1999	N
		Renal and urinary disorders	Urethral dilatation	01JAN1967	31DEC1967	N
			Urethral stenosis	01JAN1964	31DEC1967	N
			Urinary incontinence	01JAN1964	31DEC1967	N
	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1971		Y	
	Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2018		Y	
	Social circumstances	Corrective lens user	01JAN2017		Y	
		Postmenopause	01JAN2012		Y	
	Surgical and medical procedures	Shoulder operation	01JAN2016	31DEC2016	N	
		Tonsillectomy	01JAN1967	31DEC1967	N	
	C4591001 1131 11311043	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1967	31DEC1968	N
		Eye disorders	Hypermetropia	01JAN1963		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2007	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Seasonal allergy	01JAN2015	31DEC2015	N
		Infections and infestations	Herpes zoster	01JAN2014	31DEC2014	N
			Lyme disease	01JAN1987	31DEC1991	N
			Pneumonia legionella	01JAN1996	31DEC1996	N
			Post treatment Lyme disease syndrome	01JAN1987		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2017		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1131 11311044	Congenital, familial and genetic disorders	Heterotaxia	01JAN1958		Y
		Eye disorders	Dry eye	01JAN2010		Y
			Hypermetropia	01JAN2008		Y
			Myopia	01JAN2003		Y
		Gastrointestinal disorders	Nausea	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes simplex	01JAN2010		Y
			Otosalpingitis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tinea pedis	01JAN2006	31DEC2007	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
			Vitamin D deficiency	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUN2020		Y
			Rotator cuff syndrome	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998	31DEC2005	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1968		Y
				01JAN1986		Y
				01JAN1998		Y
			Idiopathic urticaria	01JAN2005	31DEC2005	N
		Social circumstances	Corrective lens user	01JAN2003		Y
			Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Jaw operation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1131 11311047	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2008	31DEC2010	N
		Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN1989	31DEC2018	N
			Gastroesophageal reflux disease	01JAN2014		Y
			Irritable bowel syndrome	01JAN2000		Y
		General disorders and administration site conditions	Fatigue	01JAN2011		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1983	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1994		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intervertebral disc protrusion	01JAN1994	31DEC1994	N
			Muscle spasms	01JAN2014		Y
			Osteoarthritis	01JAN1989		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2014	N
			Migraine	01JAN2011	31DEC2011	N
			Neuralgia	01JAN2014		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1983	31DEC1983	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1981	31DEC1981	N
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1994	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Social circumstances	Denture wearer	01JAN2014		Y
			Tobacco user	01JAN1973		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Caesarean section	01JAN1985	31DEC1985	N
			Carpal tunnel decompression	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN1989	31DEC1989	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Knee arthroplasty	01MAY2020	31MAY2020	N
				01OCT2018	31OCT2018	N
			Transfusion	01JAN1983	31DEC1983	N
	C4591001 1131 11311052	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2016		Y
		Eye disorders	Myopia	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
			Irritable bowel syndrome	01JAN1987		Y
		Immune system disorders	Anaphylactic reaction	01JAN1979		Y
			Seasonal allergy	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1995	N
		Nervous system disorders	Migraine with aura	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1975		Y
			Eczema	01JAN1987		Y
		Social circumstances	Corrective lens user	01JAN1959		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1969		Y
			Hysterectomy	01JAN1970	31DEC1970	N
			Tonsillectomy	01JAN1995	31JAN1995	N
				01JAN1970	31DEC1970	N
	C4591001 1131 11311054	Cardiac disorders	Ventricular fibrillation	01JAN2007	31DEC2007	N
		Eye disorders	Myopia	01JAN1951	31DEC1997	N
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Hiatus hernia	01JAN1942		Y
			Inguinal hernia	01JAN1987	31DEC1987	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Infections and infestations	Herpes simplex	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1997		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1947		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Eye laser surgery	01JAN1997	31DEC1997	N
			Inguinal hernia repair	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1947	31DEC1947	N
			Vasectomy	01JAN1970	31DEC1970	N
	C4591001 1131 11311055	Eye disorders	Hypermetropia	01JAN1974		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Investigations	Blood glucose increased	01OCT2019		Y
		Nervous system disorders	Migraine	01JAN1970	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1974		Y
			Ex-tobacco user	01JAN1980	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1131 11311056	Cardiac disorders	Coronary artery disease	01JAN2003		Y
			Myocardial infarction	01JAN2003	31DEC2003	N
				01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2013	31DEC2013	N
		Eye disorders	Hypermetropia	01JAN1990		Y
		Gastrointestinal disorders	Gastritis	01JAN1955	31DEC1963	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1963	31DEC1964	N
			Fall	01JAN1963	31DEC1963	N
			Rib fracture	01JAN1979	31DEC1980	N
				06JAN2017	31DEC2017	N
			Road traffic accident	06JAN2017	06JAN2017	N
		Investigations	Cardiac murmur	01JAN2003		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hyperlipidaemia	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
		Social circumstances	Physical assault	01JAN1979	31DEC1979	N
			Tobacco user	01JAN1983	31DEC2005	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Coronary artery bypass	01JAN2013	31DEC2013	N
			Stent placement	01JAN2003	31DEC2003	N
				01JAN2007	31DEC2007	N
	C4591001 1131 11311057	Ear and labyrinth disorders	Vertigo	01JAN2008		Y
		Eye disorders	Cataract	01JAN2014		Y
			Dry eye	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1993		Y
			Presbyopia	01JAN1993		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2019		Y
			Nausea	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Infections and infestations	Herpes zoster	04JUN2009	14JUN2009	N
		Injury, poisoning and procedural complications	Wrist fracture	01DEC2013	31DEC2013	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2003		Y
			Osteoarthritis	01JAN1973		Y
			Osteopenia	01JAN2010		Y
			Spinal osteoarthritis	01JAN1973		Y
				01JAN1980		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1984	31DEC2005	N
			Migraine	01JAN1989		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01NOV2016		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1998		Y
			Sleep apnoea syndrome	01JAN2010	31DEC2014	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
			Drug eruption	01JAN1967		Y
			Rash	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1993		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Knee arthroplasty	01FEB2019	28FEB2019	N
			Open reduction of fracture	01DEC2013	31DEC2013	N
			Spinal laminectomy	01JAN1983	31DEC1983	N
				01JAN2008	31DEC2008	N
	C4591001 1131 11311058	Cardiac disorders	Bundle branch block right	01JAN1998		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Investigations	Cardiac murmur	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Prostatectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1963	31DEC1963	N
			Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1131 11311059	Eye disorders	Cataract	01JAN2012	31DEC2015	N
			Hypermetropia	01JAN1966		Y
		Infections and infestations	Herpes zoster	01JAN1988	31DEC1988	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood glucose increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y
				01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Nerve compression	01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN1989	31DEC2011	N
			Depression	01JAN1989	31DEC2011	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	01JAN2010		Y
		Social circumstances	Blood donor	01JAN1982	31DEC1986	N
			Hearing aid user	01JAN2018		Y
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Cataract operation	01JAN2015	31DEC2015	N
			Continuous positive airway pressure	01JAN2018		Y
			Corneal transplant	01JAN2016	31DEC2016	N
			Prostate ablation	01JAN2016	31DEC2016	N
			Retinopexy	01JAN1974	31DEC1974	N
			Shoulder operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1958	31DEC1958	N
			Vasectomy	01JAN1986	31DEC1986	N
			Vitrectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1131 11311063	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2005		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2009		Y
		Immune system disorders	Allergy to animal	01JAN1951		Y
			Seasonal allergy	01JAN1951		Y
		Metabolism and nutrition disorders	Gout	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1980		Y
			Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2006	31DEC2006	N
			Renal cancer	01JAN2009	31DEC2012	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1969	31DEC2008	N
		Surgical and medical procedures	Abdominal hernia repair	01JAN2009	31DEC2009	N
			Cataract operation	01JAN2019	31DEC2019	N
			Continuous positive airway pressure	01JAN2000		Y
			Nephrectomy	01JAN2008	31DEC2008	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
		Vascular disorders	Aortic aneurysm	01JAN2017		Y
			Hypertension	01JAN2005		Y
	C4591001 1131 11311067	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Juvenile idiopathic arthritis	01JAN1980		Y
			Osteoporosis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wheezing	01AUG2020		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
			Tobacco user	01JAN1984		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
			Leg amputation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1131 11311068	Eye disorders	Myopia	01JAN1970	31DEC2000	N
		Investigations	Transaminases increased	01FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bone neoplasm	01JAN1963	31DEC1963	N
		Surgical and medical procedures	Bone lesion excision	01JAN1963	31DEC1963	N
			Eye laser surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1131 11311070	Eye disorders	Cataract	01JAN2018		Y
		Infections and infestations	Herpes zoster	01JUL2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Tendonitis	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Blood donor	01JAN1979	31DEC1995	N
			Corrective lens user	01JAN1980		Y
			Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311072	Blood and lymphatic system disorders	Haemolytic anaemia	01JAN2008	31DEC2013	N
			Lymphocytosis	04APR2020		Y
		Eye disorders	Myopia	01JAN2009		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2008	31DEC2008	N
			Diarrhoea	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Herpes zoster	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2005	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Spinal osteoarthritis	01JAN2017		Y
					31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2013	31DEC2013	N
			Gastrinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Neuralgia	01DEC2019		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2012	31DEC2012	N
		Social circumstances	Denture wearer	01JAN2016		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2013	31DEC2013	N
			Knee arthroplasty	01DEC2014	31DEC2014	N
				01JUN2014	30JUN2014	N
			Pancreatectomy	01JAN2008	31DEC2008	N
			Salpingo-oophorectomy unilateral	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Transfusion	01JAN2008	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1131 11311075	Blood and lymphatic system disorders	Anaemia	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2011	31DEC2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1983		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Ex-tobacco user	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
	C4591001 1131 11311082	Gastrointestinal disorders	Large intestine polyp	01JUL2019	31JUL2019	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2005		Y
			Hyperlipidaemia	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
			Tendonitis	30JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1967	31DEC1969	N
		Surgical and medical procedures	Continuous positive airway pressure	01JAN2000		Y
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1131 11311084	Eye disorders	Hypermetropia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		General disorders and administration site conditions	Pain	01JAN1995		Y
		Immune system disorders	Anaphylactic reaction	01JAN1990		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Nervous system disorders	Epilepsy	01JAN2000		Y
			Multiple sclerosis	01JAN2000		Y
			Myoclonus	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Hallucination	01JAN1979		Y
			Major depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995	31DEC2000	N
		Social circumstances	Denture wearer	01JAN1995		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1967	31DEC1967	N
			Appendicectomy	01JAN1979	31DEC1979	N
			Benign breast lump removal	01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1967	31DEC1967	N
			Tooth extraction	01JAN1995	31DEC1995	N
	C4591001 1131 11311088	Gastrointestinal disorders	Diverticulum	01MAY2019		Y
		Immune system disorders	Allergic oedema	01JAN2000	31DEC2000	N
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1983		Y
		Infections and infestations	Herpes zoster	01JAN2008	31DEC2008	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Biopsy breast normal	01JAN1995	31DEC1995	N
			Cardiac murmur	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JUL2020	01AUG2020	N
			Depression	01JUL2020	01AUG2020	N
			Insomnia	01JAN2005		Y
			Panic attack	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Urinary incontinence	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1989	31DEC2006	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000	31DEC2000	N
		Social circumstances	Corrective lens user	01JAN1996		Y
			Postmenopause	01JAN2007		Y
	C4591001 1131 11311089	Social circumstances	Corrective lens user	01JAN2005		Y
			Tobacco user	01JAN2019		Y
		Surgical and medical procedures	Cranial operation	01JAN1960	31DEC1960	N
	C4591001 1131 11311095	Endocrine disorders	Autoimmune thyroiditis	01JAN1989		Y
			Hypothyroidism	01JAN1989		Y
		Eye disorders	Cataract	01MAY2020		Y
			Myopia	01JAN1966		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2019		Y
		Nervous system disorders	Dizziness	01JAN2017		Y
			Migraine	01JAN1979		Y
		Social circumstances	Corrective lens user	01JAN1966		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2003		Y
	C4591001 1131 11311100	Blood and lymphatic system disorders	Polycythaemia	01JAN2015		Y
		Cardiac disorders	Atrioventricular block first degree	01JAN2003		Y
			Bundle branch block right	01JAN2003		Y
			Myocardial infarction	01JAN2000	31DEC2000	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2011	31DEC2011	N
		General disorders and administration site conditions	Chest pain	01JAN2003	31DEC2003	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980	31DEC2013	N
			Neck pain	01JAN2018		Y
			Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2013		Y
			Nephrolithiasis	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1965		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Continuous positive airway pressure	01JAN2015		Y
			Coronary artery bypass	01JAN2003	31DEC2003	N
			Inguinal hernia repair	01JAN2011	31DEC2011	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1131 11311101	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Wheezing	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Denture wearer	01JAN2010		Y
			Tobacco user	01JAN1995		Y
	C4591001 1131 11311110	Ear and labyrinth disorders	Hypoacusis	01MAY2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1968		Y
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1955	31DEC1955	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311114	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1981	31DEC1981	N
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Neovascular age-related macular degeneration	01SEP2018	30SEP2018	N
		Gastrointestinal disorders	Dyspepsia	01JUN2020		Y
			Faeces soft	01JAN2013		Y
			Irritable bowel syndrome	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
			Osteopenia	01JAN2012		Y
		Nervous system disorders	Carpal tunnel syndrome	01FEB2020		Y
				01MAR2020		Y
		Psychiatric disorders	Depression	01JAN1991		Y
			Insomnia	01JAN1943		Y
		Social circumstances	Corrective lens user	01JAN1983		Y
			Hearing aid user	01JAN2012		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendectomy	01JAN1949	31DEC1949	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Dental prosthesis placement	01JAN1986	31DEC1986	N
			Female sterilisation	01JAN1979	31DEC1979	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1944	31DEC1944	N
			Tympanoplasty	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01NOV2018		Y
	C4591001 1131 11311115	Eye disorders	Myopia	01JAN1965		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2014	31DEC2014	N
		Social circumstances	Corrective lens user	01JAN1965		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Phlebectomy	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Varicose vein	01JAN2005	31DEC2014	N
	C4591001 1131 11311118	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2000		Y
		Immune system disorders	Allergy to animal	01JAN1977		Y
			Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Social circumstances	Hearing aid user	01JAN2010		Y
		Surgical and medical procedures	Abscess drainage	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1131 11311119	Cardiac disorders	Angina pectoris	01AUG2001	31AUG2001	N
			Arteriosclerosis coronary artery	01AUG2001		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Eye disorders	Keratoconus	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoarthritis	01JAN2005		Y
		Renal and urinary disorders	Haematuria	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Blood donor	01JAN1975		Y
			Corrective lens user	01JAN1962		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2001		Y
	C4591001 1131 11311120	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Endocrine disorders	Hyperthyroidism	01JAN2007	31DEC2008	N
		Eye disorders	Cataract	01JAN2012	31DEC2018	N
			Myopia	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2016		Y
			Small intestinal stenosis	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Urinary tract infection	13JUL2020	16JUL2020	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Hypokalaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Essential thrombocythaemia	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN2012	31DEC2012	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2000	31DEC2012	N
			Depression	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1970		Y
			Nail growth abnormal	01JAN1960		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
			Hearing aid user	01JAN2010		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1975	31DEC1975	N
			Caesarean section	01JAN1977	31DEC1977	N
				01JAN1979	31DEC1979	N
				01JAN1983	31DEC1983	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Gastrointestinal dilation procedure	01JAN2017	31DEC2017	N
			Influenza immunisation	24AUG2020	24AUG2020	N
			Precancerous lesion excision	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1131 11311123	Eye disorders	Myopia	01JAN1969		Y
		Immune system disorders	Food allergy	01JAN2010		Y
			Rubber sensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2007	31DEC2007	N
		Nervous system disorders	Tremor	01JAN2010		Y
		Reproductive system and breast disorders	Amenorrhoea	01MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1969		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1990	31DEC1990	N
			Female sterilisation	01JAN1996	31DEC1996	N
			Skin neoplasm excision	01JAN2007	31DEC2007	N
		Vascular disorders	Hot flush	01JAN2018		Y
	C4591001 1131 11311125	Eye disorders	Cataract	01JAN2016		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
			Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2011	31DEC2011	N
				01JAN2015	31DEC2015	N
		Nervous system disorders	Migraine	01JAN1973	31DEC1974	N
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
					01JAN1981	31DEC1981
			Dental prosthesis placement	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Transfusion	01JAN1978	31DEC1978	N
	C4591001 1131 11311126	Cardiac disorders	Bundle branch block right	01JAN2016		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		Eye disorders	Cataract	01JAN2008	31DEC2010	N
			Hypermetropia	01JAN1952	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Retinal detachment	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1991	31DEC1994	N
			Intervertebral disc degeneration	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	01JAN2005		Y
		Nervous system disorders	Paraesthesia	01JAN2005		Y
		Renal and urinary disorders	Pollakiuria	01JAN2010	31DEC2011	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1952	31DEC2010	N
			Denture wearer	01JAN1962		Y
			Hearing aid user	01JAN2017	31DEC2017	N
			Tobacco user	01JAN1961		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Coronary arterial stent insertion	01JAN2016		Y
			Intervertebral disc operation	01JAN1993	31DEC1993	N
				01JAN1994	31DEC1994	N
			Retinopexy	01JAN2015	31DEC2015	N
	C4591001 1131 11311130	Gastrointestinal disorders	Haemorrhoids	01JAN1979	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Oral herpes	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
			Neuroma	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2003		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1998		Y
			Hearing aid user	01MAR2020		Y
			Tobacco user	01JAN1974		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Neurectomy	01JAN2018	31DEC2018	N
			Salpingo-oophorectomy bilateral	01JAN1993	31DEC1993	N
	C4591001 1131 11311133	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010	31DEC2017	N
		Reproductive system and breast disorders	Varicocele	01JAN1996	31DEC1996	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1971		Y
		Social circumstances	Corrective lens user	01JAN1987		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2004	31DEC2004	N
			Varicocele repair	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1131 11311137	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1993	31DEC1993	N
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Precancerous lesion excision	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2010	31DEC2012	N
	C4591001 1131 11311139	Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Continuous positive airway pressure	01JAN2017		Y
			Female sterilisation	01JAN1983	31DEC1983	N
	C4591001 1131 11311140	Vascular disorders	Hypertension	01JAN2017		Y
		Cardiac disorders	Aortic valve disease	01JAN2017	30JUN2020	N
			Coronary artery disease	01JUN2020		Y
		Ear and labyrinth disorders	Tympanic membrane perforation	18AUG2020		Y
		Eye disorders	Cataract	01JAN2017	31DEC2018	N
			Neovascular age-related macular degeneration	01JAN2007		Y
		Injury, poisoning and procedural complications	Back injury	06AUG2020		Y
		Investigations	Low density lipoprotein increased	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	30APR2016	N
		Renal and urinary disorders	Cystitis interstitial	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1949		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1949	31DEC1949	N
			Aortic valve replacement	01JUN2020	30JUN2020	N
			Cataract operation	01JAN2018	31DEC2018	N
			Coronary artery bypass	01JUN2020	01JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Eye laser surgery	01JAN2005	31DEC2005	N
			Meniscus operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1131 11311141	Blood and lymphatic system disorders	Anaemia	01JAN2010	31DEC2010	N
		Eye disorders	Myopia	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Infections and infestations	Onychomycosis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Neuralgia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974	31DEC1977	N
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JUL1992	31JUL1992	N
			Endometrial ablation	01JAN2010	31DEC2010	N
			Iridotomy	01JAN2019	31DEC2019	N
	C4591001 1131 11311145	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
			Cardiac failure	01JAN2019		Y
			Coronary artery disease	01JAN2012		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		Eye disorders	Cataract	01JAN2018	31MAR2020	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2011		Y
			Dizziness	01JAN2020	31AUG2020	N
			Neuropathy peripheral	01APR2019		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Renal and urinary disorders	Chronic kidney disease	01OCT2019		Y
			Urge incontinence	01AUG2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN1949		Y
			Denture wearer	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01MAR2020	31MAR2020	N
			Transurethral prostatectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1131 11311149	Cardiac disorders	Cardiac failure congestive	01OCT2011		Y
			Cardiomyopathy	01JAN2011		Y
			Coronary artery disease	01JAN2011		Y
		Eye disorders	Cataract	01JAN2016		Y
			Hypermetropia	01JAN1970		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2012		Y
			Oedema peripheral	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1982		Y
		Social circumstances	Corrective lens user	01JAN1970		Y
			Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Continuous positive airway pressure	01JAN1970		Y
			Coronary artery bypass	01JAN2011	31DEC2011	N
			Skin lesion removal	01JAN2020	31JAN2020	N
			Skin neoplasm excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1131 11311150	Immune system disorders	Allergy to arthropod sting	01JAN1967		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Dysphonia	01JAN2015		Y
			Pharyngeal mass	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Ovarian cystectomy	01JAN2012	31DEC2012	N
	C4591001 1131 11311151	Blood and lymphatic system disorders	Anaemia	01JAN2011		Y
		Cardiac disorders	Myocardial infarction	01JAN1990	31DEC1990	N
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1990		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1970		Y
		Eye disorders	Dry eye	01JAN2015		Y
			Glaucoma	01JAN2015		Y
			Myopia	01JAN1953		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2011	N
		Nervous system disorders	Carotid arteriosclerosis	01JAN2018		Y
			Transient ischaemic attack	01JAN2018	31DEC2018	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
			Urinary incontinence	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Ex-tobacco user	01JAN1958	31DEC1964	N
			Hearing aid user	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Nasal septal operation	01JAN1970	31DEC1970	N
			Prostatectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1131 11311154	Cardiac disorders	Ventricular extrasystoles	01JAN2015		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Keratosis pilaris	01JAN2010		Y
		Social circumstances	Blood donor	01JAN1965		Y
				01JAN2015		Y
			Corrective lens user	01JAN1965		Y
		Surgical and medical procedures	Hearing aid therapy	01JAN2000		Y
			Skin neoplasm excision	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1967	31DEC1967	N
	C4591001 1131 11311156	Cardiac disorders	Coronary artery disease	01JAN1992		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1992		Y
		Eye disorders	Cataract	01JUL2019	31AUG2020	N
		Gastrointestinal disorders	Constipation	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Hypoxia	01MAY2020	31MAY2020	N
		Social circumstances	Corrective lens user	01JAN2007		Y
			Tobacco user	01JAN1968	31DEC2016	N
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Cataract operation	25AUG2020	25AUG2020	N
			Cholecystectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1131 11311159	Eye disorders	Cataract	01JAN2018		Y
			Presbyopia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Tendonitis	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1962	31DEC1962	N
			Eye laser surgery	01JAN1990	31DEC1990	N
			Knee arthroplasty	01NOV2019	30NOV2019	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1131 11311163	Eye disorders	Cataract	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glaucoma	01JAN2019		Y
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
			Gastrooesophageal reflux disease	01JAN2014		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN1980		Y
				01JAN2015		Y
		Immune system disorders	Anaphylactic reaction	01JAN2012		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Urinary tract infection	01JAN1980	31DEC1990	N
		Investigations	Blood glucose increased	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JUN2020		Y
			Muscle spasms	01JAN2018		Y
			Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2014		Y
		Nervous system disorders	Lumbosacral radiculopathy	01JAN1990		Y
			Migraine	01JAN1980	31DEC1990	N
		Psychiatric disorders	Anxiety	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Bunion operation	01JAN1998	31DEC1998	N
			Female sterilisation	01JAN1989	31DEC1989	N
			Joint stabilisation	01JAN1991	31DEC1991	N
			Oophorectomy	01JAN1993	31DEC1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311164	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1998		Y
		Eye disorders	Cataract	01JAN2013		Y
			Myopia	01JAN1958		Y
		Gastrointestinal disorders	Abdominal hernia	01MAR2020		Y
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
			Osteoarthritis	01JAN2004		Y
			Osteonecrosis of jaw	01JAN2014	31DEC2014	N
			Osteoporosis	01JAN2000		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016	31MAR2016	N
		Social circumstances	Tobacco user	01JAN1979	30SEP2019	N
		Surgical and medical procedures	Adenoidectomy	01JAN1952	31DEC1952	N
			Bladder repair	01MAR2020	31MAR2020	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Skin neoplasm excision	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1131 11311165	Cardiac disorders	Bundle branch block left	01JAN2008		Y
		Eye disorders	Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Oesophageal stenosis	01JAN2000		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN2005		Y
		Investigations	Ureterscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1998	31DEC2004	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1976	31DEC1976	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Oesophageal dilation procedure	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1131 11311166	Immune system disorders	Seasonal allergy	01JAN1959		Y
		Infections and infestations	Herpes zoster	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	14JAN2020		Y
			Prostatomegaly	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN1979		Y
			Hearing aid user	01JAN2019		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1959	31DEC1959	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1131 11311168	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JUL2020		Y
		Eye disorders	Presbyopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Muscle strain	01JAN2019		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1970	31DEC1980	N
			Postmenopause	01JAN2015		Y
	C4591001 1131 11311169	Eye disorders	Myopia	01JAN1971	31DEC1983	N
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
			Urge incontinence	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1970		Y
			Urticaria	01JAN2016		Y
		Social circumstances	Hearing aid user	01JAN2000		Y
			Menopause	01JAN2015		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2018	31DEC2018	N
			Appendicectomy	01JAN1997	31DEC1997	N
			Caesarean section	01JAN1989	31DEC1989	N
				01JAN1994	31DEC1994	N
				01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Continuous positive airway pressure	01JAN2018		Y
			Keratotomy	01JAN1983	31DEC1983	N
			Thrombectomy	01JAN2016	31DEC2016	N
			Tooth extraction	01JUL2020	31JUL2020	N
	C4591001 1131 11311170	Ear and labyrinth disorders	Deafness unilateral	01JAN1976		Y
		Endocrine disorders	Hypothyroidism	01JAN1966	31DEC1972	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1990		Y
		Infections and infestations	Herpes zoster	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1994		Y
			Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1994		Y
		Renal and urinary disorders	Nephrolithiasis	01JUN2015	30JUN2015	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2007	31DEC2007	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1994		Y
				01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1975		Y
		Surgical and medical procedures	Arthrodesis	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2007	31DEC2007	N
			Middle ear lesion excision	01JAN1976	31DEC1976	N
			Skin lesion removal	01JAN2018	31DEC2018	N
	C4591001 1131 11311171	Cardiac disorders	Arrhythmia supraventricular	01JUN2020		Y
		Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Cataract	01JUL2020		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Gravitational oedema	01JAN2016		Y
		Immune system disorders	Anaphylactic reaction	01JAN1994		Y
			Rubber sensitivity	01JAN1994		Y
			Seasonal allergy	01JAN1995		Y
		Investigations	Arthroscopy	01JAN2003	31DEC2003	N
			Blood cholesterol increased	01JAN2003		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2004		Y
			Back pain	01JAN2004		Y
			Osteoarthritis	01JAN2003		Y
			Tendonitis	01JAN1995	31DEC2004	N
		Reproductive system and breast disorders	Amenorrhoea	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Respiratory distress	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1971		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2014	31DEC2014	N
			Tenoplasty	01JAN2011	31DEC2011	N
			Tenotomy	01JAN2004	31DEC2004	N
	C4591001 1131 11311174	Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2009		Y
		Ear and labyrinth disorders	Vertigo	01JAN2003	31DEC2010	N
		Eye disorders	Myopia	01JAN1961		Y
		Gastrointestinal disorders	Barrett's oesophagus	01MAR2013	31DEC2015	N
			Diarrhoea	01JAN1985	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gastritis	01MAR2013		Y
			Gastroesophageal reflux disease	01JAN1997		Y
			Hiatus hernia	01MAR2013		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1997		Y
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Infections and infestations	Sinusitis	01JAN1998		Y
		Investigations	Endoscopy	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Overweight	01JAN1961		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1974		Y
			Osteopenia	12MAR2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1998		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
			Sinus headache	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2001		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Granuloma annulare	01JAN2012		Y
		Social circumstances	Alcohol use	01JAN1975		Y
			Ex-tobacco user	01JAN1973	31DEC1980	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1998	31DEC1998	N
			Eye laser surgery	01JAN2001	31DEC2001	N
			Knee operation	01DEC2012	31DEC2012	N
				01OCT2012	31OCT2012	N
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
			Hot flush	01JAN1998		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN2005	31DEC2018	N
	C4591001 1131 11311175	Eye disorders	Myopia	01JAN1961		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JUL2020		Y
		Infections and infestations	Herpes zoster	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Amenorrhoea	01JAN2008		Y
		Social circumstances	Corrective lens user	01JAN1961		Y
			Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Mastectomy	01JAN2012	31DEC2012	N
	C4591001 1131 11311176	Blood and lymphatic system disorders	Anaemia	01JAN1960	31DEC1961	N
		Ear and labyrinth disorders	Hypoacusis	01JAN2010		Y
		Endocrine disorders	Goitre	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2009	N
			Hepatic steatosis	01JAN2010		Y
		Infections and infestations	Carbuncle	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2018		Y
			Trigger finger	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01OCT2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1987	31DEC1988	N
		Social circumstances	Corrective lens user	01JAN1970		Y
			Ex-tobacco user	01JAN1976	31DEC1993	N
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Continuous positive airway pressure	01JAN2018		Y
			Hysterectomy	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1131 11311177	Cardiac disorders	Ventricular extrasystoles	01JAN2013	31DEC2013	N
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
			Herpes simplex	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1995	31DEC1995	N
			Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2010		Y
		Nervous system disorders	Dizziness	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
			Insomnia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1965	31DEC2000	N
			Tobacco user	01JAN1970	31DEC1985	N
		Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
			Caesarean section	01JAN1990	31DEC1990	N
				01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Uterine dilation and curettage	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2016		Y
			Raynaud's phenomenon	01JAN2015		Y
	C4591001 1131 11311179	Cardiac disorders	Atrial fibrillation	01JAN1993		Y
			Coronary artery disease	01JAN2006		Y
		Eye disorders	Presbyopia	01JAN1973		Y
		Immune system disorders	Seasonal allergy	01JAN1957		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Surgical and medical procedures	Skin neoplasm excision	01DEC2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1976		Y
	C4591001 1131 11311180	Cardiac disorders	Mitral valve incompetence	01JAN2005		Y
			Palpitations	01JAN2005		Y
		Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2017	30SEP2019	N
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Diverticulum	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Oral herpes	01JAN2015		Y
		Investigations	Cardiac murmur	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Neck pain	01JAN2005		Y
			Osteopenia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1970	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2012	31DEC2012	N
			Depression	01JAN2012		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN1962		Y
			Ex-tobacco user	01JAN1966	31DEC1977	N
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01SEP2019	30SEP2019	N
			Mammoplasty	01JAN2004	31DEC2004	N
			Mastectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1131 11311185	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2014		Y
		Eye disorders	Presbyopia	01JAN1989		Y
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2014	31DEC2014	N
		Social circumstances	Corrective lens user	01JAN1989		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ex-tobacco user	01JAN1977	31DEC2004	N
		Surgical and medical procedures	Nasal septal operation	01JAN2015	31DEC2015	N
			Tendon operation	01JAN2014	31DEC2014	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	05AUG2020		Y
	C4591001 1131 11311186	Eye disorders	Presbyopia	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1131 11311187	Ear and labyrinth disorders	Hypoacusis	01JAN2004		Y
			Tinnitus	01JAN2015		Y
		Eye disorders	Presbyopia	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Social circumstances	Blood donor	01JAN1990	31DEC2015	N
			Corrective lens user	01JAN2002		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2007	31DEC2007	N
			Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1131 11311188	Endocrine disorders	Hyperparathyroidism	01NOV2017	30NOV2017	N
		Gastrointestinal disorders	Diverticulum	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Nervous system disorders	Facial paralysis	01MAR2019	30APR2019	N
			Head titubation	01JAN1975		Y
			Tremor	01JAN1975		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Haematuria	01JAN2017		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2000	31DEC2000	N
			Parathyroidectomy	01JAN2007	31DEC2007	N
	C4591001 1131 11311192	Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2017	N
		Cardiac disorders	Atrial fibrillation	01JAN2011	31DEC2011	N
			Tachycardia paroxysmal	01JAN2011	31DEC2011	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Eye disorders	Dry eye	01JAN2016		Y
			Myopia	01JAN1965		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2007		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2017		Y
			Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1961		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Urinary tract infection	01JAN1959	31DEC1968	N
		Investigations	Blood cholesterol increased	01JAN2001	31DEC2002	N
			Cardiac murmur	01JAN2002		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1967		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1970		Y
			Intervertebral disc degeneration	01JAN1990		Y
			Osteoarthritis	01JAN1990		Y
			Osteopenia	01JAN2005		Y
			Spinal osteoarthritis	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
			Syncope	01JAN1972		Y
				01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2006	31DEC2018	N
			Depression	01JAN2006	31DEC2018	N
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Nasal septum deviation	01JAN1976	31DEC1992	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2003		Y
		Social circumstances	Corrective lens user	01JAN1965		Y
			Hearing aid user	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Limb operation	01JAN2005	31DEC2005	N
			Rhinoplasty	01JAN1977	31DEC1977	N
			Spinal operation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311194	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Sinusitis	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Investigations	Heart rate irregular	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Trigger finger	01JAN2017	31DEC2017	N
		Nervous system disorders	Dizziness	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2015	31DEC2016	N
			Insomnia	01JAN1995	31DEC2019	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
		Social circumstances	Blood donor	01JAN1995	31DEC2010	N
			Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Arthrodesis	01JAN2016	31DEC2016	N
			Meniscus operation	01JAN2015	31DEC2015	N
			Tendon sheath incision	01JAN2017	31DEC2017	N
	C4591001 1131 11311195	Eye disorders	Cataract	01JAN2019		Y
			Myopia	01JAN1963	31DEC2001	N
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Meningitis viral	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2013		Y
			Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN1975		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
			Nephrolithiasis	01JAN2014	31DEC2014	N
		Social circumstances	Blood donor	01JAN1976		Y
		Surgical and medical procedures	Eye laser surgery	01JAN2001	31DEC2001	N
			Meniscus operation	01JAN2009	31DEC2009	N
				01OCT2019	31OCT2019	N
	C4591001 1131 11311196	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Diverticulum	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1995	31DEC1995	N
			Tendon rupture	01JAN2005	31DEC2005	N
			Wrist fracture	01JAN2005	31DEC2005	N
				01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1971		Y
		Social circumstances	Blood donor	01JAN1980	31DEC1995	N
			Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1996	31DEC1996	N
			Ligament operation	01JAN1995	31DEC1995	N
				01JAN2007	31DEC2007	N
			Tenoplasty	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311197	Ear and labyrinth disorders	Meniere's disease	01JAN2012		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN1985		Y
			Hypothyroidism	01JAN1986		Y
		Eye disorders	Amblyopia	01JAN1960	31DEC1961	N
			Hypermetropia	01JAN1960		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN1999		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1985	31DEC1986	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Headache	01JAN1988	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN1985	31DEC2015	N
			Depression	01JAN1985		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1995	31DEC1999	N
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Appendectomy	01JAN1986	31DEC1986	N
			Cholecystectomy	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Keratomileusis	01JAN2000	31DEC2000	N
	C4591001 1131 11311198	Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Astigmatism	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Herpes zoster	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Serotonin syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1969	31DEC1969	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Continuous positive airway pressure	01JAN2010		Y
			Spinal fusion surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1131 11311199	Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2019	N
			Coronary artery disease	01JAN2018		Y
		Congenital, familial and genetic disorders	Atrial septal defect	01JAN1998	31DEC1999	N
		Ear and labyrinth disorders	Deafness unilateral	01JAN1994		Y
		Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2017	N
		Immune system disorders	Allergy to arthropod bite	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2010		Y
				01JAN2019		Y
			Tendonitis	01JAN2010		Y
				01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
			Syncope	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN1997		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Apnoea	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2008		Y
		Social circumstances	Corrective lens user	01JAN1965		Y
		Surgical and medical procedures	Atrial septal defect repair	01JAN1999	31DEC1999	N
			Fracture treatment	01JAN1991		Y
				01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN1953	31DEC1953	N
				01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1959	31DEC1959	N
			Vasectomy	01JAN1978		Y
		Eye disorders	Myopia	01JAN1963		Y
	C4591001 1131 11311200	Metabolism and nutrition disorders	Hyperlipidaemia	17AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2019		Y
		Nervous system disorders	Syncope	01JAN2010		Y
		Social circumstances	Blood donor	01JAN2000		Y
			Corrective lens user	01JAN1963		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01AUG1989	31AUG1989	N
				01MAR1991	31MAR1991	N
			Keratomileusis	01JAN2001	31DEC2001	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1131 11311204	Cardiac disorders	Tonsillectomy	01JAN1960	31DEC1960	N
			Atrial fibrillation	01JAN2018		Y
		Ear and labyrinth disorders	Auditory disorder	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1985	31DEC2015	N
		Investigations	Cardiac murmur	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
			Cerebrovascular accident	01JAN2018	31DEC2018	N
			Memory impairment	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
			Denture wearer	01JAN2013		Y
			Ex-tobacco user	01JAN1945	31DEC1980	N
		Surgical and medical procedures	Cataract operation	01JAN2000	31DEC2000	N
			Hip arthroplasty	01JAN2002	31DEC2002	N
			Knee arthroplasty	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Aortic stenosis	01JAN2010		Y
	C4591001 1131 11311206	Eye disorders	Myopia	01JAN1965		Y
			Presbyopia	01JAN1997		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Infections and infestations	Chronic tonsillitis	01JAN1967	31DEC1969	N
			Herpes zoster	01JAN1961	31DEC1961	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2007	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vth nerve injury	01JAN1961		Y
		Investigations	Pelvic laparoscopy	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
			Osteoarthritis	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1984	31DEC1989	N
		Reproductive system and breast disorders	Adnexa uteri pain	01JAN1997	31DEC1998	N
			Pelvic pain	01JAN1993	31DEC1994	N
		Social circumstances	Corrective lens user	01JAN1997		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1969	31DEC1969	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
				01JAN2011	31DEC2011	N
			Oophorectomy	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Eye disorders	Presbyopia	01JAN1955		Y
	C4591001 1131 11311207	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN1955		Y
			Ex-tobacco user	01JAN1970	31DEC2010	N
		Surgical and medical procedures	Knee operation	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1955		Y
	C4591001 1131 11311208	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2016		Y
			Spinal osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Social circumstances	Blood donor	01JAN1979		Y
			Corrective lens user	01JAN1969		Y
			Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2019	31DEC2019	N
				01JAN2019	31JAN2019	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1990	31DEC1990	N
			Hypogonadism	01JAN2001		Y
	C4591001 1131 11311210	Endocrine disorders				
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1982		Y
		General disorders and administration site conditions	Pain	01JAN1996		Y
			Peripheral swelling	01JAN2012		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1994	31DEC1994	N
			Hepatic steatosis	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1968	31DEC1968	N
			Ulna fracture	21JUN2020	16AUG2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994		Y
			Intervertebral disc displacement	01JAN2015		Y
			Spinal osteoarthritis	01JAN1994		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01OCT2019	31JAN2020	N
		Nervous system disorders	Migraine	01JAN1996	31DEC2015	N
			Neuralgia	01JAN2014		Y
			Seizure	01JAN1968	31DEC1971	N
		Psychiatric disorders	Anxiety	01JAN1973		Y
			Bipolar disorder	01JAN2015		Y
			Insomnia	01JAN1969		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2019		Y
			Erectile dysfunction	01JAN2006		Y
			Prostatomegaly	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN1976		Y
			Tobacco user	01JAN1976		Y
		Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Intervertebral disc operation	01JAN2015	31DEC2015	N
			Nasal septal operation	01JAN1992	31DEC1992	N
			Spinal decompression	01JAN2014	31DEC2014	N
			Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1131 11311211	Cardiac disorders	Mitral valve prolapse	01JAN1987		Y
			Supraventricular tachycardia	01JAN1987	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Repetitive strain injury	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1996		Y
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
			Skin neoplasm excision	01JAN1990	31DEC1990	N
	C4591001 1131 11311213	Ear and labyrinth disorders	Hypoacusis	01JAN1984		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Retinal detachment	01JAN2011	31DEC2011	N
		Gastrointestinal disorders	Intestinal obstruction	01JAN1968	31DEC1968	N
		General disorders and administration site conditions	Adverse drug reaction	01JAN2016		Y
		Investigations	Cardiac murmur	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2009		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
			Erectile dysfunction	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1987		Y
		Social circumstances	Ex-tobacco user	01JAN1964	31DEC1964	N
		Surgical and medical procedures	Appendectomy	01JAN1956	31DEC1956	N
			Cataract operation	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1131 11311214	Ear and labyrinth disorders	Hypoacusis	01JAN2012	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Presbyopia	01JAN1959		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2019		Y
			Spinal stenosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	02AUG2019	02AUG2019	N
			Invasive ductal breast carcinoma	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015	31DEC2015	N
		Social circumstances	Corrective lens user	01JAN1959		Y
			Ex-tobacco user	01JAN1968	31DEC1988	N
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Intervertebral disc operation	01JAN2008	31DEC2008	N
			Meniscus operation	01JAN2019	31DEC2019	N
			Ossiculoplasty	24AUG2018	24AUG2018	N
			Spinal laminectomy	01JAN2008	31DEC2008	N
			Tympanoplasty	24AUG2018	24AUG2018	N
	C4591001 1131 11311215	Blood and lymphatic system disorders	Anaemia	01JAN1968	31DEC1980	N
		Cardiac disorders	Ventricular tachycardia	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Myopia	01JAN2000		Y
			Presbyopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN1989		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2007		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
			Migraine	01JAN1994	31DEC2000	N
			Nerve compression	01JAN2008		Y
			Syncope	01JAN1981	31DEC1982	N
		Social circumstances	Blood donor	01JAN1980	31DEC1981	N
					31DEC2016	N
			Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
			Female sterilisation	01JAN1989	31DEC1989	N
			Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1131 11311216	Ear and labyrinth disorders	Vertigo	01JAN2011	31DEC2018	N
		Endocrine disorders	Hypogonadism	01JAN1996		Y
			Hypothyroidism	01JAN1999		Y
		Eye disorders	Cataract	01JAN2005	31DEC2010	N
					31DEC2013	N
		Gastrointestinal disorders	Dysphagia	01JAN2015	31DEC2015	N
			Gastroesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Muscle rupture	01DEC2019	31JAN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2013		Y
			Tenosynovitis	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1999	31JAN2020	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016	31DEC2018	Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1988		Y
			Erectile dysfunction	01JAN2000		Y
			Peyronie's disease	01JAN2011		Y
			Prostatomegaly	01APR2019		Y
			Scrotal cyst	01JAN1996	31DEC1999	N
			Testicular retraction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
			Rash	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Inguinal hernia repair	01JAN1986	31DEC2017	N
				01JAN2016	31DEC2016	N
			Intraocular lens implant	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Muscle operation	01JAN2020	31JAN2020	N
			Oesophageal dilation procedure	01JAN2015	31DEC2015	N
			Prostatic urethral lift procedure	01MAY2019	31MAY2019	N
			Scrotal cystectomy	01JAN1999	31DEC1999	N
			Skin lesion removal	01JAN2020	31JAN2020	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1131 11311217	Blood and lymphatic system disorders	Anaemia	01JAN1980	31DEC1981	N
		Eye disorders	Cataract	01JAN2017		Y
			Glaucoma	01JAN2017		Y
			Myopia	01JAN1952		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN1965		Y
		Surgical and medical procedures	Colectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1131 11311218	Blood and lymphatic system disorders	Iron deficiency anaemia	01MAY2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Investigations	C-reactive protein increased	12FEB2019		Y
			Heart rate irregular	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2006		Y
			Gout	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2006		Y
			Vitamin D deficiency	30MAR2015		Y
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN1980	31DEC1980	N
			Back pain	01JAN1965		Y
			Neck pain	01JAN2004		Y
			Osteoarthritis	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	17JUN2020	16JUL2020	N
		Psychiatric disorders	Insomnia	01JAN2002		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2008		Y
			Urinary incontinence	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2020	01MAY2020	N
		Social circumstances	Corrective lens user	01JAN1984		Y
			Denture wearer	01JAN2015		Y
			Ex-tobacco user	01JAN1959	07APR2017	N
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Colectomy	01JAN1967	31DEC1967	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
			Wrist surgery	01JAN1980	31DEC1980	N
			Palpitations	01JUL2020		Y
	C4591001 1131 11311222	Cardiac disorders				
		Eye disorders	Myopia	01JAN1979		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JUL2020		Y
		Social circumstances	Corrective lens user	01JAN1979		Y
			Postmenopause	01JAN2016		Y
	C4591001 1131 11311223	Eye disorders	Astigmatism	01JAN1975		Y
		Infections and infestations	Herpes zoster	01JAN1998	31DEC1999	N
		Investigations	Cardiac murmur	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck pain	01JAN1985		Y
			Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1985	31DEC1992	N
		Social circumstances	Corrective lens user	01JAN1975		Y
			Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1992	31DEC1992	N
			Female sterilisation	01JAN1966	31DEC1966	N
			Mastectomy	01JAN1985	31DEC1985	N
				01JAN1986	31DEC1986	N
			Skin neoplasm excision	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1131 11311224	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Cataract	01JAN2007	31DEC2017	N
			Myopia	01JAN1950	31DEC2017	N
		Gastrointestinal disorders	Diverticulum	01JAN1998		Y
			Gastrooesophageal reflux disease	01JAN1998		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN1980		Y
			Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
			Neuropathy peripheral	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Transient ischaemic attack	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01APR2020		Y
		Social circumstances	Denture wearer	01JAN2016		Y
			Hearing aid user	01JAN2004		Y
			Tobacco user	01JAN1968	31DEC1972	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Coronary artery bypass	01JAN1995	31DEC1995	N
			Intraocular lens implant	01JAN2017	31DEC2017	N
			Skin neoplasm excision	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Arterial occlusive disease	01JAN1995	31DEC1995	N
	C4591001 1131 11311225	Cardiac disorders	Atrial fibrillation	01JAN2019	31DEC2019	N
			Cardiac failure congestive	01JAN2017		Y
			Cardiomyopathy	01JAN2000		Y
			Coronary artery disease	01JAN2000		Y
			Myocardial infarction	01JAN1997	31DEC1997	N
				01JAN2000	31DEC2000	N
				01JAN2003	31DEC2003	N
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2003		Y
		Ear and labyrinth disorders	Tinnitus	01JAN1978		Y
			Vertigo	01JAN1970		Y
		Eye disorders	Presbyopia	01JAN1968		Y
		Gastrointestinal disorders	Diverticulum	01JAN2000		Y
			Large intestine polyp	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Back injury	01JAN1974		Y
		Investigations	Cardiac murmur	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2016	31DEC2019	N
		Nervous system disorders	Transient ischaemic attack	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1993	31DEC1993	N
			Insomnia	01JAN1966		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1984		Y
		Social circumstances	Corrective lens user	01JAN1968		Y
			Tobacco user	01JAN1974	14FEB2017	N
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31DEC2019	N
			Continuous positive airway pressure	01JAN2019		Y
			Coronary artery bypass	01JAN2017		Y
			Large intestinal polypectomy	01JAN2016	31DEC2016	N
			Shoulder operation	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1131 11311226	Ear and labyrinth disorders	Hypoacusis	01JAN1990		Y
		Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Investigations	Biopsy breast normal	01JAN2014	31DEC2014	N
			Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Spinal osteoarthritis	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spondylitis	01JAN2000		Y
			Trigger finger	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1986	31DEC1986	N
				01JAN2006	31DEC2007	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
			Headache	01JAN1965	31DEC1973	N
			Migraine	01JAN1979	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2005	31DEC2006	N
			Depression	01JAN1990		Y
			Insomnia	01JAN1976		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1956		Y
				01JAN1974		Y
			Hearing aid user	01JAN2000		Y
			Menopause	01JAN2003		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1986	31DEC1986	N
			Dental implantation	01JAN2005	31DEC2005	N
			Myomectomy	01JAN2005	31DEC2005	N
			Salpingoplasty	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01MAR2019	31MAR2019	N
			Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1131 11311227	Eye disorders	Presbyopia	01JAN1984		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Postmenopause	01JAN2012		Y
	C4591001 1131 11311235	Ear and labyrinth disorders	Vertigo positional	01JAN2017		Y
		Eye disorders	Cataract	01JAN2008	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1948		Y
			Seasonal allergy	01JAN1940		Y
		Investigations	Glycosylated haemoglobin increased	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Lumbar spinal stenosis	01JAN2000	31DEC2005	N
			Neck pain	01JAN2000		Y
			Osteoarthritis	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2005	N
			Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Depression	01JAN1970		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950		Y
		Social circumstances	Blood donor	01JAN1998	31DEC2014	N
			Corrective lens user	01JAN1948		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN1998	31DEC1998	N
			Skin lesion removal	01JAN2012	30SEP2019	N
					31DEC2019	N
			Spinal operation	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1949	31DEC1949	N
	C4591001 1131 11311236	Immune system disorders	Seasonal allergy	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc compression	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2005	N
			Presyncope	01JAN1964		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2005	31DEC2005	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Spinal decompression	01MAR2020	31MAR2020	N
	C4591001 1131 11311237	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2005	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Hidradenitis	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1980		Y
			Postmenopause	01JAN2005		Y
			Tobacco user	01JAN1985		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2010	31DEC2010	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1131 11311238	Endocrine disorders	Hypothyroidism	01JAN2019	30JUN2020	N
		Eye disorders	Hypermetropia	01JAN1966		Y
			Myopia	01JAN1966		Y
		Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Osteopenia	01FEB2016		Y
			Synovial cyst	01JAN1990		Y
		Social circumstances	Corrective lens user	01JAN1966		Y
			Menopause	01JAN2007		Y
			Tobacco user	01JAN1971	31DEC1993	N
		Surgical and medical procedures	Appendectomy	01JAN2010	31DEC2010	N
			Blepharoplasty	01JAN2013	31DEC2013	N
			Eye laser surgery	01JAN2015	31DEC2015	N
			Eye operation	01JAN2007	31DEC2007	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1131 11311239	Gastrointestinal disorders	Abdominal hernia	01JAN1955	31DEC1961	N
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1967	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Neck pain	01AUG2020		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974	31DEC1974	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2015		Y
		Social circumstances	Blood donor	01JAN2007		Y
			Corrective lens user	01JAN1997		Y
			Tobacco user	01JAN1970	31DEC1995	N
				01JAN1995	31DEC2010	N
		Surgical and medical procedures	Hernia repair	01JAN1961	31DEC1961	N
			Tenoplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1131 11311244	Ear and labyrinth disorders	Hypoacusis	01NOV2019		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Investigations	Cardiac murmur	01JAN1980		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
			Neck pain	01JAN2003		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Social circumstances	Blood donor	01JAN1974		Y
				01JAN1990	31DEC1999	N
			Corrective lens user	01JAN1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Abdominoplasty	01JAN1992	31DEC1992	N
			Blepharoplasty	01JAN1989	31DEC1989	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Mammoplasty	01JAN2010	31DEC2010	N
			Neck lift	01JAN2001	31DEC2001	N
			Open reduction of fracture	01JAN1966	31DEC1966	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1131 11311245	Eye disorders	Myopia	01JAN1959		Y
		Gastrointestinal disorders	Dyspepsia	01SEP2020		Y
		Immune system disorders	Seasonal allergy	01JAN1997		Y
		Infections and infestations	Herpes zoster	01JAN2017	31DEC2017	N
		Investigations	Arthroscopy	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Osteoarthritis	01JAN1995		Y
			Scoliosis	01JAN1997		Y
			Spinal osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	19OCT1974	31DEC2005	N
		Psychiatric disorders	Depression	01JAN1970		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN1959		Y
		Surgical and medical procedures	Bladder repair	01JAN2017	31DEC2017	N
			Breast conserving surgery	01JAN2012	31DEC2012	N
			Bunion operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Radiotherapy	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1131 11311247	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
			Tinnitus	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2019		Y
					31DEC2019	N
			Diverticulum	01DEC2018		Y
		General disorders and administration site conditions	Adverse drug reaction	01JAN1981		Y
				01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1957		Y
		Infections and infestations	Diverticulitis	01DEC2018	29DEC2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hyperlipidaemia	01JAN1998		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018		Y
			Neck pain	01JAN2010		Y
			Osteoarthritis	01JAN2005		Y
			Osteopenia	01JAN2019		Y
			Osteoporosis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01FEB2019	30SEP2019	N
		Psychiatric disorders	Insomnia	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1965		Y
		Surgical and medical procedures	Abdominal cavity drainage	01NOV2019	30NOV2019	N
			Abdominal hernia repair	31OCT2019	31OCT2019	N
			Carpal tunnel decompression	01JAN1982	31DEC1982	N
			Colectomy	01JAN2019	31JAN2019	N
			Continuous positive airway pressure	01JAN2016		Y
			Fracture treatment	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Ileostomy	01JAN2019	31DEC2019	N
			Ileostomy closure	01MAR2019	31MAR2019	N
			Transfusion	01JAN2019	31DEC2019	N
			Wound treatment	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1131 11311249	Congenital, familial and genetic disorders	Chediak-Higashi syndrome	(b) (6) 1951		Y
		Eye disorders	Cataract	01JAN2016	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1996		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Social circumstances	Blood donor	01JAN1975		Y
			Corrective lens user	01JAN1952	31DEC1952	N
			Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Synovial cyst removal	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1131 11311251	Ear and labyrinth disorders	Tinnitus	01JAN1990		Y
		Eye disorders	Myopia	01JAN2002		Y
		General disorders and administration site conditions	Adverse drug reaction	16APR2003		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Injury, poisoning and procedural complications	Skin laceration	16APR2003	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
			Tendonitis	01JAN2015		Y
				01NOV2017		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
		Surgical and medical procedures	Hip arthroplasty	01FEB2018	28FEB2018	N
				01NOV2017	30NOV2017	N
			Limb reattachment surgery	16APR2003	16APR2003	N
			Sebaceous cyst excision	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1131 11311255	Blood and lymphatic system disorders	Anaemia	01JAN2016	31DEC2016	N
		Cardiac disorders	Myocardial infarction	01JAN2012	31DEC2012	N
			Myocardial ischaemia	01JAN2012		Y
		Eye disorders	Myopia	01JAN1967		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2012		Y
			Meniscus operation	01JAN2016	31DEC2016	N
			Shoulder operation	01JAN2005	31DEC2005	N
			Skin neoplasm excision	01JAN2010	30JUN2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1131 11311256	Gastrointestinal disorders	Diverticulum	01JAN2011		Y
			Inguinal hernia	01JAN1981	31DEC2012	N
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2020		Y
			Back pain	01JAN1991		Y
			Extremity contracture	01JAN2018		Y
			Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01APR2020		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Tobacco user	01JAN1977		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1974		Y
	C4591001 1131 11311258	Cardiac disorders	Arrhythmia	01JAN2014		Y
		Eye disorders	Myopia	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
			Osteoporosis	01JAN2000	31DEC2005	N
			Tendonitis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2004		Y
			Tarsal tunnel syndrome	01JAN2003	31DEC2004	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1975	31DEC1975	N
			Joint arthroplasty	01JAN2011	31DEC2011	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2011	31DEC2011	N
			Tarsal tunnel decompression	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1131 11311259	Ear and labyrinth disorders	Tinnitus	01JAN2017		Y
		Eye disorders	Myopia	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Synovial cyst	01MAR2020		Y
		Nervous system disorders	Headache	01JUN2019	31OCT2019	N
		Psychiatric disorders	Insomnia	01JAN1989		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967	31DEC1978	N
		Social circumstances	Ex-tobacco user	01JAN1980		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1965	31DEC1965	N
			Continuous positive airway pressure	01JAN2003	31DEC2016	N
			Dental implantation	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1985		Y
		Eye disorders	Myopia	01JAN1982		Y
	C4591001 1131 11311262	Injury, poisoning and procedural complications	Meniscus injury	01OCT1994	31OCT1994	N
			Muscle rupture	01FEB2019	01OCT2019	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JUN2019	01OCT2019	N
			Osteopenia	01JAN2015		Y
			Synovial cyst	01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	03SEP2019	03SEP2019	N
		Nervous system disorders	Nerve compression	01FEB2019	01OCT2019	N
		Social circumstances	Corrective lens user	01JAN1982		Y
			Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Bone lesion excision	01OCT2019	01OCT2019	N
			Meniscus operation	01JUN1995	30JUN1995	N
			Skin neoplasm excision	03SEP2019	03SEP2019	N
			Synovial cyst removal	01JAN1998	31DEC1998	N
	C4591001 1133 11331002	Eye disorders	Presbyopia	01JAN2012		Y
		Infections and infestations	Ear infection	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1995	31DEC1995	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1983	31DEC1983	N
	C4591001 1133 11331005	Eye disorders	Myopia	01JAN1958		Y
	C4591001 1133 11331006	Cardiac disorders	Cardiac failure congestive	01JAN2012		Y
			Coronary artery disease	01JAN2008		Y
		Gastrointestinal disorders	Colitis ischaemic	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Psychiatric disorders	Alcohol abuse	01JAN2000	31DEC2018	N
			Bipolar disorder	01JAN2018		Y
			Schizophrenia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Surgical and medical procedures	Cardiac operation	01JAN2009	31DEC2009	N
			Colostomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1133 11331007	Eye disorders	Myopia	01JAN1978		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1986	31DEC1986	N
		Immune system disorders	Iodine allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
			Tobacco user	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ankle operation	01JAN1978	31DEC1978	N
			Cholecystectomy	01JAN1986	31DEC1986	N
	C4591001 1133 11331008	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Presbyopia	01JAN2019		Y
	C4591001 1133 11331009	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Eye disorders	Myopia	01JAN1964		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2001		Y
		Metabolism and nutrition disorders	Hypoglycaemia	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1133 11331010	Vascular disorders	Hypertension	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2013		Y
		Injury, poisoning and procedural complications	Hip fracture	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
	C4591001 1133 11331012	Vascular disorders	Hypertension	01JAN2015		Y
		Ear and labyrinth disorders	Cerumen impaction	30JUL2020		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1133 11331013	Infections and infestations	Appendicitis	01JAN1992		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331015	Endocrine disorders	Hypogonadism	01JAN2017		Y
			Hypothyroidism	01JAN2017		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
			Myopia	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Overweight	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Rotator cuff syndrome	01JAN2020		Y
		Nervous system disorders	Tension headache	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331018	Eye disorders	Hypermetropia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331020	Endocrine disorders	Hypogonadism	01JAN2019		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Myopia	01JAN1954		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1993	31DEC1993	N
		Infections and infestations	Appendicitis	01JAN1949	31DEC1949	N
			Hepatitis A	01JAN1986	31DEC1986	N
			Tonsillitis	01JAN1947	31DEC1947	N
		Metabolism and nutrition disorders	Gout	01JAN1987		Y
			Hyperlipidaemia	01JAN2017		Y
			Hyperuricaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Nervous system disorders	Tension headache	01JAN1973		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
		Social circumstances	Ex-tobacco user	01JAN1958	31DEC1965	N
		Surgical and medical procedures	Appendectomy	01JAN1949	31DEC1949	N
			Cataract operation	01MAY2016	31MAY2016	N
			Cholecystectomy	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1947	31DEC1947	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1133 11331021	Eye disorders	Presbyopia	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331022	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331024	Cardiac disorders	Bradycardia	01JAN2018		Y
		Ear and labyrinth disorders	Deafness	01JUN2020		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2019	14MAY2020	N
		Eye disorders	Presbyopia	01JAN2010		Y
		General disorders and administration site conditions	Chest pain	01JAN2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1964	31DEC2000	N
			Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Parathyroidectomy	14MAY2020	14MAY2020	N
			Uvulectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331025	Eye disorders	Hypermetropia	01JAN1970		Y
			Myopia	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
			Micrographic skin surgery	01JAN2012	31DEC2012	N
	C4591001 1133 11331026	Eye disorders	Myopia	01JAN1990		Y
	C4591001 1133 11331027	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Eye disorders	Cataract	01JAN2017	31DEC2018	N
		Gastrointestinal disorders	Diverticulum	01JAN2018		Y
			Dyspepsia	01JAN2018		Y
		General disorders and administration site conditions	Hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN2017		Y
			Seasonal allergy	01JAN1954		Y
		Infections and infestations	Herpes zoster	01JAN2008	31DEC2008	N
			Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1133 11331029	Eye disorders	Myopia	01JAN2012		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1978	31DEC1978	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1988	31DEC1988	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1978	31DEC1978	N
			Meniscus operation	01JAN1988	31DEC1988	N
	C4591001 1133 11331031	Endocrine disorders	Hyperthyroidism	01JAN2005		Y
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Myopia	01JAN2005		Y
		Gastrointestinal disorders	Dry mouth	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1958	31DEC1958	N
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2015		Y
			Sciatic nerve neuropathy	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Gastrectomy	01JAN2018	31DEC2018	N
			Gastric banding	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Varicose vein	01JAN2012		Y
	C4591001 1133 11331033	Immune system disorders	Drug hypersensitivity	01JAN1951		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2010		Y
			Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2010		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2016	31DEC2016	N
			Shoulder operation	01JAN2003	31DEC2003	N
			Thyroidectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331034	Eye disorders	Presbyopia	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N
	C4591001 1133 11331036	Endocrine disorders	Hypothyroidism	01JAN1966		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
			Tonsillitis	01JAN1955	31DEC1955	N
		Injury, poisoning and procedural complications	Multiple fractures	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1133 11331038	Eye disorders	Presbyopia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331039	Eye disorders	Cataract	01JAN2011		Y
			Glaucoma	01JAN2011		Y
		Infections and infestations	Appendicitis	01JAN1961	31DEC1961	N
			Herpes zoster	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
			Prostatectomy	01JAN2017	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331040	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Rubber sensitivity	01JAN1989		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Facial operation	01JAN1975	31DEC1975	N
	C4591001 1133 11331046	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
		Eye disorders	Cataract	01JAN2008	31DEC2008	N
			Presbyopia	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2010		Y
		Renal and urinary disorders	Urinary retention	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1958	31DEC1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
			Intracerebral haematoma evacuation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331055	Cardiac disorders	Atrial fibrillation	01JAN2000	31DEC2018	N
			Tachycardia	01JAN2000	31DEC2018	N
		Gastrointestinal disorders	Hiatus hernia	01JAN1973	31DEC1974	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2013	N
		Psychiatric disorders	Anxiety	01JAN1960		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2012		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC2010	N
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
			Gastric bypass	01JAN2011	31DEC2011	N
			Hernia hiatus repair	01JAN2012	31DEC2012	N
			Implantable defibrillator insertion	01JAN2009		Y
			Prostatectomy	01JAN2013	31DEC2013	N
			Rhinoplasty	01JAN2012	31DEC2012	N
	C4591001 1133 11331056	Endocrine disorders	Hyperprolactinaemia	01JAN2017		Y
		Eye disorders	Cataract	01JAN2013	31DEC2013	N
			Presbyopia	01JAN2005		Y
			Retinal disorder	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN1969	31DEC2011	N
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Cataract operation	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN1979	31DEC1979	N
			Hysterectomy	01JAN1994	31DEC1994	N
			Retinal operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331057	Eye disorders	Presbyopia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1133 11331064	Eye disorders	Myopia	01JAN1971		Y
		Infections and infestations	Tonsillitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Overweight	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Nervous system disorders	Neuropathy peripheral	01AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Ex-tobacco user	01JAN1978	31DEC1989	N
		Surgical and medical procedures	Cranial operation	11AUG2016	11AUG2016	N
			Tendon sheath incision	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1983	31DEC1983	N
	C4591001 1133 11331067	Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1974	31DEC1974	N
				01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331068	Endocrine disorders	Hypothyroidism	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN1981		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
			Postmenopause	01JAN2007		Y
			Tobacco user	01JAN1998		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331071	Social circumstances	Corrective lens user	01JAN2015		Y
			Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Mammoplasty	01JAN2015	31DEC2015	N
	C4591001 1133 11331073	Eye disorders	Presbyopia	01JAN1993		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1993		Y
		Social circumstances	Alcohol use	01JAN1984		Y
	C4591001 1133 11331075	Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
		Cardiac disorders	Mitral valve prolapse	01JAN1968		Y
		Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN1968		Y
		Eye disorders	Myopia	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Adenoiditis	01JAN1968	31DEC1968	N
			Herpes zoster	01JAN2017	31DEC2017	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2004		Y
			Floating patella	01JAN2000	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1968	31DEC1968	N
			Knee operation	01JAN2000	31DEC2000	N
			Micrographic skin surgery	01JAN2012	31DEC2012	N
			Rhinoplasty	01JAN2005	31DEC2005	N
	C4591001 1133 11331076	Ear and labyrinth disorders	Tinnitus	01NOV2007		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	30SEP1993	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01SEP1993		Y
		Infections and infestations	Tonsillitis	01APR1974	30APR1974	N
		Injury, poisoning and procedural complications	Radius fracture	01APR1995	30APR1995	N
		Social circumstances	Postmenopause	01JUN2002		Y
		Surgical and medical procedures	Cholecystectomy	01SEP1993	30SEP1993	N
			Tonsillectomy	01APR1974	30APR1974	N
	C4591001 1133 11331077	Eye disorders	Hypermetropia	01JAN1979		Y
		Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1133 11331080	Eye disorders	Hypermetropia	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01FEB2020	31DEC2020	N
		Nervous system disorders	Headache	01JAN1969		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
			Varicose vein	01JAN1998		Y
	C4591001 1133 11331081	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Ex-tobacco user	01JAN1969	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331082	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Eye disorders	Glaucoma	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	24NOV2001	24NOV2001	N
				26SEP1987	26SEP1987	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1133 11331084	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331085	Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
			Ex-tobacco user	01JAN1985	31DEC1990	N
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1133 11331086	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JUL1998	31JUL1998	N
	C4591001 1133 11331089	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331090	Gastrointestinal disorders	Inguinal hernia	01JAN1972	31DEC1972	N
		General disorders and administration site conditions	Cyst	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1959	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1972	31DEC1972	N
			Skin laceration	01JAN1967	31DEC1967	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959	31DEC1959	N
		Surgical and medical procedures	Foot operation	01JAN2005	31DEC2005	N
			Fracture treatment	01JAN1972	31DEC1972	N
			Hernia repair	01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN1972	31DEC1972	N
		Eye disorders	Cataract	01MAY2006	31JUL2006	N
	C4591001 1133 11331091	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1133 11331092	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN1978	31DEC1978	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	09MAR1987	09MAR1987	N
			Hip arthroplasty	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1958	31DEC1958	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331094	Eye disorders	Cataract	01JAN2010	22JUL2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01MAY2020		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1976		Y
		Surgical and medical procedures	Cataract operation	22JUL2020	22JUL2020	N
			Nasal operation	01JAN1976	31DEC1976	N
		Vascular disorders	Varicose vein	08AUG2020		Y
	C4591001 1133 11331095	Cardiac disorders	Acute myocardial infarction	01AUG2019	31AUG2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01AUG2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC2000	N
		Surgical and medical procedures	Vascular stent insertion	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331098	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2008	31DEC2008	N
			Myopia	01JAN2000		Y
			Retinal detachment	01JAN2007	31DEC2007	N
		General disorders and administration site conditions	Hernia	02JUL2019	02JUL2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	10JUL2008	10JUL2008	N
			Meniscus removal	25SEP2014	25SEP2014	N
			Vitrectomy	22APR2007	22APR2007	N
	C4591001 1133 11331099	Eye disorders	Cataract	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
			Rheumatoid arthritis	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
			Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2017		Y
					31DEC2017	N
			Cholecystectomy	01JAN2015	31DEC2015	N
	C4591001 1133 11331100	Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Social circumstances	Corrective lens user	01JAN2012		Y
		Surgical and medical procedures	Tonsillectomy	08AUG1960	08AUG1960	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1133 11331104	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1995		Y
				01JAN2000	31DEC2000	N
		Social circumstances	Ex-tobacco user	01JAN1973	31DEC1977	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1133 11331107	Endocrine disorders	Hypogonadism	01JAN2012		Y
		Eye disorders	Cataract	01JAN1986	31DEC1990	N
			Myopia	01JAN1973		Y
			Retinal detachment	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood triglycerides increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Social circumstances	Eye prosthesis user	01JAN2003		Y
		Surgical and medical procedures	Cataract operation	01JAN1990	31DEC1990	N
			Retinopexy	01JAN2003	31DEC2003	N
	C4591001 1133 11331110	Eye disorders	Myopia	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
	C4591001 1133 11331114	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Myopia	01JAN1957		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Carotid artery occlusion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331116	Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	05MAY1999	05MAY1999	N
			Hysterectomy	01JAN2016	31DEC2016	N
	C4591001 1133 11331118	Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Infections and infestations	Appendicitis	01JAN1951	31DEC1951	N
			Helicobacter infection	01JAN2010	31DEC2010	N
			Tonsillitis	01JAN1953	31DEC1953	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Social circumstances	Ex-tobacco user	01JAN1975	31DEC2008	N
		Surgical and medical procedures	Appendicectomy	01JAN1951	31DEC1951	N
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331124	Eye disorders	Presbyopia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Abdominoplasty	01JAN1997	31DEC1997	N
			Caesarean section	06MAR1997	06MAR1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN1997	31DEC1997	N
	C4591001 1133 11331126	Eye disorders	Hypermetropia	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN2020		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1991	31DEC1991	N
			Vulvovaginal dryness	01JAN2019		Y
		Surgical and medical procedures	Oophorectomy	01JAN1991	31DEC1991	N
	C4591001 1133 11331127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN2019	10FEB2020	N
		Social circumstances	Corrective lens user	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	10FEB2020	10FEB2020	N
	C4591001 1133 11331128	Congenital, familial and genetic disorders	Hypophosphatasia	01JAN2019		Y
		Eye disorders	Myopia	01JAN1969		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Herpes virus infection	01JAN2019		Y
			Tonsillitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
			Prostate cancer	01JAN2015	31DEC2016	N
		Nervous system disorders	Migraine	01JAN2010		Y
			Parkinson's disease	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Substance use	01JAN1969	31DEC1975	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1989	31DEC1989	N
				01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1957	31DEC1957	N
			Tonsillitis	01JAN1970	31DEC1970	N
	C4591001 1133 11331133	Infections and infestations				
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
		Nervous system disorders	Migraine	01JAN1994	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Social circumstances	Corrective lens user	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1133 11331134	Infections and infestations	Tonsillitis	01JAN1946	31DEC1946	N
		Social circumstances	Ex-tobacco user	01JAN1953	31DEC1980	N
		Surgical and medical procedures	Tonsillectomy	01JAN1946	31DEC1946	N
	C4591001 1133 11331136	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
		Social circumstances	Corrective lens user	01JAN1976		Y
		Surgical and medical procedures	Limb operation	01JAN2010	31DEC2010	N
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1133 11331137	Cardiac disorders	Myocardial infarction	01FEB1993	28FEB1993	N
				01FEB2003	28FEB2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01FEB2013	28FEB2013	N
		Eye disorders	Cataract	01JAN1990	31DEC1990	N
			Glaucoma	01JAN1990	31DEC1990	N
			Myopia	01JAN1995		Y
		Injury, poisoning and procedural complications	Eye injury	01JAN1990	31DEC1990	N
			Upper limb fracture	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
			Obesity	01JAN1985	31DEC2003	N
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1965	31DEC1965	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1993	31DEC1993	N
		Social circumstances	Ex-tobacco user	01JAN1975	31DEC1993	N
		Surgical and medical procedures	Cataract operation	01OCT1990	31OCT1990	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Implantable defibrillator insertion	01FEB2005	28FEB2013	N
				01FEB2013	31MAR2020	N
				01MAR2020		Y
			Implantable defibrillator removal	01FEB2013	28FEB2013	N
				01MAR2020	31MAR2020	N
		Vascular disorders	Arteriosclerosis	01JAN1993	31DEC2002	N
			Hypertension	01JAN1985	31DEC2005	N
	C4591001 1133 11331141	Eye disorders	Myopia	01JAN1974		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000	31DEC2011	N
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2014	31DEC2014	N
	C4591001 1133 11331143	Ear and labyrinth disorders	Deafness	01JAN1968		Y
		Eye disorders	Hypermetropia	01JAN2016		Y
		Gastrointestinal disorders	Duodenal ulcer	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2019	28FEB2019	N
		Nervous system disorders	Neuropathy peripheral	13AUG2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1999		Y
		Surgical and medical procedures	Skin neoplasm excision	01FEB2019	28FEB2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331146	Congenital, familial and genetic disorders	Haemoglobinopathy	01MAR2020		Y
		Eye disorders	Myopia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1133 11331147	Gastrointestinal disorders	Pancreatic disorder	01JUL2019		Y
		Immune system disorders	Allergy to animal	01JAN2010		Y
			Dust allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1999	31DEC2009	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2017	31DEC2017	N
			Knee arthroplasty	13MAY2015	13MAY2015	N
			Mammoplasty	01JAN2017	31DEC2017	N
			Meniscus operation	01JAN1999	31DEC1999	N
				01JAN2004	31DEC2004	N
				01JAN2009	31DEC2009	N
	C4591001 1133 11331148	Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Myopia	01JAN1972		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1133 11331153	Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Myopia	01JAN1970		Y
		Metabolism and nutrition disorders	Overweight	01JAN1954		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
	C4591001 1133 11331154	Eye disorders	Amblyopia	(b) (6) 1954		Y
			Myopia	01JAN1959		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Reaction to food additive	01JAN1969		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2020		Y
			Hyperlipidaemia	01JAN1985		Y
			Obesity	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Spondylitis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1964	31DEC1996	N
			Restless legs syndrome	01MAR2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1971	31DEC1984	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Spinal fusion surgery	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1133 11331155	Eye disorders	Presbyopia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331156	Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
			Presbyopia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017	31JAN2020	N
	C4591001 1133 11331157	Eye disorders	Cataract	01JAN2019	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1974		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Infections and infestations	Hepatitis A	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2017	N
		Surgical and medical procedures	Intraocular lens implant	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331159	Eye disorders	Myopia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Obesity	01JAN1999	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Gastric bypass	01JAN2000	31DEC2000	N
			Wrist surgery	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331160	Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Retinal disorder	01JAN1984	31DEC2013	N
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Haemorrhoids	01JAN1995	31DEC2000	N
			Inguinal hernia	01JAN1995	31DEC1995	N
		Immune system disorders	Hypersensitivity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
			Nasal polyps	01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1998	31DEC1998	N
			Cataract operation	01JAN2010	31DEC2010	N
			Haemorrhoid operation	01JAN2000	31DEC2000	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
			Nasal polypectomy	01JAN2019	31DEC2019	N
			Vitrectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331161	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2017	31DEC2017	N
	C4591001 1133 11331163	Eye disorders	Myopia	01JAN1993		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Infections and infestations	Herpes zoster	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1133 11331164	Eye disorders	Hypermetropia	01JAN2006		Y
			Myopia	01JAN1964		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
			Osteoporosis	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2004	31DEC2004	N
		Nervous system disorders	Trigeminal neuralgia	01JAN2003		Y
		Reproductive system and breast disorders	Breast hyperplasia	01OCT2019		Y
		Social circumstances	Ex-tobacco user	01JAN1974	31DEC1980	N
			Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1133 11331165	Eye disorders	Myopia	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Infections and infestations	Bronchitis	01JAN2019	31JAN2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Reproductive system and breast disorders	Uterine haemorrhage	01JAN2005	31DEC2005	N
		Social circumstances	Tobacco user	01JAN1972		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Liposuction	01JAN2006	31DEC2006	N
			Skin cosmetic procedure	01JAN2006	31DEC2006	N
	C4591001 1133 11331167	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	01JAN1990		Y
			Macular degeneration	01JAN2000		Y
			Myopia	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2015	N
			Plasma cell myeloma	01JAN2000	31DEC2000	N
			Prostate cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Micrographic skin surgery	01JAN2010	31DEC2015	N
			Radiotherapy	01JAN2012	31DEC2012	N
			Umbilical hernia repair	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331168	Eye disorders	Presbyopia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2018		Y
	C4591001 1133 11331169	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN1968		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Social circumstances	Ex-tobacco user	01JAN1975	31DEC2000	N
			Postmenopause	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal operation	17MAR2020	17MAR2020	N
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1133 11331171	Ear and labyrinth disorders	Deafness unilateral	01JAN1973		Y
				01JAN1979		Y
		Eye disorders	Hypermetropia	01JAN1960		Y
			Myopia	01JAN1960		Y
			Presbyopia	01JAN1960		Y
		Gastrointestinal disorders	Short-bowel syndrome	01JAN2018		Y
		Infections and infestations	Appendicitis	01OCT2018	31OCT2018	N
		Investigations	Cardiac murmur	01JAN2010		Y
			Human papilloma virus test positive	01JAN1985	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Hypomagnesaemia	01JAN2005		Y
			Lactose intolerance	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Fibromyalgia	01JAN2015		Y
			Osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hyperhidrosis	01JUN2020		Y
		Social circumstances	Corrective lens user	01JAN1960		Y
		Surgical and medical procedures	Appendicectomy	01OCT2018	31OCT2018	N
			Gastrectomy	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1133 11331172	Eye disorders	Presbyopia	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN1963		Y
			Drug hypersensitivity	01JAN1960		Y
			Dust allergy	01JAN1963		Y
			Food allergy	01JAN1963		Y
			Seasonal allergy	01JAN1963		Y
		Infections and infestations	Herpes simplex	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1993	31DEC1998	N
			Spinal osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Joint arthroplasty	01JAN1998	31DEC1998	N
	C4591001 1133 11331173	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		General disorders and administration site conditions	Chest pain	01JAN2001	31DEC2001	N
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Social circumstances	Ex-tobacco user	01JAN1962	31DEC1976	N
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Coronary arterial stent insertion	01JAN2001	31DEC2001	N
	C4591001 1133 11331174	Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2012	31DEC2012	N
			Limb injury	01JAN2016	31DEC2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JUN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1974		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1133 11331176	Cardiac disorders	Aortic valve incompetence	01JAN2017		Y
			Mitral valve prolapse	01JAN2017		Y
		Congenital, familial and genetic disorders	Blindness congenital	(b) (6) 1953		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN2015		Y
		Eye disorders	Cataract	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Myopia	01JAN1957		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Large intestine polyp	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012	31DEC2012	N
			Osteoporosis	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	01JAN2010	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1987	31DEC1987	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Breast reconstruction	01JAN2011	31DEC2011	N
			Cataract operation	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Cervical laser therapy	01JAN1987	31DEC1987	N
			Mastectomy	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2009	31DEC2009	N
			Spinal laminectomy	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1133 11331179	Eye disorders	Myopia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005	31DEC2015	N
			Osteoarthritis	01JAN2012		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1133 11331182	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Eye disorders	Cataract	01JAN2018	31JUL2019 31MAY2019	N N
		Gastrointestinal disorders	Gastritis	01JAN2012		Y
			Inguinal hernia	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN1979	31DEC1979	N
			Stress fracture	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2013	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2009		Y
		Social circumstances	Ex-tobacco user	01JAN1968	31DEC2015	N
		Surgical and medical procedures	Bone operation	01JAN1979	31DEC1979	N
			Cataract operation	01JUL2019	31JUL2019	N
				01MAY2019	31MAY2019	N
			Inguinal hernia repair	01JAN2016	31DEC2016	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1133 11331183	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Eye disorders	Cataract	01FEB2020		Y
			Myopia	01JAN1952		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1984	31DEC1984	N
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
			Diverticulitis	01JAN2005		Y
			Osteoarthritis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders				
		Psychiatric disorders	Insomnia	01APR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Cholecystectomy	01JAN1984	31DEC1984	N
			Gastric bypass	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1133 11331184	Eye disorders	Hypermetropia	01JAN2015		Y
			Myopia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
		Social circumstances	Tobacco user	01JAN1976		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331187	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Cataract	01APR2019	30APR2019	N
				01AUG2019	31AUG2019	N
			Presbyopia	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
			Scoliosis	01JAN1962		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1995		Y
			Uterine leiomyoma	01JAN2005	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Breast mass	01JAN1992	31DEC2005	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Social circumstances	Ex-tobacco user	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	01APR2019	30APR2019	N
				01AUG2019	31AUG2019	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Spinal fusion surgery	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331189	Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	01JAN1987	31DEC1987	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1987	31DEC1987	N
			Fracture treatment	01JAN2003	31DEC2003	N
	C4591001 1133 11331190	Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1970		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331191	Eye disorders	Presbyopia	01JAN2000		Y
		Injury, poisoning and procedural complications	Skull fractured base	01JAN1998	31DEC1998	N
		Investigations	Blood triglycerides increased	01JAN1997		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Surgery	01JAN1998	31DEC1998	N
	C4591001 1133 11331192	Blood and lymphatic system disorders	Anaemia	01JAN2015	31DEC2015	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN1999	31DEC1999	N
			Presbyopia	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Social circumstances	Ex-tobacco user	01JAN1961	31DEC2000	N
			Postmenopause	01JAN1979		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Female sterilisation	01JAN1979	31DEC1979	N
			Keratomileusis	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331194	Ear and labyrinth disorders	Deafness unilateral	01JAN2017	31DEC2017	N
		Eye disorders	Cataract	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Bone anchored hearing aid implantation	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1985	31DEC1985	N
			Hip arthroplasty	01JAN2004	31DEC2004	N
			Rhinoplasty	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Varicose vein	01JAN2015		Y
	C4591001 1133 11331196	Ear and labyrinth disorders	Deafness unilateral	01JAN1975	31DEC2018	N
		Eye disorders	Hypermetropia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
				01JAN1999	31DEC1999	N
			Bone anchored hearing aid implantation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1974	31DEC1974	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1133 11331197	Eye disorders	Myopia	01JAN2000		Y
			Presbyopia	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Bone disorder	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC1990	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2018	31DEC2018	N
	C4591001 1133 11331199	Vascular disorders	Hypertension	01JAN2017		Y
		Eye disorders	Hypermetropia	01JAN1967	31DEC2004	N
			Myopia	01JAN1967	31DEC2004	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2018	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1962	31DEC1975	N
		Social circumstances	Corrective lens user	01JAN1967	31DEC2004	N
		Surgical and medical procedures	Keratomileusis	01JAN2004	31DEC2004	N
			Skin neoplasm excision	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
	C4591001 1133 11331200	Eye disorders	Hypermetropia	01JAN1960		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	01JAN1960		Y
		Infections and infestations	Poliomyelitis	01JAN1951		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JAN2000		Y
		Social circumstances	Ex-tobacco user	01JAN1968	31DEC1986	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1133 11331201	Congenital, familial and genetic disorders	Dysplastic naevus syndrome	01JAN1996		Y
		Eye disorders	Presbyopia	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2019	30JUN2019	N
		Surgical and medical procedures	Skin neoplasm excision	01JUN2019	31DEC2019	N
	C4591001 1133 11331204	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1977	31DEC1977	N
		Immune system disorders	Food allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1977	31DEC1977	N
	C4591001 1133 11331205	Congenital, familial and genetic disorders	Limb malformation	(b) (6) 1954		Y
		Eye disorders	Presbyopia	01JAN1999		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1970	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331211	Surgical and medical procedures	Umbilical hernia repair	01JAN1999	31DEC1999	N
		Eye disorders	Myopia	01JAN2000		Y
		Injury, poisoning and procedural complications	Wound	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1995		Y
	C4591001 1133 11331212	Psychiatric disorders	Anxiety	01JAN2005		Y
			Bipolar disorder	01JAN2005		Y
			Depression	01JAN2005		Y
			Schizophrenia	01JAN2005		Y
		Surgical and medical procedures	Explorative laparotomy	01JAN1981	31DEC1981	N
		Eye disorders	Presbyopia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2003	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Depression	01JAN1988		Y
	Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2004	N	
	Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N	
		Hysterectomy	01JAN2000	31DEC2000	N	
		Intervertebral disc operation	01JAN2000	31DEC2000	N	
	Vascular disorders	Hypertension	01JAN2005		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331213	Gastrointestinal disorders	Duodenal ulcer	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Intervertebral disc protrusion	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC1990	N
			Uterine leiomyoma	01OCT1997	31OCT1997	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2005		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Micrographic skin surgery	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1971	31DEC1971	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331214	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N
			Umbilical hernia	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	19APR2019	19APR2019	N
		Social circumstances	Ex-tobacco user	01JAN1967	31DEC1997	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2009	31DEC2009	N
			Laser therapy	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN2008	31DEC2008	N
			Penile prosthesis insertion	01JAN2015	31DEC2015	N
			Pleural operation	19APR2019	19APR2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331215	Eye disorders	Myopia	01JAN1966		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01MAY2020	31MAY2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01DEC2019		Y
		Surgical and medical procedures	Rotator cuff repair	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1133 11331217	Cardiac disorders	Myocardial infarction	01OCT2018	31OCT2018	N
		Eye disorders	Presbyopia	01JAN1972		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT2018	31OCT2018	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331218	Ear and labyrinth disorders	Vertigo	17AUG2020	17AUG2020	N
		Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Inguinal hernia	01DEC2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01JAN2005	31DEC2005	N
			Hip arthroplasty	01JAN2000	31DEC2000	N
			Inguinal hernia repair	01DEC2019	31DEC2019	N
	C4591001 1133 11331219	Cardiac disorders	Myocardial infarction	01JAN2011	31DEC2011	N
		Eye disorders	Hypermetropia	01JAN2017		Y
			Presbyopia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2011		Y
		Social circumstances	Ex-tobacco user	01JAN1989	31DEC2009	N
		Surgical and medical procedures	Cardiac operation	01JAN2011	31DEC2011	N
			Micrographic skin surgery	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1133 11331220	Ear and labyrinth disorders	Deafness bilateral	01JAN1984		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glaucoma	01JAN1982	31DEC1982	N
			Myopia	01JAN1984	31DEC1984	N
			Retinal disorder	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1984		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN2014	31DEC2014	N
			Stress fracture	01JAN2020	31MAY2020	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004	31DEC2004	N
			Plantar fasciitis	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
			Testis cancer	01JAN1984	31DEC1984	N
		Psychiatric disorders	Restlessness	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Fascia release	01JAN1990	31DEC1990	N
			Fracture treatment	01MAY2020	31MAY2020	N
			Glaucoma surgery	01JAN1981	31DEC1981	N
			Keratotomy	01JAN1984	31DEC1984	N
			Micrographic skin surgery	01JAN2019	31DEC2019	N
			Orchidectomy	01JAN1961	31DEC1961	N
			Retinal operation	01JAN2016	31DEC2016	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1133 11331221	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
			Micrographic skin surgery	01JAN2016	31DEC2016	N
	C4591001 1133 11331222	Eye disorders	Myopia	01JAN2000		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2009	31DEC2009	N
		Social circumstances	Ex-tobacco user	01JAN1997	31DEC2005	N
		Surgical and medical procedures	Tenoplasty	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1967		Y
	C4591001 1133 11331223	Eye disorders	Myopia	01JAN1977		Y
		Injury, poisoning and procedural complications	Skin laceration	01APR2014	30APR2014	N
		Social circumstances	Ex-tobacco user	01JAN1974	31DEC2017	N
		Surgical and medical procedures	Skin graft	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331227	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1984		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980	31DEC2005	N
			Essential tremor	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Ex-tobacco user	01FEB1982	29FEB1984	N
			Postmenopause	01AUG1985		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2005	31DEC2005	N
			Cataract operation	01JAN2008	31DEC2008	N
			Female sterilisation	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1133 11331229	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Eye disorders	Strabismus	01AUG2020		Y
		Injury, poisoning and procedural complications	Cartilage injury	01JAN1974	31DEC1974	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1981	31DEC1981	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm	01JAN1970	31DEC1970	N
		Nervous system disorders	Peroneal nerve palsy	01JAN2000		Y
		Social circumstances	Corrective lens user	01AUG2020		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1981	31DEC1981	N
			Chondroplasty	01JAN1974	31DEC1974	N
			Foot operation	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1133 11331231	Eye disorders	Myopia	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1133 11331232	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Glaucoma	01JAN2018	31DEC2018	N
			Hypermetropia	01FEB2020		Y
			Myopia	01FEB2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
		Nervous system disorders	Carpal tunnel syndrome	01APR2020		Y
		Renal and urinary disorders	Nephropathy	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN1994	31JAN2018	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Glaucoma surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1133 11331233	Ear and labyrinth disorders	Tinnitus	01JAN1992		Y
		Eye disorders	Hypermetropia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1988		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
			Herpes zoster	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331234	Eye disorders	Myopia	01JAN2005		Y
		Immune system disorders	Anaphylactic reaction	01JAN1979		Y
			Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Pneumonia	01JAN2012	31DEC2012	N
			Tonsillitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331235	Eye disorders	Myopia	01JAN2004		Y
		Immune system disorders	Food allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01SEP2007		Y
		Surgical and medical procedures	Caesarean section	22FEB1996	22FEB1996	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331237	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Presbyopia	01JAN2005		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Overweight	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1133 11331238	Eye disorders	Presbyopia	01JAN2010		Y
		Infections and infestations	Sinusitis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331239	Cardiac disorders	Myocardial infarction	26JUL2018	26JUL2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331241	Cardiac disorders	Coronary artery disease	01JAN2000	31DEC2000	N
		Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Cerebrovascular accident	01AUG2014	31AUG2014	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2000	31DEC2000	N
	C4591001 1133 11331242	Eye disorders	Presbyopia	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
		Eye disorders	Presbyopia	01JAN1987		Y
	C4591001 1133 11331243	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC2018	N
			Colon adenoma	01SEP2019	30SEP2019	N
			Tongue neoplasm malignant stage unspecified	01JAN2002	31DEC2002	N
		Nervous system disorders	Carotid artery occlusion	01JAN2012		Y
			Cerebrovascular accident	01JUN2012	30JUN2012	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Social circumstances	Ex-tobacco user	01JAN1963	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331244	Ear and labyrinth disorders	Deafness bilateral	01JAN1955		Y
		Endocrine disorders	Hypothyroidism	01JAN1965		Y
		Eye disorders	Cataract	01JAN2007	31DEC2007	N
			Glaucoma	01JAN2012		Y
		Immune system disorders	Iodine allergy	01JAN1945		Y
		Infections and infestations	Tonsillitis	01JAN1961	31DEC1961	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2011	31DEC2011	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Bunion operation	01JAN2011	31DEC2011	N
			Cataract operation	01JAN2007	31DEC2007	N
	C4591001 1133 11331247	Eye disorders	Myopia	01JAN1964	30JUN2005	N
		Gastrointestinal disorders	Hiatus hernia	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Injury, poisoning and procedural complications	Radius fracture	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2017	N
		Nervous system disorders	Restless legs syndrome	01NOV2017		Y
		Surgical and medical procedures	Keratomileusis	01JUN2005	30JUN2005	N
			Micrographic skin surgery	01JAN2007	31DEC2007	N
				01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1133 11331249	Eye disorders	Myopia	01JAN2000	31DEC2000	N
			Presbyopia	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC1990	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
			Keratomileusis	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331250	Eye disorders	Presbyopia	01SEP2012		Y
		Social circumstances	Corrective lens user	01SEP2012		Y
	C4591001 1133 11331251	Immune system disorders	Food allergy	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2015		Y
		Surgical and medical procedures	Knee operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1133 11331253	Cardiac disorders	Angina pectoris	01JAN2015	31DEC2015	N
			Coronary artery disease	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1984	31DEC1995	N
		Infections and infestations	Hepatitis A	01JAN1995	31DEC1995	N
		Investigations	Lipoprotein (a) abnormal	01JAN2013		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Central venous catheterisation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Coronary artery bypass	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331254	Endocrine disorders	Hypothyroidism	01OCT2018		Y
		Eye disorders	Hypermetropia	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1997		Y
		Social circumstances	Corrective lens user	01JAN1964		Y
			Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Oophorectomy	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331261	Eye disorders	Presbyopia	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018	30NOV2018	N
		Surgical and medical procedures	Prostatectomy	01NOV2018	30NOV2018	N
			Splenectomy	01MAY1976	31MAY1976	N
		Vascular disorders	Hypertension	01MAR2016		Y
			Varicose vein	01JUL2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331262	Cardiac disorders	Sinus tachycardia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Hypermetropia	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	19DEC2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331268	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1962		Y
		Infections and infestations	Appendicitis	01MAR2015	31MAR2015	N
		Injury, poisoning and procedural complications	Tendon rupture	01MAY2015	31MAY2015	N
		Investigations	Blood triglycerides increased	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019	31JAN2019	N
		Surgical and medical procedures	Appendectomy	01MAR1970	31MAR1970	N
			Cataract operation	01JAN2017	31DEC2017	N
			Tenotomy	01MAY2015	31MAY2015	N
			Transurethral prostatectomy	01JAN2019	31JAN2019	N
			Vasectomy	01JUN2016	30JUN2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331269	Cardiac disorders	Bradycardia	01APR2018		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1989		Y
		Eye disorders	Presbyopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
			Food allergy	01JAN2014		Y
		Infections and infestations	Herpes zoster	01NOV2012	30NOV2012	N
			Tonsillitis	01JAN1963	31DEC1963	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1981		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1973		Y
		Surgical and medical procedures	Therapeutic embolisation	01APR2018	30APR2018	N
			Tonsillectomy	01JAN1963	31DEC1963	N
			Vasectomy	01AUG1987	31AUG1987	N
		Vascular disorders	Peripheral venous disease	21JAN2019	21JAN2019	N
			Varicose vein	01JAN2000	31DEC2000	N
	C4591001 1133 11331270	Eye disorders	Myopia	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1961	31DEC1961	N
		Surgical and medical procedures	Tonsillectomy	01JAN1961	31DEC1961	N
	C4591001 1133 11331271	Infections and infestations	Herpes zoster	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Nervous system disorders	Migraine	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1994	31DEC1994	N
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Mammoplasty	01JAN1990	31DEC1990	N
	C4591001 1133 11331277	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
			Uterine leiomyoma	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1970	31DEC1970	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1133 11331279	Ear and labyrinth disorders	Deafness bilateral	01JAN2007		Y
		Eye disorders	Cataract	01AUG2018	31AUG2018	N
				01JAN2000		Y
			Subretinal fluid	01JAN2017	31DEC2017	N
		Immune system disorders	Hypersensitivity	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06MAR2006		Y
			Osteopenia	25JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN1980		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Ligament operation	01JAN2001	31DEC2001	N
			Retinal operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1995	31DEC1995	N
			Tonsillitis	01JAN1959	31DEC1959	N
	C4591001 1133 11331280	Infections and infestations				
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1133 11331281	Eye disorders	Hypermetropia	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01FEB2010		Y
		Infections and infestations	Appendicitis	01NOV1968	30NOV1968	N
		Injury, poisoning and procedural complications	Tooth fracture	01JAN1999	31OCT2009	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	24AUG2019		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2020	26JUN2020	N
		Surgical and medical procedures	Appendicectomy	01NOV1968	30NOV1968	N
			Dental implantation	01OCT2009	31OCT2009	N
	C4591001 1133 11331284	Eye disorders	Astigmatism	01JAN2006		Y
			Myopia	01JAN2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypersensitivity	01JAN2010		Y
			Mycotic allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2001	31DEC2003	N
			Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01APR2012	31MAY2012	N
			Seborrhoeic keratosis	01JAN2015	31DEC2015	N
		Social circumstances	Ex-tobacco user	01SEP1966	31DEC1985	N
			Postmenopause	01SEP2013		Y
		Surgical and medical procedures	Bunion operation	01JAN2003	31DEC2003	N
			Colectomy	01MAY2012	31MAY2012	N
	C4591001 1133 11331285	Cardiac disorders	Bundle branch block left	01JAN2004		Y
		Ear and labyrinth disorders	Tinnitus	01JAN1969		Y
		Eye disorders	Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN1954		Y
		Injury, poisoning and procedural complications	Bite	01JAN1985	31DEC1985	N
			Joint dislocation	01JAN1982	31DEC1982	N
			Wrist fracture	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2019	11SEP2020	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1955		Y
		Surgical and medical procedures	Fracture treatment	01JAN2003	31DEC2003	N
			Orthognathic surgery	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331286	Ear and labyrinth disorders	Deafness unilateral	01JAN2017		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
		Infections and infestations	Tonsillitis	01DEC2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1986	31DEC1986	N
		Social circumstances	Corrective lens user	01JAN2010		Y
			Ex-tobacco user	01JAN1972	31JAN1977	N
			Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Temporomandibular joint surgery	01JAN1986	31DEC1986	N
			Tonsillectomy	01DEC2019	31DEC2019	N
	C4591001 1133 11331287	Endocrine disorders	Hypothyroidism	01AUG2005		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31MAY2015	N
		Social circumstances	Corrective lens user	01JAN2015		Y
			Ex-tobacco user	01DEC1973	31JAN1978	N
			Postmenopause	01AUG2005		Y
		Surgical and medical procedures	Bunion operation	01MAY2015	31MAY2015	N
	C4591001 1133 11331288	Eye disorders	Presbyopia	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
	C4591001 1133 11331289	Eye disorders	Presbyopia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01FEB2003		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31JAN1994	N
	C4591001 1133 11331290	Endocrine disorders	Hypothyroidism	01JAN1959		Y
		Eye disorders	Cataract	01JAN2000	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
			Temporomandibular joint syndrome	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2005	31DEC2018	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2004	31DEC2004	N
			Cataract operation	01JAN2000	31DEC2000	N
				01JAN2016	31DEC2016	N
			Neck surgery	01JAN2006	31DEC2006	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
			Spinal operation	01JAN1996	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331297	Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JUL2020	07AUG2020	N
		Social circumstances	Corrective lens user	01JAN2001		Y
		Surgical and medical procedures	Cancer surgery	07AUG2020	07AUG2020	N
			Tonsillectomy	01JAN1954	31DEC1954	N
	C4591001 1133 11331298	Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN2010		Y
			Presbyopia	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
				01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	31DEC1990	N
				01JAN2014	31DEC2014	N
	C4591001 1133 11331299	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Myopia	01JAN1975		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Milk allergy	01JAN1985		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1133 11331300	Eye disorders	Hypermetropia	01JAN1974	31DEC2010	N
			Myopia	01JAN1974	31DEC2010	N
		Gastrointestinal disorders	Hiatus hernia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1997	31DEC1997	N
			Herpes zoster	01JAN1995	31DEC1995	N
			Oral herpes	01JAN1960		Y
			Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Calculus bladder	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Social circumstances	Ex-tobacco user	01JAN1969	31DEC1974	N
		Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
			Bladder calculus removal	01JAN2017	31DEC2017	N
			Eye laser surgery	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331302	Gastrointestinal disorders	Umbilical hernia	01JAN2000	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2011	N
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
		Surgical and medical procedures	Meniscus operation	01JAN2011	31DEC2011	N
			Umbilical hernia repair	01JAN2006	31DEC2006	N
	C4591001 1133 11331304	Eye disorders	Myopia	01JAN1965		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1133 11331305	Eye disorders	Presbyopia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
			Tonsillitis	01JAN1951	31DEC1951	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1959	31DEC1999	N
			Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Appendicectomy	01JAN1955	31DEC1955	N
			Tonsillectomy	01JAN1951	31DEC1951	N
	C4591001 1133 11331306	Eye disorders	Cataract	01JAN2010	29FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Dry mouth	01JAN2018		Y
			Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Muscle spasms	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2019		Y
			Nasal septum deviation	01JAN1963	31DEC1963	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2016		Y
		Social circumstances	Ex-tobacco user	01JAN1960	31DEC1978	N
		Surgical and medical procedures	Cataract operation	01FEB2020	31DEC2020	N
			Rhinoplasty	01JAN1963	31DEC1963	N
			Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1133 11331309	Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1133 11331312	Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Immune system disorders	Food allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2015	N
		Social circumstances	Corrective lens user	01JAN2013		Y
			Ex-tobacco user	01JAN1969	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331314	Eye disorders	Hypermetropia	01JAN2008		Y
			Myopia	01JAN2008		Y
			Presbyopia	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Cystic lung disease	01APR2001	30APR2001	N
		Social circumstances	Corrective lens user	01JAN2008		Y
			Ex-tobacco user	01JAN1978	31DEC2000	N
			Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Pulmonary bullectomy	01APR2001	30APR2001	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331315	Eye disorders	Myopia	01JAN2013		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN1992		Y
			Insomnia	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1993	31DEC1993	N
			Rhinoplasty	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1133 11331318	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Social circumstances	Corrective lens user	01JAN2003		Y
		Surgical and medical procedures	Female sterilisation	01MAR2020	31MAR2020	N
	C4591001 1133 11331319	Immune system disorders	Drug hypersensitivity	01APR1990		Y
		Infections and infestations	Tuberculosis	01MAR2011	31DEC2011	N
		Injury, poisoning and procedural complications	Ligament sprain	01JUL2001	31JUL2001	N
			Upper limb fracture	01JUL2007	31JUL2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01OCT2019		Y
		Social circumstances	Corrective lens user	01JAN1970		Y
			Postmenopause	01JUL2007		Y
		Surgical and medical procedures	Elbow operation	01JUL2007	31JUL2007	N
			Ligament operation	01JUL2001	31JUL2001	N
	C4591001 1133 11331323	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Essential tremor	01JAN1955		Y
			Hypoaesthesia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Deep brain stimulation	01JAN2017	31DEC2017	N
			Mastectomy	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1133 11331325	Eye disorders	Cataract	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Keratoconus	01JAN1985	31DEC1985	N
					31DEC2000	N
					31DEC2017	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Social circumstances	Alcohol use	01JAN1967		Y
		Surgical and medical procedures	Cataract operation	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Corneal transplant	01JAN1985	31DEC1985	N
				01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
			Lithotripsy	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1952	31DEC1952	N
	C4591001 1133 11331326	Eye disorders	Myopia	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
				01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUN2005	30JUN2005	N
		Renal and urinary disorders	Stress urinary incontinence	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2010	31DEC2010	N
			Rhinitis allergic	01JAN2008		Y
		Social circumstances	Corrective lens user	01JAN1993		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Liposuction	01JAN2016	31DEC2016	N
			Skin lesion removal	01JUN2005	30JUN2005	N
	C4591001 1133 11331327	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Infections and infestations	Appendicitis	01FEB1964	29FEB1964	N
			Hepatitis A	01APR1981	30JUN1981	N
			Tonsillitis	01JAN1966	31DEC1966	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2002		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Ex-tobacco user	01JAN1980	31JUL2000	N
			Postmenopause	01JUN2011		Y
		Surgical and medical procedures	Appendectomy	01FEB1964	29FEB1964	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1133 11331330	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN1995		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1985	31DEC1985	N
				01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JUN2020	30JUN2020	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1985	31DEC1985	N
				01JAN2006	31DEC2006	N
			Skin neoplasm excision	01JUN2020	30JUN2020	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Presbyopia	01JAN2010		Y
	C4591001 1133 11331339	Eye disorders				
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1133 11331342	Cardiac disorders	Coronary artery occlusion	01JAN2013	31DEC2013	N
		Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Anaphylactic reaction	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Ex-tobacco user	01JAN1982	31DEC2010	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2013	31DEC2013	N
	C4591001 1133 11331343	Eye disorders	Blepharospasm	01JAN2019		Y
		Gastrointestinal disorders	Pelvic floor dysfunction	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN2020	31JAN2020	N
			Hepatitis A	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament injury	01JAN2011	31DEC2011	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Nervous system disorders	Balance disorder	01JAN1972	31DEC1972	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2016		Y
		Surgical and medical procedures	Appendectomy	01JAN2020	31DEC2020	N
			Ear operation	01JAN1972	31DEC1972	N
			Ligament operation	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1133 11331344	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Mite allergy	01JAN2017		Y
		Infections and infestations	Sinusitis	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1980	31DEC1980	N
			Uterine prolapse	01DEC2013	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Nasal septum deviation	01JAN2010		Y
			Rhinitis allergic	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1980	31DEC1980	N
			Hysterectomy	01DEC2013	31DEC2013	N
	C4591001 1133 11331345	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Dental caries	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoids	01JAN1974	31JAN1974	N
		Infections and infestations	Appendicitis	01AUG1964	31AUG1964	N
			Cellulitis	01JAN2016	31JAN2017	N
			Tonsillitis	01JAN1954	31DEC1954	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteochondrosis	01JAN1960		Y
					31DEC2019	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
			Prostatomegaly	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01AUG1964	31AUG1964	N
			Haemorrhoid operation	01JAN1974	31JAN1974	N
			Knee operation	01JAN2019	31DEC2019	N
			Toe amputation	01JAN2017	31JAN2017	N
			Tonsillectomy	01JAN1954	31DEC1954	N
	C4591001 1133 11331347	Endocrine disorders	Hyperthyroidism	01DEC2010		Y
		Eye disorders	Myopia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Tonsillitis	01FEB1961	30APR1961	N
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Social circumstances	Postmenopause	01JUN2011		Y
		Surgical and medical procedures	Hip arthroplasty	01NOV2017	30SEP2018	N
			Tonsillectomy	01APR1961	30APR1961	N
	C4591001 1133 11331349	Eye disorders	Glaucoma	01JUN2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2005		Y
			Ex-tobacco user	01JAN1969	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331356	Eye disorders	Cataract	01JAN2010	31DEC2013	N
					31DEC2014	N
			Dry eye	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	31DEC2016	N
			Osteoporosis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331358	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2015		Y
			Duodenogastric reflux	01JAN2010		Y
		Injury, poisoning and procedural complications	Foreign body in eye	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Prostatectomy	01JAN2010	31DEC2010	N
			Removal of foreign body from eye	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331359	Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Dry mouth	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1952	31DEC1952	N
			Herpes zoster	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
			Ex-tobacco user	01JAN1955	31DEC1958	N
		Surgical and medical procedures	Appendicectomy	01JAN1952	31DEC1952	N
			Cataract operation	01JAN2016	31DEC2016	N
	C4591001 1133 11331361	Eye disorders	Hypermetropia	01JAN1949		Y
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01FEB2020		Y
		Social circumstances	Ex-tobacco user	01JAN1960	31DEC2000	N
			Postmenopause	01JUN1985		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Hysterectomy	01JUN1983	31DEC1983	N
			Knee arthroplasty	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oophorectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331362	Eye disorders	Cataract	01JAN2017		Y
		Gastrointestinal disorders	Umbilical hernia	01APR2019	30APR2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Surgical and medical procedures	Umbilical hernia repair	01APR2019	30APR2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331364	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		General disorders and administration site conditions	Gait disturbance	01FEB2019	28FEB2019	N
		Social circumstances	Corrective lens user	01JAN2000		Y
			Ex-tobacco user	01JAN1961	31DEC1987	N
			Postmenopause	01JAN1988		Y
		Surgical and medical procedures	Knee arthroplasty	01FEB2019	28FEB2019	N
	C4591001 1133 11331366	Eye disorders	Cataract	01JUN2019	31JUL2020	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
			Tonsillitis	01JAN1944	31DEC1944	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1965	31DEC1990	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017	31DEC2017	N
		Social circumstances	Corrective lens user	01JAN1990		Y
			Ex-tobacco user	01JAN1968	31DEC1993	N
			Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01JAN1956	31DEC1956	N
			Bone operation	01JAN1965	31DEC1965	N
			Cataract operation	01JUL2020	31JUL2020	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1944	31DEC1944	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331368	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01DEC2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331369	Eye disorders	Hypermetropia	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1998		Y
	C4591001 1133 11331371	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1988	31DEC1993	N
		Surgical and medical procedures	Caesarean section	01AUG1989	01AUG1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331372	Eye disorders	Presbyopia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1133 11331373	Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Humerus fracture	01FEB2017	28FEB2017	N
			Tibia fracture	01FEB2017	28FEB2017	N
		Surgical and medical procedures	Internal fixation of fracture	01FEB2017	28FEB2017	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1133 11331375	Eye disorders	Myopia	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1965		Y
		Social circumstances	Ex-tobacco user	01JAN1968	31DEC1969	N
		Surgical and medical procedures	Meniscus operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1133 11331377	Ear and labyrinth disorders	Deafness bilateral	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN1965		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Corrective lens user	01JAN1965		Y
			Ex-tobacco user	01JAN1960	31DEC1985	N
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331380	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2018	30JUN2019	N
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
			Tonsillitis	01JAN1949	31DEC1949	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1976	31JAN1976	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01NOV1980	30NOV1980	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1960		Y
		Social circumstances	Postmenopause	01NOV1980		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331381	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
	C4591001 1133 11331383	Social circumstances	Ex-tobacco user	01JAN1980	31JAN2020	N
		Eye disorders	Presbyopia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1986	31DEC1986	N
		Psychiatric disorders	Anxiety	01JUL2019		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Tobacco user	01JUN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1133 11331386	Vascular disorders	Hypertension	03MAR2020		Y
		Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN1979		Y
			Myopia	01JAN1979		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
			Tonsillitis	01JAN1977	31DEC1977	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1133 11331391	Eye disorders	Presbyopia	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1133 11331392	Immune system disorders	Drug hypersensitivity	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Myalgia	01JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal cancer	01JAN2005	31DEC2005	N
		Social circumstances	Ex-tobacco user	01JAN1982	31DEC1992	N
		Surgical and medical procedures	Vocal cord polypectomy	01JAN2015	31DEC2015	N
	C4591001 1133 11331394	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
			Umbilical hernia	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1969	31DEC1969	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
	C4591001 1133 11331396	Eye disorders	Presbyopia	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	27NOV2007	N
		Surgical and medical procedures	Hysterectomy	27NOV2007	27NOV2007	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1133 11331399	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN1970		Y
			Myopia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
			Upper limb fracture	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2013	31DEC2013	N
			Cerebrovascular accident	01JAN2013	31DEC2013	N
		Social circumstances	Corrective lens user	01JAN1970		Y
			Ex-tobacco user	01JAN1960	31DEC2000	N
			Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Arterial repair	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331400	Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1133 11331402	Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01MAY2018	31MAY2018	N
		Surgical and medical procedures	Rotator cuff repair	01MAY2018	31MAY2018	N
	C4591001 1133 11331403	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Blindness unilateral	01JAN1982		Y
	C4591001 1133 11331407	Infections and infestations	Hepatitis A	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Social circumstances	Ex-tobacco user	01JAN1975	31DEC2010	N
	C4591001 1133 11331412	Gastrointestinal disorders	Irritable bowel syndrome	01MAY2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Food allergy	01JUL2016		Y
		Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JUL2016		Y
			Obesity	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	15MAY2020		Y
			Depression	15MAY2020		Y
			Insomnia	15MAY2020		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01AUG2012		Y
		Surgical and medical procedures	Appendectomy	01JAN1977	31DEC1977	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Ectopic pregnancy termination	01JAN2008	31DEC2008	N
			Gastric bypass	01JUL2016	31JUL2016	N
			Salpingectomy	01JAN2008	31DEC2008	N
			Vascular disorders	Hypertension	01JAN2016	
	C4591001 1133 11331415	Cardiac disorders	Coronary artery disease	01NOV2017	30NOV2017	N
		Eye disorders	Cataract	01JAN2019	29FEB2020	N
		Infections and infestations	Tonsillitis	01JAN2002	31DEC2005	N
		Injury, poisoning and procedural complications	Tendon rupture	01OCT2018	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Obesity	01JAN1980	31DEC2006	N
			Type 2 diabetes mellitus	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01FEB2020	29FEB2020	N
			Coronary artery bypass	01NOV2017	30NOV2017	N
			Gastric banding	01JAN2006	31DEC2006	N
			Tenoplasty	01DEC2019	31DEC2019	N
			Tonsillectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331416	Cardiac disorders	Supraventricular tachycardia	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1970	31DEC1970	N
		Social circumstances	Ex-tobacco user	01JAN1975	31DEC1979	N
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Caesarean section	08DEC1990	08DEC1990	N
			Ovarian cystectomy	01JAN1970	31DEC1970	N
			Rhinoplasty	01JAN1990	31DEC1990	N
	C4591001 1133 11331417	Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN1958		Y
		Gastrointestinal disorders	Dyspepsia	01FEB2020		Y
		Injury, poisoning and procedural complications	Subdural haematoma	01DEC1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1990		Y
		Surgical and medical procedures	Craniotomy	01DEC1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331420	Eye disorders	Hypermetropia	01JAN1970		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1976	31DEC1976	N
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC1985	N
				01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1972	31DEC1972	N
			Inguinal hernia repair	01JAN1976	31DEC1976	N
			Micrographic skin surgery	01JAN1985	31DEC1985	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331421	Blood and lymphatic system disorders	Anaemia	01MAY2020		Y
		Eye disorders	Myopia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
		Infections and infestations	Bronchitis	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	29FEB2008	N
		Nervous system disorders	Ageusia	01JAN2017		Y
			Anosmia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neuropathy peripheral	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2017		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01FEB2008	29FEB2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331424	Eye disorders	Presbyopia	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
			Tonsillitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Prostatectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1133 11331425	Endocrine disorders	Hyperthyroidism	01JAN1990		Y
		Immune system disorders	Food allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Caesarean section	02MAY1977	02MAY1977	N
				06DEC1978	06DEC1978	N
				06JUL1975	06JUL1975	N
				27AUG1973	27AUG1973	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331426	Social circumstances	Ex-tobacco user	01JAN2008	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1133 11331429	Ear and labyrinth disorders	Deafness unilateral	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Blepharospasm	01JAN1995		Y
			Cataract	01JAN2012	31DEC2012	N
			Myopia	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Injury, poisoning and procedural complications	Thoracic vertebral fracture	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Social circumstances	Corrective lens user	01JAN2012		Y
			Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2000	31DEC2000	N
			Caesarean section	22AUG1990	22AUG1990	N
				29SEP1985	29SEP1985	N
			Cataract operation	01JAN2012	31DEC2012	N
			Myectomy	01JAN2009	31DEC2009	N
			Spinal operation	01JAN1991	31DEC1991	N
	C4591001 1133 11331430	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Eye disorders	Dry eye	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Umbilical hernia	01JAN2018		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
			Tonsillitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ear neoplasm	01JAN2010	31DEC2010	N
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Insomnia	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1976	31DEC1976	N
			Inner ear operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1133 11331431	Eye disorders	Myopia	01JAN1980		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2005	31OCT2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Social circumstances	Corrective lens user	01JAN1980		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1963	31DEC1963	N
			Umbilical hernia repair	01OCT2005	31OCT2005	N
	C4591001 1133 11331433	Eye disorders	Myopia	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1133 11331434	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
			Presbyopia	01JAN2000		Y
		Immune system disorders	Dust allergy	01JAN1995		Y
			Mycotic allergy	01JAN1995		Y
		Infections and infestations	Hepatitis A	01JAN1983	31DEC1983	N
			Herpes simplex	01JAN1987		Y
	C4591001 1133 11331437	Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1982		Y
		Eye disorders	Cataract	01NOV2019	30NOV2019	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	31JAN2011	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	17DEC2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	21JUN1994	21JUN1994	N
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01NOV2019	30NOV2019	N
			Cholecystectomy	01JAN2011	31JAN2011	N
			Hysterectomy	21JUN1994	21JUN1994	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1133 11331443	Endocrine disorders	Hyperparathyroidism	01JAN1995	31DEC2004	N
		Eye disorders	Hypermetropia	01JAN1971		Y
			Myopia	01JAN1971		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Gastrectomy	01JAN2014	31DEC2014	N
			Parathyroidectomy	01JAN2004	31DEC2004	N
	C4591001 1133 11331444	Gastrointestinal disorders	Umbilical hernia	01JAN2015		Y
		Social circumstances	Ex-tobacco user	01JAN1987	31DEC2018	N
	C4591001 1133 11331445	Eye disorders	Presbyopia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1133 11331446	Eye disorders	Presbyopia	01JAN2003		Y
		Metabolism and nutrition disorders	Overweight	01JAN2003		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1133 11331447	Eye disorders	Presbyopia	01JAN2013		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Gout	01JAN2008	31DEC2013	N
			Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Ex-tobacco user	01JAN1976	31DEC1995	N
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331449	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Presbyopia	01JAN1973		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01APR2020	09JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Social circumstances	Postmenopause	01FEB2011		Y
		Surgical and medical procedures	Hysterectomy	09JUN2020	09JUN2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1133 11331451	Gastrointestinal disorders	Inguinal hernia	01JAN1960	31DEC1960	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1984		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1984		Y
		Skin and subcutaneous tissue disorders	Skin discolouration	01JAN2010		Y
		Surgical and medical procedures	Gastric banding	01JAN2005		Y
					31DEC2005	N
			Inguinal hernia repair	01JAN1960	31DEC1960	N
		Vascular disorders	Peripheral venous disease	01JAN2005		Y
	C4591001 1133 11331453	Cardiac disorders	Atrial fibrillation	01JAN2010	31DEC2010	N
		Eye disorders	Myopia	01JAN1980		Y
		Hepatobiliary disorders	Cirrhosis alcoholic	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1951		Y
			Food allergy	01JAN2017		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN1960	31DEC1960	N
		Social circumstances	Alcohol use	01JAN2000	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tobacco user	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Bone lesion excision	01JAN1960	31DEC1960	N
			Fracture treatment	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331454	Congenital, familial and genetic disorders	Haemophilia	01JAN1956		Y
		Eye disorders	Hypermetropia	01JAN1970		Y
		Investigations	Liver function test increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
			Spinal synovial cyst	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Surgical and medical procedures	Bone cyst excision	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
	C4591001 1133 11331455	Eye disorders	Presbyopia	01JAN2000		Y
			Pterygium	01JAN2000	31DEC2000	N
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Reproductive system and breast disorders	Varicocele	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Pterygium operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1958	31DEC1958	N
			Varicocele repair	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331457	Ear and labyrinth disorders	Deafness bilateral	01JAN2016		Y
		Eye disorders	Myopia	01JAN1967		Y
	C4591001 1133 11331459	Endocrine disorders	Hyperparathyroidism	01JAN2014	31DEC2014	N
			Hyperthyroidism	01JAN2000	31DEC2000	N
		Eye disorders	Myopia	01JAN1966		Y
			Presbyopia	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2015	31DEC2015	N
			Foot fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
			Parathyroidectomy	01JAN2014	31DEC2014	N
			Skin neoplasm excision	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1133 11331464	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2001	31DEC2001	N
		Renal and urinary disorders	Nephrolithiasis	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intervertebral disc operation	01JAN2001	31DEC2001	N
			Renal stone removal	01AUG2020	31AUG2020	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1133 11331466	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1133 11331469	Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331470	Eye disorders	Hypermetropia	01JAN1969		Y
		Injury, poisoning and procedural complications	Ankle fracture	01APR2017	30APR2017	N
			Joint dislocation	01APR2017	31MAY2017	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01MAR2020		Y
		Surgical and medical procedures	Fracture treatment	01APR2017	30APR2017	N
			Joint dislocation reduction	01MAY2017	31MAY2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331471	Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN1967	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1133 11331472	Gastrointestinal disorders	Inguinal hernia	01JAN2015	30APR2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2019		Y
			Nasal congestion	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01APR2020	30APR2020	N
			Lithotripsy	01JAN2017	31DEC2017	N
	C4591001 1133 11331477	Endocrine disorders	Hypothyroidism	01JAN1966		Y
		Eye disorders	Presbyopia	01AUG2008		Y
		Immune system disorders	Drug hypersensitivity	01JUL1975		Y
			Food allergy	01JUL2015		Y
		Infections and infestations	Appendicitis	01NOV1976	30NOV1976	N
			Herpes zoster	01AUG2005	30SEP2005	N
		Injury, poisoning and procedural complications	Cartilage injury	01SEP2016	30SEP2016	N
			Wrist fracture	01FEB1977	31DEC1977	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Surgical and medical procedures	Appendectomy	01NOV1976	30NOV1976	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chondroplasty	01SEP2016	30SEP2016	N
	C4591001 1133 11331481	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1951	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2019		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1951	31DEC1951	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1133 11331486	Cardiac disorders	Bradycardia	01JAN2018		Y
		Eye disorders	Presbyopia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N
			Caesarean section	14JAN1983	14JAN1983	N
				17APR1987	17APR1987	N
			Cholecystectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1133 11331487	Eye disorders	Cataract	01JAN2014	31DEC2018	N
			Myopia	01JAN1954		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Bronchitis	01JAN1954	31DEC1955	N
			Hepatitis C	01JAN2001	31DEC2004	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
			Lower limb fracture	01JAN2000	31DEC2000	N
		Social circumstances	Tobacco user	01JAN1961		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Fracture treatment	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1133 11331488†	Eye disorders	Macular oedema	01JAN2015		Y
			Myopia	01JAN1969		Y
			Presbyopia	01JAN2000		Y
		Investigations	HIV test positive	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Ex-tobacco user	01JAN1980	31DEC2019	N
			Postmenopause	01JAN2010		Y
	C4591001 1133 11331500	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN1984		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1994	31DEC1994	N
		Psychiatric disorders	Drug abuse	01JAN1994	31DEC2010	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Social circumstances	Ex-tobacco user	01JAN1967	31DEC2010	N
		Surgical and medical procedures	Adrenalectomy	01JAN2018	31DEC2018	N
			Inguinal hernia repair	01JAN1994	31DEC1994	N
			Varicocele repair	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1133 11331503	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JAN2019		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Ligament rupture	04MAR2020	04MAR2020	N
		Surgical and medical procedures	Joint arthroplasty	04MAR2020	04MAR2020	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1133 11331507	Eye disorders	Myopia	01AUG2020		Y
		Social circumstances	Corrective lens user	01AUG2020		Y
	C4591001 1133 11331513	Ear and labyrinth disorders	Tinnitus	01NOV2018		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Infections and infestations	Appendicitis	01OCT2017	31OCT2017	N
			Hepatitis A	01SEP1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Intervertebral disc protrusion	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN1995	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1957		Y
		Social circumstances	Ex-tobacco user	01JAN1972	31DEC1994	N
		Surgical and medical procedures	Appendicectomy	01OCT2017	31OCT2017	N
			Bladder neoplasm surgery	01JAN1995	31DEC1995	N
		Vascular disorders	Arteriosclerosis	01NOV2018		Y
			Hypertension	01NOV2018		Y
	C4591001 1133 11331516	Eye disorders	Presbyopia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1133 11331517	Social circumstances	Corrective lens user	01JAN2000		Y
		Eye disorders	Myopia	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Sinusitis	01JAN1970	31DEC1970	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Spinal stenosis	01JAN2016		Y
		Nervous system disorders	Hypoaesthesia	01DEC2019	31DEC2019	N
				01NOV2010	30NOV2019	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Carpal tunnel decompression	01DEC2019	31DEC2019	N
				01NOV2019	30NOV2019	N
	C4591001 1133 11331518		Female sterilisation	01JAN1995	31DEC1995	N
			Open reduction of fracture	01JAN2006	31DEC2006	N
			Sinus operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2004		Y
		Endocrine disorders	Hypothyroidism	01SEP2018		Y
		Eye disorders	Glaucoma	01JAN2008		Y
			Retinal disorder	01FEB2015	28FEB2015	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Retinal operation	01JUN2015	30JUN2015	N
	C4591001 1133 11331519	Eye disorders	Presbyopia	01JAN2012		Y
		Gastrointestinal disorders	Gastritis	01JAN2018		Y
			Inguinal hernia	01JAN2008		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2008		Y
	C4591001 1134 11341001	Gastrointestinal disorders	Umbilical hernia	01JAN2009		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10APR2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2008	31DEC2008	N
			Malignant melanoma	01JAN2016	31JAN2016	N
		Nervous system disorders	Diabetic neuropathy	01JAN2013		Y
		Renal and urinary disorders	Chronic kidney disease	01AUG2019		Y
			Hypertonic bladder	01JAN2007		Y
			Urinary incontinence	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1997		Y
			Rosacea	01JUN2016		Y
		Social circumstances	Postmenopause	01JUN2008		Y
	C4591001 1134 11341002	Cardiac disorders	Coronary artery disease	01JAN1999		Y
			Myocardial infarction	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Thyroid mass	09NOV2017	09NOV2017	N
		Eye disorders	Macular telangiectasia	01JAN2016		Y
			Presbyopia	01JAN2001		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
			Catheterisation cardiac	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1999	31DEC1999	N
			Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Neuropathy peripheral	01MAY2020		Y
		Renal and urinary disorders	Chronic kidney disease	24OCT2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Cataract operation	01JAN2008	31DEC2008	N
			Eye operation	01MAR2016	31MAR2016	N
			Gastric bypass	01JAN1998	31DEC1998	N
			Heart valve replacement	12NOV2018	12NOV2018	N
			Spinal operation	01JAN1999	31DEC1999	N
			Stent placement	01JAN2009	31DEC2009	N
			Thyroidectomy	09NOV2017	09NOV2017	N
		Vascular disorders	Arteriosclerosis	01JAN1999		Y
			Hypertension	01JAN1995		Y
	C4591001 1134 11341004	Gastrointestinal disorders	Anal fissure	01JAN2005	31DEC2005	N
		General disorders and administration site conditions	Oedema peripheral	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	19OCT2019		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Affective disorder	01JAN2013		Y
			Depression	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Anorectal operation	01JAN2005	31DEC2005	N
			Caesarean section	01JAN1985	31DEC1985	N
				01JAN1987	31DEC1987	N
			Gastrectomy	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Renal stone removal	01JAN2004	31DEC2004	N
			Rhinoplasty	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1134 11341010	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995		Y
	C4591001 1134 11341011	Investigations	Cardiac murmur	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JUN2017		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1134 11341014	Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N
		Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Gout	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2001		Y
			Vitamin D deficiency	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	30APR2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01FEB2007	28FEB2007	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2013		Y
		Surgical and medical procedures	Appendectomy	01JAN1957	31DEC1957	N
			Cholecystectomy	01JAN1988	31DEC1988	N
			Hysterectomy	01FEB2007	28FEB2007	N
			Knee arthroplasty	01APR2017	30APR2017	N
				01DEC2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341015	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Vitamin B complex deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2001	31DEC2001	N
			Nasal septal operation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1134 11341016	Eye disorders	Dry eye	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
			Caesarean section	01JAN1973	31DEC1978	N
			Cataract operation	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1134 11341017	Reproductive system and breast disorders	Prostatomegaly	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Prostatic operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341019	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2015	31DEC2015	N
			Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341020	Ear and labyrinth disorders	Hypoacusis	01JAN2019		Y
		Infections and infestations	Diverticulitis	01MAY2015	11MAY2015	N
			Onychomycosis	08AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1999		Y
				01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1987	31DEC1987	N
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341021	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Appendicitis perforated	01JAN1960	31DEC1960	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Appendectomy	01JAN1960	31DEC1960	N
			Hysterectomy	01JAN1987	31DEC1987	N
			Knee operation	01JAN2019	31DEC2019	N
	C4591001 1134 11341022	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341023	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01JAN1989	31DEC1989	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341024	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1956		Y
		Infections and infestations	Genital herpes	01JAN1992		Y
			Onychomycosis	01JAN2018		Y
			Tonsillitis	01JAN1978	31DEC1978	N
		Injury, poisoning and procedural complications	Patella fracture	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1995	31DEC1995	N
			Thyroid neoplasm	01JAN2004	31DEC2004	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1970	31DEC1970	N
			Ectopic pregnancy	01JAN1970	31DEC1970	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2013		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1971	31DEC1971	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast conserving surgery	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
			Bunion operation	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Knee operation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
			Thyroid operation	01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1978	31DEC1978	N
			Uterine operation	01JAN1971	31DEC1971	N
	C4591001 1134 11341025	Eye disorders	Cataract	01JAN2010		Y
			Dry eye	01JAN2013		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Sinus headache	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Surgical and medical procedures	Abscess drainage	01JAN1999	31DEC1999	N
			Haemorrhoid operation	01JAN1997	31DEC1997	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1134 11341026	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1997		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1971		Y
		Infections and infestations	Sinusitis	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Compression fracture	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nerve injury	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N
		Renal and urinary disorders	Bladder prolapse	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Rhinoplasty	01JAN2007	31DEC2007	N
			Spinal operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1988	31DEC1988	N
			Urinary bladder suspension	01JAN2008	31DEC2008	N
	C4591001 1134 11341027	Blood and lymphatic system disorders	Anaemia	01JAN1979		Y
		Eye disorders	Cataract	01DEC2018	31JAN2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1989		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Hypertriglyceridaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2009	31DEC2009	N
			Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Sinus headache	01JAN1969		Y
			Transient ischaemic attack	01JAN2009	31DEC2009	N
		Psychiatric disorders	Insomnia	01JAN2009		Y
		Surgical and medical procedures	Cataract operation	01DEC2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2019	31JAN2019	N
			Shoulder operation	01JAN2011	31DEC2011	N
			Spinal laminectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1134 11341029	Eye disorders	Cataract	01JAN2007	31DEC2007	N
				22SEP2016	22SEP2016	N
			Myopia	01JAN1995		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2007	31DEC2007	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
				22SEP2016	22SEP2016	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
	C4591001 1134 11341030	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	31DEC2019	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01AUG2018	31AUG2018	N
				01FEB2019	28FEB2019	N
	C4591001 1134 11341032	Eye disorders	Glaucoma	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01MAR2020		Y
		Nervous system disorders	Headache	01JAN2019		Y
		Surgical and medical procedures	Gastrectomy	01JUL2016	31JUL2016	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1134 11341034	Ear and labyrinth disorders	Vertigo	01JAN2007		Y
		Nervous system disorders	Tension headache	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987		Y
	C4591001 1134 11341035	Eye disorders	Myopia	01JAN1973		Y
		Gastrointestinal disorders	Diarrhoea	01SEP2015		Y
			Gastroesophageal reflux disease	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01SEP2015	30SEP2015	N
			Non-alcoholic steatohepatitis	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
			Osteoarthritis	01JAN2013		Y
			Spinal osteoarthritis	01JAN2013		Y
			Tendonitis	01JAN2004		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Cholecystectomy	01SEP2015	30SEP2015	N
			Female sterilisation	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341036	Eye disorders	Macular degeneration	01JAN2017		Y
			Retinal detachment	01FEB2019	28FEB2019	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2007		Y
		Surgical and medical procedures	Eye operation	01FEB2019	28FEB2019	N
			Prostatectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1134 11341037	Ear and labyrinth disorders	Deafness	01APR2011		Y
		Endocrine disorders	Hypothyroidism	01AUG2016		Y
		Eye disorders	Cataract	01JUN2020	30JUN2020	N
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1977	31DEC1977	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2009		Y
				01JAN2013		Y
			Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	01MAY2015		Y
		Infections and infestations	Staphylococcal infection	01MAY2009	31MAY2009	N
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1976	31DEC1976	N
		Renal and urinary disorders	Hypertonic bladder	01AUG2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1977	31DEC1977	N
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bladder repair	01JAN1976	31DEC1976	N
			Bunion operation	05DEC2017	05DEC2017	N
			Cataract operation	01JUN2020	01JUN2020	N
				15JUN2020	15JUN2020	N
			Cholecystectomy	01JAN1977	31DEC1977	N
			Hysterectomy	01JAN1977	31DEC1977	N
	C4591001 1134 11341038	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN2005		Y
				01JAN2009		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2019		Y
	C4591001 1134 11341040	Cardiac disorders	Atrial fibrillation	01JAN2006		Y
		Eye disorders	Cataract	06NOV2017	10DEC2017	N
		Gastrointestinal disorders	Proctitis ulcerative	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1994	31DEC2012	N
			Exostosis	30JAN2015	30JAN2015	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2017		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2006	31DEC2006	N
			Cataract operation	06NOV2017	06NOV2017	N
				10DEC2017	10DEC2017	N
			Hip arthroplasty	07NOV2017	07NOV2017	N
				10JUL2017	10JUL2017	N
			Shoulder operation	30JAN2015	30JAN2015	N
			Spinal fusion surgery	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341042	Immune system disorders	Allergy to arthropod sting	01JAN2012	31DEC2012	N
				01JAN1965		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
	C4591001 1134 11341043	Surgical and medical procedures	Rotator cuff syndrome	01JAN2005	31DEC2005	N
			Spinal osteoarthritis	01JAN2005		Y
		Immune system disorders	Shoulder operation	01JAN2005	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1134 11341044	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Surgical and medical procedures	Hernia repair	01JAN1984	31DEC1984
		Immune system disorders		01JAN1992	31DEC1992	N
				07JUN2016	07JUN2016	N
		Drug hypersensitivity	01JAN2016		Y	
			Food allergy	01JAN2002		Y
		Injury, poisoning and procedural complications	Ulna fracture	01AUG2016	31AUG2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	02MAR2020	N
					02MAR2020	
			Pain in extremity	28JUL2020	28JUL2020	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Bunion operation	28JUL2020	28JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip arthroplasty	02MAR2020	02MAR2020	N
			Wrist surgery	01AUG2016	31AUG2016	N
	C4591001 1134 11341045	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2017	31DEC2017	N
			Upper limb fracture	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Elbow operation	01JAN2015	31DEC2015	N
			Knee operation	01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1134 11341047	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Nervous system disorders	Migraine	01JAN1998		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1998	31DEC1998	N
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1134 11341048	General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
			Type 2 diabetes mellitus	10SEP2012		Y
		Surgical and medical procedures	Vasectomy	01NOV1983	30NOV1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341050	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Investigations	Arthroscopy	01JAN2009	31DEC2009	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2009		Y
			Osteoarthritis	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2006		Y
		Surgical and medical procedures	Meniscus removal	01JAN2009	31DEC2009	N
			Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1134 11341051	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
			Inguinal hernia	01JAN1982	31DEC1982	N
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1955	31DEC1955	N
			Coronary arterial stent insertion	01JAN2001	31DEC2001	N
			Coronary artery bypass	01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN1982	31DEC1982	N
	C4591001 1134 11341052	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Eye disorders	Eyelid ptosis	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Abdominal hernia	01JAN1952	31DEC1952	N
			Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Injury, poisoning and procedural complications	Arthropod sting	01JUL2020	31JUL2020	N
			Jaw fracture	01JAN1968	31DEC1968	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2005	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Pneumothorax	01JAN1965	31DEC1965	N
			Upper-airway cough syndrome	01JAN2015		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2005	31DEC2005	N
			Hernia repair	01JAN1952	31DEC1952	N
			Jaw operation	01JAN1968	31DEC1968	N
			Lung operation	01JAN1965	31DEC1965	N
			Prostatic operation	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1956	31DEC1956	N
			Vasectomy	01JAN1977		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1134 11341053	Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
	C4591001 1134 11341055	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	01JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN2015		Y
			Trigger finger	01JAN2013	31DEC2013	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2013	31DEC2013	N
			Tension headache	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1977	31DEC1977	N
				01JAN1979	31DEC1979	N
				01JAN1983	31DEC1983	N
			Carpal tunnel decompression	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN1983	31DEC1983	N
			Tendon sheath incision	01JAN2013	31DEC2013	N
	C4591001 1134 11341056	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2008	31DEC2008	N
		Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Immune system disorders	Perfume sensitivity	01JAN2008		Y
			Seasonal allergy	01JAN2008		Y
			Smoke sensitivity	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1981	30JUN1981	N
		Surgical and medical procedures	Ear operation	01JUN1981	30JUN1981	N
			Lithotripsy	23JAN2020	23JAN2020	N
			Orchidectomy	23JAN2020	23JAN2020	N
			Plastic surgery to the face	01FEB2019	28FEB2019	N
				01MAR2018	01MAR2018	N
			Rhinoplasty	01FEB2019		Y
			Skin cosmetic procedure	01MAY2018	31MAY2018	N
			Transgender operation	01JAN2017		Y
			Tympanoplasty	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341057	Gastrointestinal disorders	Inguinal hernia	01JAN2011	31DEC2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Vitamin D deficiency	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1974	31DEC1974	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2011	31DEC2011	N
			Mammoplasty	01JAN2000	31DEC2000	N
	C4591001 1134 11341058	Investigations	Blood cholesterol increased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1972		Y
			Osteoarthritis	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
			Prostatitis	11APR2019	25APR2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01MAY2017	31MAY2017	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1134 11341059	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Blepharoplasty	01JAN1995	31DEC1995	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341061	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Infections and infestations	Herpes simplex	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
	C4591001 1134 11341062	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN2019	31JAN2019	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1970	31DEC1970	N
			Tendon rupture	01JAN2003	31DEC2003	N
				01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01JAN2006		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2019	31JAN2019	N
			Rhinoplasty	01JAN1970	31DEC1970	N
			Tenoplasty	01JAN2003	31DEC2003	N
				01JAN2010	31DEC2010	N
	C4591001 1134 11341063	Gastrointestinal disorders	Haemorrhoids	01JAN1970	31DEC1970	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2020	31JAN2020	N
		Psychiatric disorders	Affect lability	30MAY2020		Y
			Anxiety	01JAN2012		Y
			Stress	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Haemorrhoid operation	01JAN1970	31DEC1970	N
			Shoulder operation	01JAN2020	31JAN2020	N
			Varicose vein operation	01JAN1971	31DEC1971	N
				01JAN1972	31DEC1972	N
		Vascular disorders	Varicose vein	01JAN1970	31DEC1972	N
	C4591001 1134 11341064	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Cataract	01FEB2014	31DEC2018	N
		Gastrointestinal disorders	Diarrhoea	01JAN1975		Y
			Irritable bowel syndrome	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2007		Y
		Surgical and medical procedures	Mammoplasty	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1134 11341065	Cardiac disorders	Cardiac failure	01JAN2019		Y
			Myocardial infarction	01JAN2018	31DEC2018	N
		Eye disorders	Retinal detachment	01MAY2020	31MAY2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
			Intervertebral disc protrusion	01JAN1999	31DEC1999	N
			Osteoarthritis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Retinal operation	01MAY2020	31MAY2020	N
			Spinal operation	01JAN1999	31DEC1999	N
			Stent placement	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341066	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1134 11341067	Gastrointestinal disorders	Inguinal hernia	01JAN2016	31DEC2016	N
		Infections and infestations	Osteomyelitis	01JAN1954	31DEC1954	N
		Nervous system disorders	Headache	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
			Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Bone operation	01JAN1954	31DEC1954	N
			Hernia repair	01JAN2016	31DEC2016	N
			Vasectomy	01JAN1985		Y
	C4591001 1134 11341069	Cardiac disorders	Ventricular extrasystoles	01JAN2000		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1996	31DEC1996	N
		Immune system disorders	Seasonal allergy	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2014		Y
			Osteoarthritis	01JAN2018	31DEC2018	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1134 11341071	Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JAN2002	31DEC2002	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2015		Y
	C4591001 1134 11341073	Cardiac disorders	Atrial fibrillation	01JAN2018	31DEC2018	N
		Immune system disorders	Food allergy	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2003		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1991		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2018	31DEC2018	N
	C4591001 1134 11341074	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2004	31DEC2004	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Nervous system disorders	Seizure	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Spinal operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1134 11341075	Injury, poisoning and procedural complications	Lower limb fracture	01JAN1971	31DEC1971	N
			Skull fracture	01JAN1971	31DEC1971	N
		Investigations	Cardiac murmur	(b) (6) 1949		Y
		Nervous system disorders	Coma	01JAN1971	31DEC1971	N
			Migraine	01JAN1960		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2011		Y
		Skin and subcutaneous tissue disorders	Rash	03JAN2017	31AUG2017	N
	C4591001 1134 11341076	Gastrointestinal disorders	Abdominal distension	01AUG2019		Y
			Abdominal pain	01AUG2019		Y
			Inguinal hernia	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Upper limb fracture	02AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JUN2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1980		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
				01JAN2015	31DEC2015	N
			Hernia repair	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1134 11341078	General disorders and administration site conditions	Hernia	01JAN1978	31DEC2009	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1978	31DEC1978	N
				01JAN2009	31DEC2009	N
	C4591001 1134 11341079	Cardiac disorders	Atrial fibrillation	01NOV2018	31JAN2019	N
			Coronary artery disease	01JAN2005		Y
		Gastrointestinal disorders	Enterovesical fistula	01APR2015	30APR2015	N
			Gastroesophageal reflux disease	01JAN1978		Y
		Infections and infestations	Diverticulitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Gout	01JAN1978		Y
			Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01APR2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2001	31DEC2001	N
				01JAN2005	31DEC2005	N
				01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1958		Y
		Surgical and medical procedures	Bladder operation	01JAN2001	31DEC2001	N
				01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008	31DEC2008	N
			Coronary artery bypass	01JAN2005		Y
			Fistulotomy	01APR2015	30APR2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341080	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
	C4591001 1134 11341081	Gastrointestinal disorders	Abdominal hernia	01JAN1962	31DEC1962	N
				01JAN1964	31DEC1964	N
			Dyspepsia	01JAN2013	31DEC2017	N
		Immune system disorders	Allergy to animal	01JAN2017		Y
			Seasonal allergy	01JAN2006		Y
		Injury, poisoning and procedural complications	Iris injury	01JAN1966		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2014		Y
			Pruritus	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Hernia repair	01JAN1962	31DEC1962	N
				01JAN1964	31DEC1964	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN1994	31DEC1994	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Raynaud's phenomenon	01JAN2017		Y
	C4591001 1134 11341082	Eye disorders	Cataract	01JAN2014	31MAY2017	N
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Investigations	Cardiac murmur	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
					30JUN2017	N
		Renal and urinary disorders	Bladder prolapse	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1134 11341083	Ear and labyrinth disorders	Hypoacusis	01JAN2003		Y
		Injury, poisoning and procedural complications	Rib fracture	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1134 11341084	Gastrointestinal disorders	Inguinal hernia	01JAN1997	31DEC1997	N
		Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
			Tonsillitis	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1957	31DEC1957	N
			Inguinal hernia repair	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1134 11341085	Cardiac disorders	Atrial fibrillation	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Exeresis	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Shoulder operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1134 11341087	Ear and labyrinth disorders	Deafness bilateral	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1992		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Small intestine carcinoma	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Cancer surgery	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Nasal polypectomy	01JAN1990	31DEC1990	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1945	31DEC1945	N
	C4591001 1134 11341091	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN2011		Y
		Infections and infestations	Diverticulitis	07AUG2020	13AUG2020	N
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
			Synovial cyst	01JAN2005	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1989		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hip arthroplasty	10MAR2016	10MAR2016	N
			Lipoma excision	01JAN2014	31DEC2014	N
			Lithotripsy	01JAN1998	31DEC1998	N
			Sebaceous cyst excision	01JAN2015	31DEC2015	N
			Synovial cyst removal	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341092	Cardiac disorders	Atrial fibrillation	01OCT2019		Y
		Eye disorders	Dry eye	01JAN2019		Y
			Hypermetropia	01JAN2006		Y
		Gastrointestinal disorders	Constipation	01JAN1996		Y
			Diverticulum	01JAN2015		Y
		Immune system disorders	Food allergy	01JUN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2001		Y
			Osteoporosis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2001		Y
		Nervous system disorders	Notalgia paraesthetica	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1958		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1134 11341094	Ear and labyrinth disorders	Tinnitus	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1134 11341095	Hepatobiliary disorders	Cholecystitis	01JAN1990	31DEC1990	N
		Infections and infestations	Appendicitis	01JAN1968	31DEC1968	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31AUG2014	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1968	31DEC1968	N
			Breast conserving surgery	01JAN2013	31DEC2013	N
			Caesarean section	01JAN1981	31DEC1981	N
			Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1134 11341096	Cardiac disorders	Aortic valve disease	01FEB2020	29FEB2020	N
			Coronary artery disease	01JAN1995		Y
		General disorders and administration site conditions	Chest pain	01JAN1995		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Aortic valve replacement	01FEB2020	31DEC2020	N
			Cholecystectomy	01JAN2016	31DEC2016	N
			Coronary arterial stent insertion	01JAN1995	31DEC2014	N
			Coronary artery bypass	01JAN1995	31DEC1995	N
			Intervertebral disc operation	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1134 11341097	Metabolism and nutrition disorders	Gout	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Shoulder operation	01JAN1990	31DEC1990	N
	C4591001 1134 11341098	Cardiac disorders	Coronary artery disease	16NOV2006		Y
		Eye disorders	Cataract	01JUN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		General disorders and administration site conditions	Chest pain	01JAN2006	31DEC2006	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2006		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Nasal septum deviation	23JUL2008	23JUL2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2002		Y
		Surgical and medical procedures	Coronary arterial stent insertion	16NOV2006	16NOV2006	N
			Nasal septal operation	23JUL2008	23JUL2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341099	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01DEC2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2016	31DEC2016	N
			Nasal septal operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1134 11341100	General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2009	31DEC2009	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1134 11341101	Ear and labyrinth disorders	Vertigo	01JAN2017		Y
		Eye disorders	Dry eye	01JAN2007		Y
			Macular degeneration	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN2002		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1989		Y
			Hypercholesterolaemia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
			Osteopenia	01FEB2019		Y
		Nervous system disorders	Migraine	01JAN1968		Y
			Morton's neuralgia	01JAN2010	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2012		Y
			Insomnia	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Caesarean section	01JAN1968	31DEC1968	N
				01JAN1972	31DEC1972	N
			Cholecystectomy	01JAN2014	31DEC2014	N
			Female sterilisation	01JAN1978	31DEC1978	N
			Neurectomy	01JAN2011	31DEC2011	N
				01JAN2016	31DEC2016	N
	C4591001 1134 11341103	Ear and labyrinth disorders	Deafness unilateral	01JAN2004		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Infections and infestations	Herpes zoster	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2006	31DEC2006	N
					31DEC2008	N
		Nervous system disorders	Sinus headache	01JAN1965		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	07FEB2012	07FEB2012	N
			Skin neoplasm excision	01JAN2006	31DEC2006	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2008	31DEC2008	N
			Vasectomy	01JAN1971	31DEC1971	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1134 11341105	Hepatobiliary disorders	Cholecystitis	01JAN1975	31DEC1975	N
		Investigations	Blood potassium decreased	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1975	31DEC1975	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Lymphadenectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1134 11341108	Eye disorders	Blindness unilateral	(b) (6) 1949		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Injury, poisoning and procedural complications	Ligament rupture	01MAY2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2001		Y
			Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Rhinitis perennial	01JAN1999		Y
			Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341109	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tongue geographic	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
				01JAN2014		Y
				01JAN2016		Y
				01JAN2018		Y
			Rubber sensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2017	31DEC2017	N
			Upper limb fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Limb operation	01JAN2012	31DEC2012	N
			Spinal operation	01JAN2017	31DEC2017	N
	C4591001 1134 11341110	Hepatobiliary disorders	Cholelithiasis	01JAN2009	19MAR2009	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Injury, poisoning and procedural complications	Wrist fracture	19NOV2019		Y
		Nervous system disorders	Migraine	01JAN1973		Y
		Renal and urinary disorders	Bladder prolapse	23DEC2019	23DEC2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1963	31DEC1963	N
			Cholecystectomy	19MAR2009	19MAR2009	N
			Hysterectomy	23DEC2019	23DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urinary bladder suspension	23DEC2019	23DEC2019	N
		Vascular disorders	Hypertension	24JAN2020		Y
	C4591001 1134 11341113	Eye disorders	Cataract	01JAN2018	30NOV2019	N
			Macular degeneration	01JAN2008		Y
			Myopia	01JAN1953	31DEC2003	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Iodine allergy	01JAN1972		Y
		Investigations	Blood cholesterol increased	01DEC2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2006	31DEC2006	N
		Nervous system disorders	Transient ischaemic attack	01DEC2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
				01NOV2019	30NOV2019	N
			Keratomileusis	01JAN2003	31DEC2003	N
			Lymphadenectomy	01JAN2010	31DEC2010	N
			Sinus operation	01JAN1996	31DEC1996	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1134 11341114	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01FEB2020		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
			Depression	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341115	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Seasonal affective disorder	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1134 11341119	Cardiac disorders	Mitral valve incompetence	15MAY2019	15MAY2019	N
		Ear and labyrinth disorders	Vertigo	22JUL2017		Y
		Investigations	Blood cholesterol increased	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1970		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Hip arthroplasty	01JAN1989	31DEC1989	N
				01JAN2008	31DEC2008	N
			Mitral valve repair	15MAY2019	15MAY2019	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1134 11341120	Eye disorders	Cataract	01JAN2017	31DEC2018	N
			Presbyopia	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
			Seasonal allergy	01JAN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Meniscus operation	01JAN2000	31DEC2000	N
			Synovial cyst removal	01JAN2003	31DEC2003	N
		Vascular disorders	Aortic aneurysm	01JAN2009		Y
	C4591001 1134 11341121	Eye disorders	Cataract	01JAN2003	10SEP2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1993	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN1999		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
			Osteoporosis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01OCT2018	31OCT2018	N
				10SEP2018	10SEP2018	N
			Cholecystectomy	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1134 11341122	Infections and infestations	Appendicitis	01JAN1996	31DEC1996	N
		Nervous system disorders	Headache	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1985	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Renal and urinary disorders	Nephrolithiasis	01JAN1996		Y	
		Social circumstances	Postmenopause	01JAN2015		Y	
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N	
			Renal stone removal	01JAN2004	31DEC2004	N	
				01JAN2017	31DEC2017	N	
				01NOV2019	31DEC2019	N	
	C4591001 1134 11341123	Eye disorders	Cataract	01JUL2019	31AUG2019	N	
		Surgical and medical procedures	Cataract operation	01AUG2019	31AUG2019	N	
				01JUL2019	31JUL2019	N	
	C4591001 1134 11341124	Vascular disorders	Hypertension	01JAN2019		Y	
		Hepatobiliary disorders	Cholecystitis	01JAN1988	31DEC1988	N	
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y	
					31DEC1979		N
		Metabolism and nutrition disorders	Gout	01JAN2011		Y	
				Hypercholesterolaemia	01JAN2000		Y
				Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2011		Y	
		Nervous system disorders	Restless legs syndrome	01JAN2012		Y	
		Psychiatric disorders	Depression	01JAN2012		Y	
		Social circumstances	Postmenopause	01JAN2000		Y	
		Surgical and medical procedures	Cholecystectomy	01JAN1988	31DEC1988	N	
	C4591001 1134 11341125	Vascular disorders	Hypertension	01JAN1998		Y	
		Ear and labyrinth disorders	Vertigo	01AUG2014		Y	
		Eye disorders	Glaucoma	01NOV2014		Y	
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01AUG2014		Y
		Injury, poisoning and procedural complications	Ankle fracture	01AUG2014	01AUG2014	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2002		Y
			Spinal osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
			Benign neoplasm	01JAN2008	31DEC2008	N
		Psychiatric disorders	Insomnia	01JAN1998		Y
		Reproductive system and breast disorders	Breast cyst	01JAN2000	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Ankle operation	01JAN2014	31DEC2014	N
			Benign tumour excision	01JAN2008	31DEC2008	N
			Breast cyst excision	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2003	31DEC2003	N
	C4591001 1134 11341126	Eye disorders	Iridocorneal endothelial syndrome	01JAN2011		Y
			Ocular vascular disorder	01DEC2003	31DEC2003	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1989		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN1996		Y
				01JAN1998		Y
				01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1972	31DEC1972	N
			Sinusitis	01JAN2015		Y
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1996	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JAN1996		Y
			Type 2 diabetes mellitus	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Compartment syndrome	01JAN1996	31OCT1999	N
			Osteoarthritis	01JAN2011		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998	31DEC2016	N
			Seizure	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Renal and urinary disorders	Chronic kidney disease	01JUL2019		Y
			Nephrolithiasis	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Pulmonary mass	01JAN2014		Y
			Sleep apnoea syndrome	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN1972	31DEC1972	N
			Carpal tunnel decompression	01JAN1999	31DEC1999	N
				01JAN2016	31DEC2016	N
			Fracture treatment	01JAN1996	31DEC1996	N
			Leg amputation	01JAN1999	31DEC1999	N
			Limb operation	01JAN2018	31DEC2018	N
			Skin graft	01JAN1996	31DEC1996	N
				01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1134 11341127	Gastrointestinal disorders	Dyspepsia	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast cyst excision	01NOV2014		Y
			Endometrial ablation	06AUG2013		Y
		Vascular disorders	Hysterectomy	26JAN2019	26JAN2019	N
		Immune system disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341128		Drug hypersensitivity	01JAN1989		Y
		Injury, poisoning and procedural complications	Meniscus injury	01FEB2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	03JUN1989	03JUN1989	N
				04MAR1986	04MAR1986	N
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1134 11341130	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1974	31DEC1974	N
		Psychiatric disorders	Anxiety	01JAN1996		Y
			Bipolar disorder	01JAN1996		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1965		Y
		Surgical and medical procedures	Cancer surgery	01JAN2010	31DEC2010	N
			Carpal tunnel decompression	01JAN1974	31DEC1974	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
			Spinal operation	01JAN2013	31DEC2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2014	31DEC2014	N
			Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341131	Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1134 11341132	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1990		Y
		Surgical and medical procedures	Medical device implantation	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341133	Gastrointestinal disorders	Barrett's oesophagus	01JAN2015	29FEB2020	N
			Dyspepsia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2019	30SEP2019	N
		Nervous system disorders	Headache	01JAN2017		Y
		Surgical and medical procedures	Limb operation	01JAN2014	31DEC2014	N
			Oesophageal operation	01FEB2020	29FEB2020	N
				01MAY2019	31MAY2019	N
				01OCT2019	31OCT2019	N
			Synovial cyst removal	01SEP2019	30SEP2019	N
			Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1134 11341135	Eye disorders	Amblyopia strabismic	(b) (6) 1949	31DEC1954	N
			Cataract	01OCT2019	31OCT2019	N
				01SEP2019	30SEP2019	N
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Nervous system disorders	Headache	01JAN1990		Y
		Renal and urinary disorders	Ureteric stenosis	(b) (6) 1949	31DEC1997	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Cataract operation	01OCT2019	31OCT2019	N
				01SEP2019	30SEP2019	N
			Eye muscle operation	01JAN1954	31DEC1954	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
			Urethral repair	01JAN1997	31DEC1997	N
	C4591001 1134 11341136	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2004	31DEC2004	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Colectomy	01JAN2004	31DEC2004	N
			Rotator cuff repair	01JAN2016	31DEC2016	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Uterine dilation and curettage	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1134 11341137	Nervous system disorders	Migraine	01JAN1972		Y
		Renal and urinary disorders	Urethral dilatation	01JAN1964	31DEC1964	N
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1134 11341138	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2000	31DEC2000	N
			Colon cancer	01JAN2013	31DEC2013	N
		Nervous system disorders	Neuropathy peripheral	01JAN2009		Y
			Restless legs syndrome	01JAN1989		Y
		Surgical and medical procedures	Bladder neoplasm surgery	01JAN2000	31DEC2000	N
			Colectomy	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1134 11341139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
	C4591001 1134 11341140	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Hepatobiliary disorders	Gallbladder hypofunction	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Infections and infestations	Chronic sinusitis	01JAN1989	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
			Urinary incontinence	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Reproductive system and breast disorders	Adenomyosis	01JAN2005	31DEC2006	N	
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2013		Y	
		Surgical and medical procedures	Appendicectomy	01OCT2018	31OCT2018	N	
			Benign breast lump removal	01JAN1984	31DEC1984	N	
				01JAN2000	31DEC2000	N	
				Bladder operation	01JAN2008	31DEC2008	N
				Caesarean section	01JAN1984	31DEC1984	N
				Cholecystectomy	01JAN2002	31DEC2002	N
				Hysterectomy	01DEC2006	31DEC2006	N
				Knee operation	01JAN2017	31DEC2017	N
				Renal stone removal	01JAN2015	31DEC2015	N
				Skin neoplasm excision	01JAN2005	31DEC2005	N
	C4591001 1134 11341142		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
			Immune system disorders	Drug hypersensitivity	01JAN1979		Y
					01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y	
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1989	31DEC1989	N	
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N	
			Hysterectomy	01JAN1989	31DEC1989	N	
			Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341143	General disorders and administration site conditions	Drug intolerance	01JAN2003		Y	
		Immune system disorders	Seasonal allergy	01JAN2010		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1986		Y
			Spinal osteoarthritis	01JAN1986		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid adenoma	01JAN1995	31DEC1995	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1972	31DEC1972	N
				01JAN1982	31DEC1982	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
			Meniscus operation	01JAN2001	31DEC2001	N
			Thyroidectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341144	Injury, poisoning and procedural complications	Skull fracture	01JAN1958	31DEC1958	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2019		Y
		Nervous system disorders	Headache	01JAN1958		Y
			Migraine	01JAN1968		Y
			Nerve compression	01JAN2009	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Cranial operation	01JAN1958	31DEC1958	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Neck surgery	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341145	Congenital, familial and genetic disorders	Ear malformation	01JAN1957	31DEC2013	N
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1963	31DEC1963	N
			Irritable bowel syndrome	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1997		Y
			Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2007		Y
		Nervous system disorders	Sinus headache	01JAN1967		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1967		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hernia repair	01JAN1963	31DEC1963	N
			Hysterectomy	01JAN2005	31DEC2005	N
			Otoplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2004		Y
			Raynaud's phenomenon	01JAN1980		Y
	C4591001 1134 11341146	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Bursitis	01AUG2020		Y
			Osteoarthritis	01JAN2016		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017	31DEC2017	N
			Rhinitis perennial	01JAN1978		Y
		Surgical and medical procedures	Appendicectomy	01JAN1984	31DEC1984	N
			Bone lesion excision	01JAN2016	31DEC2016	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
			Sinus operation	01JAN2017	31DEC2017	N
	C4591001 1134 11341148	Investigations	Intraocular pressure increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Skin neoplasm excision	01MAR2020	31MAR2020	N
			Uvulectomy	01JAN2001	31DEC2001	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1134 11341152	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic neoplasm	01JAN2017	31DEC2017	N
			Thyroid cancer	01JAN2017	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prostatomegaly	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341155	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN2003		Y
			Blood triglycerides increased	01JAN2003		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety disorder	01JAN1988		Y
			Depression	01JAN1984		Y
			Insomnia	01JAN1966		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1992		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Urinary bladder suspension	01JAN1992	31DEC1992	N
		Vascular disorders	Hot flush	01JAN2008		Y
	C4591001 1134 11341156	Gastrointestinal disorders	Hiatus hernia	01JAN1970	31DEC1970	N
		Nervous system disorders	Tension headache	01DEC2013		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN1970	31DEC1970	N
	C4591001 1134 11341158	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Intestinal obstruction	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Investigations	Blood cholesterol increased	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1134 11341159	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
		Nervous system disorders	Headache	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1134 11341160	Cardiac disorders	Atrial tachycardia	01MAR2020		Y
			Coronary artery disease	01FEB2016		Y
			Myocardial infarction	01FEB2017	28FEB2017	N
		Ear and labyrinth disorders	Vertigo	01JAN1975		Y
		Vascular disorders	Orthostatic hypotension	01JAN1975		Y
	C4591001 1134 11341161	Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1979	31DEC1979	N
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
	C4591001 1134 11341162	Immune system disorders	Seasonal allergy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Nervous system disorders	Disturbance in attention	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1134 11341163	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341164	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Infections and infestations	Tonsillitis	01JAN1978	31DEC1978	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1979	31DEC1979	N
				01JAN1984	31DEC1984	N
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
			Tonsillectomy	01JAN1978	31DEC1978	N
	C4591001 1134 11341166	Eye disorders	Glaucoma	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Lipoma excision	01JAN2018	31DEC2018	N
			Trabeculectomy	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
	C4591001 1134 11341167	Cardiac disorders	Coronary artery disease	01JAN2001		Y
		Gastrointestinal disorders	Constipation	01JUN2016		Y
			Dyspepsia	01JAN2002		Y
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Metabolism and nutrition disorders	Vitamin B complex deficiency	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2013		Y
		Nervous system disorders	Headache	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2001	22JUN2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2012		Y
		Surgical and medical procedures	Percutaneous coronary intervention	09MAY2001	09MAY2001	N
			Prostatectomy	01JUN2016	30JUN2016	N
	C4591001 1134 11341168	General disorders and administration site conditions	Oedema peripheral	01NOV2019		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
			Hepatic steatosis	01JAN1990		Y
		Immune system disorders	Iodine allergy	01JAN1979		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341170	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2019		Y
		Vascular disorders	Deep vein thrombosis	01JAN2011	31DEC2011	N
	C4591001 1134 11341171	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1958	31DEC1958	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341172	Blood and lymphatic system disorders	Pernicious anaemia	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2011		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2011		Y
			Neuropathy peripheral	01JAN2011		Y
			Tension headache	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Bipolar disorder	01JAN1985		Y
			Depression	01JAN1976		Y
			Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Abdominal exploration	01JAN2010	31DEC2010	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Intraocular lens implant	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341175	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01SEP2018		Y
		Infections and infestations	Infectious mononucleosis	01JAN1976	31DEC1976	N
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006	31DEC2006	N
			Spinal osteoarthritis	17JUN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN1985		Y
		Surgical and medical procedures	Spinal operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1134 11341178	Eye disorders	Hypermetropia	01JAN1985		Y
		General disorders and administration site conditions	Pain	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JAN1994	31DEC1994	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Surgical and medical procedures	Meniscus operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341179	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUN2020		Y
			Osteoarthritis	01JAN2018		Y
				01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341181	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2001		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hypercholesterolaemia	01JAN2005		Y
			Vitamin B12 deficiency	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
				01MAY2014	31MAY2014	N
			Prostate cancer	01JAN1998	31DEC1998	N
		Psychiatric disorders	Insomnia	01JAN2007		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
				01MAY2014	31MAY2014	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1134 11341182	Eye disorders	Entropion	15DEC2018	18FEB2019	N
			Eyelid ptosis	01AUG2019	31AUG2019	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2016	31DEC2016	N
				10JAN2019	31MAR2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1989		Y
				01JAN2015		Y
			Osteoarthritis	01JAN2000		Y
					31AUG2012	N
					31OCT2011	N
			Spinal osteoarthritis	01JAN2000		Y
		Nervous system disorders	Amnesia	01JAN2016		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1967	31DEC1967	N
				01JAN1969	31DEC1969	N
				01JAN1971	31DEC1971	N
				01JAN1982	31DEC1982	N
		Psychiatric disorders	Depression	01JAN1986		Y
			Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Arthrodesis	01JAN2019	31DEC2019	N
			Blepharoplasty	01AUG2019	31AUG2019	N
				18FEB2019	18FEB2019	N
			Hip arthroplasty	01AUG2012	31AUG2012	N
				01OCT2011	31OCT2011	N
			Meniscus operation	01JAN2016	31DEC2016	N
				01MAR2019	31MAR2019	N
	C4591001 1134 11341185	Endocrine disorders	Thyroid cyst	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Constipation	01JAN2018		Y
			Rectal fissure	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	07SEP2018	07SEP2018	N
			Osteopenia	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1963		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN1980	31DEC1980	N
				01JAN1982	31DEC1982	N
			Muscle operation	01JAN2008	31DEC2008	N
			Spinal operation	07SEP2018	07SEP2018	N
			Thyroid cystectomy	01JAN2007	31DEC2007	N
	C4591001 1134 11341187	Congenital, familial and genetic disorders	Vitello-intestinal duct remnant	01JAN1980	31DEC1980	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2002	31DEC2002	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2016		Y
		Surgical and medical procedures	Ligament operation	01JAN2002	31DEC2002	N
			Small intestine operation	01JAN1980	31DEC1980	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1134 11341193	Cardiac disorders	Coronary artery disease	01JAN2003		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		General disorders and administration site conditions	Non-cardiac chest pain	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN2004		Y
		Investigations	Blood cholesterol increased	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01AUG2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2003	31DEC2003	N
			Coronary artery bypass	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1134 11341194	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Infections and infestations	Tonsillitis	01JAN1948	31DEC1948	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015	31DEC2017	N
			Spinal osteoarthritis	01JAN1999		Y
					31DEC2019	N
					31DEC2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Fracture treatment	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN1971	31DEC1971	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1948	31DEC1948	N
	C4591001 1134 11341196	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1134 11341197	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1973	31DEC1977	N
				01JAN1977	31DEC1977	N
				01JAN1979	31DEC1979	N
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1134 11341198	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Injury, poisoning and procedural complications	Iliotibial band syndrome	01JUN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1983	31DEC1983	N
	C4591001 1134 11341199	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341200	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
	C4591001 1134 11341201	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2018		Y
		Infections and infestations	Infection	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Incisional hernia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
			Osteoporosis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Colostomy	01JAN2016	31DEC2016	N
			Colostomy closure	01JAN2018	31DEC2018	N
			Knee operation	01JAN2016	31DEC2016	N
	C4591001 1134 11341202	Injury, poisoning and procedural complications	Cartilage injury	01NOV2019	30NOV2019	N
			Joint dislocation	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Knee arthroplasty	01NOV2019	30NOV2019	N
			Shoulder operation	01JAN2013	31DEC2013	N
	C4591001 1134 11341205	Investigations	Blood cholesterol increased	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01DEC2018	31DEC2018	N
		Surgical and medical procedures	Renal stone removal	01DEC2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1134 11341206	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1134 11341207	Eye disorders	Cataract	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1996	31DEC1996	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Contrast media allergy	01JAN2014		Y
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN1967	31DEC1967	N
		Nervous system disorders	Headache	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Bronchitis chronic	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01DEC2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Transurethral prostatectomy	01JAN2005	31DEC2005	N
	C4591001 1134 11341208	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Strabismus	(b) (6) 1960	31DEC1961	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Obesity	01JAN2010	31MAR2018	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1975	31DEC1975	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JAN1979	31DEC1979	N
				01JAN1980	31DEC1980	N
				01JAN1982	31DEC1982	N
				01JAN1984	31DEC1984	N
			Eye muscle operation	01JAN1961	31DEC1961	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1984	31DEC1984	N
			Gastric bypass	01MAR2018	31MAR2018	N
			Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1134 11341209	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Nasal septal operation	01JAN1985	31DEC1985	N
			Renal stone removal	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341212	Infections and infestations	Appendicitis	01JAN1977	31DEC1977	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2005	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hot flush	01JAN2017		Y
			Hypertension	01JAN2016		Y
	C4591001 1134 11341214	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Injury, poisoning and procedural complications	Fall	12JUL2020	12JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tooth injury	12JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1978		Y
			Foot deformity	01JAN1998	31DEC1998	N
			Osteoarthritis	01JAN2012		Y
			Scoliosis	01JAN1963		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Bunion operation	01JAN1998	31DEC1998	N
			Joint arthroplasty	01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
	C4591001 1134 11341215	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		General disorders and administration site conditions	Pain	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Coronary angioplasty	01JAN2018	31DEC2018	N
			Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Thyroidectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341216	Eye disorders	Cataract	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Hip arthroplasty	01JAN2002	31DEC2002	N
	C4591001 1134 11341217	Gastrointestinal disorders	Constipation	01JAN2010	31DEC2018	N
		General disorders and administration site conditions	Oedema peripheral	22JUN2019	25JUN2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
				01JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2001		Y
			Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2011		Y
			Nocturia	01JAN2013		Y
			Urge incontinence	01JAN2011		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2001	28FEB2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1951	31DEC1957	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hot flush	01JAN2014	28FEB2019	N
			Hypertension	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341218	Endocrine disorders	Hypothyroidism	01MAY2020		Y
		Eye disorders	Cataract	18AUG2020		Y
		Infections and infestations	Diverticulitis	01MAY2017	31MAY2017	N
			Urinary tract infection	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1992	31DEC2001	N
			Osteopenia	01JAN1992		Y
		Renal and urinary disorders	Incontinence	01JAN1991	31DEC1991	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN1992	31DEC1992	N
				01JAN2001	31DEC2001	N
			Cataract operation	19AUG2020	19AUG2020	N
			Urinary bladder suspension	01JAN1991	31DEC1991	N
	C4591001 1134 11341219	Infections and infestations	Appendicitis	01JAN1957	31DEC1957	N
			Tonsillitis	01JAN1980	31DEC1980	N
		Investigations	Medical observation	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
			Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1957	31DEC1957	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1134 11341220	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1972		Y
		Infections and infestations	Bacterial toxemia	01JAN1983	31DEC1983	N
			Herpes simplex	01JAN1970	31DEC2012	N
			Tonsillitis	01JAN1964	31DEC1964	N
		Investigations	Blood cholesterol increased	01SEP2017		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2004	31DEC2004	N
			Osteoarthritis	01JAN2004		Y
			Spinal osteoarthritis	01JAN2004		Y
			Spinal stenosis	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2004	31DEC2014	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	01JAN2004	31DEC2004	N
			Caesarean section	01JAN1980	31DEC1980	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Spinal laminectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1134 11341221	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2002		Y
		Infections and infestations	Myocarditis infectious	01MAY2020	31MAY2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Psychogenic seizure	01JAN1984		Y
		Psychiatric disorders	Anxiety	01JAN1984		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Post-traumatic stress disorder	01JAN1986		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1134 11341227	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Injury, poisoning and procedural complications	Meniscus injury	01OCT2019	31OCT2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2015	31DEC2015	N
			Knee operation	01OCT2019	31OCT2019	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
	C4591001 1134 11341229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2018	31DEC2018	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	10AUG2020		Y
		Surgical and medical procedures	Bone operation	01JAN2018	31DEC2018	N
			Renal stone removal	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341231	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
			Lipoma	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Nephrolithiasis	09NOV2014	11NOV2014	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Lipoma excision	01JAN2012	31DEC2012	N
			Lithotripsy	11NOV2014	11NOV2014	N
			Micrographic skin surgery	01JAN2007	31DEC2007	N
		Eye disorders	Cataract	01JAN1995	31DEC1995	N
	C4591001 1134 11341233	Gastrointestinal disorders	Large intestine polyp	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Infections and infestations	Tonsillitis	01JAN1956	31DEC1956	N
		Nervous system disorders	Tension headache	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN2018	31DEC2018	N
			Cataract operation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1956	31DEC1956	N
			Uterine dilation and curettage	01JAN2010	31DEC2010	N
	C4591001 1134 11341238	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Nervous system disorders	Tension headache	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
				01JAN2001	31DEC2001	N
				01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN2004	31DEC2004	N
	C4591001 1134 11341239	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1964	31DEC1965	N
		Eye disorders	Cataract	01JAN2010	30NOV2010	N
					31OCT2010	N
			Dry eye	01JAN1968		Y
			Lenticular opacities	01JAN2017	31DEC2017	N
			Vitreous floaters	01JUL2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
				01JAN2005		Y
			Seasonal allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Hand fracture	12DEC2019	12DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01SEP2012	31DEC2012	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01NOV1987	30NOV1987	N
				01OCT1990	31OCT1990	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Adenotonsillectomy	01JAN1969	31DEC1969	N
			Cataract operation	01NOV2010	30NOV2010	N
				01OCT2010	31OCT2010	N
			Cholecystectomy	01JAN2013	31DEC2013	N
			Lens capsulotomy	01JAN2017	31DEC2017	N
			Limb operation	12DEC2019	12DEC2019	N
			Neurectomy	01SEP2012	30SEP2012	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
		Vascular disorders	Hypotension	01JAN1970		Y
	C4591001 1134 11341240	Gastrointestinal disorders	Intestinal obstruction	01JAN2020	31JAN2020	N
			Irritable bowel syndrome	01JAN1988		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2005	31DEC2005	N
			Lumbar spinal stenosis	01JAN2000		Y
		Nervous system disorders	Sciatica	01JAN2000		Y
		Renal and urinary disorders	Bladder prolapse	01APR2019	30APR2019	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01APR2019	30APR2019	N
			Spinal laminectomy	01JAN2007	31DEC2007	N
	C4591001 1134 11341243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Seasonal allergy	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	29FEB2020	N
					31MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
			Spinal osteoarthritis	01JAN2000		Y
			Trigger finger	01JAN2008	31DEC2008	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006	31DEC2006	N
		Psychiatric disorders	Anxiety	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Knee arthroplasty	01FEB2020	29FEB2020	N
				01MAY2020	31MAY2020	N
			Limb operation	01JAN2008	31DEC2008	N
			Tenotomy	01JUN2017	30JUN2017	N
	C4591001 1134 11341245	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Herpes simplex	01JAN1976		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Bunion operation	01JAN2000	31DEC2000	N
			Caesarean section	01JAN1979	31DEC1979	N
			Female sterilisation	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341246	General disorders and administration site conditions	Pain	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Back injury	21JUL2001	22JUL2001	N
			Neck injury	21JUL2001	21JUL2001	N
			Spinal cord injury	01JAN2001		Y
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Headache	01JAN1956		Y
			Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
			Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012		Y
			Shoulder arthroplasty	06MAR2020	06MAR2020	N
			Transurethral prostatectomy	01JAN2014	31DEC2014	N
		Eye disorders	Cataract	01JAN2015		Y
	C4591001 1134 11341250	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1949	31DEC1949	N
			Labyrinthitis	12SEP2018	18SEP2018	N
			Tonsillitis	01JAN1953	31DEC1953	N
		Injury, poisoning and procedural complications	Femur fracture	01DEC2017	01DEC2017	N
		Metabolism and nutrition disorders	Gout	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1979	31DEC1979	N
			Rheumatoid arthritis	01JAN1970		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2009		Y
		Renal and urinary disorders	Nephrolithiasis	01AUG2020	31AUG2020	N
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Appendicectomy	01JAN1949	31DEC1949	N
			Fracture treatment	01DEC1971	01DEC1971	N
			Toe operation	01JAN1979	31DEC1979	N
			Tonsillectomy	01JAN1953	31DEC1953	N
	C4591001 1134 11341251	Gastrointestinal disorders	Inguinal hernia	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Metabolism and nutrition disorders	Gout	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31JAN2019	N
		Psychiatric disorders	Panic attack	01JAN1990		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31JAN2019	N
			Inguinal hernia repair	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341252	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Caesarean section	01SEP1988	01SEP1988	N
				10SEP1997	10SEP1997	N
				11DEC1990	11DEC1990	N
				13JUN1993	13JUN1993	N
	C4591001 1134 11341255	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN1971	31DEC1971	N
		Endocrine disorders	Goitre	01JAN1999	31DEC1999	N
			Hypothyroidism	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Splenectomy	01JAN1971	31DEC1971	N
	C4591001 1134 11341256	Immune system disorders	Food allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01MAR2019		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1134 11341257	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01OCT2019	31MAR2020	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01DEC2019		Y
			Hysterectomy	01JAN2005		Y
	C4591001 1134 11341258	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Eye disorders	Cataract	01JAN2006	31DEC2006	N
			Diabetic retinopathy	01JAN2012		Y
			Eyelid ptosis	01JAN2013		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Injury, poisoning and procedural complications	Upper limb fracture	01APR2017	30APR2017	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2010	N
			Osteoarthritis	01JAN1963		Y
			Osteoporosis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN1970		Y
					30APR2017	N
		Skin and subcutaneous tissue disorders	Rash	01JUL2020	31JUL2020	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1134 11341261	Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1134 11341262	Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1977	31DEC1977	N
		Musculoskeletal and connective tissue disorders	Pain in extremity	30AUG2020		Y
			Rotator cuff syndrome	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Limb operation	01JAN1977	31DEC1977	N
			Shoulder operation	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341264	Gastrointestinal disorders	Inguinal hernia	01JAN1994	31DEC1994	N
				01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	02SEP2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
			Spinal operation	01JAN1998	31DEC1998	N
	C4591001 1134 11341265	Eye disorders	Presbyopia	01JAN1968		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
			Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015	31DEC2015	N
			Spinal osteoarthritis	01JAN2010		Y
	C4591001 1134 11341266	Surgical and medical procedures	Spinal operation	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1976	31DEC1976	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
			Knee operation	01JAN1976	31DEC1976	N
	C4591001 1134 11341270	Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01APR2018	30APR2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Prostatectomy	01APR2019	30APR2019	N
	C4591001 1134 11341271	Gastrointestinal disorders	Inguinal hernia	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Oedema	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
			Vitamin D deficiency	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2009	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Endometrial ablation	01JAN2009	31DEC2009	N
			Inguinal hernia repair	01JAN2009	31DEC2009	N
			Metabolic surgery	01JAN2008	31DEC2008	N
			Skin operation	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1996	31DEC1996	N
	C4591001 1134 11341273	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1955		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1995	31DEC1995	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341274	Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
	C4591001 1134 11341275	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Renal and urinary disorders	Urge incontinence	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	14SEP1988	14SEP1988	N
			Female sterilisation	01JAN2010	31DEC2010	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341277	Gastrointestinal disorders	Coeliac disease	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Investigations	Blood cholesterol increased	01MAY2017		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01MAY2017		Y
		Psychiatric disorders	Insomnia	01JAN2007		Y
	C4591001 1134 11341278	Reproductive system and breast disorders	Endometriosis	01JAN2002	31DEC2002	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1134 11341279	Eye disorders	Dry eye	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN2013		Y
			Seasonal allergy	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341284	Eye disorders	Retinal detachment	01JAN2018	31DEC2018	N
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Eye operation	01NOV2017	30NOV2017	N
				01SEP2018	30SEP2018	N
			Skin neoplasm excision	01JAN2014	31DEC2014	N
	C4591001 1134 11341285	Metabolism and nutrition disorders	Gout	01JAN1997		Y
			Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
			Rotator cuff syndrome	01JAN2008	31DEC2009	N
		Nervous system disorders	Carpal tunnel syndrome	01OCT2010	31OCT2010	N
			Neuropathy peripheral	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2007		Y
		Surgical and medical procedures	Carpal tunnel decompression	01OCT2010	31OCT2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip arthroplasty	01FEB2020	29FEB2020	N
			Knee arthroplasty	01JAN1990	31DEC1990	N
				01JAN2008	31DEC2008	N
				01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
				01JAN2020	31DEC2020	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
				01JAN2009	31DEC2009	N
			Shoulder arthroplasty	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1134 11341287	Metabolism and nutrition disorders	Gout	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
	C4591001 1134 11341288	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2005	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341289	Cardiac disorders	Atrial fibrillation	01JAN1985		Y
			Bradycardia	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
			Irritable bowel syndrome	01JAN1998		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2018		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1965	31DEC1965	N
				01JAN1966	31DEC1966	N
			Delivery	01JAN1968	31DEC1968	N
		Psychiatric disorders	Anxiety	01JAN1963		Y
		Renal and urinary disorders	Nephropathy	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN1987	31DEC1987	N
			Female sterilisation	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN1963		Y
	C4591001 1134 11341291	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Inguinal hernia	01JAN1981	31DEC1981	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
			Wrist fracture	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
			Fracture treatment	01JAN1953	31DEC1953	N
				01JAN1995	31DEC1995	N
			Inguinal hernia repair	01JAN1981	31DEC1981	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1134 11341294	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Injury, poisoning and procedural complications	Head injury	01APR2018	30APR2018	N
			Injury	01APR2018	30APR2018	N
		Nervous system disorders	Cerebral thrombosis	01APR2018	30APR2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1134 11341297	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN2003	31DEC2003	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign salivary gland neoplasm	01JAN2000	31DEC2000	N
			Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Bipolar disorder	01JAN1990		Y
			Insomnia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Salivary gland operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1134 11341298	Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2005		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2010	N
			Tension headache	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1987	31DEC1987	N
		Psychiatric disorders	Depression	01JAN2005		Y
				01JAN2020		Y
		Reproductive system and breast disorders	Uterine polyp	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2010	31DEC2010	N
			Uterine polypectomy	01JAN2014	31DEC2014	N
	C4591001 1134 11341300	Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1985	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN1990	31DEC1990	N
	C4591001 1134 11341302	Immune system disorders	Drug hypersensitivity	01FEB2020		Y
			Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1998	31DEC1998	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1997	31DEC1997	N
			Muscle spasms	01JAN1990		Y
			Osteoarthritis	01JAN2014	31DEC2015	N
			Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC2013	28FEB2014	N
		Nervous system disorders	Dizziness	01JAN2018		Y
			Migraine	01JAN1964		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1964	31DEC1990	N
		Surgical and medical procedures	Breast conserving surgery	01FEB2014	28FEB2014	N
				01JAN2014	31JAN2014	N
			Bunion operation	01JAN1997	31DEC1997	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Meniscus operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341305	Eye disorders	Cataract	01JAN2018	13JUL2020	N
		Gastrointestinal disorders	Umbilical hernia	01DEC1985	31DEC1985	N
		General disorders and administration site conditions	Oedema peripheral	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Tonsillitis	01JAN1947	31DEC1947	N
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN1992		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1947	31DEC1947	N
			Umbilical hernia repair	01DEC1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1134 11341306	Endocrine disorders	Hypothyroidism	01OCT2014		Y
		Eye disorders	Cataract	01JAN2016	31AUG2017 31JUL2017	N N
			Myopia	01JAN1995		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
			Hiatus hernia	01JAN1980	31DEC1980	N
				01JAN1992	31DEC1992	N
				01JAN2004	31DEC2004	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1971	31DEC1971	N
		Infections and infestations	Appendicitis	01JAN1945	31DEC1945	N
		Metabolism and nutrition disorders	Gout	01JAN1968		Y
			Hypercholesterolaemia	01JAN1975		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1991		Y
				01JAN2007		Y
		Renal and urinary disorders	Chronic kidney disease	03MAY2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1945	31DEC1945	N
			Cataract operation	01AUG2017	31AUG2017	N
				01JUL2017	31JUL2017	N
			Cholecystectomy	01JAN1971	31DEC1971	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia hiatus repair	01JAN1980	31DEC1980	N
				01JAN1992	31DEC1992	N
				01JAN2004	31DEC2004	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
				01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1134 11341307	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Kidney infection	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
			Nephrectomy	01JAN2005	31DEC2005	N
	C4591001 1134 11341309	Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
			Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Nerve injury	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2004		Y
			Intervertebral disc protrusion	01JAN2002	31DEC2004	N
			Rotator cuff syndrome	01JAN2019		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Neck surgery	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2004	31DEC2004	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1134 11341310	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1965	31DEC1966	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Glaucoma	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
			Rectal haemorrhage	01JAN1962	31DEC1962	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1948	31DEC1948	N
		Investigations	Biopsy breast normal	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	31DEC2004	N
					31DEC2010	N
				01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Benign breast neoplasm	01JAN1969	31DEC1969	N
			Uterine leiomyoma	01JAN1984	31DEC1984	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1965	31DEC1965	N
				01JAN1968	31DEC1968	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1948	31DEC1948	N
			Female sterilisation	01JAN1969	31DEC1969	N
			Hysterectomy	01JAN1984	31DEC1984	N
			Intestinal resection	01JAN1962	31DEC1962	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01APR2004	30APR2004	N
				01SEP2004	30SEP2004	N
			Knee operation	01JAN2010	31DEC2010	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Tympanoplasty	01JAN1965	31DEC1965	N
				01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1134 11341311	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB2019	28FEB2019	N
		Psychiatric disorders	Depression	01MAR2020		Y
		Renal and urinary disorders	Hypertonic bladder	01JUN2020		Y
			Urge incontinence	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Spinal operation	01FEB2019	28FEB2019	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1134 11341312	Gastrointestinal disorders	Inguinal hernia	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Oral herpes	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Inguinal hernia repair	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1134 11341316	Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
	C4591001 1134 11341318	Infections and infestations	Tonsillitis	01JAN1950	31DEC1950	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1975	31DEC1975	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1134 11341319	Gastrointestinal disorders	Oesophageal spasm	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
			Tonsillitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Back injury	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2015	31DEC2015	N
			Ovarian cyst	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1969	31DEC1969	N
			Appendectomy	01JAN1967	31DEC1967	N
			Female sterilisation	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN2016	31DEC2016	N
			Joint arthroplasty	01JAN2018	31DEC2018	N
			Oophorectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2017		Y
			Hypertension	01JAN2019		Y
	C4591001 1134 11341320	Gastrointestinal disorders	Large intestine polyp	01JAN2000	31DEC2000	N
		General disorders and administration site conditions	Axillary pain	29OCT2019		Y
			Non-cardiac chest pain	29OCT2019		Y
			Oedema	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	16OCT2019	29OCT2019	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intestinal resection	01JAN2000	31DEC2000	N
			Mastectomy	29OCT2019	29OCT2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341331	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1985	31DEC1985	N
		Investigations	Cardiac murmur	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Joint debridement	01JAN1986	31DEC1986	N
			Joint irrigation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1134 11341333	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
	C4591001 1134 11341334	Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2020	31DEC2020	N
			Venomous sting	01SEP2020	01SEP2020	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Knee operation	19FEB2020	31DEC2020	N
			Spinal fusion surgery	01JAN2018	31DEC2018	N
	C4591001 1134 11341339	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N
				01JAN1991	31DEC1991	N
	C4591001 1134 11341341	Injury, poisoning and procedural complications	Wrist fracture	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	14AUG2020	21AUG2020	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Fracture treatment	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01MAR2020	31MAR2020	N
	C4591001 1134 11341342	Congenital, familial and genetic disorders	Corneal dystrophy	01NOV2019		Y
		Eye disorders	Cataract	01NOV2019	31JAN2020	N
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Herpes virus infection	01JAN2005		Y
			Oral herpes	01JAN2005		Y
		Injury, poisoning and procedural complications	Arthropod bite	24AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01MAR2020		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2020	31JAN2020	N
				01NOV2019	30NOV2019	N
	C4591001 1134 11341343	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Appendicitis perforated	01JAN1973	31DEC1973	N
			Tonsillitis	01JAN1971	31DEC1971	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1995		Y
			Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendectomy	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN2011	31DEC2011	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1971	31DEC1971	N
	C4591001 1134 11341345	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
				01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2011		Y
		Surgical and medical procedures	Knee operation	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341346	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2010	31DEC2010	N
			Uterine leiomyoma	01JAN1985	31DEC1985	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
			Knee arthroplasty	01JAN2014	31DEC2014	N
			Knee operation	01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1134 11341347	Injury, poisoning and procedural complications	Ankle fracture	10AUG2016	10OCT2016	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Laryngeal operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hot flush	01JAN2014		Y
	C4591001 1134 11341349	Ear and labyrinth disorders	Deafness bilateral	01JAN1980		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1982	31DEC1990	N
		Psychiatric disorders	Depression	01JAN1985		Y
			Insomnia	01AUG2020		Y
			Schizophrenia	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Ear operation	01JAN1990	31DEC1990	N
			Shoulder operation	01JAN1982	31DEC1982	N
			Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341350	Gastrointestinal disorders	Haemorrhoids	01JAN1970	31DEC1970	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN2007	31DEC2007	N
			Joint dislocation	01JAN1984	31DEC1984	N
			Rib fracture	01JUN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2005		Y
			Intervertebral disc protrusion	01JUN2018		Y
			Osteoarthritis	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1973		Y
		Nervous system disorders	Nerve compression	01JAN2005		Y
			Syncope	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1970	31DEC1970	N
			Hip arthroplasty	04MAR2019	04MAR2019	N
			Knee operation	01JAN1984	31DEC1984	N
			Plastic surgery to the face	01JAN2007	31DEC2007	N
			Prostatic urethral lift procedure	21DEC2018	21DEC2018	N
	C4591001 1134 11341353	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Umbilical hernia	01DEC2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Rubber sensitivity	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Renal stone removal	01JAN2015	31DEC2015	N
			Umbilical hernia repair	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1134 11341354	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Endocrine disorders	Androgen deficiency	01JAN2018		Y
		Eye disorders	Eye disorder	01JAN1990	31DEC1990	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN1978	31DEC1978	N
				01JAN1981	31DEC1981	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01AUG2020		Y
		Nervous system disorders	Facial spasm	01JAN2013	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Craniotomy	01JAN2017	31DEC2017	N
			Eye operation	01JAN1990	31DEC1990	N
			Foot operation	01JAN1978	31DEC1978	N
				01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia repair	01JAN1990	31DEC1990	N
			Knee operation	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Prostatic operation	01JAN2019	31DEC2019	N
			Wisdom teeth removal	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2010	31DEC2010	N
	C4591001 1134 11341357	Immune system disorders	Drug hypersensitivity	01JAN1952		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoporosis	01JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01SEP2018	31OCT2018	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1963	31DEC1963	N
				01JAN1964	31DEC1964	N
				01JAN1971	31DEC1971	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN1996	31DEC1996	N
			Lung neoplasm surgery	01OCT2018	31OCT2018	N
	C4591001 1134 11341358	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1984		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1996	31DEC1996	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1134 11341359	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Malignant melanoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pharyngeal disorder	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Pharyngeal operation	01JAN2002	31DEC2002	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
	C4591001 1134 11341360	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1947	31DEC1947	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood triglycerides increased	01JAN2010		Y
			Cardiac murmur	01JAN1951		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
			Pain in extremity	01JAN2015		Y
		Nervous system disorders	Seizure	01JAN1980	31DEC1980	N
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN1980	31DEC1980	N
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2014		Y
		Surgical and medical procedures	Thyroid operation	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1947	31DEC1947	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341361	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
			Plantar fasciitis	01JAN1997	31DEC1997	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01MAY2020	28JUN2020	N
		Nervous system disorders	Migraine	01JAN1970		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Nasal turbinate hypertrophy	01JAN1990	31DEC1990	N
		Skin and subcutaneous tissue disorders	Rash	01OCT2019	30NOV2019	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	01JAN1982	31JAN1982	N
				01JAN1986	31JAN1986	N
			Fascial operation	01JAN1997	31DEC1997	N
			Skin neoplasm excision	28JUN2020	28JUN2020	N
			Tonsillectomy	01JAN1957	31DEC1957	N
			Turbinectomy	01JAN1990	31DEC1990	N
			Wisdom teeth removal	01JAN1968	31DEC1968	N
	C4591001 1134 11341362	Cardiac disorders	Myocardial infarction	01JAN2008	31DEC2008	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
			Sciatica	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary angioplasty	01JAN2008	31DEC2008	N
			Coronary arterial stent insertion	01JAN2008	31DEC2008	N
			Spinal nerve stimulator implantation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1134 11341366	Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1998	31DEC1998	N
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2017		Y
		Surgical and medical procedures	Fracture treatment	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1976	31DEC1976	N
			Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1134 11341367	Gastrointestinal disorders	Barrett's oesophagus	21AUG2008		Y
			Gastrooesophageal reflux disease	01JAN2003		Y
			Hiatus hernia	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Diverticulitis	10NOV2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1983	31DEC1983	N
				01JAN1986	31DEC1986	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341368	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Eye disorders	Vision blurred	01JAN2004	31DEC2006	N
		Investigations	Cardiac murmur	01JAN1959		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
			Malignant melanoma	01JAN2001	31DEC2001	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1980	31DEC1980	N
				01JAN1985	31DEC1985	N
		Reproductive system and breast disorders	Menstrual disorder	01JAN2000	31DEC2001	N
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1995	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Eye operation	01JAN1995	31DEC1995	N
			Mastectomy	01JAN2014	31DEC2014	N
			Skin neoplasm excision	01JAN2001	31DEC2001	N
			Uterine dilation and curettage	01JAN2001	31DEC2001	N
			Vitrectomy	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
	C4591001 1134 11341369	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341371	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
			Spinal osteoarthritis	01JAN1980		Y
	C4591001 1134 11341374	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01APR2020	30APR2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01APR2020	30APR2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341375	Eye disorders	Glaucoma	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Hiatus hernia	01JAN1990		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	11JUL2011		Y
			Hypersensitivity	11JUL2011	11JUL2011	N
			Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN2005	31DEC2005	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Investigations	Blood potassium decreased	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
					31DEC2000	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
			Nephrolithiasis	01JUL2020	31JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Fracture treatment	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Knee arthroplasty	01JAN2000	31DEC2000	N
			Salpingo-oophorectomy bilateral	01JAN1983	31DEC1983	N
			Tonsillectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Raynaud's phenomenon	01JAN2010		Y
	C4591001 1134 11341377	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1991	31DEC1991	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01OCT2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1999	31DEC1999	N
			Nasal septal operation	01JAN1985	31DEC1985	N
			Rhinoplasty	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1134 11341380	Eye disorders	Cataract	01MAR2019	02APR2019	N
					25APR2019	N
		Gastrointestinal disorders	Gastric ulcer	01JAN2016		Y
			Inguinal hernia	01APR2020	30APR2020	N
			Intestinal perforation	01JUN2017	30JUN2017	N
			Irritable bowel syndrome	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Cataract operation	02APR2019	02APR2019	N
				25APR2019	25APR2019	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Inguinal hernia repair	01APR2020	30APR2020	N
			Intestinal operation	01JUN2017	30JUN2017	N
			Urinary bladder suspension	01JAN2002	31DEC2002	N
	C4591001 1134 11341382	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2019	31DEC2019	N
			Hip fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2011		Y
			Morton's neuralgia	01JAN2016	31DEC2016	N
			Nerve compression	01JAN2011	31DEC2011	N
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Foot operation	01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Limb operation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1134 11341384	Injury, poisoning and procedural complications	Muscle rupture	01APR2019	22AUG2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
		Surgical and medical procedures	Limb operation	15APR2019	15APR2019	N
				21JUN2019	21JUN2019	N
				22AUG2019	22AUG2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1134 11341386	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013		Y
			Rotator cuff syndrome	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Rotator cuff repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01DEC2016		Y
	C4591001 1134 11341387	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
	C4591001 1134 11341388	Eye disorders	Dry eye	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1946		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1951	31DEC1951	N
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1948	31DEC1948	N
			Joint dislocation	01JAN1986	31DEC1986	N
			Rib fracture	01JAN1983	31DEC1983	N
			Thermal burns of eye	01JAN1991	31DEC1991	N
		Investigations	Blood cholesterol increased	01JAN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Blood testosterone decreased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Exostosis	01JAN2016	30NOV2018	N
		Nervous system disorders	Restless legs syndrome	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
			Prostatomegaly	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2000		Y
			Sinus polyp	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Corneal operation	01JAN1991	31DEC1991	N
			Dental implantation	01JAN1958	31DEC1958	N
			Eye laser surgery	01JAN2001	31DEC2001	N
			Fracture treatment	01JAN1948	31DEC1948	N
				01JAN1983	31DEC1983	N
			Paranasal sinus polypectomy	01JAN1971	31DEC1971	N
			Penile prosthesis insertion	01JUN2019	30JUN2019	N
			Shoulder operation	01JAN1986	31DEC1986	N
			Spinal operation	01NOV2018	30NOV2018	N
			Tonsillectomy	01JAN1951	31DEC1951	N
			Wisdom teeth removal	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341390	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2005	31DEC2005	N
			Osteoarthritis	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	01JAN1969	31DEC1969	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1975	31DEC1975	N
				01JAN1976	31DEC1976	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N
			Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1953	31DEC1953	N
	C4591001 1134 11341394	Cardiac disorders	Coronary artery disease	01MAR2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2019		Y
			Pain	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Periodontitis	01JAN1969	31DEC1969	N
			Staphylococcal skin infection	01JAN2013	31JAN2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2017	31OCT2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary artery bypass	01MAR2019	31MAR2019	N
			Debridement	01JAN2013	31JAN2013	N
			Gingival operation	01JAN1969	31DEC1969	N
			Penile prosthesis insertion	01OCT2017	31OCT2017	N
		Vascular disorders	Hypertension	01OCT2017		Y
	C4591001 1134 11341395	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2019		Y
			Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
					31DEC2016	N
					31DEC2018	N
			Spinal osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	31DEC2018	N
			Large intestinal polypectomy	01JAN2015	31DEC2015	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1134 11341396	General disorders and administration site conditions	Pain	01JAN2015		Y
		Injury, poisoning and procedural complications	Spinal cord injury cervical	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341398	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
			Urinary tract infection	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Bladder injury	01JAN1962	31DEC1962	N
		Investigations	Blood cholesterol increased	01JAN2008		Y
			Blood triglycerides increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Fistula	01JAN1972	31DEC1972	N
			Trigger finger	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Fistula repair	01JAN1972	31DEC1972	N
			Tendon sheath incision	01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1953	31DEC1953	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1134 11341401	Eye disorders	Cataract	01JAN2016		Y
					31JUL2020	N
		Gastrointestinal disorders	Gastric ulcer	01JAN2015	31DEC2015	N
			Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1990		Y
				01JAN2002		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31DEC2006	N
			Rotator cuff syndrome	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JUL2020	31JUL2020	N
			Elbow operation	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2001	31DEC2001	N
			Meniscus operation	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1134 11341402	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1134 11341403	Gastrointestinal disorders	Constipation	01JAN2013		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1978	31DEC1978	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Depression	01JAN2012		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN1978	31DEC1978	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1134 11341405	Reproductive system and breast disorders	Uterine prolapse	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Hysterectomy	01JAN1973		Y
	C4591001 1134 11341409	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1993		Y
			Seasonal allergy	01JAN1973		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2001	31DEC2001	N
				01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Adenomyosis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
				01JAN2017	31DEC2017	N
			Caesarean section	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN1993	31DEC1993	N
	C4591001 1134 11341410	Cardiac disorders	Arrhythmia	01JAN1998	31DEC1998	N
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Aortic valve replacement	01JAN1980	31DEC1980	N
			Cardiac pacemaker insertion	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Aortic stenosis	01JAN1980	31DEC1980	N
			Hypertension	01JAN2010		Y
	C4591001 1134 11341411	Cardiac disorders	Coronary artery disease	01OCT2013		Y
			Myocardial infarction	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000		Y
		Surgical and medical procedures	Coronary angioplasty	01OCT2013	31DEC2013	N
			Coronary arterial stent insertion	01OCT2013	31OCT2013	N
			Cryotherapy	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1134 11341412	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Back pain	01JAN2012		Y
			Foot deformity	01JAN2016	31DEC2016	N
			Osteoporosis	01JAN2017		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1974	31DEC1974	N
				01JAN1978	31DEC1978	N
		Psychiatric disorders	Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Foot operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1134 11341414	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Inguinal hernia	01JAN1998	31DEC1998	N
		Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Insulin-requiring type 2 diabetes mellitus	01JAN2003		Y
			Iron deficiency	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1134 11341415	Infections and infestations	Herpes zoster	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Nerve injury	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1991	31DEC1991	N
				01JAN1994	31DEC1994	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
			Nephrolithiasis	01JAN1978	31DEC1978	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Laparoscopic surgery	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Uterine leiomyoma embolisation	01JAN2009	31DEC2009	N
	C4591001 1134 11341418	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2016		Y
			Muscle spasms	01JAN2010		Y
			Spinal osteoarthritis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1965		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2018	31JAN2018	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1134 11341419	Eye disorders	Cataract	01JAN2019	29FEB2020	N
					31MAR2020	N
		Gastrointestinal disorders	Haemorrhoids	01JAN1978	31DEC1978	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fistula	01JAN1998	31DEC1998	N
			Osteoarthritis	01JAN2003		Y
			Spinal osteoarthritis	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01FEB2020	29FEB2020	N
				01MAR2020	31MAR2020	N
			Fistula repair	01JAN1998	31DEC1998	N
			Haemorrhoid operation	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1134 11341422	Ear and labyrinth disorders	Hypoacusis	01JAN2017		Y
			Tinnitus	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2019		Y
		Nervous system disorders	Tension headache	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN1978	31DEC1978	N
			Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1134 11341423	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1991	31DEC1991	N
		Nervous system disorders	Headache	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1991	31DEC1991	N
	C4591001 1134 11341429	Hepatobiliary disorders	Cholelithiasis	01JAN1974	31DEC1974	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2010	31DEC2010	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Muscle spasms	01JAN1970		Y
			Osteopenia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2000	N
		Nervous system disorders	Sinus headache	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis perennial	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1974	31DEC1974	N
			Knee operation	01JAN2010	31DEC2010	N
			Mastectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341430	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		General disorders and administration site conditions	Oedema	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
			Thrombosis	01JAN2017	31DEC2017	N
	C4591001 1134 11341431	Cardiac disorders	Atrial flutter	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2000		Y
			Vertebral osteophyte	01JAN2000	31DEC2012	N
		Psychiatric disorders	Mood swings	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2000	31DEC2000	N
				01JAN2012	31DEC2012	N
	C4591001 1134 11341432	Infections and infestations	Perirectal abscess	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
		Surgical and medical procedures	Abscess drainage	01JAN2000	31DEC2000	N
			Ankle operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1134 11341434	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Eye disorders	Dry age-related macular degeneration	01JAN2018		Y
			Neovascular age-related macular degeneration	01JAN2018		Y
		General disorders and administration site conditions	Cyst	01JAN2012	31DEC2012	N
			Oedema peripheral	01JAN1961		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Infections and infestations	Appendicitis	01JAN1949	31DEC1949	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
			Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01NOV1989	31DEC1989	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1961	31DEC1961	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1964	31DEC1964	N
				01JAN1965	31DEC1965	N
		Surgical and medical procedures	Appendicectomy	01JAN1949	31DEC1949	N
			Breast conserving surgery	01JAN1989	31DEC1989	N
			Cholecystectomy	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Haemorrhage	01JAN1989	31DEC1989	N
			Hypertension	01JAN1992		Y
	C4591001 1134 11341439	Ear and labyrinth disorders	Otosclerosis	01JAN1990	31DEC1990	N
		Endocrine disorders	Thyroid mass	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
			Lipoma	01JAN2010	31DEC2010	N
			Malignant melanoma	16SEP2020	16SEP2020	N
			Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01OCT2019		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Lipoma excision	01JAN2010	31DEC2010	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
				01JAN2010	31DEC2010	N
				16SEP2020	16SEP2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Stapedectomy	01JAN1990	31DEC1990	N
			Thyroidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1135 11351003	Eye disorders	Cataract	01JAN2015	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
			Osteoporosis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1981	31DEC1981	N
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1981		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1985	31DEC1985	N
			Hysterectomy	01JAN1981	31DEC1981	N
	C4591001 1135 11351005	Vascular disorders	Hypertension	01JAN2000		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Cataract	01JAN2015	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351012	Eye disorders	Myopia	01JAN1979		Y
		Gastrointestinal disorders	Constipation	01JAN1984		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Escherichia bacteraemia	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Overweight	01JAN1984		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Transient global amnesia	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1979		Y
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
				01JAN1987	31DEC1987	N
			Gastric bypass	01JAN2008		Y
					31DEC2008	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1135 11351013	Eye disorders	Presbyopia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1135 11351014	Eye disorders	Myopia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	19AUG2019	19AUG2019	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1135 11351015	Eye disorders	Myopia	01JAN1965		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2013	31DEC2013	N
	C4591001 1135 11351019	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC2007	N
		Psychiatric disorders	Anxiety	01OCT2001		Y
		Surgical and medical procedures	Caesarean section	01OCT1998	01OCT1998	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1135 11351028	Eye disorders	Keratitis	01JAN2000		Y
			Myopia	01JAN2000		Y
		Hepatobiliary disorders	Biliary dyskinesia	01JAN2014	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1950		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Shoulder operation	01JAN1996	31DEC1996	N
	C4591001 1135 11351031	Eye disorders	Strabismus	01JAN1958	31DEC1958	N
		Surgical and medical procedures	Strabismus correction	01JAN1958	31DEC1958	N
	C4591001 1135 11351032	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1135 11351033	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Cataract	01JAN2017		Y
			Myopia	01JAN1966		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2017	31DEC2017	N
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Bone lesion excision	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN1991	31DEC1991	N
			Nasal septal operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351035	Eye disorders	Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2015	31DEC2015	N
		Psychiatric disorders	Bipolar disorder	01JAN2008		Y
		Surgical and medical procedures	Bunion operation	01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2008	31DEC2008	N
	C4591001 1135 11351039	Eye disorders	Presbyopia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Exostosis		31DEC2018	N
			Rotator cuff syndrome	01JAN2019	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1985		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351043	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Bladder calculus removal	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351045	Infections and infestations	Cellulitis	01JAN2018	31DEC2018	N
			Herpes zoster	01JAN2015	31DEC2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351046	Social circumstances	Corrective lens user	01JAN2018		Y
		Eye disorders	Hypermetropia	01JAN1993		Y
			Myopia	01JAN1993		Y
			Presbyopia	01JAN1993		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Drug hypersensitivity	01JAN1974		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2011	N
		Reproductive system and breast disorders	Menorrhagia	01JAN1990	31DEC1991	N
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2011	31DEC2011	N
	C4591001 1135 11351047		Uterine dilation and curettage	01JAN1991	31DEC1991	N
		Eye disorders	Astigmatism	01JAN1960		Y
			Retinal detachment	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Surgical and medical procedures	Retinopexy	01JAN2014	31DEC2014	N
	C4591001 1135 11351048	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
	C4591001 1135 11351049	Eye disorders	Myopia	01JAN1966		Y
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
			Squamous cell carcinoma	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cancer surgery	01JAN2019	31DEC2019	N
			Mammoplasty	01JAN2001	31DEC2001	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
	C4591001 1135 11351051	Eye disorders	Presbyopia	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
			Toe operation	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1135 11351055	Eye disorders	Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Dust allergy	01JAN1956		Y
			Seasonal allergy	01JAN1956		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1135 11351062	Eye disorders	Hypermetropia	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351063	Eye disorders	Myopia	01JAN1975		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1135 11351064	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bunion operation	01JAN2015	31DEC2015	N
	C4591001 1135 11351070	Blood and lymphatic system disorders	Coagulopathy	01JAN2010		Y
		Congenital, familial and genetic disorders	Congenital renal disorder	01JAN1948		Y
		Eye disorders	Astigmatism	01JAN2005		Y
			Cataract	01JAN2019		Y
			Myopia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Face lift	01JAN1995	31DEC1995	N
			Meniscus operation	01APR2019	30APR2019	N
			Plastic surgery to the face	01JAN1995	31DEC1995	N
			Renal surgery	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1135 11351071	Eye disorders	Cataract	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
	C4591001 1135 11351074	Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Hysterosalpingo-oophorectomy	01JAN2001	31DEC2001	N
	C4591001 1135 11351076	Eye disorders	Myopia	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2003		Y
		Investigations	Arthroscopy	01JAN1988	31DEC1988	N
				01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Overweight	01JAN2006		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
			Fibromyalgia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	01JAN1953	31DEC1954	N
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Neurectomy	01JAN1954	31DEC1954	N
	C4591001 1135 11351077	Ear and labyrinth disorders	Deafness bilateral	01JAN2016		Y
		Eye disorders	Macular degeneration	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Arthroscopic surgery	01JAN1993	31DEC1993	N
	C4591001 1135 11351078	Eye disorders	Myopia	01JAN1995		Y
	C4591001 1135 11351079	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1942		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Knee operation	01JAN2016	31DEC2016	N
	C4591001 1135 11351081	Social circumstances	Corrective lens user	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351087	Gastrointestinal disorders	Constipation	01JAN1995		Y
			Dyspepsia	01JAN2005		Y
			Haemorrhoids	01JAN1995	31DEC1995	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Haemorrhoid operation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1135 11351092	Eye disorders	Astigmatism	01JAN1962		Y
			Cataract	01JAN2015	31DEC2015	N
			Myopia	01JAN1960		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Inguinal hernia	01JAN1959	31DEC1959	N
		Investigations	Colonoscopy	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Joint range of motion decreased		31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN1959	31DEC1959	N
			Nasal septal operation	01JAN2015	31DEC2015	N
			Prostatectomy	01JAN2004	31DEC2004	N
			Toe operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1135 11351093	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1998		Y
			Foot deformity	01JAN1998		Y
					31DEC2003	N
			Osteoarthritis	01JAN2015	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Bunion operation	01JAN2003	31DEC2003	N
			Foot operation	01JAN2019	31DEC2019	N
			Hip arthroplasty	01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN2018	31DEC2018	N
	C4591001 1135 11351094	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Infections and infestations	Herpes simplex	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Chemotherapy	01JAN1980	31DEC1980	N
			Radical prostatectomy	01JAN1980	31DEC1980	N
	C4591001 1135 11351096	Eye disorders	Hypermetropia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2010	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351098	Endocrine disorders	Hyperthyroidism	01JAN1992	31DEC1996	N
			Hypothyroidism	01JAN1996		Y
		Eye disorders	Dry eye	01JAN2012		Y
			Endocrine ophthalmopathy	01JAN2012		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Aphthous ulcer	01JAN1967		Y
		Immune system disorders	Allergy to animal	01JAN1967		Y
			Drug hypersensitivity	01JAN2012		Y
			Food allergy	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1966		Y
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Spinal compression fracture	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Osteopenia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967	31DEC1975	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
			Nasal operation	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1135 11351101	Eye disorders	Myopia	01JAN1977		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2008		Y
			Hyperlipidaemia	01JAN2008		Y
		Nervous system disorders	Neuralgic amyotrophy	01JAN2002		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1973		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1966	31DEC1966	N
			Wisdom teeth removal	01JAN1995	31DEC1995	N
	C4591001 1135 11351102	Eye disorders	Myopia	01JAN1959		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2004	31DEC2004	N
		Nervous system disorders	Vocal cord paralysis	01JAN1967		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351106	Surgical and medical procedures	Orthopaedic procedure	01JAN2004	31DEC2004	N
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
			Presbyopia	01JAN1966		Y
		Immune system disorders	Anaphylactic reaction	01JAN2001		Y
			Contrast media allergy	01JAN1999		Y
			Rubber sensitivity	01JAN1975		Y
			Seasonal allergy	01JAN1960		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1999	31DEC1999	N
				01JAN2011	31DEC2011	N
			Uterine leiomyoma	01JAN1975	31DEC1995	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1975	31DEC1975	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1999	31DEC1999	N
			Cataract operation	01JAN2019	31DEC2019	N
		Hysterectomy	01JAN1995	31DEC1995	N	
		Mastectomy	01JAN2011	31DEC2011	N	
		Ovarian cystectomy	01JAN1975	31DEC1975	N	
	Vascular disorders	Hypertension	01JAN2018		Y	
	C4591001 1135 11351108	Eye disorders	Presbyopia	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
			Varicella	01JAN1965	31DEC1965	N
	Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N	
	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y	
	Social circumstances	Postmenopause	01JAN2010		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1135 11351110	Surgical and medical procedures	Tonsillectomy	01JAN1963	31DEC1963	N	
		Eye disorders	Astigmatism	01JAN1960		Y	
				Presbyopia	01JAN2005		Y
		Injury, poisoning and procedural complications	Hip fracture	01JAN2018	31DEC2019	N	
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y	
		Psychiatric disorders	Anxiety	01JAN2018		Y	
			Depression	01JAN1984	31DEC2018	N	
		Social circumstances	Menopause	01JAN2012		Y	
		Surgical and medical procedures	Caesarean section	01JAN1979	31DEC1979	N	
				01JAN1981	31DEC1981	N	
				01JAN1986	31DEC1986	N	
				Hip surgery	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N	
		C4591001 1135 11351116	Eye disorders	Hypermetropia	01JAN1997		Y
			Myopia	01JAN1997		Y	
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		Uterine leiomyoma	01JAN2008	31DEC2010	N	
	Psychiatric disorders		Insomnia	01JAN2008		Y	
	Social circumstances		Postmenopause	01JAN2012		Y	
	Surgical and medical procedures		Caesarean section	03JUN1999	03JUN1999	N	
				10SEP2001	10SEP2001	N	
			Endometrial ablation	01JAN2010	31DEC2010	N	
			Eye operation	01JAN2017	31DEC2017	N	
			Toe operation	01JAN2010	31DEC2010	N	
			Varicose vein operation	01JAN2017	31DEC2017	N	
	Vascular disorders	Varicose vein	01JAN2011	31DEC2017	N		

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2017		Y
	C4591001 1135 11351117	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351118	Eye disorders	Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1971		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2012	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Prostatectomy	01JAN2010	31DEC2010	N
			Radiotherapy	01JAN2010	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351122	Nervous system disorders	Headache	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2005	31DEC2005	N
			Post-traumatic stress disorder	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Wisdom teeth removal	01JAN1990	31DEC1990	N
	C4591001 1135 11351123	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 1 diabetes mellitus	01JAN2008		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01JAN2013	31DEC2013	N
	C4591001 1135 11351125	Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Presbyopia	01JAN2017		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2010		Y
		Metabolism and nutrition disorders	Overweight	01JAN1960		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Large intestinal polypectomy	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
				01JAN2016	31DEC2016	N
			Vascular stent insertion	01JAN2018	31DEC2018	N
		Vascular disorders	Arteriosclerosis	01JAN2017		Y
			Hypertension	01JAN2010		Y
	C4591001 1135 11351128	Eye disorders	Hypermetropia	01JAN1959		Y
			Strabismus	01JAN1957	31DEC1959	N
		Immune system disorders	Seasonal allergy	01JAN1957		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ocular neoplasm	01JAN1964	31DEC1964	N
		Surgical and medical procedures	Eye operation	01JAN1964	31DEC1964	N
			Strabismus correction	01JAN1959	31DEC1959	N
			Suture removal	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1135 11351130	Eye disorders	Myopia	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351131	Eye disorders	Myopia	01JAN1964		Y
	C4591001 1135 11351135	Eye disorders	Astigmatism	01JAN2010		Y
			Myopia	01JAN1966		Y
		General disorders and administration site conditions	Cyst	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Insulin resistance	01APR2020		Y
			Overweight	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1987	31DEC1987	N
			Dupuytren's contracture operation	01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1135 11351138	Eye disorders	Myopia	01JAN1972		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1135 11351143	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Limb injury	01JAN2011	31DEC2011	N
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
			Hyperlipidaemia	01FEB2020		Y
			Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Nervous system disorders	Cataplexy	01JAN2000		Y
			Circadian rhythm sleep disorder	01JAN2018		Y
			Narcolepsy	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01APR2020		Y
			Sleep apnoea syndrome	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Keloid scar	01JAN1966		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
			Shoulder arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351146	Ear and labyrinth disorders	Deafness	01JAN2012		Y
		Eye disorders	Cataract	01JAN2015	31DEC2019	N
			Presbyopia	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Infections and infestations	Bronchitis	01JAN2017		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2000	31DEC2004	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					31DEC2006	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Back pain	01JAN2000		Y
			Osteoporosis	01JAN1998		Y
		Social circumstances	Corrective lens user	01JAN1979		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Knee operation	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
			Peripheral artery surgery	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Peripheral arterial occlusive disease	01JAN2015	31DEC2016	N
	C4591001 1135 11351147	Ear and labyrinth disorders	Deafness unilateral	01JAN2012		Y
		Eye disorders	Cataract	01JAN2015	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351149	Eye disorders	Hypermetropia	01JAN2003		Y
		Gastrointestinal disorders	Dyspepsia	01DEC2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1135 11351150	Eye disorders	Hypermetropia	01JAN2012		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1965	31DEC1965	N
	C4591001 1135 11351153	Cardiac disorders	Mitral valve prolapse	01JAN1962		Y
		Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Eye disorders	Presbyopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1993	31DEC1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2017	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2017	31DEC2017	N
			Bunion operation	01JAN1994	31DEC1994	N
			Hysterectomy	25APR2019	25APR2019	N
	C4591001 1135 11351157	Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1960	31DEC1960	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1960	31DEC1960	N
			Ligament operation	01JAN1998	31DEC1998	N
	C4591001 1135 11351159	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Myopia	01JAN2010		Y
		Investigations	Heart rate irregular	01JAN2005	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012	31DEC2012	N
				01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1135 11351160	Eye disorders	Cataract	01JAN2018	31DEC2018	N
			Myopia	01JAN1955		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31DEC2019	N
		Infections and infestations	Urinary tract infection	01JAN2015		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN2011	31DEC2015	N
				01JAN2012	31DEC2013	N
				01JAN2018	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb injury	01JAN2005	31DEC2010	N
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
				01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2008		Y
			Gout	01JAN2016		Y
			Obesity	01JAN2005		Y
			Overweight	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2019	31DEC2019	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1135 11351161	Eye disorders	Hypermetropia	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Osteoarthritis	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2013	31DEC2013	N
			Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351162	Eye disorders	Presbyopia	01JAN2015		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1965	31DEC1965	N
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Plastic surgery to the face	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351167	Eye disorders	Myopia	01JAN2016		Y
		Injury, poisoning and procedural complications	Ankle fracture	06JUN2020		Y
			Foot fracture	06JUN2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2020		Y
	C4591001 1135 11351174	Eye disorders	Myopia	01JAN1971		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1135 11351180	Eye disorders	Myopia	01JAN1960		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
			Hiatus hernia	01JAN2012	31DEC2013	N
				01JAN2015	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Overweight	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2013	31DEC2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351181	Eye disorders	Myopia	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
			Overweight	01JAN1980		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1968	31DEC1968	N
			Vasectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1135 11351182	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1987	31DEC1987	N
		Metabolism and nutrition disorders	Gout	01JAN2014	31DEC2014	N
			Hyperlipidaemia	01JAN2000		Y
			Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1987	31DEC1987	N
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1135 11351183	Eye disorders	Presbyopia	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	31DEC1989	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1994		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1135 11351185	Eye disorders	Myopia	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1986	31DEC1986	N
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1135 11351186	Surgical and medical procedures	Appendicectomy	01JAN1986	31DEC1986	N
		Eye disorders	Astigmatism	01JAN1950		Y
			Cataract	01JAN2016	31DEC2016	N
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
			Tonsillitis	01JAN1950	31DEC1950	N
		Injury, poisoning and procedural complications	Limb injury	01JAN1995		Y
		Metabolism and nutrition disorders	Gout	01JAN2010	31DEC2010	N
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
			Squamous cell carcinoma	01JAN1960	31DEC2017	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2013	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2012	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1942		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Cancer surgery	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2016	31DEC2016	N
			Prostatectomy	01JAN2012	31DEC2012	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1950	31DEC1950	N
			Vasectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351187	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1947		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2020		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985	31DEC1985	N
			Osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Shoulder arthroplasty	01JAN2019	31DEC2019	N
			Spinal operation	01JAN2019	31DEC2019	N
	C4591001 1135 11351188	Ear and labyrinth disorders	Deafness	01JAN1995		Y
		Eye disorders	Myopia	01JAN1978		Y
		Infections and infestations	Tonsillitis	01JAN1955		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Overweight	01JAN2015		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1955	31DEC1955	N
			Vasectomy	01JAN1983	31DEC1983	N
	C4591001 1135 11351192	Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1985		Y
			Foot deformity	01JAN2015	31DEC2015	N
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2016	31DEC2016	N
			Bunion operation	01JAN2015	31DEC2015	N
	C4591001 1135 11351193	Cardiac disorders	Myocardial infarction	01JAN2000	31DEC2000	N
		Eye disorders	Cataract	01JAN2020		Y
					31AUG2020	N
			Myopia	01JAN1958		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2009	31DEC2009	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1135 11351196	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351197	Surgical and medical procedures	Umbilical hernia repair	01JAN1980	31DEC1980	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Infections and infestations	Ear infection	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN1996		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2010		Y
		C4591001 1135 11351202	Ear and labyrinth disorders	Deafness	01JAN2019	
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Hypermetropia	01JAN1978		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
			Iodine allergy	01JAN1982		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Back injury	01JAN1972	31DEC1972	N
			Facial bones fracture	01JAN1981	31DEC1981	N
			Limb injury	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
			Cataract operation	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2005	31DEC2005	N
			Female sterilisation	01JAN1977	31DEC1977	N
			Rhinoplasty	01JAN1981	31DEC1981	N
			Shoulder operation	01JAN2018	31DEC2018	N
			Spinal operation	01JAN1972	31DEC1972	N
			Cataract	01JAN2005	31DEC2005	N
	C4591001 1135 11351204		Eye disorders			
		Immune system disorders	Allergy to plants	01JAN1960		Y
			Seasonal allergy	01JAN1960		Y
				01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017	31DEC2017	N
					01JAN2019	31DEC2019
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1135 11351215	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Eye disorders	Myopia	01JAN1963		Y
		Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Hyperlipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1997		Y
			Overweight	01JAN1997		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2008		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
			Implantable defibrillator insertion	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN1999		Y
	C4591001 1135 11351218	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Hepatitis A	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Obesity	01JAN2010	31DEC2012	N
			Overweight	01JAN2010	31DEC2012	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Gastrectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351219	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Myopia	01JAN1960	31DEC2000	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Umbilical hernia	01JAN2012	31DEC2017	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	28MAY2019	28MAY2020	N
			Tremor	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	28MAY2020	28MAY2020	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
			Prostatic operation	01JAN2002	31DEC2002	N
			Sinus operation	01JAN2018	31DEC2018	N
			Umbilical hernia repair	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351223	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
			Postmenopause	01JAN2003		Y
	C4591001 1135 11351224	Eye disorders	Myopia	01JAN2010		Y
		General disorders and administration site conditions	Oedema	01JAN2018		Y
		Injury, poisoning and procedural complications	Skin abrasion	30AUG2020		Y
		Metabolism and nutrition disorders	Overweight	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986		Y
	C4591001 1135 11351232	Eye disorders	Myopia	01JAN1956		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Cholecystectomy	01JAN1992	31DEC1992	N
	C4591001 1135 11351233	Eye disorders	Myopia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1956	31DEC1956	N
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign pancreatic neoplasm	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Pancreaticoduodenectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1135 11351236	Eye disorders	Myopia	01JAN1965		Y
	C4591001 1135 11351237	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Endometrial cancer	01JAN2002	31DEC2002	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2020	31DEC2020	N
			Breast conserving surgery	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Mole excision	01AUG2020	05AUG2020	N
		Eye disorders	Myopia	01JAN1980		Y
C4591001 1135 11351238		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Overweight	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Gastric bypass	01JAN2016	31DEC2016	N
			Neck surgery	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2014		Y
C4591001 1135 11351240		Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
C4591001 1135 11351246		Cardiac disorders	Coronary artery disease	01JAN2012	31DEC2012	N
		Eye disorders	Hypermetropia	01JAN1958		Y
		Gastrointestinal disorders	Gastritis	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Infections and infestations	Herpes zoster	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2013		Y
			Rheumatoid arthritis	01JAN2013		Y
			Spinal stenosis	01JAN2015	31DEC2015	N
		Nervous system disorders	Transient ischaemic attack	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
		Surgical and medical procedures	Catheter placement	01JAN2012	31DEC2012	N
			Spinal laminectomy	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Deep vein thrombosis	01JAN2019	31DEC2019	N
			Hypertension	01JAN2010		Y
	C4591001 1135 11351249	Immune system disorders	Drug hypersensitivity	01JAN1991		Y
		Nervous system disorders	Headache	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1996	31JUL2020	N
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2015		Y
			Rash	01JAN1992		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
	C4591001 1135 11351252	General disorders and administration site conditions	Oedema peripheral	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Overweight	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2001	31DEC2001	N
		Skin and subcutaneous tissue disorders	Acne	01JAN1968	31DEC1971	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Dermabrasion	01JAN1971	31DEC1971	N
	C4591001 1135 11351254	Eye disorders	Hypermetropia	01JAN2018		Y
	C4591001 1135 11351255	Cardiac disorders	Mitral valve prolapse	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2015	31DEC2017	N
			Osteoarthritis	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Bunion operation	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1135 11351257	Cardiac disorders	Coronary artery disease	01JAN2014	31DEC2014	N
			Myocardial infarction	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1986	31DEC2004	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1135 11351258	Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Inguinal hernia	01JAN2007	31DEC2007	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2010		Y
			Spermatocele	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Bone operation	01JAN2016	31DEC2016	N
			Epididymal cyst removal	01JAN2010	31DEC2010	N
			Inguinal hernia repair	01JAN2007	31DEC2007	N
			Vasectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1135 11351260	Endocrine disorders	Hyperthyroidism	01JAN1980	11NOV1980	N
			Hypothyroidism	11NOV1980		Y
		Eye disorders	Cataract	01JAN2016		Y
			Myopia	01JAN1950		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2009	31DEC2009	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2009	31DEC2009	N
		Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2009	31AUG2009	N
			Tendon dislocation	01AUG2009	31AUG2009	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Intervertebral disc protrusion	01JAN2014		Y
			Osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1981	08JAN1981	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	28DEC1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Hysterectomy	08JAN1981	08JAN1981	N
			Synovial cyst removal	19NOV1997	19NOV1997	N
			Thyroidectomy	11NOV1980	11NOV1980	N
			Tonsillectomy	01JAN1957	31JAN1957	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1135 11351261	Eye disorders	Glaucoma	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Wisdom teeth removal	01JAN1989	31DEC1989	N
	C4591001 1135 11351266	Cardiac disorders	Tachycardia	01JAN2020		Y
		Eye disorders	Astigmatism	01JAN1960		Y
			Hypermetropia	01JAN1960		Y
			Myopia	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Depression	01JAN1990		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1985	31DEC1990	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
			Knee arthroplasty	01JAN2005	31DEC2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2012	31DEC2012	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
	C4591001 1135 11351270	Eye disorders	Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2005		Y
			Overweight	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01JAN1999	31DEC1999	N
			Skin lesion removal	01JAN1968	31DEC1968	N
			Tonsillectomy	01JAN1970	31DEC1970	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1135 11351273	Eye disorders	Myopia	01JAN1963		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
	C4591001 1135 11351275	Endocrine disorders	Goitre	01JAN2008	31DEC2008	N
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2014	31DEC2014	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Muscle operation	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN2008	31DEC2008	N
	C4591001 1135 11351277	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Myopia	01JAN1961		Y
		Immune system disorders	Allergy to plants	01JAN1964		Y
			Drug hypersensitivity	01JAN1985		Y
			Dust allergy	01JAN1964		Y
			Mycotic allergy	01JAN1964		Y
			Seasonal allergy	01JAN1964		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
			Sterilisation reversal	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1135 11351278	Eye disorders	Astigmatism	01JAN1974		Y
			Myopia	01JAN1974		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN1974		Y
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Vasectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351280	Eye disorders	Myopia	01JAN1972		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Urinary tract infection	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Urinary tract infection	01JAN2019	31DEC2019	N
			Back pain	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1980	31DEC1980	N
	C4591001 1135 11351283	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2001	31DEC2001	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2006	31DEC2006	N
			Spinal fusion surgery	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1135 11351289	Eye disorders	Cataract	01JAN2018		Y
			Myopia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1135 11351296	Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N	
		Eye disorders	Myopia	01JAN1965		Y	
		Gastrointestinal disorders	Constipation	01JAN2018		Y	
			Umbilical hernia	01JAN2007	31DEC2007	N	
			Infections and infestations	Tonsillitis	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Obesity	01JAN1985	31DEC2018	N	
			Overweight	01JAN1985	31DEC2018	N	
			Nervous system disorders	Headache	01JAN2015		Y
			Renal and urinary disorders	Nephrolithiasis	01JAN1997	31DEC2001	N
			Surgical and medical procedures	Gastrectomy	01MAR2018	31MAR2018	N
				Lithotripsy	01JAN2001	31DEC2001	N
				Tonsillectomy	01JAN1992	31DEC1992	N
				Umbilical hernia repair	01JAN2007	31DEC2007	N
				Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1135 11351298	Vascular disorders	Hypertension	01JAN1985		Y	
		Endocrine disorders	Hypothyroidism	01JAN2010		Y	
		Eye disorders	Myopia	01JAN1975	31DEC1995	N	
		Nervous system disorders	Migraine	01JAN2005	31MAR2020	N	
	C4591001 1135 11351299	Surgical and medical procedures	Keratomileusis	01JAN1995	31DEC1995	N	
		Vascular disorders	Hypertension	01JAN2017		Y	
		Endocrine disorders	Hypothyroidism	01JAN2012		Y	
		Eye disorders	Myopia	01JAN1984		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y	
			Seasonal allergy	01JAN1965		Y	
		Infections and infestations	Sinusitis	01JAN1965		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN2008		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Rhinitis allergic	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2014	31DEC2014	N
			Sinus operation	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
	C4591001 1135 11351300	Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1135 11351303	Cardiac disorders	Supraventricular tachycardia	01JAN2020	31MAY2020	N
		Endocrine disorders	Hypothyroidism	01MAY2008		Y
		Eye disorders	Dry eye	01JAN2012		Y
			Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
			Intestinal polyp	01JAN2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01MAR1983		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2008		Y
			Hyperlipidaemia	01JAN2006		Y
			Obesity	01JAN2001		Y
			Overweight	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1135 11351306	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
	C4591001 1135 11351309	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Presbyopia	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
			Hiatus hernia	01JAN1976	31DEC1976	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2010		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN1976	31DEC1976	N
			Limb reconstructive surgery	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1135 11351311	Ear and labyrinth disorders	Deafness	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN1971		Y
			Myopia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	23AUG1988		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351312	Ear and labyrinth disorders	Deafness unilateral	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Intestinal obstruction	01MAY2011	31MAY2011	N
		Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAY2011	31MAY2011	N
		Psychiatric disorders	Insomnia	01MAY2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2011		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2011	31MAY2011	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Radical prostatectomy	01MAY2011	31MAY2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1135 11351314	Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2020		Y
		Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1135 11351316	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2003		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1135 11351317	Eye disorders	Myopia	01JAN1975	31DEC2010	N
		Gastrointestinal disorders	Tooth impacted	01JAN1985	31DEC1985	N
		Immune system disorders	Allergy to arthropod sting	01JAN1963		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1995	31DEC1995	N
			Limb injury	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Overweight	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2005		Y
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
			Limb operation	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1962	31DEC1962	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
			Oedema peripheral	01JAN2019		Y
	C4591001 1135 11351319	General disorders and administration site conditions				
		Infections and infestations	Tonsillitis	01JAN1951	31DEC1951	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1951	31DEC1951	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1135 11351320	Infections and infestations	Herpes simplex	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
	C4591001 1135 11351321	Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1135 11351324	Eye disorders	Myopia	01JAN1966		Y
			Strabismus	01JAN1960	31DEC1965	N
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1980		Y
			Osteoarthritis	01JAN1980		Y
				01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Spinal osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN1977		Y
			Depression	01JAN1977		Y
		Surgical and medical procedures	Appendicectomy	01JAN2013	31DEC2013	N
			Cholecystectomy	01JAN2013		Y
			Cholelithotomy	01JAN2013	31DEC2013	N
			Hip arthroplasty	01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
			Strabismus correction	01JAN1960	31DEC1960	N
				01JAN1965	31DEC1965	N
	C4591001 1135 11351325	Endocrine disorders	Hyperparathyroidism	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Diverticulum	01JAN2019		Y
		Infections and infestations	Diverticulitis	01NOV2019	30NOV2019	N
			Tonsillitis	01JAN1956	31DEC1956	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1974	31DEC1980	N
			Rhinitis allergic	01JAN1990		Y
			Sinus polyp	01JAN1998	31DEC1998	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Colectomy	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Paranasal sinus polypectomy	01JAN1998	31DEC1998	N
			Parathyroidectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1956	31DEC1956	N
	C4591001 1135 11351333	Ear and labyrinth disorders	Deafness	01JAN1980		Y
			Otosclerosis	01JAN1995	31DEC1995	N
		Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1959		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cartilage operation	01JAN2017	31DEC2017	N
			Cataract operation	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Stapedectomy	01JAN1995	31DEC1995	N
			Vasectomy	01JAN2001	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351337	Eye disorders	Myopia	01JAN1966		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Nasal injury	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1975	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2008	31DEC2009	N
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Bunion operation	01JAN2015	31DEC2015	N
			Thyroidectomy	01JAN2009	31DEC2009	N
	C4591001 1135 11351339	Immune system disorders	Seasonal allergy	01JAN1956		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
			Helicobacter infection	01JAN2008		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN1989	31DEC1989	N
			Limb injury	01JAN1996	31DEC1996	N
			Meniscus injury	01JAN1986	31DEC1986	N
			Neck injury	01JAN2010	31DEC2010	N
		Investigations	Arthroscopy	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN1952		Y
			Overweight	01JAN1952		Y
			Type 2 diabetes mellitus	01JAN1980		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2013		Y
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			Cholecystectomy	01JAN1994	31DEC1994	N
			Intervertebral disc operation	01JAN2010	31DEC2010	N
			Meniscus operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351344	Eye disorders	Hypermetropia	01JAN2002		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JAN1981	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2019		Y
	C4591001 1135 11351345	Eye disorders	Myopia	01JAN1974		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN2019		Y
	C4591001 1135 11351348	Eye disorders	Hypermetropia	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tonsillitis	01JAN1972	31DEC1972	N
		Injury, poisoning and procedural complications	Ligament injury	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Ligament operation	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1135 11351353	Eye disorders	Myopia	01JAN1973		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN1995		Y
			Overweight	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01JAN1992		Y
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1135 11351354	Ear and labyrinth disorders	Deafness	01JAN1993		Y
		Eye disorders	Presbyopia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Juvenile melanoma benign	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN1992	31DEC1992	N
			Vasectomy	01JAN2006	31DEC2006	N
	C4591001 1135 11351364	Eye disorders	Hypermetropia	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Knee operation	01JAN2006	31DEC2006	N
				01JAN2007	31DEC2007	N
	C4591001 1135 11351371	Eye disorders	Myopia	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1135 11351372	Eye disorders	Myopia	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Benign breast lump removal	01JAN2000	31DEC2000	N
	C4591001 1135 11351380	Eye disorders	Presbyopia	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Food allergy	01JAN2015		Y
			Seasonal allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Sports injury	01JUN2001	01JUN2001	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Migraine	01JAN1975		Y
			Neuralgia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1974		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
			Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Breast operation	01JUN2001	01JUN2001	N
			Spinal fusion surgery	17JAN2017	17JAN2017	N
			Spinal operation	20JUN2020	20JUN2020	N
		Vascular disorders	Hot flush	01JAN2015		Y
	C4591001 1135 11351388	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1989	31DEC1989	N
		Social circumstances	Corrective lens user	01JAN2016		Y
			Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1135 11351390	Eye disorders	Hypermetropia	01JAN1980		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Gastritis	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351395	Cardiac disorders	Coronary artery disease	01JAN2005		Y
			Myocardial infarction	01JAN2018	31DEC2018	N
		Eye disorders	Cataract	01JUL2020		Y
			Myopia	01JAN2000		Y
			Presbyopia	01JAN2000		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Milk allergy	01JAN1976		Y
			Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
			Coronary angioplasty	03MAY2018	03MAY2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1135 11351396	Ear and labyrinth disorders	Deafness	01JAN1959		Y
		Eye disorders	Myopia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1962		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Obesity	01JAN2013		Y
			Overweight	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1996		Y
			Back pain	01JAN1973		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2007	31DEC2007	N
			Coronary artery bypass	01FEB2011	28FEB2011	N
			Rhinoplasty	01MAR1977	31MAR1977	N
	C4591001 1135 11351398	Eye disorders	Presbyopia	01JAN2014		Y
		Gastrointestinal disorders	Diverticulum	01JAN2015		Y
			Dyspepsia	01JAN2015	31DEC2016	N
			Haemorrhoids	01JAN1990	31DEC2016	N
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
			Peritonitis	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	07JUL2020	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
			Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Haemorrhoid operation	01JAN2016	31DEC2016	N
			Hysterectomy	07JUL2020	07JUL2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351407	Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1135 11351409	Gastrointestinal disorders	Haemorrhoids	01JAN2018	31DEC2018	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351413	Eye disorders	Cataract	01JAN2017	31DEC2017	N
			Myopia	01JAN2017		Y
		Immune system disorders	Iodine allergy	01JAN1971		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
			Overweight	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
	C4591001 1135 11351424	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Hypermetropia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1135 11351426	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01MAY2020		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1135 11351427	Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1136 11361008	Hepatobiliary disorders	Hepatic cyst	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361009	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Gastrointestinal disorders	Diarrhoea	01JAN2010		Y
			Inguinal hernia	01JAN2009	31DEC2009	N
			Intestinal obstruction	01NOV2010	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Infections and infestations	Appendicitis	01MAR2010	31MAR2010	N
		Injury, poisoning and procedural complications	Hip fracture	01JUN2019	30JUN2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016	31DEC2016	N
			Rotator cuff syndrome	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1995	31DEC1995	N
			Uterine leiomyoma	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Appendicectomy	01MAR2010	31MAR2010	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Inguinal hernia repair	01AUG2009	31AUG2009	N
			Intestinal resection	01JAN2010	31DEC2010	N
			Mammoplasty	01NOV2007	30NOV2007	N
			Open reduction of fracture	01JAN2019	30JUN2019	N
			Radical mastectomy	01JAN1995	31DEC1995	N
			Rotator cuff repair	01JAN2003	31DEC2003	N
	C4591001 1136 11361011	Ear and labyrinth disorders	Deafness unilateral	01JAN2005		Y
		Eye disorders	Cataract	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Silicosis	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2015	31DEC2015	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Dupuytren's contracture operation	01JAN2015	31DEC2015	N
	C4591001 1136 11361014	Eye disorders	Cataract	01AUG2019		Y
			Presbyopia	01JAN1978		Y
		Immune system disorders	Dust allergy	01JAN1960		Y
		Infections and infestations	Pneumonia	01JAN1974	31DEC1974	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1957	31DEC1963	N
		Surgical and medical procedures	Chondrectomy	01JAN1991	31DEC1991	N
			Skin neoplasm excision	01JAN2008	31DEC2008	N
	C4591001 1136 11361015	Cardiac disorders	Atrial fibrillation	01JAN1983		Y
		Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Cataract	01FEB2019	28FEB2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
				01JAN1987		Y
				01JAN1999		Y
			Food allergy	01JAN1983		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Surgical and medical procedures	Cataract operation	01FEB2019	28FEB2019	N
			Wrist surgery	01JAN2015	31DEC2015	N
	C4591001 1136 11361016	Endocrine disorders	Hypothyroidism	01NOV2019		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
			Tonsillitis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Reproductive system and breast disorders	Menopausal symptoms	01MAY2020		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N
			Open reduction of fracture	01JAN2006	31DEC2006	N
			Skin cosmetic procedure	01JAN2015	31DEC2015	N
	C4591001 1136 11361017	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Inguinal hernia	01FEB2020	31MAY2020	N
		Surgical and medical procedures	Hernia repair	01MAY2020	31MAY2020	N
	C4591001 1136 11361019	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Hiatus hernia	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Forearm fracture	01JAN2012	31DEC2012	N
			Joint injury	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Depression	01JAN1983		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Hernia hiatus repair	01JAN2015	31DEC2015	N
			Knee operation	01JAN2017	31DEC2017	N
			Limb operation	01JAN2012	31DEC2012	N
	C4591001 1136 11361023	Congenital, familial and genetic disorders	Morton's syndrome	02AUG2018		Y
		Ear and labyrinth disorders	Tinnitus	13FEB1991		Y
		Gastrointestinal disorders	Splenic artery aneurysm	08MAY2018	08MAY2018	N
		Hepatobiliary disorders	Hepatic cyst	08MAY2018		Y
		Immune system disorders	Food allergy	01DEC2013		Y
		Infections and infestations	Genital herpes	01JAN1980		Y
		Investigations	Arthroscopy	02FEB2017	02FEB2017	N
		Metabolism and nutrition disorders	Lactose intolerance	01DEC2013		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01FEB2017	28FEB2017	N
			Spondylitis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	31JUL2020	N
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Skin lesion	01JAN2020	31OCT2020	N
		Surgical and medical procedures	Hysterectomy	01FEB1997	28FEB1997	N
			Skin neoplasm excision	01JUL2020	31JUL2020	N
			Splenic artery embolisation	08MAY2018	08MAY2018	N
	C4591001 1136 11361033	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Social circumstances	Hearing aid user	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361038	Eye disorders	Cataract	01JAN1994	31DEC1994	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1983	31DEC1983	N
			Cataract operation	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1136 11361041	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Tonsillitis	01JAN1963	31DEC1963	N
		Investigations	Blood cholesterol increased	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Adenotonsillectomy	01JAN1963	31DEC1963	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1136 11361050	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN1998	31DEC1998	N
				01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1136 11361051	Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361052	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1136 11361053	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Schizophrenia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1136 11361055	Investigations	Cardiac murmur	01JAN1985		Y
		Social circumstances	Postmenopause	01JUN2009		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1136 11361056	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
	C4591001 1136 11361057	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
	C4591001 1136 11361059	Endocrine disorders	Hypothyroidism	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2009	31DEC2009	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Bone operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361066	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1974		Y
				01JAN1994		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2020		Y
	C4591001 1136 11361070	Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
			Hiatus hernia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
			Seasonal allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Female sterilisation	01JAN2000	31DEC2000	N
			Meniscus operation	01JAN2014		Y
	C4591001 1136 11361074	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
		Vascular disorders	Hypertension	01MAY2000		Y
	C4591001 1136 11361075	Infections and infestations	Ear infection	01JAN2001	31DEC2002	N
		Injury, poisoning and procedural complications	Limb injury	01JAN1973	31DEC1973	N
			Meniscus injury	01JAN2020	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN1973	31DEC1973	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2020	31JAN2020	N
			Lipoma excision	01JAN2000	31DEC2000	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
			Tympanoplasty	01JAN2001	31DEC2001	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1136 11361077	Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N
			Hepatic steatosis	01JAN2019		Y
		Immune system disorders	Food allergy	01JAN1969		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2017	31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN2002		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Gout	01JAN2002		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Fracture treatment	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2002		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1136 11361078	Eye disorders	Cataract	01JAN2005	31DEC2006	N
		Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastrooesophageal reflux disease	01JAN2008		Y
			Inguinal hernia	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	10JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01AUG2020		Y
			Rash macular	01SEP2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2008	31DEC2008	N
			Limb operation	01JAN2007	31DEC2007	N
				01JAN2012	31DEC2012	N
				01JAN2018	31DEC2018	N
	C4591001 1136 11361079	Hepatobiliary disorders	Cholelithiasis	01JAN2008	31AUG2008	N
		Immune system disorders	Allergy to animal	01JAN1989		Y
			Drug hypersensitivity	01JAN2010		Y
			Dust allergy	01JAN1989		Y
			Seasonal allergy	01JAN1976		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
				01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Panic attack	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	22APR1988	22APR1988	N
			Cholecystectomy	01AUG2008	31AUG2008	N
			Skin neoplasm excision	01JAN2009	31DEC2009	N
				01JAN2019	31DEC2019	N
			Tooth extraction	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1136 11361080	Infections and infestations	Appendicitis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1136 11361081	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Gastrointestinal disorders	Dyspepsia	10OCT2019		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Injury, poisoning and procedural complications	Skin laceration	31JUL2018	31JUL2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
			Finger repair operation	31JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1136 11361085	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Eye disorders	Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Large intestine polyp	01MAR1996		Y
		Infections and infestations	Tonsillitis	01JAN1949	31DEC1949	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Surgical and medical procedures	Angioplasty	11FEB2008	11FEB2008	N
			Coronary arterial stent insertion	03JUL2008	03JUL2008	N
			Joint dislocation reduction	01JAN1970	31DEC1970	N
			Tonsillectomy	01JAN1949	31DEC1949	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1136 11361088	Blood and lymphatic system disorders	Increased tendency to bruise	01JAN2016		Y
		Eye disorders	Glaucoma	01JAN1984		Y
		Immune system disorders	Allergy to animal	01JAN1969		Y
			Allergy to plants	01JAN1969		Y
			Drug hypersensitivity	01JAN2018		Y
			Dust allergy	01JAN1969		Y
			Seasonal allergy	01JAN1969		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN1968	31DEC1968	N
			Road traffic accident	01JAN1978	31DEC1978	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1968		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
			Transient ischaemic attack	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Appendectomy	01JAN1960	31DEC1960	N
			Breast operation	01JAN1956	31DEC1956	N
			Cholecystectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Gingivectomy	01JAN1965	31DEC1969	N
			Spinal fusion surgery	01DEC2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1136 11361089	Ear and labyrinth disorders	Deafness bilateral	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2008	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2013	31DEC2013	N
			Intervertebral disc operation	01JAN2004	31DEC2004	N
			Prostatectomy	01JAN2008	31DEC2008	N
	C4591001 1136 11361093	Eye disorders	Cataract	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
	C4591001 1136 11361096	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1136 11361097	Gastrointestinal disorders	Haemorrhoids	01JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Seasonal allergy	01JAN1966		Y
		Infections and infestations	Diverticulitis	01JUL2020		Y
			Pneumonia	01JAN1969	31DEC1969	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1136 11361102	Congenital, familial and genetic disorders	Heart disease congenital	01JAN1944	31DEC1949	N
		Ear and labyrinth disorders	Deafness bilateral	01JAN1957		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Patent ductus arteriosus repair	01JAN1947	31DEC1947	N
				01JAN1949	31DEC1949	N
	C4591001 1136 11361103	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
		Infections and infestations	Appendicitis	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1995	N
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hernia repair	01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
				01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1136 11361104	Cardiac disorders	Bundle branch block left	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary artery disease	01FEB2019		Y
			Mitral valve incompetence	01JAN2019		Y
			Myocardial infarction	01FEB2019	28FEB2019	N
			Tricuspid valve incompetence	01JAN2019		Y
		Eye disorders	Glaucoma	01JAN2014		Y
		Injury, poisoning and procedural complications	Silicosis	01JAN2019		Y
		Investigations	Blood triglycerides increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Surgical and medical procedures	Knee operation	01JAN1992	31DEC1992	N
			Rotator cuff repair	01JAN2000	31DEC2000	N
	C4591001 1136 11361105	Infections and infestations	Pneumonia	01JAN2017	31DEC2017	N
		Nervous system disorders	Tremor	01JAN1980		Y
	C4591001 1136 11361106	Cardiac disorders	Tachycardia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Eye disorders	Presbyopia	01JAN1958		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Inguinal hernia	01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N
		Infections and infestations	Tonsillitis	01JAN1955	31DEC1955	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1953	31DEC1953	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of skin	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1136 11361107	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1136 11361110	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1139 11391002	Gastrointestinal disorders	Gastric ulcer haemorrhage	30JUN2015	30JUN2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	30NOV2007		Y
		Vascular disorders	Hypertension	30JUN2000		Y
	C4591001 1139 11391003	Endocrine disorders	Hypothyroidism	30JUN2012		Y
		Vascular disorders	Hypertension	30JUN2010		Y
	C4591001 1139 11391004	Immune system disorders	Food allergy	30JUN1978		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	25JUL2020		Y
	C4591001 1139 11391005	Gastrointestinal disorders	Gastrooesophageal reflux disease	30JUN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	15SEP2015	15SEP2015	N
		Psychiatric disorders	Depression	30JUN1991		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1139 11391006	Endocrine disorders	Hypothyroidism	30JUN2000		Y
		Metabolism and nutrition disorders	Hypokalaemia	30JUN2000		Y
		Vascular disorders	Hypertension	30JUN2000		Y
	C4591001 1139 11391009	Investigations	Blood glucose increased	15OCT2019		Y
		Metabolism and nutrition disorders	Overweight	30JUN2010		Y
		Surgical and medical procedures	Cholecystectomy	14FEB2020	14FEB2020	N
			Knee arthroplasty	11FEB2019	11FEB2019	N
		Vascular disorders	Hypertension	15OCT2019		Y
	C4591001 1139 11391011	Eye disorders	Hypermetropia	30JUN1960	30JUN1995	N
		Hepatobiliary disorders	Cholelithiasis	15JUL2019	15JUL2019	N
		Infections and infestations	Appendicitis	30JUN2000	30JUN2000	N
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	30JUN2018	15JAN2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	30JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1960		Y
		Surgical and medical procedures	Appendicectomy	30JUN2000	30JUN2000	N
			Carpal tunnel decompression	15JAN2020	15JAN2020	N
			Cholecystectomy	15JUL2019	15JUL2019	N
			Keratomileusis	30JUN1995	30JUN1995	N
	C4591001 1139 11391012	Ear and labyrinth disorders	Hypoacusis	15JUN2019		Y
		Eye disorders	Presbyopia	30JUN2017		Y
		Gastrointestinal disorders	Abdominal hernia	30JUN2009	30JUN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	30JUN2018	30JUN2018	N
		Surgical and medical procedures	Abdominal hernia repair	30JUN2009	30JUN2009	N
			Cataract operation	30JUN2017	30JUN2017	N
			Gastric bypass	30JUN1984	30JUN1984	N
	C4591001 1139 11391013	Ear and labyrinth disorders	Deafness	30JUN2015		Y
		Eye disorders	Myopia	30JUN1988		Y
			Presbyopia	30JUN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30JUN2009		Y
			Rotator cuff syndrome	30JUN2007	30JUN2007	N
		Surgical and medical procedures	Knee arthroplasty	30JUN2009	30JUN2009	N
			Rotator cuff repair	30JUN2007	30JUN2007	N
	C4591001 1139 11391014	Ear and labyrinth disorders	Deafness unilateral	30JUN2009		Y
		Eye disorders	Myopia	30JUN2000		Y
		Immune system disorders	Drug hypersensitivity	30JUN2012		Y
		Investigations	Cardiac murmur functional	30JUN1974		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	30JUN2009		Y
			Basal cell carcinoma	15NOV2019		Y
			Lipoma	30JUN2000		Y
				30JUN2004		Y
		Nervous system disorders	Tension headache	30JUN1984		Y
		Renal and urinary disorders	Stress urinary incontinence	30JUN1973		Y
		Surgical and medical procedures	Acoustic neuroma removal	30JUN2009	30JUN2009	N
			Lipoma excision	30JUN2004		Y
	C4591001 1139 11391018	Immune system disorders	Seasonal allergy	30JUN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	30JUN1985	30JUN2018	N
		Psychiatric disorders	Depression	30JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2009		Y
		Surgical and medical procedures	Hysterectomy	30JUN2010	30JUN2010	N
			Oophorectomy	30JUN2010	30JUN2010	N
			Tonsillectomy	30JUN1956	30JUN1956	N
	C4591001 1139 11391019	Psychiatric disorders	Depression	30JUN2005		Y
		Vascular disorders	Hypertension	30JUN2015		Y
	C4591001 1139 11391020	Ear and labyrinth disorders	Deafness unilateral	15OCT2018		Y
		Eye disorders	Myopia	30JUN1974		Y
		Immune system disorders	Seasonal allergy	30JUN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	30JUN2010		Y
		Nervous system disorders	Tension headache	30JUN2010		Y
		Psychiatric disorders	Anxiety	30JUN2001		Y
		Skin and subcutaneous tissue disorders	Rash	30JUN2015		Y
		Surgical and medical procedures	Female sterilisation	30JUN2001	30JUN2001	N
	C4591001 1139 11391024	Injury, poisoning and procedural complications	Joint injury	15JAN2008	12DEC2012	N
			Limb injury	30JUN2014	15AUG2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2008		Y
		Surgical and medical procedures	Knee arthroplasty	12DEC2012	12DEC2012	N
			Shoulder operation	15AUG2014	15AUG2014	N
		Vascular disorders	Hypertension	30JUN2015		Y
	C4591001 1139 11391026	Gastrointestinal disorders	Gastrooesophageal reflux disease	30JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	30JUN2018	30JUN2018	N
	C4591001 1139 11391030	Vascular disorders	Hypertension	30AUG2000		Y
	C4591001 1139 11391031	Endocrine disorders	Hypothyroidism	30JUN1999		Y
		Musculoskeletal and connective tissue disorders	Myalgia	30JUN1998		Y
			Osteoarthritis	30JUN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid adenoma	30JUN1999	30JUN1999	N
		Psychiatric disorders	Sleep disorder	30JUN2000		Y
		Surgical and medical procedures	Knee arthroplasty	30JUN2015	30JUN2015	N
			Thyroidectomy	30JUN1999	30JUN1999	N
	C4591001 1139 11391032	General disorders and administration site conditions	Hernia	15APR2019	15APR2019	N
		Injury, poisoning and procedural complications	Epicondylitis	30JUN2013		Y
		Investigations	Blood cholesterol increased	30JUN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	15FEB2020		Y
		Surgical and medical procedures	Elbow operation	30JUN2014	30JUN2014	N
		Vascular disorders	Hypertension	30JUN1993		Y
	C4591001 1139 11391034	Ear and labyrinth disorders	Meniere's disease	22DEC2017		Y
		Immune system disorders	Seasonal allergy	30JUN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2014		Y
	C4591001 1139 11391035	Eye disorders	Presbyopia	30JUN2000		Y
		Immune system disorders	Drug hypersensitivity	30JUN1965		Y
			Seasonal allergy	30JUN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30JUN2018		Y
	C4591001 1139 11391039	Eye disorders	Presbyopia	30JUN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	15OCT2019		Y
	C4591001 1139 11391040	Social circumstances	Postmenopause	15JUN2012		Y
		Eye disorders	Astigmatism	30JUN2000		Y
		Hepatobiliary disorders	Biliary colic	15MAY2019	25JUN2019	N
		Immune system disorders	Seasonal allergy	30JUN2014		Y
		Metabolism and nutrition disorders	Diabetic complication	30JUN2014		Y
			Hypercholesterolaemia	30JUN2014		Y
			Type 2 diabetes mellitus	30JUN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	30JUN2012		Y
		Renal and urinary disorders	Nephrolithiasis	30JUN2010		Y
		Surgical and medical procedures	Cholecystectomy	25JUN2019	25JUN2019	N
		Vascular disorders	Hypertension	30JUN2012		Y
	C4591001 1139 11391043	Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2001		Y
			Type 2 diabetes mellitus	30JUN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	30JUN2003		Y
		Vascular disorders	Hypertension	30JUN2001		Y
	C4591001 1139 11391045	Cardiac disorders	Arrhythmia	30JUN2010		Y
		Congenital, familial and genetic disorders	Atrial septal defect	(b) (6) 1954		Y
		Eye disorders	Presbyopia	30JUN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	30JUN1983		Y
				30JUN1999		Y
				30JUN2000		Y
			Seasonal allergy	30JUN2000		Y
		Infections and infestations	Appendicitis	30JUN2013	30JUN2013	N
		Injury, poisoning and procedural complications	Lower limb fracture	30JUN2018	30JUN2018	N
			Muscle strain	30JUN2020		Y
			Pelvic fracture	30JUN1999	30JUN1999	N
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2000		Y
		Surgical and medical procedures	Appendectomy	30JUN2013	30JUN2013	N
		Vascular disorders	Hypertension	30JUN2010		Y
	C4591001 1139 11391050	Eye disorders	Myopia	30JUN1966		Y
		Injury, poisoning and procedural complications	Joint injury	30JUN2012	30JUN2012	N
			Limb injury	30JUN1960	30JUN1960	N
				30JUN1962	30JUN1962	N
		Surgical and medical procedures	Foot operation	30JUN1960	30JUN1960	N
			Limb operation	30JUN1962	30JUN1962	N
			Wrist surgery	30JUN2012	30JUN2012	N
	C4591001 1139 11391051	Eye disorders	Astigmatism	30JUN1969		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	30JUN2005	30JUN2017	N
		Surgical and medical procedures	Knee operation	30JUN1970	30JUN1970	N
			Rotator cuff repair	30JUN2012	30JUN2012	N
	C4591001 1139 11391054	Cardiac disorders	Atrial fibrillation	15JUN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	30JUN1963		Y
			Ocular vascular disorder	30JUN2010	30JUN2010	N
			Retinal artery occlusion	30JUN2015	30JUN2015	N
		Injury, poisoning and procedural complications	Fracture	15JAN2020	15JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	30JUN2018	30JUN2018	N
		Surgical and medical procedures	Appendectomy	30JUN1966	30JUN1966	N
			Therapeutic procedure	15JAN2020	15JAN2020	N
			Vasectomy	30JUN1990	30JUN1990	N
	C4591001 1139 11391055	Eye disorders	Myopia	30JUN1962		Y
		Injury, poisoning and procedural complications	Ankle fracture	30JUN1970	30JUN1970	N
			Spinal fracture	30JUN1994		Y
			Upper limb fracture	30JUN1959	30JUN1959	N
		Musculoskeletal and connective tissue disorders	Back pain	30JUN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer in situ	30JUN2000	30JUN2000	N
		Surgical and medical procedures	Mastectomy	30JUN2000	30JUN2000	N
		Vascular disorders	Hypertension	30JUN2019		Y
	C4591001 1139 11391057	Cardiac disorders	Supraventricular tachycardia	30JUN1990		Y
		Endocrine disorders	Hypothyroidism	30JUN1964		Y
		Eye disorders	Glaucoma	30JUN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	30JUN2000	31DEC2000	N
			Hyperlipidaemia	30JUN2005		Y
			Vitamin D deficiency	30JUN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	20JUN2016		Y
		Vascular disorders	Hypertension	30JUN1990		Y
	C4591001 1139 11391059	Metabolism and nutrition disorders	Glucose tolerance impaired	30JUN2014		Y
			Gout	30JUN2005		Y
			Hypercholesterolaemia	30JUN2017		Y
		Vascular disorders	Hypertension	30JUN2009		Y
	C4591001 1139 11391060	Eye disorders	Amblyopia	30JUN2000		Y
			Presbyopia	30JUN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	30JUN2018		Y
			Osteoarthritis	30JUN2017	18FEB2020	N
		Nervous system disorders	Parkinsonism	30JUN2018		Y
			Small fibre neuropathy	30JUN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	30JUN2008		Y
		Surgical and medical procedures	Cataract operation	30JUN2018	30JUN2018	N
			Female sterilisation	14FEB1974	14FEB1974	N
			Knee arthroplasty	18FEB2020	18FEB2020	N
	C4591001 1139 11391061	Immune system disorders	Seasonal allergy	30JUN1956		Y
		Infections and infestations	Orchitis	30JUN1991	30JUN1991	N
		Investigations	Blood testosterone decreased	30JUN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	30JUN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	30JUN2015		Y
		Surgical and medical procedures	Appendectomy	30JUN1991	30JUN1991	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	30JUN1995	30JUN1995	N
			Cholecystectomy	30JUN1992	30JUN1992	N
			Prostatic operation	06JUL2020	20JUL2020	N
			Seasonal allergy	30JUN1966		Y
	C4591001 1139 11391063	Immune system disorders				
		Musculoskeletal and connective tissue disorders	Osteoporosis	30JUN2019		Y
		Social circumstances	Postmenopause	30JUN2014		Y
	C4591001 1139 11391066	Endocrine disorders	Hypothyroidism	30JUN2005		Y
		Eye disorders	Astigmatism	30JUN2009		Y
			Myopia	30JUN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2011		Y
		Infections and infestations	Influenza	15MAR2017	15MAR2017	N
			Pneumonia bacterial	15MAR2017	15MAR2017	N
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	30JUN2013	30JUN2013	N
			Exostosis	30JUN2017	30JUN2017	N
			Intervertebral disc protrusion	30JUN1988	30JUN1988	N
			Ligament calcification	30JUN2008		Y
			Myalgia	30JUN1990		Y
		Reproductive system and breast disorders	Endometriosis	30JUN1992	30JUN1992	N
		Surgical and medical procedures	Adenoidectomy	30JUN1964	30JUN1964	N
			Hysterectomy	30JUN1998	30JUN1998	N
			Intervertebral disc operation	30JUN1988	30JUN1988	N
			Tonsillectomy	30JUN1964	30JUN1964	N
	C4591001 1139 11391067	Eye disorders	Myopia	30JUN1972		Y
		Immune system disorders	Seasonal allergy	30JUN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Upper limb fracture	30JUN1974	30JUN1974	N
		Nervous system disorders	Migraine	30JUN2000		Y
		Surgical and medical procedures	Appendicectomy	30JUN1982	30JUN1982	N
	C4591001 1139 11391068	Immune system disorders	Allergy to animal	30JUN1970		Y
		Surgical and medical procedures	Skin neoplasm excision	31JAN2019	31JAN2019	N
			Tonsillectomy	30JUN1968	30JUN1968	N
		Vascular disorders	Hypertension	30JUN2018		Y
	C4591001 1139 11391069	Immune system disorders	Food allergy	30JUN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	31JAN2020		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	30JUN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer stage IV	28FEB2015	31JAN2017	N
			Thyroid cancer stage IV	29FEB2016	30SEP2016	N
		Vascular disorders	Hypertension	31AUG1971		Y
	C4591001 1139 11391074	Eye disorders	Presbyopia	30JUN2008		Y
		General disorders and administration site conditions	Atrophy	15MAY1948		Y
		Immune system disorders	Drug hypersensitivity	30JUN1998		Y
			Rubber sensitivity	30JUN2004		Y
			Seasonal allergy	30JUN2000		Y
		Infections and infestations	Poliomyelitis	15MAY1948		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30JUN2015	30JUN2015	N
		Psychiatric disorders	Depression	30JUN2000		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN2003		Y
		Surgical and medical procedures	Cataract operation	15JUL2016	15JUL2016	N
			Hysterectomy	27JUN2002	27JUN2002	N
			Intraocular lens implant	15JUL2016	15JUL2016	N
			Knee arthroplasty	30JUN2015	30JUN2015	N
			Spinal fusion surgery	30JUN2017	30JUN2017	N
		Vascular disorders	Hypertension	30JUN1990		Y
	C4591001 1139 11391075	Blood and lymphatic system disorders	Polycythaemia	30JUN2015		Y
		Eye disorders	Myopia	30JUN1962		Y
		Immune system disorders	Seasonal allergy	30JUN2017		Y
		Metabolism and nutrition disorders	Haemochromatosis	30JUN2015		Y
			Hyperlipidaemia	30JUN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	30JUN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	30JUN2018	30JUN2018	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	23JUL2008		Y
		Skin and subcutaneous tissue disorders	Precancerous skin lesion	30JUN2019		Y
		Vascular disorders	Hypertension	30JUN2015		Y
	C4591001 1139 11391077	Eye disorders	Presbyopia	30JUN2004		Y
		Immune system disorders	Food allergy	30JUN1980		Y
			Seasonal allergy	(b) (6) 1963		Y
		Musculoskeletal and connective tissue disorders	Neck pain	05AUG2020		Y
		Reproductive system and breast disorders	Prostatitis	30JUN2015	30JUN2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1963		Y
	C4591001 1139 11391078	Gastrointestinal disorders	Irritable bowel syndrome	30JUN2014		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	30JUN1985	30JUN1985	N
		Psychiatric disorders	Anxiety	30JUN2000		Y
		Surgical and medical procedures	Salpingectomy	30JUN1985	30JUN1985	N
		Vascular disorders	Hypertension	30JUN2005		Y
	C4591001 1139 11391079	Cardiac disorders	Myocardial infarction	30JUN1991	30JUN1991	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	30JUN2017	30JUN2020	N
		Psychiatric disorders	Insomnia	30JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	30JUN2000		Y
		Surgical and medical procedures	Coronary artery bypass	30JUN1991	30JUN1991	N
			Prostatectomy	30JUN2017	30JUN2017	N
		Vascular disorders	Hypertension	30JUN2005		Y
	C4591001 1139 11391080	Immune system disorders	Allergy to animal	30JUN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	30JUN2015		Y
		Surgical and medical procedures	Parathyroidectomy	30JUN2015	30JUN2015	N
			Retinal operation	30JUN2016	30JUN2016	N
	C4591001 1139 11391082	Eye disorders	Cataract	30JUN2005	30JUN2005	N
			Glaucoma	15MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Myopia	30JUN1956		Y
		Injury, poisoning and procedural complications	Cartilage injury	30JUN2005	30JUN2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	30JUN2004	30JUN2004	N
		Surgical and medical procedures	Cataract operation	30JUN2005	30JUN2005	N
			Knee operation	30JUN2005	30JUN2005	N
			Spinal fusion surgery	30JUN2016	30JUN2016	N
	C4591001 1139 11391084	Cardiac disorders	Coronary artery disease	30JUN2000		Y
		Eye disorders	Myopia	30JUN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2000		Y
			Type 2 diabetes mellitus	30JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Diaphragmatic paralysis	30JUN2000		Y
		Surgical and medical procedures	Coronary artery bypass Surgery	15FEB2017	15FEB2017	N
				30JUN2015	30JUN2015	N
		Vascular disorders	Hypertension	30JUN2000		Y
	C4591001 1139 11391085	Vascular disorders	Hypertension	30JUN2018		Y
	C4591001 1139 11391088	Blood and lymphatic system disorders	Anaemia	30JUN1990		Y
		Eye disorders	Presbyopia	30JUN2015		Y
		Immune system disorders	Seasonal allergy	30JUN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	30JUN2004	30JUN2004	N
		Surgical and medical procedures	Spinal laminectomy	30JUN2004	30JUN2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391092	Cardiac disorders	Coronary artery disease	15MAR2017		Y
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Coronary artery bypass	15MAR2017	15MAR2017	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1139 11391093	Endocrine disorders	Basedow's disease	30JUN1997		Y
		Investigations	Cardiac murmur	30JUN2010		Y
		Musculoskeletal and connective tissue disorders	Bone deformity	30JUN1990		Y
			Foot deformity	30JUN2000		Y
				30JUN2005		Y
			Posterior tibial tendon dysfunction	30JUN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	15MAY2012	15MAY2012	N
		Nervous system disorders	Neuropathy peripheral	30JUN2012		Y
		Skin and subcutaneous tissue disorders	Hyperkeratosis	30JUN2010		Y
			Rosacea	30JUN1985		Y
		Vascular disorders	Hypertension	15MAY2012		Y
	C4591001 1139 11391095	Investigations	Prostatic specific antigen increased	30JUN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	30JUN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
	C4591001 1139 11391096	Infections and infestations	Hepatitis C	15MAR2016	16OCT2016	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	15MAY2020	06OCT2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	30JUN2010		Y
	C4591001 1139 11391097	Immune system disorders	Seasonal allergy	30SEP2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN1995		Y
		Psychiatric disorders	Depression	30JUN1988		Y
	C4591001 1139 11391098	Gastrointestinal disorders	Small intestinal obstruction	30JUN2015	30JUN2015	N
		Musculoskeletal and connective tissue disorders	Arthritis	30JUN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	30JUN2017		Y
		Surgical and medical procedures	Cataract operation	30JUN2016	30JUN2016	N
			Transurethral prostatectomy	30JUN2010	30JUN2017	N
		Vascular disorders	Hypertension	30JUN1961		Y
	C4591001 1139 11391104	Immune system disorders	Seasonal allergy	30JUN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	15JUL2020		Y
	C4591001 1139 11391111	Eye disorders	Myopia	30JUN2000		Y
		Gastrointestinal disorders	Dyspepsia	01SEP2020		Y
			Gingival pain	09OCT2020	09OCT2020	N
		Injury, poisoning and procedural complications	Ankle fracture	30JUN1972	30JUN1972	N
			Hand fracture	30JUN2018	30JUN2018	N
			Wrist fracture	30JUN1978	30JUN1978	N
		Surgical and medical procedures	Caesarean section	24OCT2001	24OCT2001	N
	C4591001 1139 11391115	Investigations	Blood testosterone decreased	30JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30JUN2000		Y
	C4591001 1139 11391118	Nervous system disorders	Headache	30JUN2000		Y
	C4591001 1139 11391121	Immune system disorders	Seasonal allergy	30DEC2005		Y
		Infections and infestations	Hepatitis A	30JUN1976	30JUN1976	N
		Investigations	Blood cholesterol increased	30JUN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	13JUN2013		Y
		Respiratory, thoracic and mediastinal disorders	Snoring	30JUN2015		Y
		Surgical and medical procedures	Female sterilisation	28APR1983	28APR1983	N
			Nasal septal operation	30JUN1971	30JUN1971	N
			Skin neoplasm excision	30APR2017	30APR2017	N
		Vascular disorders	Hypertension	30JUN2018		Y
	C4591001 1139 11391122	Cardiac disorders	Supraventricular tachycardia	30JUN2005		Y
		Gastrointestinal disorders	Large intestine polyp	14JUL2016	14JUL2016	N
		Investigations	Colonoscopy	14JUL2016	14JUL2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	30JUN1995		Y
		Musculoskeletal and connective tissue disorders	Arthritis	30JUN2012		Y
				30JUN2014		Y
		Surgical and medical procedures	Hysterectomy	30JUN1979	30JUN1979	N
			Knee arthroplasty	30JUN2016	30JUN2016	N
			Tonsillectomy	30JUN1960	30JUN1960	N
		Vascular disorders	Hypertension	30JUN1995		Y
	C4591001 1139 11391124	Infections and infestations	Oral herpes	30JUN1960		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1139 11391126	Endocrine disorders	Hypothyroidism	30JAN1998		Y
		Eye disorders	Hypermetropia	30JUN2000		Y
		Gastrointestinal disorders	Constipation	30JUN2016		Y
		Injury, poisoning and procedural complications	Radius fracture	30JAN2014	28FEB2014	N
	C4591001 1139 11391128	Psychiatric disorders	Attention deficit hyperactivity disorder	30JUN2014		Y
			Depression	30JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1990		Y
	C4591001 1139 11391129	Immune system disorders	Seasonal allergy	30JUN2002		Y
		Nervous system disorders	Headache	30JUN1979		Y
	C4591001 1140 11401002	Cardiac disorders	Coronary artery dissection	07DEC2019	31DEC2019	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1140 11401003	Eye disorders	Cataract	01JAN2000	31JAN2012	N
			Glaucoma	01JAN1990		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1988		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Hypolipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31JAN1980	N
		Vascular disorders	Hypertension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401004	Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1140 11401005	Infections and infestations	Herpes zoster	15AUG2019	01SEP2019	N
	C4591001 1140 11401007	Cardiac disorders	Myocardial infarction	01MAY2009	01MAY2009	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	01JAN2008	N
		Surgical and medical procedures	Adenotonsillectomy	01MAY1965	01MAY1965	N
			Coronary arterial stent insertion	01MAY2009	01MAY2009	N
			Ligament operation	01FEB2003	01FEB2003	N
			Phlebectomy	01MAR2010	01MAR2010	N
				01MAY2016	01MAY2016	N
	C4591001 1140 11401008	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Investigations	Vitamin D decreased	30JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypotension	01JAN2005		Y
	C4591001 1140 11401012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1960		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31OCT2019	N
	C4591001 1140 11401013	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Eye disorders	Idiopathic orbital inflammation	01JUL2010	01JUL2011	N
		Gastrointestinal disorders	Inflammatory bowel disease	01JUN1969	01APR2003	N
			Irritable bowel syndrome	01JUN1968		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1973		Y
			Seasonal allergy	01MAY1979		Y
		Infections and infestations	Herpes zoster	01FEB1971	01FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Laparoscopy	01JUN1974	01JUN1974	N
				01MAY1982	01MAY1982	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1996		Y
		Nervous system disorders	Trigeminal neuralgia	01JUL2015		Y
		Psychiatric disorders	Anxiety	01JAN1987		Y
			Depression	01JAN1987		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JUN1974	01JUN2000	N
		Surgical and medical procedures	Colectomy	01APR2003	01APR2003	N
			Hip surgery	01JUL1985	01JUL1985	N
			Rotator cuff repair	01SEP2012	01SEP2012	N
	C4591001 1140 11401014	Investigations	Biopsy lung	01FEB2014	01FEB2014	N
		Nervous system disorders	Neuropathy peripheral	01FEB2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUL2019		Y
		Skin and subcutaneous tissue disorders	Skin mass	01FEB2020	01FEB2020	N
		Social circumstances	Drug abuser	01JAN2000	01JAN2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JUL2007	01JUL2007	N
			Umbilical hernia repair	01JUL2007	01JUL2007	N
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1140 11401018	Metabolism and nutrition disorders	Glucose tolerance impaired	21APR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2014		Y
		Psychiatric disorders	Anxiety	01JUN1985		Y
			Depression	01JUN1985		Y
		Surgical and medical procedures	Rotator cuff repair	30APR2020	30APR2020	N
			Vasectomy	01AUG1986	01AUG1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1140 11401026	Endocrine disorders	Hypothyroidism	01AUG2003		Y
		Injury, poisoning and procedural complications	Foot fracture	07JUL2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
	C4591001 1140 11401029	Investigations	Blood chromium increased	01JAN2010		Y
			Blood cobalt increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JUN2013	01JUN2013	N
		Psychiatric disorders	Anxiety	23JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01OCT2018		Y
			Wheezing	01OCT2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	01FEB2009	N
				01JUN2009	01JUN2009	N
			Hip surgery	01JAN2011	01JAN2011	N
	C4591001 1140 11401034	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Nervous system disorders	Neuralgia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2017	31AUG2017	N
			Gastric bypass	01JUN2009	30JUN2009	N
			Hysterectomy	01JUN2010	30JUN2010	N
	C4591001 1140 11401035	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Pyrexia	01JAN2012	31DEC2012	N
		Infections and infestations	Peritonsillar abscess	01JAN1984	31DEC1984	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
			Tuberculin test positive	01JAN1984	31DEC1984	N
		Skin and subcutaneous tissue disorders	Idiopathic urticaria	01JAN2008		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1140 11401036	Blood and lymphatic system disorders	Anaemia	01AUG2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2019		Y
		Surgical and medical procedures	Appendectomy	01AUG2018	01AUG2018	N
			Strabismus correction	01AUG1959	01AUG1959	N
			Tonsillectomy	01AUG1960	01AUG1960	N
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1140 11401041	Immune system disorders	Seasonal allergy	01OCT2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	06MAR2020	06APR2020	N
		Nervous system disorders	Migraine	01JUL1974		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01SEP1968	01SEP1968	N
			Appendectomy	01JUL2019	01JUL2019	N
			Mastectomy	23MAR2020	23MAR2020	N
			Tonsillectomy	01SEP1968	01SEP1968	N
	C4591001 1140 11401042	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2003		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1960	31DEC1960	N
			Pancreaticoduodenectomy	01DEC2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1140 11401043	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Lithotripsy	01FEB2020	29FEB2020	N
	C4591001 1140 11401047	Eye disorders	Eye swelling	01JAN2009		Y
			Glaucoma	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	22MAR2016	04APR2016	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2009		Y
		Surgical and medical procedures	Cataract operation	14SEP2010	14SEP2010	N
				29SEP2010	29SEP2010	N
	C4591001 1140 11401056	Immune system disorders	Seasonal allergy	01MAY1990		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2017		Y
			Gout	01AUG1998		Y
			Hyperlipidaemia	01OCT1995		Y
		Renal and urinary disorders	Pollakiuria	01NOV2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1981	01JAN1981	N
			Umbilical hernia repair	01FEB2003	01FEB2003	N
			Vasectomy	01JUL1997	01JUL1997	N
	C4591001 1140 11401058	Gastrointestinal disorders	Constipation	01AUG2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2012		Y
			Osteoarthritis	01AUG1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG1985	01AUG2000	N
			Prostate cancer	01AUG2016	01FEB2018	N
		Psychiatric disorders	Depression	01AUG2005		Y
			Insomnia	01AUG2012		Y
		Surgical and medical procedures	Gastric bypass	01AUG2000	01AUG2000	N
			Spinal fusion surgery	01AUG2007	01AUG2007	N
			Spinal operation	01AUG2012	01AUG2012	N
				01AUG2014	01AUG2014	N
	C4591001 1140 11401060	Congenital, familial and genetic disorders	Atrial septal defect	01AUG2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2010		Y
			Vitamin D deficiency	01AUG2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2016		Y
		Nervous system disorders	Essential tremor	01AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01AUG2005		Y
		Renal and urinary disorders	Bladder spasm	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01AUG2017		Y
		Vascular disorders	Hypertension	01AUG1968		Y
	C4591001 1140 11401064	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01NOV2012	01NOV2017	N
		Reproductive system and breast disorders	Erectile dysfunction	01NOV2012		Y
		Surgical and medical procedures	Tonsillectomy	01NOV1957	01NOV1957	N
			Vasectomy	01OCT2002	01OCT2002	N
	C4591001 1140 11401066	Blood and lymphatic system disorders	Lymphadenopathy	01MAY2020		Y
		General disorders and administration site conditions	Fatigue	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2010		Y
		Psychiatric disorders	Insomnia	01OCT2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01OCT2016		Y
		Surgical and medical procedures	Umbilical hernia repair	01AUG2018	01AUG2018	N
		Vascular disorders	Hypertension	01OCT2017		Y
	C4591001 1140 11401075	Psychiatric disorders	Alcoholism	01JAN1980	23APR2014	N
			Anxiety	01JAN2000		Y
			Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
	C4591001 1140 11401077	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Nervous system disorders	Migraine	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	09NOV1992	09NOV1992	N
				24APR1989	24APR1989	N
			Gastric bypass	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN1986	31DEC1986	N
	C4591001 1140 11401078	Hepatobiliary disorders	Gallbladder disorder	01JAN2013		Y
		Investigations	Catheterisation cardiac	07DEC2011		Y
			Pulmonary function test decreased	01FEB2012		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2019		Y
			Hyperlipidaemia	07DEC2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01OCT2011	01FEB2012	N
		Surgical and medical procedures	Appendicectomy	01OCT1965	01OCT1965	N
			Lung lobectomy	11JAN2012	11JAN2012	N
		Vascular disorders	Hypertension	01APR2018		Y
	C4591001 1140 11401080	Blood and lymphatic system disorders	Lymphadenopathy	01JAN1990		Y
		Gastrointestinal disorders	Abdominal pain	01JUL2020		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	01JUL2020		Y
		Psychiatric disorders	Anxiety	01JAN1991		Y
			Depression	01JAN1990		Y
	C4591001 1140 11401081	Immune system disorders	Seasonal allergy	01APR1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bronchial neoplasm	01OCT1979	01NOV1979	N
		Psychiatric disorders	Anxiety	01MAY2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01NOV1979		Y
		Skin and subcutaneous tissue disorders	Alopecia	01FEB2000		Y
		Surgical and medical procedures	Lung lobectomy	01NOV1979	01NOV1979	N
	C4591001 1140 11401082	Endocrine disorders	Hypothyroidism	01AUG2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01NOV2018		Y
		Psychiatric disorders	Anxiety	01SEP2001		Y
		Vascular disorders	Hypertension	01AUG2011		Y
	C4591001 1140 11401083	Endocrine disorders	Basedow's disease	01JAN1984	31DEC1984	N
			Hypothyroidism	01JAN1984		Y
		Immune system disorders	Seasonal allergy	01JAN1954		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Hernia repair	01JAN2008	31DEC2008	N
			Thyroidectomy	01JAN1984	31DEC1984	N
	C4591001 1140 11401086	Cardiac disorders	Palpitations	01JAN2019		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1140 11401087	Cardiac disorders	Mitral valve prolapse	01NOV1986		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01MAR1983		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2018	01DEC2018	N
	C4591001 1140 11401089	Cardiac disorders	Coronary artery disease	01APR2016		Y
		Immune system disorders	Food allergy	01APR1959		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2016		Y
		Psychiatric disorders	Anxiety	01AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR1970		Y
		Surgical and medical procedures	Inguinal hernia repair	01MAY2003	01MAY2003	N
		Vascular disorders	Hypertension	01APR2016		Y
	C4591001 1140 11401090	Immune system disorders	Seasonal allergy	01AUG2001		Y
		Renal and urinary disorders	Nephrolithiasis	01MAY2019		Y
	C4591001 1140 11401096	Immune system disorders	Seasonal allergy	01AUG1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01OCT2015	04MAR2016	N
		Renal and urinary disorders	Nephrolithiasis	01AUG2000	01AUG2018	N
		Surgical and medical procedures	Cataract operation	01NOV2019	01NOV2019	N
				02JAN2020	02JAN2020	N
				11JAN2020	11JAN2020	N
				20DEC2019	20DEC2019	N
			Renal stone removal	01AUG2018	01AUG2018	N
	C4591001 1140 11401099	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG1980		Y
			Obesity	01AUG1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01JAN2016	01MAR2016	N
		Surgical and medical procedures	Nephrectomy	01MAR2016	01MAR2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAR1980		Y
	C4591001 1140 11401102	Cardiac disorders	Atrial fibrillation	01AUG2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2005		Y
			Obesity	01AUG2005		Y
			Type 2 diabetes mellitus	01AUG2018		Y
	C4591001 1140 11401104	Vascular disorders	Hypertension	01AUG2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01DEC2018		Y
			Depression	01AUG2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2019		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1140 11401111	Musculoskeletal and connective tissue disorders	Peripheral arterial occlusive disease Osteoarthritis	01MAR2020 01JAN2019		Y
	C4591001 1140 11401113	Psychiatric disorders	Anxiety	01JAN2017		Y
	C4591001 1140 11401114	Endocrine disorders	Goitre	01OCT2019		Y
		Immune system disorders	Seasonal allergy	01APR2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01SEP1976	01AUG2010	N
			Squamous cell carcinoma	01JUL2020	01JUL2020	N
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01AUG2015		Y
		Surgical and medical procedures	Hip arthroplasty	01APR2012	01APR2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401117	Cardiac disorders	Coronary artery disease	01AUG2015		Y
		Metabolism and nutrition disorders	Hyperglycaemia	01JUN2020		Y
			Hyperlipidaemia	01JUN2019		Y
			Obesity	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01AUG2010		Y
			Osteoarthritis	01FEB2014		Y
		Psychiatric disorders	Depression	01AUG2018		Y
		Surgical and medical procedures	Knee arthroplasty	01FEB2014	01FEB2014	N
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1140 11401119	Psychiatric disorders	Anxiety	01JUN2000		Y
			Sleep disorder	01JUN2000		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1965	01JAN1965	N
			Hip arthroplasty	17JUN2020	17JUN2020	N
			Hysterectomy	01FEB1979	01FEB1979	N
			Shoulder operation	01JAN1978	01JAN1978	N
				01JUN1978	01JUN1978	N
			Skin neoplasm excision	01JUN2005	01JUN2005	N
			Tonsillectomy	01JAN1951	01JAN1951	N
	C4591001 1140 11401121	Endocrine disorders	Hypothyroidism	01JUN2012		Y
		Infections and infestations	Diverticulitis	01DEC2018	01MAR2020	N
		Metabolism and nutrition disorders	Gout	01APR2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01AUG2016	01AUG2016	N
		Surgical and medical procedures	Inguinal hernia repair	01JUN1995	01JUN1995	N
				01JUN2005	01JUN2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01SEP2012	02SEP2012	N
			Vasectomy	01MAR1977	01MAR1977	N
	C4591001 1140 11401123	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2000		Y
			Obesity	01JAN1999		Y
			Type 2 diabetes mellitus	01AUG2017		Y
		Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1140 11401125	Cardiac disorders	Aortic valve incompetence	01JUN2014		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2008		Y
		Renal and urinary disorders	Renal mass	01MAR2019		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2000		Y
				01JAN2018		Y
			Urticaria	01JAN1994		Y
	C4591001 1140 11401126	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN1962		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1140 11401131	Surgical and medical procedures	Inguinal hernia repair	01APR2001	01APR2001	N
				01APR2015	01APR2015	N
	C4591001 1140 11401132	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01AUG2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01OCT2019	30NOV2019	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
	C4591001 1140 11401133	Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JUN1988	01JUN1988	N
			Hysterectomy	01JUN2007	01JUN2007	N
			Tonsillectomy	01JUN1961	01JUN1961	N
	C4591001 1140 11401134	Eye disorders	Macular degeneration	01AUG2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2019		Y
		Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1140 11401138	Surgical and medical procedures	Hip arthroplasty	10OCT2011	10OCT2011	N
				10OCT2012	10OCT2012	N
	C4591001 1140 11401140	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2017		Y
			Inguinal hernia	01JUL2011	01JUL2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Seasonal allergy	01MAR2017		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2015		Y
		Nervous system disorders	Migraine with aura	01MAR2016		Y
			Seizure	01JAN1958		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01AUG2011	01AUG2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JUN1963	01JUN1963	N
		Vascular disorders	Hypertension	01AUG1985		Y
	C4591001 1140 11401141	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Allergy to animal	01JAN1981		Y
			Food allergy	01JAN1981		Y
			Mycotic allergy	01JAN1981		Y
			Seasonal allergy	01JAN1981		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	04JAN2018	04JAN2018	N
	C4591001 1140 11401142	Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN1995	31AUG1995	N
		Surgical and medical procedures	Breast conserving surgery	01AUG1995	31AUG1995	N
			Inguinal hernia repair	01JAN1994	31JAN1994	N
				01JAN2003	31JAN2003	N
	C4591001 1140 11401143	Endocrine disorders	Goitre	01MAR2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2018		Y
			Seasonal allergy	01MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2000		Y
			Type 2 diabetes mellitus	01MAR2017		Y
		Nervous system disorders	Migraine	01AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2016		Y
		Skin and subcutaneous tissue disorders	Rosacea	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401145	Vascular disorders	Hypertension	01SEP2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Allergic oedema	01JAN2012		Y
			Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01APR2015		Y
		Infections and infestations	Appendicitis perforated	01DEC1963	01DEC1963	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010		Y
			Squamous cell carcinoma	01AUG2000	01AUG2000	N
		Renal and urinary disorders	Cystitis interstitial	01NOV2019	01NOV2019	N
		Social circumstances	Cystitis interstitial	01JAN2015		Y
		Surgical and medical procedures	Postmenopause	01JAN1999		Y
			Adenoidectomy	01JUN1963	01JUN1963	N
	Appendicectomy		01DEC1963	01DEC1963	N	
	Tonsillectomy		01JUN1963	01JUN1963	N	
	Macular degeneration		01JUN1963	01JUN1963	N	
	C4591001 1140 11401146	Eye disorders	Macular degeneration	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Bunion operation	01JAN2000	31DEC2000	N
			Cataract operation	01JAN2019	31DEC2019	N
			Female sterilisation	01JAN1975	31DEC1975	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
			Rotator cuff repair	01JAN2017	31DEC2017	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2018	31DEC2018	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1140 11401147	Endocrine disorders	Goitre	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01APR2012	01MAY2012	N
		Surgical and medical procedures	Foot operation	01MAY2012	01MAY2012	N
			Mammoplasty	01JAN2019	01JAN2019	N
		Vascular disorders	Hypertension	01JUN2009		Y
	C4591001 1140 11401152	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2010		Y
		Renal and urinary disorders	Renal injury	01MAY1963	01MAY1963	N
		Surgical and medical procedures	Nephrectomy	01MAY1963	01MAY1963	N
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1140 11401155	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Irritable bowel syndrome	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
			Seasonal allergy	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1140 11401156	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2016		Y
			Coronary artery bypass	01JAN2011	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Arteriosclerosis	01JAN2011		Y
			Hypertension	01JAN2010		Y
	C4591001 1140 11401161	Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2017	31JAN2020	N
		Surgical and medical procedures	Foot operation	01JAN2020	31JAN2020	N
	C4591001 1140 11401163	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Nervous system disorders	Stiff person syndrome	01JAN2015		Y
	C4591001 1140 11401165	Injury, poisoning and procedural complications	Ligament injury	01JAN2018		Y
			Nerve injury	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1140 11401167	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
			Seasonal allergy	01JAN1956		Y
		Investigations	Blood testosterone decreased	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
	C4591001 1140 11401168	Endocrine disorders	Hypothyroidism	01MAR2005		Y
		Immune system disorders	Seasonal allergy	01MAR1988		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
			Vitamin D deficiency	01MAR2012		Y
		Psychiatric disorders	Anxiety	01MAR2007		Y
		Surgical and medical procedures	Cataract operation	01FEB2020	01FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401169	Endocrine disorders	Hypothyroidism	01NOV1993		Y
		Metabolism and nutrition disorders	Gout	01MAR2010		Y
			Hyperlipidaemia	01NOV1995		Y
			Obesity	01NOV1956		Y
			Type 2 diabetes mellitus	01NOV1995		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV2018	01FEB2019	N
		Surgical and medical procedures	Mastectomy	01FEB2019	01FEB2019	N
		Vascular disorders	Hypertension	01NOV1995		Y
	C4591001 1140 11401171	General disorders and administration site conditions	Oedema	01JUN2012		Y
		Metabolism and nutrition disorders	Obesity	01APR1960		Y
		Nervous system disorders	Neuropathy peripheral	01AUG2019		Y
		Psychiatric disorders	Depression	01JUN2003		Y
		Surgical and medical procedures	Gastric bypass	01MAR2016	01MAR2016	N
			Hysterectomy	01MAY1999	01MAY1999	N
			Shoulder operation	01AUG1993	01AUG1993	N
	C4591001 1140 11401172	Blood and lymphatic system disorders	Anaemia	01AUG2018		Y
		Endocrine disorders	Hypogonadism	01AUG2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2005		Y
			Type 2 diabetes mellitus	01NOV2018		Y
	C4591001 1140 11401173	Injury, poisoning and procedural complications	Ligament rupture	01JUN1990	01JUN1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2010		Y
		Surgical and medical procedures	Hip surgery	01JUN2008	01JUN2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Ligament operation	01JUN1990	01JUN1990	N
	C4591001 1140 11401174	Psychiatric disorders	Anxiety	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01DEC2019	01DEC2019	N
	C4591001 1140 11401175	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2020		Y
		Immune system disorders	Allergic oedema	01JAN2009		Y
			Drug hypersensitivity	01JAN2009		Y
			Seasonal allergy	01AUG2010		Y
		Metabolism and nutrition disorders	Gout	01AUG2015		Y
			Hyperlipidaemia	01AUG2019		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2016		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2004		Y
		Surgical and medical procedures	Tenoplasty	01FEB2015	01FEB2015	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1140 11401179	Reproductive system and breast disorders	Menopausal symptoms	01APR2012		Y
		Surgical and medical procedures	Female sterilisation	29APR1988	29APR1988	N
			Inguinal hernia repair	01APR2018	01APR2018	N
			Shoulder operation	01FEB2008	01FEB2008	N
	C4591001 1140 11401181	Gastrointestinal disorders	Dry mouth	01JUN2015		Y
		Surgical and medical procedures	Cataract operation	01NOV2019	01NOV2019	N
				14NOV2019	14NOV2019	N
			Knee arthroplasty	01MAR2017	01MAR2017	N
	C4591001 1140 11401182	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01NOV1990		Y
		Vascular disorders	Hypertension	01NOV2005		Y
	C4591001 1140 11401183	Psychiatric disorders	Anxiety	01JUN2002		Y
			Depression	01JUN2002		Y
		Reproductive system and breast disorders	Breast cyst	01JUN1975	01JUN2010	N
		Surgical and medical procedures	Myomectomy	01JUN1993	01JUN1993	N
	C4591001 1140 11401185	Immune system disorders	Seasonal allergy	01JUN1970		Y
		Investigations	Blood calcium decreased	01JAN2012		Y
			Blood cholesterol increased	01AUG2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01AUG2010	28FEB2011	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31JAN1989	N
			Parathyroidectomy	01JAN2012		Y
			Thyroidectomy	01JAN2012	31JAN2012	N
	C4591001 1140 11401186	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2005		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1140 11401189	Musculoskeletal and connective tissue disorders	Osteoporosis	01JUN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01APR2018	01JUN2018	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Breast conserving surgery	01APR2018	01APR2018	N
			Radiotherapy to breast	01MAY2018	01JUN2018	N
	C4591001 1140 11401190	Social circumstances	Tobacco user	01AUG1962		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2003		Y
		Vascular disorders	Hypertension	01AUG2003		Y
	C4591001 1140 11401191	Cardiac disorders	Coronary artery disease	01MAY1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2015		Y
			Prostate cancer	01OCT2009	01OCT2010	N
		Surgical and medical procedures	Coronary artery bypass	01MAY1995	01MAY1995	N
	C4591001 1140 11401194	Ear and labyrinth disorders	Deafness neurosensory	20AUG2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1999	31DEC1999	N
			Retinopexy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1140 11401195	Endocrine disorders	Hypothyroidism	01JUL2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01APR1968		Y
		Psychiatric disorders	Anxiety	01APR1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01APR1986		Y
		Social circumstances	Menopause	01JAN2006	31DEC2006	N
	C4591001 1140 11401197	General disorders and administration site conditions	Pain	01AUG2010		Y
		Social circumstances	Menopause	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1140 11401199	Endocrine disorders	Hypothyroidism	01AUG2000		Y
		Immune system disorders	Seasonal allergy	01AUG1972		Y
		Social circumstances	Menopause	01JAN2010	31DEC2010	N
	C4591001 1140 11401200	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	30JUN2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1140 11401204	Immune system disorders	Allergy to arthropod sting	01AUG1993		Y
			Seasonal allergy	01AUG2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2000		Y
		Social circumstances	Menopause	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1140 11401207	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN2001		Y
				01JAN2006		Y
				01JAN2015		Y
		Investigations	Blood cholesterol increased	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JUN2020		Y
		Psychiatric disorders	Anxiety	01APR2018		Y
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2007	30JUN2007	N
	C4591001 1140 11401208	Endocrine disorders	Hypogonadism	01AUG2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2013		Y
			Type 2 diabetes mellitus	01AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2019		Y
		Surgical and medical procedures	Limb reconstructive surgery	01AUG2014	01AUG2014	N
			Meniscus operation	01AUG2017	01AUG2017	N
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1140 11401213	Social circumstances	Menopause	01JAN2015		Y
	C4591001 1140 11401217	Investigations	Blood cholesterol increased	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2017		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2016	31DEC2016	N
	C4591001 1140 11401218	Immune system disorders	Contrast media allergy	01JAN2000		Y
			Seasonal allergy	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2019		Y
		Renal and urinary disorders	Nephrolithiasis	01MAR2000	01AUG2000	N
		Surgical and medical procedures	Spinal laminectomy	01DEC2019	01DEC2019	N
			Tenoplasty	01DEC2019	01DEC2019	N
		Vascular disorders	Hypertension	01AUG2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401220	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1140 11401222	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1140 11401223	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01AUG1968		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2016		Y
		Nervous system disorders	Transient ischaemic attack	01AUG2013	01AUG2013	N
		Surgical and medical procedures	Appendicectomy	01AUG1989	01AUG1989	N
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1140 11401225	Eye disorders	Cataract	01NOV2014	30NOV2014	N
				01OCT2014	31OCT2014	N
		Immune system disorders	Contrast media allergy	01JAN1980		Y
			Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1975		Y
		Injury, poisoning and procedural complications	Arthropod sting	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1969		Y
			Osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2000	31DEC2000	N
			Ligament operation	01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2013	31DEC2013	N
			Spinal laminectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1140 11401226	Investigations	Eosinophil count increased	08JUN2018		Y
			White blood cell count decreased	08JUN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01SEP1993		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1140 11401227	Gastrointestinal disorders	Barrett's oesophagus	01APR2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01MAR1969		Y
		Surgical and medical procedures	Cholecystectomy	01AUG1990	01AUG1990	N
			Gastric bypass	01APR2013	01APR2013	N
			Hysterectomy	01NOV2015	01NOV2015	N
			Rotator cuff repair	01JUL2015	01JUL2015	N
			Tonsillectomy	01APR1979	01APR1979	N
	C4591001 1140 11401228	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2012		Y
			Type 2 diabetes mellitus	01AUG2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01AUG2014	01MAR2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2017		Y
		Surgical and medical procedures	Prostatectomy	01MAR2018	01MAR2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1140 11401230	Immune system disorders	Contrast media allergy	01JAN2018		Y
			Drug hypersensitivity	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01MAR2018	31MAR2018	N
			Pilonidal sinus repair	01JAN2013	31DEC2013	N
			Tonsillectomy	01DEC1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1140 11401233	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Carpectomy	01MAY2019	31MAY2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1140 11401235	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG1975		Y
		Infections and infestations	Chronic sinusitis	01AUG1979		Y
		Surgical and medical procedures	Appendicectomy	01AUG1979	01AUG1979	N
			Cholecystectomy	01AUG1979	01AUG1979	N
		Vascular disorders	Hypertension	01AUG1999		Y
	C4591001 1140 11401236	Endocrine disorders	Hypothyroidism	01DEC2002		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2016		Y
		Nervous system disorders	Migraine	01AUG2000		Y
		Psychiatric disorders	Anxiety	01AUG2010		Y
		Social circumstances	Menopause	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Tonsillectomy	01AUG1968	01AUG1968	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401237	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1986		Y
			Spinal stenosis	01JAN1986		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1985		Y
			Depression	01JAN1985		Y
		Social circumstances	Menopause	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Gastric bypass	01JAN2013	31DEC2013	N
			Ovarian cystectomy	01JAN2000	31DEC2000	N
			Spinal nerve stimulator implantation	01JAN2014		Y
			Spinal operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1140 11401238	General disorders and administration site conditions	Pain	01AUG1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1980		Y
			Seasonal allergy	01AUG2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1991		Y
		Surgical and medical procedures	Appendectomy	01DEC1966	01DEC1966	N
			Cholecystectomy	01AUG2005	01AUG2005	N
			Hysterectomy	01AUG1986	01AUG1986	N
			Spinal laminectomy	01AUG2012	01AUG2012	N
			Tonsillectomy	01AUG1956	01AUG1956	N
		Vascular disorders	Hypertension	01SEP2012		Y
	C4591001 1140 11401242	Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2011	01AUG2011	N
			Rotator cuff repair	01AUG2015	01AUG2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01DEC2018		Y
	C4591001 1140 11401244	Eye disorders	Macular degeneration	01DEC2018		Y
		Gastrointestinal disorders	Gastrointestinal pain	01JAN2012		Y
		Immune system disorders	Contrast media allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	24JUN2015	24JUN2015	N
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Breast conserving surgery	01AUG2015	01AUG2015	N
			Cholecystectomy	01SEP2012	01SEP2012	N
		Vascular disorders	Hypertension	01SEP1995		Y
	C4591001 1140 11401245	Immune system disorders	Hypersensitivity	01SEP1955		Y
		Nervous system disorders	Neuropathy peripheral	01SEP2017		Y
		Psychiatric disorders	Depression	01SEP1968		Y
		Surgical and medical procedures	Gastric bypass	01SEP2008	01SEP2008	N
			Tonsillectomy	01SEP1951	01SEP1951	N
	C4591001 1140 11401247	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2005		Y
		Surgical and medical procedures	Tonsillectomy	01SEP1953	01SEP1953	N
	C4591001 1140 11401248	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2006		Y
				01JAN2011		Y
			Seasonal allergy	01AUG2015		Y
		Metabolism and nutrition disorders	Obesity	01AUG2019		Y
			Vitamin D deficiency	01OCT2015		Y
		Psychiatric disorders	Depression	01APR2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2015		Y
	C4591001 1140 11401254	Gastrointestinal disorders	Dyspepsia	01AUG1990		Y
		Immune system disorders	Hypersensitivity	01AUG2010		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2015		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01AUG2017		Y
			Osteopenia	01AUG2015		Y
		Psychiatric disorders	Anxiety	01AUG2001		Y
			Insomnia	01AUG2001		Y
		Skin and subcutaneous tissue disorders	Photosensitivity reaction	01AUG2010		Y
		Surgical and medical procedures	Cholecystectomy	01MAR1989	01MAR1989	N
			Hysterectomy	01OCT1990	01OCT1990	N
			Inguinal hernia repair	01MAR1989	01MAR1989	N
			Shoulder operation	01JAN2017	01JAN2017	N
	C4591001 1140 11401256	Endocrine disorders	Hypothyroidism	01SEP1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				01JAN1990		Y
				01JAN2010		Y
		Social circumstances	Menopause	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Cholecystectomy	01SEP2005	01SEP2005	N
			Knee arthroplasty	01DEC2018	01DEC2018	N
				01SEP2017	01SEP2017	N
			Thyroidectomy	01SEP1999	01SEP1999	N
	C4591001 1140 11401258	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Infections and infestations	Hepatitis C	01JAN1997	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1140 11401260	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1140 11401261	Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31JAN2010	N
		Surgical and medical procedures	Prostatectomy	01JAN2010	31JAN2010	N
			Vasectomy	01AUG1995	31AUG1995	N
		Vascular disorders	Hypertension	01OCT2005		Y
	C4591001 1140 11401263	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2010		Y
		Immune system disorders	Seasonal allergy	01APR2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2016		Y
		Psychiatric disorders	Insomnia	01JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2014		Y
		Surgical and medical procedures	Hysterectomy	01JUL2000	31JUL2000	N
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1140 11401265	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2005		Y
		Metabolism and nutrition disorders	Hyperglycaemia	05NOV2019		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Tonsillectomy	01DEC1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1140 11401266	Endocrine disorders	Hypothyroidism	01JAN1974		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
				01JAN2015		Y
				01JAN2017		Y
		Investigations	Arthroscopy	01JUN2000	30JUN2000	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01SEP2020		Y
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01SEP2000	30SEP2000	N
			Ligament operation	01JUN2003	30JUN2003	N
			Tenoplasty	01APR2018	30APR2018	N
				01FEB2010	28FEB2010	N
			Thyroidectomy	01JAN2000	31DEC2000	N
			Urinary bladder suspension	01DEC2014	31DEC2014	N
	C4591001 1140 11401267	Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31JAN1984	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
	C4591001 1140 11401268	Immune system disorders	Drug hypersensitivity	01JAN1959		Y
				01JAN1990		Y
				01JAN2003		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Sinus operation	01JAN2000	31DEC2000	N
			Skin neoplasm excision	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Eye disorders	Dry eye	01JAN2008		Y
	C4591001 1140 11401269	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1994		Y
		Infections and infestations	Ophthalmic herpes zoster	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Elbow operation	01JAN2013	31DEC2013	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Shoulder operation	01AUG2015	01AUG2015	N
			Skin neoplasm excision	01SEP2000	01SEP2000	N
	C4591001 1140 11401270†	Congenital, familial and genetic disorders	Arnold-Chiari malformation	01OCT2013		Y
		Eye disorders	Ocular hypertension	01NOV2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
				01JAN2018		Y
				01JAN2019		Y
			Seasonal allergy	01AUG2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	HIV infection	01OCT1982		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2013		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01AUG2014		Y
		Nervous system disorders	Lumbar radiculopathy	01FEB2019		Y
			Migraine	01SEP2020		Y
			Neuropathy peripheral	01FEB2019		Y
			Seizure	01APR2011		Y
		Psychiatric disorders	Anxiety	01NOV2017		Y
			Depression	01NOV2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	18FEB2020	18FEB2020	N
			Spinal operation	02JUN2020	02JUN2020	N
		Vascular disorders	Raynaud's phenomenon	01AUG2014		Y
	C4591001 1140 11401271	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	30OCT1996	30OCT1996	N
		Social circumstances	Postmenopause	01JAN2006	31DEC2006	N
	C4591001 1140 11401273	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01DEC1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Bone operation	01DEC1996	01DEC1996	N
			Bunion operation	01JAN2007	31DEC2007	N
			Cataract operation	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1980	31DEC1980	N
			Mammoplasty	01JAN1981	31DEC1981	N
			Mastectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1140 11401274	Hepatobiliary disorders	Cholangitis sclerosing	01JAN2000		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01OCT2018		Y
	C4591001 1140 11401275	Cardiac disorders	Coronary artery disease	01MAR2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Investigations	Cardiac murmur	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1960		Y
		Surgical and medical procedures	Coronary artery bypass	01MAR2018	01MAR2018	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Spinal operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1140 11401276	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1140 11401277	Cardiac disorders	Atrioventricular block first degree	03JUL2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1991		Y
				01JAN1998		Y
				01JAN2007		Y
			Seasonal allergy	01JAN2015		Y
		Infections and infestations	Herpes simplex	01JAN1974		Y
			Onychomycosis	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast hyperplasia	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	05APR1989	05APR1989	N
			Urinary bladder suspension	01APR2006	30APR2006	N
	C4591001 1140 11401278	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Congenital, familial and genetic disorders	Congenital urethral anomaly	01JAN1988	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Surgical and medical procedures	Appendectomy	01JAN1971	31DEC1971	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1140 11401280	Cardiac disorders	Coronary artery disease	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN1996		Y
		Immune system disorders	Seasonal allergy	01OCT2001		Y
		Investigations	Blood cholesterol increased	01JAN1994		Y
			Vitamin B12 decreased	01SEP2020		Y
			Vitamin D decreased	01SEP2020		Y
		Psychiatric disorders	Depression	01MAY2019		Y
			Insomnia	01APR2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2002		Y
		Surgical and medical procedures	Cholecystectomy	01JUN2015	30JUN2015	N
			Rotator cuff repair	01DEC2016	28FEB2017	N
				01JUN2016	30SEP2016	N
			Thyroidectomy	01SEP2015	31OCT2015	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1140 11401283	Gastrointestinal disorders	Duodenogastric reflux	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2020	31AUG2020	N
	C4591001 1140 11401286	Surgical and medical procedures	Prostatic operation	01AUG2020	31AUG2020	N
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Nervous system disorders	Migraine	01JAN1973		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Parathyroidectomy	01JAN2006	31DEC2006	N
			Strabismus correction	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1959	31DEC1959	N
	C4591001 1140 11401287	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Hypersensitivity	01JAN1962		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Social circumstances	Menopause	01JAN1985		Y
	C4591001 1140 11401288	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1140 11401289	Immune system disorders	Seasonal allergy	01JAN2003	31DEC2003	N
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1140 11401291	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Spondylitis	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hot flush	01JAN2000		Y
	C4591001 1140 11401292	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1140 11401293	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2020		Y
			Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2013	31DEC2013	N
	C4591001 1140 11401297	Immune system disorders	Anaphylactic reaction	01JAN2012		Y
			Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1140 11401300	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer stage I	09OCT2020		Y
	C4591001 1140 11401302	Immune system disorders	Seasonal allergy	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1140 11401305	Immune system disorders	Seasonal allergy	01JAN1976		Y
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Tonsillectomy	01JAN1966	31DEC1966	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1140 11401307	Immune system disorders	Food allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
			Vitamin D deficiency	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
			Sleep apnoea syndrome	01APR2004		Y
		Surgical and medical procedures	Carpal tunnel decompression	01FEB2015	30NOV2015	N
			Rotator cuff repair	01OCT2014	31OCT2014	N
			Spinal fusion surgery	01OCT2012	31OCT2012	N
	C4591001 1140 11401312	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Infections and infestations	Conjunctivitis	20OCT2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2015		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y
			Osteoporosis	01OCT2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menopausal symptoms	01OCT2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01FEB2016	31AUG2016	N
			Cholecystectomy	01OCT1999	31OCT1999	N
	C4591001 1140 11401313	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Vitamin D deficiency	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1986	01JAN1986	N
			Squamous cell carcinoma	01JAN2005	01JAN2005	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1991		Y
		Surgical and medical procedures	Tendon operation	01JAN2010	01JAN2010	N
	C4591001 1141 11411001	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2001		Y
			Pancreatitis	01JAN2020	15FEB2020	N
		Infections and infestations	Rhinitis	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	06JUN2007		Y
		Surgical and medical procedures	Cholecystectomy	17JAN2020	17JAN2020	N
		Vascular disorders	Hypertension	06JUN2007		Y
	C4591001 1141 11411015	Cardiac disorders	Atrial flutter	01JAN2017	01JAN2017	N
			Coronary artery disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Renal and urinary disorders	Renal cyst	24DEC2019		Y
	C4591001 1141 11411028	Gastrointestinal disorders	Abdominal adhesions	02SEP2013	02SEP2013	N
			Small intestinal obstruction	02SEP2013	02SEP2013	N
		Infections and infestations	Herpes simplex	01APR2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	30APR2012	30APR2012	N
		Social circumstances	Postmenopause	20JAN1995		Y
		Surgical and medical procedures	Abscess drainage	09JUL2008	09JUL2008	N
				18APR2011	18APR2011	N
			Colectomy	11NOV2013	11NOV2013	N
			Micrographic skin surgery	30APR2012	30APR2012	N
			Atrial fibrillation	01JAN2018		Y
	C4591001 1141 11411034	Cardiac disorders				
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2010		Y
		Gastrointestinal disorders	Anal fissure	01JAN2000	31DEC2000	N
		Infections and infestations	Tonsillitis	01JAN1967	31DEC1967	N
		Nervous system disorders	Transient ischaemic attack	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Surgical and medical procedures	Anorectal operation	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1141 11411040	Immune system disorders	Seasonal allergy	01JAN1988		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Major depression	01JAN2005		Y
	C4591001 1141 11411043	Endocrine disorders	Hypothyroidism	01JAN1983		Y
		Psychiatric disorders	Persistent depressive disorder	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411047	Cardiac disorders	Atrial fibrillation	01JAN2012	31DEC2018	N
			Cardiac failure acute	01JAN2012	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Hypermetropia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Headache	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2019		Y
	C4591001 1141 11411058	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1141 11411059	Ear and labyrinth disorders	Deafness unilateral	01JAN2012		Y
		Eye disorders	Myopia	01JAN1971		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Infections and infestations	Ear infection	01JAN1965	31DEC1967	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Prognathism	01JAN1976	31DEC1980	N
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01NOV2016		Y
		Surgical and medical procedures	Jaw operation	01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1141 11411063	Eye disorders	Myopia	01JAN1977		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Coeliac disease	01JAN2010		Y
		Infections and infestations	Rhinitis	01JAN1966		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2009	31DEC2009	N
			Spinal osteoarthritis	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
		Surgical and medical procedures	Arthrodesis	01DEC2019	31DEC2019	N
			Bone operation	01JAN2012	31DEC2012	N
			Intervertebral disc operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1141 11411066	Eye disorders	Myopia	01JAN2015		Y
		Infections and infestations	Pharyngitis streptococcal	01JAN1984	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01SEP2013	30SEP2013	N
		Psychiatric disorders	Depression	01FEB1992		Y
		Social circumstances	Tattoo	01JAN2002	31DEC2017	N
		Surgical and medical procedures	Hysterectomy	01SEP2013	30SEP2013	N
			Tonsillectomy	01JAN2002	31DEC2002	N
	C4591001 1141 11411069	Eye disorders	Myopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1141 11411071	Eye disorders	Myopia	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2002		Y
		Nervous system disorders	Restless legs syndrome	01JAN1977		Y
		Psychiatric disorders	Depressed mood	01JAN1997		Y
			Insomnia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Vascular disorders	Hot flush	01JAN1997	31DEC2002	N
	C4591001 1141 11411083	General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2017		Y
				01JAN2004		Y
		Nervous system disorders	Restless legs syndrome	01OCT2009		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	07OCT2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	31AUG2015		Y
		Surgical and medical procedures	Hip arthroplasty	01OCT2019	31OCT2019	N
		Vascular disorders	Essential hypertension	07OCT2006		Y
	C4591001 1141 11411100	Infections and infestations	Appendicitis	01JAN1966	31DEC1966	N
		Investigations	Blood creatinine abnormal	01JAN1985	31DEC1985	N
			Glomerular filtration rate	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN1966	31DEC1966	N
			Knee arthroplasty	01JAN2009	31DEC2009	N
	C4591001 1141 11411101	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01AUG1996		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1141 11411105	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2010		Y
		Infections and infestations	Pertussis	01AUG2013	01AUG2013	N
		Metabolism and nutrition disorders	Hypokalaemia	01APR2013		Y
		Vascular disorders	Hypertension	01AUG1990		Y
	C4591001 1141 11411111	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
			Osteopenia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2019		Y
			Depression	01JAN2008		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
			Chemotherapy	01JAN2010	31DEC2010	N
			Radiotherapy to breast	01JAN2010	31DEC2010	N
	C4591001 1141 11411117	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2017		Y
					03JUN2020	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Bunion operation	03JUN2020	03JUN2020	N
	C4591001 1141 11411134	Eye disorders	Cataract	01JAN2018	31JAN2018	N
		Metabolism and nutrition disorders	Vitamin D deficiency	27JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011	31DEC2013	N
					31OCT2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y	
		Social circumstances	Postmenopause	01JAN2004		Y	
		Surgical and medical procedures	Cataract operation	01JAN2018	31JAN2018	N	
			Hip arthroplasty	01JAN2013	31DEC2013	N	
				01OCT2018	31OCT2018	N	
				01JAN1995		Y	
	C4591001 1141 11411138	Eye disorders	Glaucoma	01JAN1995		Y	
				Hypermetropia	01JAN1998		Y
				Myopia	01JAN1998		Y
				Drug hypersensitivity	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y	
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y	
		Surgical and medical procedures	Tonsillectomy	01JAN1966	31DEC1966	N	
	C4591001 1141 11411143	Eye disorders	Myopia	01JAN1975		Y	
		General disorders and administration site conditions	Fat tissue increased	01JAN1999	30APR2017	N	
			Pain	01JAN1980		Y	
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y	
				Intervertebral disc degeneration	01JAN2007	29MAR2007	N
				Osteoarthritis	01APR2018	29MAY2018	N
				Insomnia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y	
			Seasonal affective disorder	01JAN1999		Y	
		Social circumstances	Postmenopause	01JAN2018		Y	
		Surgical and medical procedures	Abdominoplasty	01APR2017	30APR2017	N	
				Hip arthroplasty	29MAY2018	29MAY2018	N
				Spinal operation	29MAR2007	29MAR2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1141 11411145	Endocrine disorders	Hypothyroidism	01JAN2010		Y
			Thyroid mass	01JAN2010	31DEC2010	N
		Eye disorders	Hypermetropia	01JAN1992		Y
			Myopia	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1141 11411155	Surgical and medical procedures	Thyroid nodule removal	01JAN2010	31DEC2010	N
		Eye disorders	Hypermetropia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Laparoscopy	01JAN1994	31DEC1994	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	30NOV1999	N
		Reproductive system and breast disorders	Endometriosis	01JAN1985	30NOV1999	N
	C4591001 1141 11411157	Surgical and medical procedures	Hysterectomy	01NOV1999	30NOV1999	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1985	31DEC1995	N
			Inguinal hernia	01JAN2019	31DEC2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Arthrodesis	01JAN2014	31DEC2014	N
			Haemorrhoid operation	01JAN1995	31DEC1995	N
			Inguinal hernia repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411160	General disorders and administration site conditions	Pain	01JAN2000		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
	C4591001 1141 11411178	Eye disorders	Hypermetropia	01JAN1990		Y
	C4591001 1141 11411183	Eye disorders	Myopia	01JAN1969		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1989	30SEP1989	N
			Hepatic atrophy	01JAN2012	31DEC2012	N
		Infections and infestations	Sepsis	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Social circumstances	Postmenopause	01SEP2012		Y
		Surgical and medical procedures	Cholecystectomy	01SEP1989	30SEP1989	N
			Gastric operation	01OCT1989	31OCT1989	N
			Hepatectomy	01JAN2012	31DEC2012	N
			Small intestine operation	01OCT1989	31OCT1989	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1141 11411189	Eye disorders	Hypermetropia	01JAN1966		Y
		General disorders and administration site conditions	Gait disturbance	25AUG2020	25AUG2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1972	31DEC1972	N
		Infections and infestations	Appendicitis	01JAN1958	31DEC1958	N
			Bronchitis	01JAN2014		Y
			Tonsillitis	01JAN1960	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Skin abrasion	25AUG2020		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2020	29FEB2020	N
		Psychiatric disorders	Anxiety	01JAN1980	31DEC1980	N
		Surgical and medical procedures	Appendectomy	01JAN2010		Y
			Appendectomy	01JAN1958	31DEC1958	N
			Skin neoplasm excision	01FEB2020	29FEB2020	N
				01JAN1980	31DEC1980	N
			Tonsillectomy	01JAN1972	31DEC1972	N
			Hypothyroidism	01JAN2015		Y
	C4591001 1141 11411190	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Renal and urinary disorders	Renal cyst	01JAN2010		Y
		Vascular disorders	Aortic dilatation	01JAN2013		Y
			Hypertension	01JAN1975		Y
	C4591001 1141 11411191	Congenital, familial and genetic disorders	Cleft palate	(b) (6) 1957	31DEC1979	N
		General disorders and administration site conditions	Hernia	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1975		Y
				01JAN1977	31DEC2000	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998	31DEC1998	N
			Headache	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1998	31DEC1998	N
			Cleft palate repair	(b) (6) 1957	(b) (6) 1957	N
			Hernia repair	01JAN2001	31DEC2001	N
			Spinal laminectomy	01JAN2000	31DEC2000	N
	C4591001 1141 11411196	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
			Tinnitus	01JAN2010		Y
		Eye disorders	Astigmatism	01JAN1973		Y
			Hypermetropia	01JAN1973		Y
			Myopia	01JAN1973		Y
		Immune system disorders	Drug hypersensitivity	01JAN1966		Y
		Infections and infestations	Tonsillitis	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Meniscus injury	01MAY2020	31MAY2020	N
		Musculoskeletal and connective tissue disorders	Periarthritis	01MAY2020	31MAY2020	N
			Rotator cuff syndrome	01MAY2020	31MAY2020	N
		Social circumstances	Hearing aid user	01JAN2018		Y
	C4591001 1141 11411200	Surgical and medical procedures	Adenotonsillectomy	01JAN1966	31DEC1966	N
		Cardiac disorders	Atrial fibrillation	01JAN2013	31DEC2013	N
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2019	31DEC2019	N
		Surgical and medical procedures	Cardiac ablation	01JAN2013	31DEC2013	N
			Skin operation	01DEC2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1141 11411207	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Humerus fracture	01JAN2015	31DEC2015	N
		Investigations	Blood magnesium decreased	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	05MAR1999	05MAR1999	N
			Fracture treatment	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1141 11411210	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1974	31DEC2017	N
			Foot deformity	01JAN2012	31DEC2015	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2015	N
			Hypotonia	01JAN2000	31DEC2000	N
			Incoherent	01JAN2001	31DEC2003	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2001	31DEC2003	N
		Skin and subcutaneous tissue disorders	Lichen sclerosus	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2000	31DEC2000	N
			Bunion operation	01JAN2015	31DEC2015	N
			Carpal tunnel decompression	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1996	31DEC1996	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Mammoplasty	01APR2017	30APR2017	N
			Pelvic floor repair	01JAN2010	31DEC2010	N
	C4591001 1141 11411216	Immune system disorders	Food allergy	01JUN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1141 11411225	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1141 11411232	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
			Ventricular extrasystoles	01JAN1997		Y
			Wolff-Parkinson-White syndrome	01JAN1997		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1996	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN1997		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019		Y
	C4591001 1141 11411233	Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01MAY1991	31MAY1991	N
			Clavicle fracture	01MAY1991	31MAY1991	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Bone operation	01MAY1991	31MAY1991	N
			Spinal fusion surgery	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1141 11411244	Psychiatric disorders	Depression	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1141 11411253	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2001		Y
			Back pain	01JAN2000		Y
			Plantar fasciitis	01JAN2019		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Surgical and medical procedures	Knee operation	01JAN2001		Y
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Deep vein thrombosis	01JAN2018	31DEC2019	N
			Hypertension	01JAN2000		Y
	C4591001 1141 11411258	Infections and infestations	Diverticulitis	01JAN2013	24JUN2014	N
		Nervous system disorders	Neuralgia	24JAN2018		Y
		Psychiatric disorders	Sleep disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sinus polyp	01DEC2017	31DEC2017	N
		Surgical and medical procedures	Colectomy	24JUN2014	24JUN2014	N
			Sinus operation	24JAN2018	24JAN2018	N
	C4591001 1141 11411259	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1141 11411268	Cardiac disorders	Atrial fibrillation	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1142 11421003	Ear and labyrinth disorders	Tinnitus	01NOV2011		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Fatigue	18JUN2012		Y
		Immune system disorders	Drug hypersensitivity	18JUN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11OCT2010		Y
		Musculoskeletal and connective tissue disorders	Diastasis recti abdominis	03OCT2015		Y
		Psychiatric disorders	Depression	11OCT2010		Y
		Skin and subcutaneous tissue disorders	Lipodystrophy acquired	03NOV2015		Y
			Panniculitis	13OCT2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Essential hypertension	18JUN2012		Y
	C4591001 1142 11421005	Immune system disorders	Drug hypersensitivity	01JAN1994		Y
				01JAN1998		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Appendectomy	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Elbow operation	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Peripheral nerve decompression	01JAN2010	31DEC2010	N
			Tenoplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1142 11421006	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2015	12JUN2015	N
			Malignant melanoma	28JAN2020	28JUL2020	N
		Surgical and medical procedures	Coronary arterial stent insertion	01MAR2020	31MAR2020	N
			Coronary artery bypass	04DEC2019	04DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hernia repair	22DEC2009	22DEC2009	N
			Tumour excision	30APR2018	30APR2018	N
	C4591001 1142 11421012	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN1982	31DEC1982	N
		Nervous system disorders	Seizure	01JAN1969	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
			Oophorectomy	01JAN1982	31DEC1982	N
			Salpingectomy	01JAN1982	31DEC1982	N
	C4591001 1142 11421013	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN1964	31DEC1964	N
		Immune system disorders	Rubber sensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1970		Y
		Social circumstances	Postmenopause	18NOV2016		Y
	C4591001 1142 11421017	Cardiac disorders	Atrial fibrillation	02JUL2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	14FEB2008		Y
		Vascular disorders	Hypertension	28JUL2009		Y
	C4591001 1142 11421019	Immune system disorders	Drug hypersensitivity	22FEB2018		Y
				25APR2016		Y
				29JUN2017		Y
				29MAY2018		Y
		Infections and infestations	Ophthalmic herpes simplex	01JAN1970		Y
		Surgical and medical procedures	Corneal transplant	01JAN1971	31DEC1971	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1142 11421030	Surgical and medical procedures	Hernia repair	09MAY2013	09MAY2013	N
			Hip arthroplasty	17FEB2020	17FEB2020	N
			Transurethral prostatectomy	07SEP2012	07SEP2012	N
	C4591001 1142 11421031	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Ankle operation	11NOV2016	11NOV2016	N
			Caesarean section	01JAN1991	31DEC1991	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Knee operation	25AUG2016	25AUG2016	N
	C4591001 1142 11421032	Cardiac disorders	Atrial fibrillation	19JAN2018		Y
		Gastrointestinal disorders	Hiatus hernia	09APR2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12JUL2018		Y
		Nervous system disorders	Cerebrovascular accident	25AUG2017	25AUG2017	N
			Migraine	12JUL2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	20MAY2019		Y
		Vascular disorders	Hypertension	09APR2018		Y
	C4591001 1142 11421034	Immune system disorders	Drug hypersensitivity	29DEC2004		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	21JUN2006		Y
		Social circumstances	Postmenopause	01FEB2009		Y
	C4591001 1142 11421035	Cardiac disorders	Coronary artery disease	11SEP2014		Y
		Gastrointestinal disorders	Diverticulum intestinal	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Hyperlipidaemia	09APR2013		Y
		Vascular disorders	Hypertension	04SEP2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421036	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Adenoidectomy	01JAN1953	31DEC1953	N
			Hysterectomy	01JAN1981	31DEC1981	N
			Mammoplasty	01JAN1981	31DEC1981	N
			Open reduction of fracture	01JAN2006	31DEC2006	N
			Rhinoplasty	01JAN1989	31DEC1989	N
			Sinus operation	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1953	31DEC1953	N
	C4591001 1142 11421038	Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Investigations	Catheterisation cardiac	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1956		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1142 11421044	Cardiac disorders	Atrial fibrillation	11APR2015		Y
		Eye disorders	Blepharitis	23AUG2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1947		Y
		Surgical and medical procedures	Hysterectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	12JUL2007		Y
	C4591001 1142 11421047	Hepatobiliary disorders	Fatty liver alcoholic	08NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	10JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				30JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	31JUL2007		Y
	C4591001 1142 11421048	Surgical and medical procedures	Haemorrhoid operation	01JAN1990	31DEC1990	N
			Hernia repair	01JAN2002	31DEC2002	N
	C4591001 1142 11421053	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
			Ventricular extrasystoles	01JAN2005		Y
		Congenital, familial and genetic disorders	Gilbert's syndrome	01JAN1971		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Investigations	Biopsy colon	17FEB2020	17FEB2020	N
			Biopsy liver	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Rotator cuff repair	01JAN1975	31DEC1975	N
		Vascular disorders	Essential hypertension	30JAN2007		Y
	C4591001 1142 11421054	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	18JUL2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987		Y
	C4591001 1142 11421055	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1142 11421057	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
	C4591001 1142 11421061	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
				01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421064	Surgical and medical procedures	Hernia repair	01JAN2018	31DEC2018	N
			Ligament operation	01JAN1989	31DEC1989	N
			Limb operation	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1142 11421065	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Surgical and medical procedures	Hip arthroplasty	01APR2004	30APR2004	N
				01DEC2004	31DEC2004	N
				01FEB1994	28FEB1994	N
				01NOV1993	31DEC2004	N
				01OCT2004	31OCT2004	N
			Knee arthroplasty	06MAY2019		Y
			Shoulder arthroplasty	01JAN2018	31DEC2018	N
			Toe operation	01JAN2018	31DEC2018	N
	C4591001 1142 11421069	Skin and subcutaneous tissue disorders	Pruritus allergic	01JUL2005		Y
		Surgical and medical procedures	Bladder operation	01JAN2000	30JUN2012	N
			Bunion operation	01JAN1989	31DEC1989	N
			Haemorrhoid operation	01JAN2005	31DEC2005	N
			Lipoma excision	18JUN2014	30JUN2014	N
	C4591001 1142 11421073	Social circumstances	Tobacco user	01JAN1975	31DEC2006	N
	C4591001 1142 11421077	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1986		Y
	C4591001 1142 11421083	Surgical and medical procedures	Ankle operation	01JAN1982	31DEC1982	N
			Fracture treatment	01JAN2005	31DEC2005	N
			Knee operation	01JAN1977	31DEC1977	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb reattachment surgery	01MAR2020	31MAR2020	N
			Nasal septal operation	01JAN1985	31DEC1985	N
	C4591001 1142 11421091	Cardiac disorders	Supraventricular tachycardia	25JUN2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	25JUN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1947	31DEC1947	N
			Eye operation	01JAN1949	31DEC1949	N
				01JAN1990	31DEC1990	N
			Prostatectomy	01JAN2011	31DEC2011	N
	C4591001 1142 11421093	Immune system disorders	Drug hypersensitivity	20NOV2014		Y
				28APR2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2010		Y
		Surgical and medical procedures	Gastric bypass	16JUL2014	16JUL2014	N
	C4591001 1142 11421097	Cardiac disorders	Acute myocardial infarction	28DEC2017	28DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage III	01JAN2018	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JUL2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01DEC2018	31DEC2018	N
			Chemotherapy	01JUL2018	31OCT2018	N
			Lymphadenectomy	01DEC2018	31DEC2018	N
			Radiotherapy to breast	01FEB2018	30APR2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Essential hypertension	25MAR2009		Y
	C4591001 1142 11421102	Metabolism and nutrition disorders	Gout	01JAN2004		Y
	C4591001 1142 11421103	Cardiac disorders	Tachycardia	27JAN2020	15MAR2020	N
			Ventricular extrasystoles	10FEB2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	20AUG2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	29JUL2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	14MAR2019		Y
		Surgical and medical procedures	Cataract operation	15JUL2011	15JUL2011	N
				24APR2018	24APR2018	N
			Fracture treatment	31JAN2013	31JAN2013	N
			Knee arthroplasty	01JUL2013	31JUL2013	N
				01MAY2013	31MAY2013	N
			Retinopexy	01JAN2010	31DEC2010	N
			Spinal laminectomy	16SEP2019	16SEP2019	N
			Tenoplasty	14FEB2018	14FEB2018	N
			Vasectomy	01AUG1985	31AUG1985	N
		Vascular disorders	Essential hypertension	27JAN2020		Y
	C4591001 1142 11421104	General disorders and administration site conditions	Adverse drug reaction	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2020		Y
	C4591001 1142 11421105	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Injury, poisoning and procedural complications	Hand fracture	05MAY2019	18NOV2019	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	14DEC2016		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Dermatitis contact	01MAY2012		Y
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	05MAY2016	05MAY2016	N
				27JUL2017	27JUL2017	N
			Cholecystectomy	24MAY2012	24MAY2012	N
			Hysterosalpingo-oophorectomy	28MAY2012	28MAY2012	N
			Jaw operation	01JAN1980	31DEC1980	N
			Ovarian cystectomy	28MAY2012	28MAY2012	N
			Wound closure	29JUN2012	29JUN2012	N
	C4591001 1142 11421108	Surgical and medical procedures	Inguinal hernia repair	01JAN1964	31DEC1964	N
	C4591001 1142 11421109	Surgical and medical procedures	Inguinal hernia repair	01JAN2012	31DEC2012	N
	C4591001 1142 11421111	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1142 11421114	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2002	N
		Psychiatric disorders	Depression	11FEB2009		Y
		Surgical and medical procedures	Mastectomy	01JAN2002	31DEC2002	N
	C4591001 1142 11421116	Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1961	31DEC1961	N
			Tonsillectomy	01JAN1961	31DEC1961	N
			Varicose vein operation	01JAN1987	31DEC1987	N
			Wisdom teeth removal	01JAN1975	31DEC1975	N
	C4591001 1142 11421117	Investigations	Biopsy prostate	24JUL2020	24JUL2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Strabismus correction	01DEC2017	01DEC2017	N
	C4591001 1142 11421120	Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN1957	31DEC1957	N
			Hernia repair	01JAN1954	31DEC1954	N
			Prostatic operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1142 11421121	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Social circumstances	Menopause	01JAN2009		Y
	C4591001 1142 11421122	Endocrine disorders	Hypothyroidism	20AUG2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	27DEC2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15JAN2015		Y
	C4591001 1142 11421125	Surgical and medical procedures	Hysterectomy	01JAN1992		Y
	C4591001 1142 11421127	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Surgical and medical procedures	Skull fracture treatment	01JAN1965	31DEC1965	N
	C4591001 1142 11421133	Cardiac disorders	Atrial fibrillation	01JAN2012	31JAN2016	N
			Atrial flutter	01JAN2016	30JUN2016	N
			Atrioventricular block first degree	01JAN2012	30JUN2016	N
			Ventricular extrasystoles	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Biopsy prostate	01MAY2011	31MAY2011	N
				01NOV2011	30NOV2011	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01DEC2015	31JAN2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Cardiac ablation	02MAR2012	02MAR2012	N
				19JAN2016	19JAN2016	N
				31MAY2016	31MAY2016	N
	C4591001 1142 11421134	Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Hysterectomy	01JAN1992		Y
	C4591001 1142 11421135	Hepatobiliary disorders	Hepatic steatosis	02SEP2014		Y
		Immune system disorders	Drug hypersensitivity	01OCT2015		Y
				18JUL2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Cholecystectomy	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1142 11421136	Investigations	Biopsy lung	22NOV2013	22NOV2013	N
		Surgical and medical procedures	Bone lesion excision	20MAY2008	20MAY2008	N
				28JUN2011	28JUN2011	N
			Cataract operation	03AUG2020	03AUG2020	N
				17AUG2020	17AUG2020	N
				30JAN2020	30JAN2020	N
			Foot operation	10JUN2020	10JUN2020	N
				11JUN2019	11JUN2019	N
			Photorefractive keratectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421137	Cardiac disorders	Atrial fibrillation	01AUG2017		Y
			Cardiac failure chronic	01AUG2017		Y
		Investigations	Cardiac murmur	(b) (6) 1958		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2017		Y
		Surgical and medical procedures	Hernia repair	01APR1959	30APR1959	N
				01JAN1968	31DEC1968	N
	C4591001 1142 11421140	Immune system disorders	Contrast media allergy	26OCT2017		Y
		Renal and urinary disorders	Renal mass	25JUL2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	18MAR2016		Y
	C4591001 1142 11421143	Immune system disorders	Drug hypersensitivity	23JUN2007		Y
		Surgical and medical procedures	Sigmoidectomy	23JUN2007	23JUN2007	N
	C4591001 1142 11421145	Immune system disorders	Drug hypersensitivity	26MAR2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	27APR2007		Y
		Surgical and medical procedures	Duodenectomy	01JAN2000	31DEC2000	N
	C4591001 1142 11421146	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01AUG2018	31AUG2018	N
			Uterine leiomyoma	01JAN2008	31MAY2010	N
		Social circumstances	Menopause	18DEC2014		Y
		Surgical and medical procedures	Breast conserving surgery	30AUG2018	30AUG2018	N
			Caesarean section	14FEB1988	14FEB1988	N
			Carpal tunnel decompression	01JUN2018		Y
					31DEC2018	N
			Endometrial ablation	01MAY2010	31MAY2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421151	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
	C4591001 1142 11421152	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2013	31MAR2013	N
		Surgical and medical procedures	Breast reconstruction	01OCT2014	31OCT2014	N
			Hysterectomy	01OCT2012	31OCT2012	N
			Mastectomy	01MAR2013	31MAR2013	N
	C4591001 1142 11421154	Metabolism and nutrition disorders	Hypercholesterolaemia	17JAN2018		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1142 11421156	Surgical and medical procedures	Skin neoplasm excision	01APR2017	30APR2017	N
				01NOV2016	30NOV2016	N
			Vasectomy	01SEP1996	30SEP1996	N
	C4591001 1142 11421159	Nervous system disorders	Transient ischaemic attack	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1142 11421160	Immune system disorders	Drug hypersensitivity	01JAN1951		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Gastrointestinal ulcer management	01JAN2010	31DEC2010	N
	C4591001 1142 11421162	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Coronary artery bypass	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1142 11421165	Musculoskeletal and connective tissue disorders	Osteoarthritis	16JAN2015		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	26NOV2019	08MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	13APR2018	31JAN2019	N
	C4591001 1142 11421167	Surgical and medical procedures	Cataract operation	01MAR2020	31MAR2020	N
			Tonsillectomy	01JAN1963	31DEC1963	N
	C4591001 1142 11421168	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01MAR2013	01APR2013	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01APR2013	01APR2013	N
			Knee arthroplasty	05NOV2019	05NOV2019	N
			Lacrimal duct procedure	01JAN2010	31DEC2010	N
	C4591001 1142 11421169	Surgical and medical procedures	Cholecystectomy	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Mammoplasty	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1142 11421171	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN1990		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1995	31DEC1995	N
				01JAN2001	31DEC2001	N
	C4591001 1142 11421172	Immune system disorders	Allergy to arthropod sting	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1985	31DEC1985	N
	C4591001 1142 11421174	Immune system disorders	Drug hypersensitivity	01JAN1999		Y
		Social circumstances	Menopause	24SEP2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1999	31DEC1999	N
				01JAN2001	31DEC2001	N
			Cardiac ablation	22DEC2010	22DEC2010	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1142 11421176	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Investigations	Colonoscopy	22JUN2020	22JUN2020	N
			Oesophagogastroduodenoscopy	22JUN2020	22JUN2020	N
		Surgical and medical procedures	Tenoplasty	01JAN2010	31DEC2010	N
	C4591001 1142 11421177	Infections and infestations	Pneumonia	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Cancer surgery	12APR2020	12APR2020	N
			Hip arthroplasty	01JAN2002	31DEC2002	N
			Hip surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1142 11421180	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1142 11421189	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Social circumstances	Menopause	01SEP2020		Y
	C4591001 1142 11421191	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Food allergy	01JAN1989		Y
		Investigations	Biopsy breast	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Caesarean section	23MAR1999	23MAR1999	N
				25JAN1997	25JAN1997	N
			Cholecystectomy	01JAN1989	31DEC1989	N
			Hysterectomy	02OCT2005	03OCT2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Strabismus correction	01JAN1985	31DEC1985	N
				01JAN2000	31DEC2000	N
		Vascular disorders	Essential hypertension	02APR2013	04SEP2013	N
	C4591001 1142 11421192	Investigations	Biopsy breast	23MAY2019	23MAY2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	12MAY2017		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Spinal operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	02JUN2010		Y
	C4591001 1142 11421193	Gastrointestinal disorders	Hiatus hernia	01OCT2016	31OCT2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1142 11421195	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Splenectomy	01JUL1988	31JUL1988	N
	C4591001 1142 11421201	Metabolism and nutrition disorders	Gout	01JAN2007		Y
			Hyperlipidaemia	24MAR2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1962		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1142 11421207	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2020		Y
		Surgical and medical procedures	Gastric bypass	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Urinary bladder suspension	01JAN2010	31DEC2010	N
	C4591001 1142 11421208	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01FEB2020	29FEB2020	N
			Squamous cell carcinoma	01MAY2020	04SEP2020	N
		Surgical and medical procedures	Arterial stent insertion	27APR2017		Y
			Coronary artery bypass	27APR2017	27APR2017	N
	C4591001 1142 11421209	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Knee operation	01JAN1985	31DEC1985	N
			Shoulder arthroplasty	01JAN2015	31DEC2015	N
			Shoulder operation	01JAN2001	31DEC2001	N
			Tonsillectomy	01JAN1964	31DEC1964	N
			Uterine dilation and curettage	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1142 11421210	Metabolism and nutrition disorders	Hyperlipidaemia	14NOV2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	14NOV2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1142 11421211	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1142 11421215	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN1977		Y
		Surgical and medical procedures	Caesarean section	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2005	31DEC2005	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1142 11421217	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1988	31DEC1988	N
				01JAN1989	31DEC1989	N
				01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
			Hip arthroplasty	01JAN2009	31DEC2009	N
				01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Spinal nerve stimulator implantation	01OCT2010	31OCT2010	N
			Toe operation	01JAN2018	31DEC2018	N
				04AUG2020	04AUG2020	N
			Urinary bladder suspension	01JAN2006	31DEC2006	N
	C4591001 1142 11421221	Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2015		Y
		Surgical and medical procedures	Wrist surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1142 11421224	Surgical and medical procedures	Foot operation	01JAN1995	31DEC1995	N
			Fracture treatment	01JAN1987	31DEC1987	N
	C4591001 1142 11421225	Immune system disorders	Drug hypersensitivity	01JAN1950		Y
				01JAN2017		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2017	31DEC2017	N
			Haemorrhoid operation	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mitral valve replacement	01JAN2017	31DEC2017	N
	C4591001 1142 11421226	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Pharyngeal operation	01JAN2015	31DEC2015	N
	C4591001 1142 11421227	Cardiac disorders	Myocardial infarction	01JAN1999	31DEC1999	N
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
				01JAN1976		Y
				01JAN1990		Y
				01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1998	31DEC1998	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1998	31DEC1998	N
			Coronary arterial stent insertion	01JAN2000	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1142 11421228	Infections and infestations	Herpes simplex	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Mammoplasty	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1142 11421232	Cardiac disorders	Atrial fibrillation	01JAN2004		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1980	31DEC1980	N
	C4591001 1142 11421236	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2005		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421238	Immune system disorders	Allergy to arthropod sting	01SEP1994		Y
			Drug hypersensitivity	01JAN1952		Y
				01JAN1975		Y
				01JAN1980		Y
		Infections and infestations	Mycobacterium avium complex infection	01JAN1992	31DEC1992	N
			Pneumonia	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01JAN1994		Y
	C4591001 1142 11421240	Cardiac disorders	Cardiac failure congestive	20MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	28OCT2016		Y
			Obesity	22DEC2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	25NOV2015		Y
			Sleep apnoea syndrome	22DEC2014		Y
		Vascular disorders	Hypertension	23DEC2015		Y
	C4591001 1142 11421243	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1142 11421247	Cardiac disorders	Atrial fibrillation	08APR2015		Y
			Atrioventricular block complete	01JAN1996		Y
			Sinus node dysfunction	27JUN2012		Y
			Supraventricular tachycardia	11MAY2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Breast reconstruction	01JAN1992	31DEC1992	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cardiac pacemaker insertion	01JAN1996		Y
			Mastectomy	01JAN1992	31DEC1992	N
	C4591001 1142 11421249	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1979		Y
		Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
			Meniscus operation	01JAN2001	31DEC2001	N
			Nerve graft	01JUL1994	31JUL1994	N
			Peripheral nerve operation	01JUL1994	31JUL1994	N
		Vascular disorders	Essential hypertension	01JAN1982		Y
	C4591001 1142 11421252	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Cataract operation	01JAN2002	31DEC2002	N
				01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2004	31DEC2004	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Essential hypertension	01JAN2000		Y
	C4591001 1142 11421254	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1142 11421259	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
	C4591001 1142 11421263	Endocrine disorders	Growth hormone deficiency	15JUN2016		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1988	31DEC1988	N
				01JAN1998	31DEC1998	N
			Fracture treatment	01JAN1980	31DEC1980	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
	C4591001 1142 11421266	Gastrointestinal disorders	Nausea	01JAN1988		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast reconstruction	01JAN2006	31DEC2006	N
			Female sterilisation	01JAN1993	31DEC1993	N
			Intervertebral disc operation	01JAN2001	31DEC2001	N
			Jaw operation	01JAN1988	31DEC1988	N
			Mastectomy	01JAN2006	31DEC2006	N
	C4591001 1142 11421267	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1142 11421268	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1142 11421272	Gastrointestinal disorders	Colitis ulcerative	01JAN1985	31DEC1986	N
		Surgical and medical procedures	Colectomy	01JAN1986	31DEC1986	N
			Knee operation	01JUN2019	30JUN2019	N
			Renal stone removal	01JAN2014	31DEC2014	N
	C4591001 1142 11421273	Immune system disorders	Food allergy	01AUG1999		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN1998	31DEC1998	N
	C4591001 1142 11421278	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1142 11421285	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Surgical and medical procedures	Ankle operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1142 11421288	General disorders and administration site conditions	Generalised oedema	11SEP2006		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	19OCT2005		Y
			Type 2 diabetes mellitus	08SEP2017		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2005		Y
		Vascular disorders	Essential hypertension	29AUG2016		Y
	C4591001 1142 11421294	Endocrine disorders	Hypothyroidism	01FEB2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Seasonal allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	11MAY2020		Y
		Social circumstances	Menopause	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Caesarean section	25NOV1991	25NOV1991	N
			Lipoma excision	01JAN1994	31DEC1994	N
		Vascular disorders	Essential hypertension	01JAN1993		Y
	C4591001 1142 11421296	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
				01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rubber sensitivity	31JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	31JAN2017		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2017	31DEC2017	N
			Caesarean section	09SEP2011	09SEP2011	N
			Cholecystectomy	01JAN1999	31DEC1999	N
			Oophorectomy	01JAN2000	31DEC2000	N
			Salmonellosis	01JAN2020	31JAN2020	N
	C4591001 1142 11421297†	Infections and infestations				
		Investigations	HIV test positive	01JAN1992		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1980	31DEC1980	N
	C4591001 1142 11421301	Surgical and medical procedures	Foot operation	01JAN2020	31JAN2020	N
			Hysterectomy	01JAN1982	31DEC1982	N
			Spinal operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1142 11421302	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Bone lesion excision	01JAN1995	31DEC1995	N
			Caesarean section	03JUN1969	03JUN1969	N
				16OCT1973	16OCT1973	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Limb operation	01JUN2020	30JUN2020	N
			Lipoma excision	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1142 11421304	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Surgical and medical procedures	Lithotripsy	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1951	31DEC1951	N
	C4591001 1142 11421305	Injury, poisoning and procedural complications	Asbestosis	01JAN1985		Y
		Surgical and medical procedures	Skin neoplasm excision	01SEP2020	30SEP2020	N
	C4591001 1142 11421309	Cardiac disorders	Bundle branch block	01JAN2016		Y
			Tachycardia paroxysmal	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Renal and urinary disorders	Bladder prolapse	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1142 11421311†	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	HIV test positive	01JAN1985		Y
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1142 11421312	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
	C4591001 1142 11421320	Infections and infestations	Hepatitis C	01JAN2006	31DEC2007	N
			Sinusitis bacterial	18NOV2020	23NOV2020	N
		Injury, poisoning and procedural complications	Femur fracture	17JUN2020	17JUN2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Osteopenia	01JAN2018		Y
			Osteoporosis	01JAN2004	31DEC2018	N
		Nervous system disorders	Migraine	01JAN1962		Y
		Psychiatric disorders	Anorexia nervosa	01JAN1972		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2006	31DEC2006	N
				04JUN2004	30JUN2004	N
			Hysterectomy	14FEB2012	14FEB2012	N
			Open reduction of fracture	23JUN2020	23JUN2020	N
			Vaginal prolapse repair	14FEB2012	14FEB2012	N
	C4591001 1145 11451005	Ear and labyrinth disorders	Meniere's disease	30JUN1994		Y
		Immune system disorders	Allergy to animal	30JUN1973		Y
			Seasonal allergy	30JUN1973		Y
		Investigations	Blood cholesterol increased	30JUN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	30JUN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	30JUN1973		Y
	C4591001 1145 11451006	Cardiac disorders	Atrial fibrillation	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Idiopathic pulmonary fibrosis	01MAR2017		Y
	C4591001 1145 11451008	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Vascular disorders	Thrombophlebitis	01JAN2002		Y
	C4591001 1145 11451009	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Food allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
	C4591001 1145 11451012	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1988		Y
		Immune system disorders	Allergy to plants	01JAN1991		Y
			Drug hypersensitivity	01JAN1991		Y
			Food allergy	01JAN1991		Y
			Seasonal allergy	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Nervous system disorders	Seizure	01AUG1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1991		Y
	C4591001 1145 11451014	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Rubber sensitivity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1948		Y
	C4591001 1145 11451016	Immune system disorders	Allergy to arthropod sting	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastric cancer	01JUN2012	31DEC2012	N
		Nervous system disorders	Migraine	01JAN1983		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1957	31DEC1957	N
	C4591001 1145 11451023	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
				01JAN2014		Y
			Seasonal allergy	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Myalgia	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1982	31DEC1982	N
				01JAN1987	31DEC1987	N
		Surgical and medical procedures	Blood pressure management	01JAN2017		Y
			Bunion operation	01JAN2015	31DEC2015	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1145 11451024	Blood and lymphatic system disorders	Anaemia	01APR2006	30APR2006	N
		General disorders and administration site conditions	Precancerous condition	01JAN1983	31DEC1983	N
		Immune system disorders	Hypersensitivity	01JAN2016		Y
			Seasonal allergy	01AUG2020		Y
		Infections and infestations	Mycobacterium avium complex infection	01MAR2019	30SEP2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1971	31DEC1971	N
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Bronchoscopy abnormal	01MAR2018	31MAR2018	N
			Colposcopy	01JAN1983	31DEC1983	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JUN2018	30JUN2018	N
			Knee operation	01JAN1966	31DEC2010	N
			Shoulder operation	01JAN1971	31DEC1971	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
			Vitamin supplementation	01JAN2015		Y
	C4591001 1145 11451027	Cardiac disorders	Ventricular extrasystoles	01JAN2017		Y
		Eye disorders	Macular degeneration	01JAN2019		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2006	31DEC2006	N
			Road traffic accident	01JAN2006	31DEC2006	N
		Investigations	Cardiac murmur	01JAN1957		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
				05AUG2020		Y
		Vascular disorders	Deep vein thrombosis	01JAN2006	31DEC2006	N
			Hypertension	01APR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451028	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2017		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
	C4591001 1145 11451029	Ear and labyrinth disorders	Hypoacusis	01JAN2017		Y
		Infections and infestations	Staphylococcal infection	01JAN1975	31DEC1975	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Social circumstances	Hearing aid user	01JAN2017		Y
		Surgical and medical procedures	Ligament operation	01JAN2016	31DEC2016	N
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1145 11451032	Endocrine disorders	Thyroid disorder	01JAN2008	31DEC2010	N
		Immune system disorders	Allergy to arthropod sting	01JAN1998		Y
			Food allergy	(b) (6) 1948		Y
		Injury, poisoning and procedural complications	Postoperative thrombosis	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Nervous system disorders	Resting tremor	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JAN2018		Y
			Sinus disorder	(b) (6) 1948		Y
		Surgical and medical procedures	Hernia repair	01MAY2014	31MAY2014	N
			Rehabilitation therapy	01JAN2014	31DEC2014	N
	C4591001 1145 11451038	Cardiac disorders	Atrial fibrillation	01JAN1999		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1968		Y
		Immune system disorders	Rubber sensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1145 11451040	Cardiac disorders	Atrioventricular block	01JAN1990	31MAY1994	N
		Gastrointestinal disorders	Gastric ulcer	01JAN1994	31DEC1994	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Gout	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01NOV2018		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01DEC2018	31DEC2018	N
			Coronary artery bypass	01MAY1994	31MAY1994	N
			Skin neoplasm excision	01OCT2003	31OCT2003	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1145 11451041	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1959		Y
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN1987	31DEC1987	N
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Hospitalisation	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1145 11451046	Injury, poisoning and procedural complications	Procedural intestinal perforation	01JAN2001	31DEC2001	N
		Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN2004	31DEC2005	N
		Psychiatric disorders	Depression	01JAN2001		Y
		Surgical and medical procedures	Sigmoidectomy	01JAN2001	31DEC2001	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N
	C4591001 1145 11451052	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990	31DEC2016	N
		Immune system disorders	Allergy to animal	01JAN1987		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N
			Spinal laminectomy	01JAN2014	31DEC2014	N
			Synovial cyst removal	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1145 11451055	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Exfoliation glaucoma	01JAN2005		Y
		Surgical and medical procedures	Eyelid operation	01JAN1980	31DEC1980	N
			Lacrimal duct procedure	01JAN2000	31DEC2000	N
			Liposuction	01JAN2000	31DEC2000	N
			Trabeculectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451056	Cardiac disorders	Palpitations	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1973		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
	C4591001 1145 11451058	Immune system disorders	Rubber sensitivity	01JAN1984		Y
			Seasonal allergy	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1960		Y
			Hand dermatitis	01JAN1994		Y
		Surgical and medical procedures	Hernia repair	01JAN2010	31DEC2010	N
	C4591001 1145 11451061	Immune system disorders	Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Oral herpes	01JAN1968		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1145 11451062	Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1145 11451065	Cardiac disorders	Myocardial infarction	01JAN1994	31DEC1994	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN1994		Y
			Cardiac murmur	01JAN2015		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC1980	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Heart valve replacement	01JUN2015	30JUN2015	N
			Stent placement	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1145 11451066	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1951		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2000	31DEC2001	N
		Nervous system disorders	Migraine with aura	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN1990	31DEC1995	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Peripheral nerve operation	01JAN2017	31DEC2017	N
	C4591001 1145 11451069	Gastrointestinal disorders	Crohn's disease	01JAN1992		Y
			Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Chlamydial infection	01JAN1967	31DEC1967	N
			Gonorrhoea	01JAN1967	31DEC1967	N
		Investigations	Cardiac murmur	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1145 11451070	Eye disorders	Cataract	01JAN2005	31DEC2005	N
	C4591001 1145 11451072	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1972		Y
			Rotator cuff syndrome	01SEP2018	30SEP2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Renal and urinary disorders	Ureteral disorder	01NOV2016	30NOV2016	N
		Surgical and medical procedures	Knee operation	01JAN1972	31DEC1972	N
				01JAN1985	31DEC1985	N
			Renal stone removal	01NOV2016	30NOV2016	N
			Vasectomy	01JAN1999	31DEC1999	N
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1145 11451073	Injury, poisoning and procedural complications	Foot fracture	01OCT2015		Y
					31DEC2017	N
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Nervous system disorders	Paraesthesia	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
				01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cataract operation	01JAN2018		Y
			Spinal fusion surgery	01JAN1990	31DEC1990	N
				01JAN1995	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1145 11451076	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Surgical and medical procedures	Herpes zoster immunisation	13FEB2020	13FEB2020	N
				25JUL2020	25JUL2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1145 11451078	Injury, poisoning and procedural complications	Road traffic accident	01JAN1981	31DEC1981	N
	C4591001 1145 11451083	Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN1990	31DEC2010	N
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2010		Y
			Eczema	01JAN2010		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1145 11451084	Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Wisdom teeth removal	01JAN1980	31DEC1980	N
	C4591001 1145 11451089	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN2002	31DEC2007	N
			Lung neoplasm malignant	01JAN2017	31DEC2019	N
		Surgical and medical procedures	Antiviral prophylaxis	01MAY2020	31MAY2020	N
			Bone cyst excision	01JAN1972	31DEC1972	N
			Hernia repair	01JAN1960	31DEC1960	N
			Knee operation	01JAN1985	31DEC1986	N
			Tonsillectomy	01JAN1950	31DEC1950	N
	C4591001 1145 11451095	Endocrine disorders	Hypothyroidism	01JAN2015		Y
			Thyroid mass	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN2010		Y
	C4591001 1145 11451096	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Glaucoma	01JAN2017	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2000		Y
		Infections and infestations	Kidney infection	01JAN2000	31DEC2000	N
			Urinary tract infection	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2007		Y
			Electrocardiogram ST segment abnormal	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Surgical and medical procedures	Ankle operation	01DEC2005	31DEC2005	N
			Blepharoplasty	01OCT2019	31OCT2019	N
			Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN1980	31DEC1980	N
			Coronary arterial stent insertion	01JUN2017	30JUN2017	N
			Lipoma excision	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1145 11451098	Cardiac disorders	Myocardial infarction	01DEC2013	31DEC2013	N
		Gastrointestinal disorders	Rectal haemorrhage	28JUL2020	31JUL2020	N
		Hepatobiliary disorders	Drug-induced liver injury	01JAN2012	31DEC2012	N
		Immune system disorders	Sarcoidosis	01JAN2017	31DEC2018	N
		Infections and infestations	Diverticulitis	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUN2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hernia repair	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
			Knee operation	01JAN2012	31DEC2012	N
			Limb operation	01JAN2012	31DEC2012	N
			Prostatectomy	01JAN2002	31DEC2002	N
			Ptosis repair	01JAN2014	31DEC2014	N
			Retinal operation	01JAN2019	31DEC2019	N
			Rhinoplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1145 11451099	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JUL2017	31JUL2017	N
			Meniscus operation	01JAN2002	31DEC2002	N
	C4591001 1145 11451100	Hepatobiliary disorders	Gallbladder disorder	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
		Investigations	Cardiac murmur	01JAN1974		Y
	C4591001 1145 11451102	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1145 11451109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2001		Y
		Immune system disorders	Seasonal allergy	01JAN1996		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Allergic respiratory symptom	01JAN2001		Y
		Surgical and medical procedures	Fracture treatment	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1145 11451111	Gastrointestinal disorders	Abdominal discomfort	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2000		Y
	C4591001 1145 11451114	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2009	31DEC2015	N
		Surgical and medical procedures	Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1146 11461001	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	29JUL2013	N
		Surgical and medical procedures	Knee arthroplasty	29JUL2013	29JUL2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461005	Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2020	17SEP2020	N
		Renal and urinary disorders	Urinary incontinence	01DEC2010		Y
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1146 11461012	Investigations	Blood cholesterol increased	01JUL2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2019		Y
		Vascular disorders	Hypertension	01JUL2019		Y
	C4591001 1146 11461015	Gastrointestinal disorders	Gastroesophageal reflux disease	23JUN1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	23JUN1997		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Spinal stenosis	15JUN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	06APR2020	29JUN2020	N
		Nervous system disorders	Cerebrovascular accident	15AUG2016		Y
			Post herpetic neuralgia	19FEB2020		Y
		Vascular disorders	Hypertension	03OCT1988		Y
	C4591001 1146 11461016	Injury, poisoning and procedural complications	Joint injury	01JAN2013		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1146 11461017	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Psychiatric disorders	Insomnia	01AUG2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1146 11461018	Eye disorders	Dry eye	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1146 11461019	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1146 11461022	Cardiac disorders	Coronary artery disease	01JAN1995		Y
		Ear and labyrinth disorders	Vertigo	01JAN1995		Y
		Endocrine disorders	Thyroid mass	01JAN2016	31DEC2016	N
		Eye disorders	Macular degeneration	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia	01JAN1996	31DEC1996	N
		Investigations	Blood cholesterol increased	01JAN1995		Y
			Catheterisation cardiac	01JAN1995	31DEC1995	N
				01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
			Vitamin D deficiency	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
			Malignant melanoma	01JAN1975	31DEC1975	N
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1993	31DEC1993	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1950		Y
		Surgical and medical procedures	Appendectomy	01JAN1950	31DEC1950	N
			Cataract operation	01JAN2004	31DEC2004	N
			Transurethral prostatectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1146 11461024	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Iodine allergy	01JAN1995		Y
			Seasonal allergy	01AUG1980	31DEC2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2017		Y
			Alopecia	01JUL2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Mammoplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hot flush	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461025	Endocrine disorders	Hypothyroidism	01JAN1995		Y
	C4591001 1146 11461026	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1146 11461027	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1146 11461035	Injury, poisoning and procedural complications	Back injury	01OCT2019		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461036	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	13JAN2020		Y
		Vascular disorders	Hypertension	18MAY2015		Y
	C4591001 1146 11461037	Blood and lymphatic system disorders	Anaemia	01APR2018	23SEP2019	N
		Cardiac disorders	Arteriosclerosis coronary artery	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUN2018		Y
			Prostate cancer	06JAN1998	06JAN2009	N
			Squamous cell carcinoma	01JUN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2013	31AUG2013	N
			Prostatectomy	01JAN2009	31DEC2009	N
			Toe operation	10MAY2010	14JUN2010	N
	C4591001 1146 11461039	Investigations	Blood cholesterol increased	01JAN2005		Y
			Blood testosterone decreased	01JAN2010		Y
			Cardiac murmur	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2015	31JAN2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31JAN2015	N
		Surgical and medical procedures	Transurethral bladder resection	01JAN2015	31JAN2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461040	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
			Atrial flutter	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461042	Nervous system disorders	Dural arteriovenous fistula	01JAN2020	31MAR2020	N
			Tremor	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Surgical and medical procedures	Therapeutic embolisation	06MAR2020	06MAR2020	N
	C4591001 1146 11461045	Cardiac disorders	Mitral valve incompetence	16JUL2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Infections and infestations	Urinary tract infection	03JAN2019	12JAN2019	N
				16JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2009	31DEC2009	N
		Renal and urinary disorders	Trigonitis	01JAN2011		Y
			Ureteric stenosis	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Micrographic skin surgery	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1146 11461051	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
	C4591001 1146 11461057	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Mitral valve repair	14FEB2005	14FEB2005	N
	C4591001 1146 11461060	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
	C4591001 1146 11461062	Metabolism and nutrition disorders	Diabetes mellitus	01JAN1994		Y
	C4591001 1146 11461065	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Surgical and medical procedures	Coronary artery bypass	06JUN2016	06JUN2016	N
			Inguinal hernia repair	16JUN2019	16JUN2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1146 11461066	Cardiac disorders	Coronary artery occlusion	01JAN2016	31DEC2016	N
		Eye disorders	Cataract	01JAN2020	31DEC2020	N
		Gastrointestinal disorders	Dyspepsia	01JAN2020		Y
		Investigations	Blood cholesterol increased	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Cataract operation	01JAN2020	31DEC2020	N
			Coronary arterial stent insertion	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461067	Eye disorders	Glaucoma	01JUL2020		Y
	C4591001 1146 11461068	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1986		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1973		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1146 11461072	Skin and subcutaneous tissue disorders	Hair growth abnormal	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1146 11461073	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Stasis dermatitis	01FEB2020		Y
	C4591001 1146 11461074	Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461079	Investigations	Blood testosterone decreased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Thyroidectomy	01JAN1996	31DEC1996	N
	C4591001 1146 11461087	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
	C4591001 1146 11461088	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
	C4591001 1146 11461089	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1987		Y
			Metabolic syndrome	01JAN2018		Y
			Obesity	01JAN2018		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Coronary artery bypass	30AUG2017	30AUG2017	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1146 11461095	Endocrine disorders	Hypothyroidism	01JAN2014		Y
	C4591001 1146 11461101	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Social circumstances	Menopause	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461106	Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2000		Y
			Type 1 diabetes mellitus	01MAR2007		Y
	C4591001 1146 11461107	Immune system disorders	Seasonal allergy	01MAR2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01FEB1996		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01FEB1970		Y
		Vascular disorders	Hypertension	01FEB2010		Y
	C4591001 1146 11461109	Cardiac disorders	Coronary artery disease	01JAN2018		Y
			Coronary artery occlusion	01NOV2017	30NOV2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01NOV2017	30NOV2017	N
			Toe amputation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Peripheral vascular disorder	01JAN2015		Y
	C4591001 1146 11461114	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1146 11461120	Investigations	Blood cholesterol increased	28FEB2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cerebrovascular accident	28FEB2017	01JUN2017	N
		Vascular disorders	Hypertension	28FEB2017		Y
	C4591001 1146 11461127	Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2015		Y
		Surgical and medical procedures	Ligament operation	01JUL1996	31DEC1996	N
			Meniscus operation	01AUG2010	31AUG2010	N
	C4591001 1146 11461132	Endocrine disorders	Hypothyroidism	01JUL2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01AUG2000		Y
		Social circumstances	Menopause	01AUG2011		Y
	C4591001 1146 11461135	Vascular disorders	Hypertension	01JAN1968		Y
	C4591001 1146 11461136	Investigations	Blood cholesterol increased	01JUN2005		Y
		Nervous system disorders	Migraine	01SEP1974		Y
		Psychiatric disorders	Anxiety	01SEP2014		Y
	C4591001 1146 11461137	Social circumstances	Menopause	01MAY2019		Y
	C4591001 1146 11461138	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1146 11461143	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Inguinal hernia	01JAN2010	29JUL2020	N
		Investigations	Blood cholesterol increased	01JAN1984		Y
		Metabolism and nutrition disorders	Gout	01JAN1996		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	01JAN2015	31AUG2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Surgical and medical procedures	Inguinal hernia repair	29JUL2020	29JUL2020	N
			Stem cell transplant	01AUG2016	31AUG2016	N
			Vasectomy	01JAN1979	31DEC1979	N
	C4591001 1146 11461148	Eye disorders	Dry eye	01JUN2017		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01APR2020		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01AUG2005		Y
		Surgical and medical procedures	Infection prophylaxis	01JUL2020		Y
	C4591001 1146 11461149	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1146 11461151	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Metabolic disorder prophylaxis	01JAN2010		Y
	C4591001 1146 11461152	Cardiac disorders	Bradycardia	01JUL2010	13JUL2010	N
			Myocardial infarction	10JUL2010	13JUL2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01DEC2017	28DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Cough	01DEC2019		Y
		Vascular disorders	Intermittent claudication	01JUN2005	31JUL2019	N
	C4591001 1146 11461153	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Attention deficit hyperactivity disorder	01JAN1970		Y
			Depression	01JAN1970		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N
			Shoulder arthroplasty	01JAN2013	31DEC2013	N
				01JAN2018	31DEC2018	N
	C4591001 1146 11461154	Metabolism and nutrition disorders	Gout	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461156	Infections and infestations	Osteomyelitis	01AUG1972	31AUG1978	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2017		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1146 11461161	Blood and lymphatic system disorders	Thymic cyst	01JUL2019	19JUL2019	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thymus	01JUL2019	31JUL2019	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN1978	31DEC1978	N
		Surgical and medical procedures	Thymectomy	01JUL2019	19JUL2019	N
		Vascular disorders	Deep vein thrombosis	15DEC2018	31DEC2018	N
			Thrombosis	01JAN1972	31DEC1972	N
	C4591001 1146 11461162	Investigations	Blood cholesterol increased	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01DEC2005	31DEC2005	N
	C4591001 1146 11461164	Vascular disorders	Hypertension	01JAN2010		Y
		Cardiac disorders	Coronary artery disease	01FEB2003		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01FEB2010	28FEB2010	N
			Coronary artery bypass	01JUL2003	31JUL2003	N
	C4591001 1146 11461165	Vascular disorders	Hypertension	01FEB2003		Y
		Cardiac disorders	Atrial fibrillation	01JAN2015		Y
			Coronary artery occlusion	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1965	31DEC1965	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1146 11461169	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1982		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2007		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
	C4591001 1146 11461174	Congenital, familial and genetic disorders	Factor V Leiden mutation	01MAR2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Insomnia	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01MAR2019	31MAR2019	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1146 11461175	Investigations	Blood cholesterol increased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1146 11461180	Cardiac disorders	Atrial fibrillation	01MAR2020		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Renal and urinary disorders	Diabetic nephropathy	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1146 11461181	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461182	Investigations	Blood cholesterol increased	01MAY2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01MAY2005		Y
	C4591001 1146 11461188	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Seasonal allergy	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2007	31DEC2007	N
		Social circumstances	Menopause	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461189	Investigations	Blood cholesterol increased	01JAN2000		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1146 11461191	Cardiac disorders	Arrhythmia	01FEB2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
			Sleep apnoea syndrome	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1146 11461194	Musculoskeletal and connective tissue disorders	Neck pain	01NOV2018		Y
			Pain in extremity	01JAN2018		Y
	C4591001 1146 11461203	Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1146 11461208	Immune system disorders	Seasonal allergy	01SEP2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAY2016	30AUG2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast conserving surgery	01JUN2016	31AUG2016	N
			Radiotherapy to breast	02AUG2016	30AUG2016	N
	C4591001 1146 11461209	Cardiac disorders	Cardiomyopathy	01JAN2009		Y
			Coronary artery disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
			Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	29MAY2020		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2009		Y
	C4591001 1146 11461214	Injury, poisoning and procedural complications	Hip fracture	01JUN2019	30JUN2019	N
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1146 11461215	Investigations	Blood cholesterol increased	01JAN2009		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1146 11461222	Cardiac disorders	Supraventricular tachycardia	01JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01SEP1988	26DEC2000	N
		Surgical and medical procedures	Hysterectomy	26DEC2000	26DEC2000	N
		Vascular disorders	Hypertension	01APR2000		Y
	C4591001 1146 11461223	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1146 11461224	Investigations	Blood cholesterol increased	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2014		Y
	C4591001 1146 11461226	Vascular disorders	Hypertension	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colorectal cancer	01JAN2008	31DEC2013	N
			Prostate cancer	01JAN2007	31DEC2007	N
		Psychiatric disorders	Depression	01JAN2008		Y
	C4591001 1146 11461228	Vascular disorders	Hypertension	01JAN2010		Y
		Ear and labyrinth disorders	Meniere's disease	01MAR2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAY2012		Y
		Investigations	Blood cholesterol increased	29JUL2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2017		Y
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1146 11461230	Injury, poisoning and procedural complications	Meniscus injury	01APR2012	17OCT2018	N
		Surgical and medical procedures	Knee arthroplasty	17OCT2018	17OCT2018	N
	C4591001 1146 11461231	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1146 11461232	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1968		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461233	Cardiac disorders	Myocardial infarction	01JUL2005	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Neuropathy peripheral	01JUL2020		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JUL2005	31JUL2005	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1146 11461242	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461244	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Pancreatitis	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01MAY2015	31MAY2015	N
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Tendon rupture	01APR2015	30APR2015	N
		Musculoskeletal and connective tissue disorders	Costochondritis	01JUL2020		Y
		Nervous system disorders	Facial paralysis	01JAN2020	31JAN2020	N
			Migraine	01JAN2010		Y
			Multiple sclerosis	01AUG1992		Y
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Cholecystectomy	01MAY2015	31MAY2015	N
			Tenoplasty	01APR2015	30APR2015	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1146 11461247	Investigations	Blood cholesterol increased	01JUN2003		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1996		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary artery bypass	01JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1146 11461252	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1146 11461253	Investigations	Blood cholesterol increased	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2013	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1990		Y
			Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1146 11461254	Surgical and medical procedures	Radiotherapy to prostate	01JAN2014	31DEC2014	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
			Blood testosterone decreased	01JAN2002		Y
		Nervous system disorders	Ischaemic stroke	01JAN2000	31DEC2000	N
			Monoplegia	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
			Prostatomegaly	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1146 11461259	Investigations	Blood cholesterol increased	01JAN2010	29FEB2020	N
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1146 11461260	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01DEC2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1146 11461261	Nervous system disorders	Transient ischaemic attack	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1146 11461262	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1146 11461264	General disorders and administration site conditions	Pain	01JAN2016		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Depression	02SEP2020		Y
			Insomnia	01JAN2016		Y
			Post-traumatic stress disorder	01JAN2014		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
			Muscle operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1146 11461266	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1147 11471004	Cardiac disorders	Arteriosclerosis coronary artery	08JUL2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2005		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01MAR2016		Y
		Vascular disorders	Essential hypertension	01JUN2018		Y
	C4591001 1147 11471006	Endocrine disorders	Hypogonadism	01JUN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2006		Y
		Nervous system disorders	Tremor	01MAR2020		Y
	C4591001 1147 11471009	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Diverticulitis	01JAN1981		Y
			Rhinitis	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Scoliosis	01AUG2018		Y
		Psychiatric disorders	Depression	01JAN1986		Y
			Grief reaction	01AUG2018		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	08SEP2018		Y
			Menopausal symptoms	01MAY2020		Y
		Vascular disorders	Hypertension	01JAN2009		Y
		Cardiac disorders	Coronary artery disease	01DEC2019		Y
	C4591001 1147 11471012			01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JUN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1147 11471015	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2018		Y
	C4591001 1147 11471018	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000		Y
	C4591001 1147 11471020	Cardiac disorders	Palpitations	01OCT2010		Y
		Endocrine disorders	Sinus bradycardia	08APR2006		Y
			Hypogonadism	01JAN2010		Y
			Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2011		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
	C4591001 1147 11471023	Cardiac disorders	Bundle branch block right	01JAN2000		Y
			Sinus bradycardia	01JAN2000		Y
		Immune system disorders	Hypersensitivity	01JAN2000		Y
		Investigations	Electrocardiogram abnormal	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Vascular disorders	Essential hypertension	01JAN2017		Y
			Infarction	01JAN2000		Y
	C4591001 1147 11471024	Eye disorders	Cataract	01JAN2015		Y
				01JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2019		Y
			Type 2 diabetes mellitus	01DEC2017		Y
		Vascular disorders	Hypertension	01DEC2017		Y
	C4591001 1147 11471028	Congenital, familial and genetic disorders	Hydrocele	01JAN1989		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2018		Y
		Investigations	Cardiac murmur	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Foot deformity	08SEP2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	17MAR2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y
			Sleep apnoea syndrome	10NOV2017		Y
		Vascular disorders	Essential hypertension	01JAN1996		Y
	C4591001 1147 11471029	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1147 11471030	Endocrine disorders	Hypothyroidism	16JAN2017		Y
		Psychiatric disorders	Anxiety	30DEC2016		Y
			Depression	30DEC2016		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1147 11471034	Ear and labyrinth disorders	Ear pain	22DEC2016		Y
		Endocrine disorders	Hypothyroidism	19APR2016		Y
		Gastrointestinal disorders	Large intestine polyp	16JUN2016		Y
		Infections and infestations	Diverticulitis	16JUN2016		Y
			Ear infection	20APR2016		Y
			Folliculitis	25APR2016		Y
			Rhinitis	24APR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	26APR2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	26APR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rash	19APR2016		Y
			Seborrhoeic dermatitis	16APR2016		Y
	C4591001 1147 11471036	Metabolism and nutrition disorders	Hypercholesterolaemia	28NOV2012		Y
			Hyperlipidaemia	28NOV2012		Y
			Vitamin D deficiency	16OCT2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	16OCT2012		Y
		Psychiatric disorders	Anxiety disorder	28NOV2012		Y
			Insomnia	16OCT2012		Y
		Renal and urinary disorders	Renal artery stenosis	18DEC2019		Y
		Vascular disorders	Essential hypertension	25OCT2018		Y
	C4591001 1147 11471037	Endocrine disorders	Hypothyroidism	08MAY2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21FEB2014		Y
			Vitamin D deficiency	15JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05FEB2014		Y
		Vascular disorders	Hypertension	05FEB2013		Y
	C4591001 1147 11471040	Eye disorders	Astigmatism	01JAN1999		Y
			Cataract	04OCT2018		Y
			Corneal opacity	01MAR2013		Y
			Corneal scar	01MAR2013		Y
		Gastrointestinal disorders	Dysphagia	07JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Dysphonia	07JUL2020		Y
	C4591001 1147 11471042	Eye disorders	Cataract nuclear	09JUL2019		Y
			Macular fibrosis	06FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Large intestine polyp	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenoma benign	23JAN2013		Y
		Reproductive system and breast disorders	Erectile dysfunction	06FEB2018		Y
			Peyronie's disease	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	16JUL2019		Y
	C4591001 1147 11471043	Metabolism and nutrition disorders	Iron deficiency	01JAN2019		Y
		Reproductive system and breast disorders	Menopausal symptoms	19MAR2016		Y
		Social circumstances	Menopause	19MAR2016		Y
		Surgical and medical procedures	Hysterectomy	14FEB2020	14FEB2020	N
	C4591001 1147 11471044	Vascular disorders	Essential hypertension	22NOV2016		Y
		Cardiac disorders	Atrial fibrillation	10MAY2018		Y
			Coronary artery disease	18SEP2012		Y
		Investigations	Cardiac murmur	18MAY2018		Y
			Tuberculin test positive	01JAN2018		Y
	C4591001 1147 11471050	Cardiac disorders	Tachycardia	14JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Neck pain	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2010		Y
			Trigeminal neuralgia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	16JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1147 11471052	Surgical and medical procedures	Hysterectomy	01JAN2001		Y	
		Eye disorders	Cataract nuclear	06JAN2020		Y	
				Mydriasis	06JAN2002		Y
			Injury, poisoning and procedural complications	Injury	06JAN2020		Y
			Psychiatric disorders	Adjustment disorder	17SEP2019		Y
			Renal and urinary disorders	Nephrolithiasis	22NOV2013		Y
			Reproductive system and breast disorders	Erectile dysfunction	22NOV2013		Y
	C4591001 1147 11471055	Surgical and medical procedures	Cataract operation	06JAN2020		Y	
		Vascular disorders	Hypertension	22NOV2013		Y	
		Endocrine disorders	Thyroid mass	01JAN2010		Y	
			Infections and infestations	Herpes simplex	01JAN2000		Y
			Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2014		Y
				Hyperlipidaemia	01JAN2014		Y
			Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
	C4591001 1147 11471057	Social circumstances	Postmenopause	01JAN2011		Y	
		Vascular disorders	Hypertension	01JAN2010		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2013		Y	
		C4591001 1147 11471058	Gastrointestinal disorders	Diverticulum	22MAR2017		Y
				Gastrooesophageal reflux disease	01JAN2014		Y
				Large intestine polyp	01DEC2016		Y
				Metabolism and nutrition disorders	Glucose tolerance impaired	01APR2013	
			Gout	01JAN2013		Y	
			Hyperlipidaemia	01JUN2008		Y	



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01DEC2016		Y
		Psychiatric disorders	Anxiety	01JAN2013		Y
			Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2013		Y
		Surgical and medical procedures	Colectomy	01DEC2016		Y
		Vascular disorders	Venous thrombosis	01JUN2014		Y
	C4591001 1147 11471060	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2017		Y
	C4591001 1147 11471061	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2011		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2017		Y
	C4591001 1147 11471062	Infections and infestations	Herpes simplex	19OCT2018		Y
		Metabolism and nutrition disorders	Obesity	11MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2013		Y
	C4591001 1147 11471063	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		General disorders and administration site conditions	Pain	20FEB2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Back pain	01JAN2019		Y
			Intervertebral disc degeneration	31JUL2012		Y
			Intervertebral disc protrusion	01JAN2019		Y
			Spinal osteoarthritis	13FEB2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma of liver	01JAN2016		Y
	C4591001 1147 11471067	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2017		Y
		Metabolism and nutrition disorders	Gout	04JAN2013		Y
			Hyperlipidaemia	04JAN2013		Y
			Type 2 diabetes mellitus	01NOV2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	04JAN2013		Y
		Vascular disorders	Hypertension	04JAN2013		Y
	C4591001 1147 11471068	Reproductive system and breast disorders	Menopausal symptoms	01JAN2017		Y
	C4591001 1147 11471071	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Gastrointestinal disorders	Diarrhoea	30JAN2019		Y
			Nausea	30JAN2019		Y
			Periodontal disease	11FEB2016		Y
		Investigations	Total bile acids increased	01DEC2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	20SEP2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	30JAN2019		Y
		Nervous system disorders	Narcolepsy	14AUG2012		Y
			Restless legs syndrome	01JAN2000		Y
		Renal and urinary disorders	Bladder spasm	01APR2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urinary incontinence	01APR2003		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	14FEB2013		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2020		Y
			Psoriasis	21JAN2019		Y
	C4591001 1147 11471072	Gastrointestinal disorders	Gastrooesophageal reflux disease	05JUN2018		Y
		Hepatobiliary disorders	Cholelithiasis	12JUL2018	12JUL2018	N
		Infections and infestations	Cystitis	19AUG2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24MAY2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	08JAN2020		Y
		Psychiatric disorders	Generalised anxiety disorder	11SEP2018		Y
			Major depression	08JAN2020		Y
			Sleep disorder	23OCT2018		Y
		Vascular disorders	Hypertension	05JUN2018		Y
	C4591001 1147 11471074	Metabolism and nutrition disorders	Hyperlipidaemia	19DEC2011		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	19DEC2011		Y
		Vascular disorders	Hypertension	19DEC2011		Y
	C4591001 1147 11471075	Investigations	Low density lipoprotein increased	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2004		Y
			Insomnia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1147 11471076	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	08JUL2013	08JUL2013	N
				09SEP2013		Y
			Cholecystectomy	01JAN2013	31DEC2013	N
			Colectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1147 11471081	Endocrine disorders	Thyroid disorder	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Post-traumatic stress disorder	01JAN2006		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Varicose vein	01JAN2006		Y
	C4591001 1147 11471082	Gastrointestinal disorders	Barrett's oesophagus	01JAN2011		Y
			Gastroesophageal reflux disease	01JAN2011		Y
			Large intestine polyp	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN1982		Y
				01JAN1987		Y
				01JAN1990		Y
				01JAN2011		Y
				10AUG1978		Y
			Food allergy	01JAN2007		Y
			Seasonal allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN1975		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1147 11471084	Infections and infestations	Genital herpes	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2018		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2018		Y
	C4591001 1147 11471086	Blood and lymphatic system disorders	Iron deficiency anaemia	12FEB2020		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	12OCT2012		Y
		Endocrine disorders	Autoimmune hypothyroidism	10OCT2012		Y
			Autoimmune thyroiditis	12OCT2012		Y
		Hepatobiliary disorders	Biliary colic	07MAR2019		Y
		Investigations	Colonoscopy	04FEB2020	04FEB2020	N
			Cystoscopy	13MAR2020	13MAR2020	N
			Oesophagogastroduodenoscopy	04FEB2020	04FEB2020	N
		Metabolism and nutrition disorders	Vitamin D deficiency	12OCT2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	30AUG2019		Y
		Social circumstances	Tobacco user	30AUG2019		Y
		Surgical and medical procedures	Cholecystectomy	07MAR2019	07MAR2019	N
			Gastrectomy	24SEP2014		Y
			Renal stone removal	30APR2020	30APR2020	N
	C4591001 1147 11471087	Musculoskeletal and connective tissue disorders	Arthritis	02AUG2019		Y
		Renal and urinary disorders	Urinary incontinence	19FEB2018		Y
	C4591001 1147 11471088	Eye disorders	Macular hole	01MAR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1997		Y
		Infections and infestations	Onychomycosis	20JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1147 11471090	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Gout	09OCT2019		Y
			Hyperlipidaemia	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1147 11471091	Ear and labyrinth disorders	Tinnitus	31JUL2019		Y
		Infections and infestations	Herpes virus infection	30AUG2007		Y
		Injury, poisoning and procedural complications	Epicondylitis	11JUL2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11JUL2008		Y
		Nervous system disorders	Hyposmia	31JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	24JAN2019		Y
	C4591001 1147 11471093	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1147 11471096	Eye disorders	Astigmatism	26JUL2016		Y
			Cataract nuclear	26JUL2016		Y
			Visual impairment	03MAY2016		Y
		Investigations	Prostatic specific antigen increased	30MAY2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	18APR2017		Y
		Renal and urinary disorders	Pollakiuria	03MAY2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	13JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	30MAY2013		Y
			Sinus congestion	29JUN2017		Y
			Sleep apnoea syndrome	30MAY2013		Y
	C4591001 1147 11471097	Injury, poisoning and procedural complications	Meniscus injury	13MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1147 11471099	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN2012		Y
		Nervous system disorders	Restless legs syndrome	01JAN2012		Y
		Surgical and medical procedures	Dacryocystorhinostomy	08JAN2020		Y
			Tendon sheath incision	12JUN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1147 11471101	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
		General disorders and administration site conditions	Gait disturbance	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1976		Y
		Infections and infestations	Cystitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
			Hyperlipidaemia	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Nervous system disorders	Essential tremor	01JAN1980		Y
			Meige's syndrome	01JAN1980		Y
		Renal and urinary disorders	Mixed incontinence	01JAN2010		Y
			Pollakiuria	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1986		Y
	C4591001 1147 11471102	Cardiac disorders	Sinus bradycardia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN2017		Y
				03APR2019		Y
			Gastrooesophageal reflux disease	12MAY2014		Y
			Rectal haemorrhage	01JAN2017		Y
		General disorders and administration site conditions	Localised oedema	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	03SEP2015		Y
		Renal and urinary disorders	Pollakiuria	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1945		Y
		Vascular disorders	Deep vein thrombosis	06MAY2020		Y
			Essential hypertension	01JAN1990		Y
			Peripheral arterial occlusive disease	22MAR2019		Y
	C4591001 1147 11471103	Eye disorders	Retinal degeneration	17JUL2016		Y
		Infections and infestations	Herpes simplex	01APR2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471104	Endocrine disorders	Hypothyroidism	14NOV2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	06JUN2013		Y
		Infections and infestations	Chronic sinusitis	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	07JAN2004		Y
		Social circumstances	Postmenopause	01FEB2019		Y
		Vascular disorders	Hypertension	06JUN2013		Y
	C4591001 1147 11471105	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Renal and urinary disorders	Chronic kidney disease	31JUL2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1147 11471106	Cardiac disorders	Supraventricular tachycardia	01JAN2017		Y
			Tachycardia	01AUG2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2016		Y
			Osteopenia	01AUG2016		Y
				31OCT2017		Y
		Surgical and medical procedures	Implantable cardiac monitor insertion	02JUN2020	02JUN2020	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1147 11471108	Endocrine disorders	Goitre	17OCT2012		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01MAY2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01AUG2013		Y
			Osteoarthritis	19FEB2018		Y
		Nervous system disorders	Lumbar radiculopathy	13SEP2016		Y
		Psychiatric disorders	Anxiety	24OCT2012		Y
			Depression	17OCT2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	17OCT2018		Y
	C4591001 1147 11471111	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Infections and infestations	Otitis externa	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Tobacco abuse	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1147 11471113	Cardiac disorders	Mitral valve incompetence	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
			Irritable bowel syndrome	01NOV2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2014		Y
			Type 2 diabetes mellitus	01NOV2014		Y
		Psychiatric disorders	Anxiety	01NOV2014		Y
			Major depression	01NOV2015		Y
			Nicotine dependence	01JAN2005		Y
		Renal and urinary disorders	Chronic kidney disease	01MAY2015		Y
		Reproductive system and breast disorders	Breast cyst	01JUN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1147 11471114	Metabolism and nutrition disorders	Dyslipidaemia	27JUN2015		Y
	C4591001 1147 11471116	Investigations	Hyperlipidaemia	01JAN2014		Y
		Investigations	Blood potassium decreased	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Desmoid tumour	01JAN2018		Y
		Nervous system disorders	Restless legs syndrome	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1147 11471117	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2013		Y
			Osteoporosis	01JAN2017		Y
			Plantar fascial fibromatosis	01JAN1969		Y
	C4591001 1147 11471124	Gastrointestinal disorders	Constipation	25SEP2012		Y
		Investigations	Blood pressure increased	05JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	09JAN2017		Y
			Vitamin B12 deficiency	05JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
			Foot deformity	25SEP2012		Y
			Osteoporosis	13OCT2010		Y
		Vascular disorders	Essential hypertension	13JUN2018		Y
	C4591001 1147 11471125	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Investigations	Prostatic specific antigen increased	01MAY2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	19OCT2018		Y
			Rotator cuff syndrome	19OCT2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01SEP2013		Y
		Renal and urinary disorders	Chronic kidney disease	12FEB2016		Y
			Renal cyst	16SEP2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2014		Y
	C4591001 1147 11471126	Metabolism and nutrition disorders	Vitamin D deficiency	12FEB2018		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	19JUL2014		Y
		Nervous system disorders	Migraine	05FEB2018		Y
		Psychiatric disorders	Anxiety	09AUG2019		Y
			Binge eating	01AUG2019		Y
			Depression	09AUG2019		Y
		Renal and urinary disorders	Stress urinary incontinence	25JAN2019		Y
		Reproductive system and breast disorders	Polycystic ovaries	19JUL2014		Y
	C4591001 1147 11471127	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
	C4591001 1147 11471130	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2012		Y
		Infections and infestations	Herpes simplex	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
			Vitamin D deficiency	15MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1147 11471137	Cardiac disorders	Sinus bradycardia	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JAN2013		Y
			Sinusitis	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN1961		Y
		Nervous system disorders	Syncope	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1147 11471138	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1147 11471141	Endocrine disorders	Hypothyroidism	20MAR2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05MAR2018		Y
			Hypokalaemia	08MAR2019		Y
			Obesity	30JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10SEP2018		Y
		Surgical and medical procedures	Hysterectomy	01JUL1999	31JUL1999	N
		Vascular disorders	Hypertension	01AUG2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471146	Hepatobiliary disorders	Hepatic steatosis	10JUN2013		Y
		Metabolism and nutrition disorders	Diabetes mellitus	14OCT2013		Y
			Dyslipidaemia	14JAN2014		Y
	C4591001 1147 11471148	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2018		Y
			Glucose tolerance impaired	01JAN2018		Y
			Hyperlipidaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1147 11471155	Reproductive system and breast disorders	Erectile dysfunction	01OCT2018		Y
		Vascular disorders	Hypertension	22JAN2020		Y
	C4591001 1147 11471157	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Rhinitis allergic	01JAN1997		Y
			Sleep apnoea syndrome	18AUG2019		Y
	C4591001 1147 11471158	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1147 11471159	Eye disorders	Dry eye	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Vitamin D deficiency	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN1994		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y
	C4591001 1147 11471162	Endocrine disorders	Hypogonadism male	16OCT2018		Y
		Eye disorders	Cataract nuclear	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2015		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1147 11471167	Endocrine disorders	Hypothyroidism	23DEC2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	23DEC2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	23DEC2016		Y
	C4591001 1147 11471169	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Conjunctivitis allergic	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Infections and infestations	Chronic sinusitis	01JAN2019		Y
		Injury, poisoning and procedural complications	Meniscus injury	26SEP2017	21AUG2020	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1147 11471170	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Oesophageal stenosis	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1961		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glucose tolerance impaired	01JAN2018		Y
			Gout	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1147 11471175	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1147 11471177	Eye disorders	Presbyopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1147 11471178	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
			Osteoarthritis	01JAN2013		Y
			Osteopenia	01JAN2014		Y
	C4591001 1147 11471179	Cardiac disorders	Mitral valve prolapse	01JAN2012		Y
			Palpitations	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Senile osteoporosis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1147 11471181	Blood and lymphatic system disorders	Thrombocytosis	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
			Obesity	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2020		Y
		Vascular disorders	Essential hypertension	01JAN2016		Y
			Peripheral venous disease	01JAN2016		Y
	C4591001 1147 11471185	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1998		Y
		Surgical and medical procedures	Prostatectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1147 11471187	Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN2006		Y
		Eye disorders	Cataract nuclear	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Obesity	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
			Joint range of motion decreased	01MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteopenia	01JAN2004		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Chloasma	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1147 11471190	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Iodine allergy	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Bone pain	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1147 11471192	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Surgical and medical procedures	Prostatectomy	01MAR2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1147 11471193	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypertriglyceridaemia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Social circumstances	Tobacco user	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1147 11471196	Cardiac disorders	Cardiomegaly	01JAN2010		Y
			Mitral valve prolapse	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1997		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1147 11471198	Immune system disorders	Seasonal allergy	01OCT2010		Y
	C4591001 1147 11471199	Congenital, familial and genetic disorders	Sickle cell trait	01JAN1952		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Gout	01JAN2011		Y
			Obesity	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1147 11471200	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1982		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1988		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Attention deficit hyperactivity disorder	01JAN2014		Y
			Depression	01JAN2005		Y
		Vascular disorders	Essential hypertension	01JAN2005		Y
	C4591001 1147 11471205	Musculoskeletal and connective tissue disorders	Torticollis	27MAY2019		Y
		Nervous system disorders	Dystonic tremor	27MAY2019		Y
			Neuropathy vitamin B6 deficiency	13AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471208	Cardiac disorders	Myocardial infarction	01JAN2015	31DEC2015	N
		Congenital, familial and genetic disorders	Thalassaemia beta	01JAN1979		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	19MAR2019		Y
		Nervous system disorders	Sciatica	25JUN2018		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2015		Y
		Vascular disorders	Aortic dilatation	20APR2018		Y
	C4591001 1147 11471218	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN1969		Y
			Scoliosis	01JAN1969		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1969		Y
			Nicotine dependence	01JAN1980		Y
		Renal and urinary disorders	Single functional kidney	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1147 11471221	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
	C4591001 1147 11471224	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Nervous system disorders	Restless legs syndrome	01JAN2002		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1147 11471228	Surgical and medical procedures	Hysterectomy	01JAN1979		Y	
		Endocrine disorders	Hypothyroidism	01JAN1999		Y	
		Immune system disorders		Drug hypersensitivity	01JAN1980		Y
					01JAN1985		Y
					01JAN1971		Y
		Musculoskeletal and connective tissue disorders		Arthritis	01JAN1990		Y
	C4591001 1147 11471229	Reproductive system and breast disorders	Atrophic vulvovaginitis	27JUN2013		Y	
		Social circumstances	Postmenopause	01JAN2012		Y	
		Endocrine disorders	Hypothyroidism	01JAN2015		Y	
	C4591001 1147 11471230	Immune system disorders		Drug hypersensitivity	01JAN2015	Y	
					01JAN2010		Y
		Social circumstances	Menopause	01JAN2010		Y	
		Cardiac disorders	Coronary artery disease	01JAN2019		Y	
		Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2014		Y	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y	
		Immune system disorders			Drug hypersensitivity	01JAN2000	Y
					01JAN2018		Y
	Infections and infestations		Rhinitis	01JAN2011		Y	
	Musculoskeletal and connective tissue disorders			Intervertebral disc degeneration	01JAN2000	Y	
	Nervous system disorders			Pain in extremity	01JAN2017	Y	
					01JAN2000		Y
					01JAN2015		Y
	Psychiatric disorders			Migraine without aura	01JAN2015	Y	
					01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1147 11471232	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
				13MAR2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1147 11471233	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Eye disorders	Cataract	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2013		Y
	C4591001 1147 11471238	Blood and lymphatic system disorders	Leukopenia	16OCT2012		Y
			Thrombocytopenia	16OCT2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	23OCT2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	19OCT2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1147 11471239	Immune system disorders	Seasonal allergy	03DEC2012		Y
		Psychiatric disorders	Anxiety	13SEP2018		Y
		Reproductive system and breast disorders	Menorrhagia	18APR2019		Y
			Menstruation irregular	18APR2019		Y
		Social circumstances	Menopause	01JAN2019		Y
		Vascular disorders	Hypertension	14SEP2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471240	Endocrine disorders	Endocrine disorder	01JAN2004		Y
			Hypothyroidism	01JAN2004		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Post procedural complication	09JUL2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	28DEC2012		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1147 11471241	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1147 11471242	Blood and lymphatic system disorders	Leukopenia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
	C4591001 1147 11471244	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1994		Y
		Social circumstances	Menopause	01JAN2005		Y
	C4591001 1147 11471247	Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Ear and labyrinth disorders	Vertigo positional	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
			Haemorrhoids	01JAN2018		Y
			Irritable bowel syndrome	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2014		Y
		Infections and infestations	Diverticulitis	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Nervous system disorders	Migraine with aura	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1147 11471249	Endocrine disorders	Hypothyroidism	07SEP2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	14JAN2019		Y
			Spinal osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	09APR2016		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Continuous positive airway pressure	09APR2016		Y
	C4591001 1147 11471250	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Iritis	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01DEC1950		Y
		Infections and infestations	Herpes simplex	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
				01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1147 11471251	Endocrine disorders	Thyroid disorder	01JAN2020		Y
		Eye disorders	Eye disorder	01JAN2016		Y
		Nervous system disorders	Disturbance in attention	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Menopause	01DEC2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1149 11491004	Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
			Depression	01JAN2016		Y
		Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2015	31DEC2015	N
	C4591001 1149 11491009	Gastrointestinal disorders	Inguinal hernia	01JAN2015	31DEC2015	N
	C4591001 1149 11491017	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Investigations	Blood triglycerides increased	01JAN2018		Y
	C4591001 1149 11491018	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal cancer	01JAN2011	31DEC2012	N
	C4591001 1149 11491019	Investigations	Blood cholesterol increased	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2011	31DEC2011	N
		Renal and urinary disorders	Urinary retention	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hearing aid user	01JAN2015		Y
	C4591001 1149 11491022	Social circumstances	Corrective lens user	01JAN1991		Y
	C4591001 1149 11491026	Social circumstances	Corrective lens user	01JAN1994		Y
	C4591001 1149 11491039	Eye disorders	Denture wearer Uveitis	01JAN2018 01JAN2000		Y Y
	C4591001 1149 11491041	Surgical and medical procedures Gastrointestinal disorders	Cataract operation Gastroesophageal reflux disease	01JAN2015 01JAN2010	31DEC2015	N Y
	C4591001 1149 11491042	Investigations Skin and subcutaneous tissue disorders Endocrine disorders	Blood cholesterol increased Psoriasis Hypothyroidism	01JAN1999 01JAN2005 01JAN2013		Y Y Y
	C4591001 1149 11491043	Eye disorders Investigations Vascular disorders	Hypermetropia Blood cholesterol increased Hypertension	01JAN2017 01JAN2005 01JAN2013		Y Y Y
	C4591001 1149 11491048	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
	C4591001 1149 11491052	Eye disorders Investigations Vascular disorders	Hypermetropia Blood cholesterol increased Hypertension	01JAN2012 01JAN2011 01JAN2011		Y Y Y
	C4591001 1149 11491052	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2018		Y
	C4591001 1149 11491053	Renal and urinary disorders Social circumstances Eye disorders	Nephrolithiasis Menopause Myopia	01JAN2017 01JAN2005 01JAN1970		Y Y Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1149 11491056	Eye disorders	Hypermetropia	01JAN1962		Y
			Myopia	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2015		Y
		Social circumstances	Menopause	01JAN2005		Y
	C4591001 1149 11491060	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Myopia	01JAN1967		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2003	31DEC2003	N
	C4591001 1149 11491064	Eye disorders	Myopia	01JAN1972		Y
		Gastrointestinal disorders	Gastric ulcer perforation	01JAN2013	31DEC2013	N
			Gastroesophageal reflux disease	01JAN2012		Y
		Infections and infestations	Appendicitis perforated	01JAN2014	31DEC2014	N
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1149 11491071	Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
	C4591001 1149 11491072	Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
	C4591001 1149 11491078	Cardiac disorders	Mitral valve incompetence	01JAN2014	31DEC2015	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
	C4591001 1149 11491080	Ear and labyrinth disorders	Hypoacusis	01JAN1990		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Bone operation	01JAN2012	31DEC2012	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1149 11491081	Reproductive system and breast disorders	Prostatomegaly	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tenoplasty	01JAN2019	31DEC2019	N
			Vasectomy	01JAN2003	31DEC2003	N
	C4591001 1149 11491090	Surgical and medical procedures	Knee arthroplasty	01JAN2008		Y
	C4591001 1149 11491091	Social circumstances	Corrective lens user	01JAN2001		Y
			Menopause	01JAN1990		Y
	C4591001 1149 11491094	Gastrointestinal disorders	Large intestine perforation	01JAN2004	31DEC2004	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Inguinal hernia repair	01JAN2014	31DEC2014	N
			Prostatectomy	01JAN2012	31DEC2012	N
			Wrist surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491095	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1947		Y
	C4591001 1149 11491101	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
	C4591001 1149 11491102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
		Social circumstances	Hearing aid user	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Cholecystectomy	01JAN1970	31DEC1970	N
			Hysterectomy	01JAN1984	31DEC1984	N
	C4591001 1149 11491103	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Social circumstances	Hearing aid user	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Meniscus operation	01JAN2010	31DEC2010	N
	C4591001 1149 11491104	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
		Surgical and medical procedures	Appendectomy	01JAN1965	31DEC1965	N
	C4591001 1149 11491105	Congenital, familial and genetic disorders	Intracranial lipoma	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491106	Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Gastric bypass	01JAN2003	31DEC2003	N
			Mammoplasty	01JAN2004	31DEC2004	N
	C4591001 1149 11491107	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN1990		Y
	C4591001 1149 11491112	Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1149 11491113	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018	31DEC2018	N
		Social circumstances	Hearing aid user	01JAN2014		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1149 11491118	Investigations	Blood cholesterol increased	01JUL2020		Y
	C4591001 1149 11491122	Injury, poisoning and procedural complications	Tendon rupture	01FEB2019		Y
	C4591001 1149 11491123	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Social circumstances	Corrective lens user	01JAN1972		Y
			Hearing aid user	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mastectomy	01JAN2010		Y
	C4591001 1149 11491124	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Social circumstances	Hearing aid user	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2000		Y
			Prostatectomy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1149 11491126	Gastrointestinal disorders	Haemorrhoids	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000		Y
			Knee operation	01JAN1981	31DEC1981	N
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1149 11491127	Investigations	Blood cholesterol increased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013	31DEC2014	N
	C4591001 1149 11491130	Gastrointestinal disorders	Haemorrhoids	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
			Seasonal allergy	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1149 11491132	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2001		Y
			Haemorrhoids	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
			Tuberculin test positive	01JAN1987	31DEC1987	N
			White blood cell count decreased	01JAN1986		Y
	C4591001 1149 11491134	Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Eye disorders	Presbyopia	01JAN1995		Y
		Immune system disorders	Food allergy	01JAN1960		Y
		Infections and infestations	Cystitis	01JAN1975	31DEC2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Spondylitis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2015	31DEC2015	N
		Nervous system disorders	Headache	01JAN2000		Y
			Migraine	01JAN1975	31DEC2000	N
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1149 11491135	Eye disorders	Cataract	01JAN1984	31DEC2004	N
		Immune system disorders	Allergy to silk	01JAN1951		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN1975	31DEC1975	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Childhood asthma	01JAN1951	31DEC1964	N
		Surgical and medical procedures	Ankle operation	01JAN1994	31DEC1994	N
			Cataract operation	01JAN2004	31DEC2004	N
		Vascular disorders	Deep vein thrombosis	01JAN2018	31DEC2018	N
	C4591001 1149 11491138	Eye disorders	Hypermetropia	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1149 11491139	Congenital, familial and genetic disorders	Phimosis	01JAN1962		Y
		Eye disorders	Hypermetropia	01JAN1954		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
	C4591001 1149 11491143	Ear and labyrinth disorders	Auditory disorder	01JAN1986		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
		Surgical and medical procedures	Abscess drainage	01JAN2016	31DEC2016	N
	C4591001 1149 11491144	Eye disorders	Myopia	01JAN1990		Y
	C4591001 1149 11491152	Eye disorders	Cataract	01JAN2015	31DEC2018	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Multiple sclerosis	01JAN2000		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1149 11491153	Cardiac disorders	Atrial fibrillation	01JAN2004		Y
			Cardiac failure congestive	01JAN2016		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2016	31DEC2016	N
		Infections and infestations	Syphilis	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
			Dupuytren's contracture	01JAN2018	31DEC2018	N
		Social circumstances	Corrective lens user	01JAN1966		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Mammoplasty	01JAN2019	31DEC2019	N
			Skin cosmetic procedure	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1149 11491159	Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Meniscus operation	01JAN2005	31DEC2005	N
	C4591001 1149 11491161	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Dizziness	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1149 11491167	Endocrine disorders	Hypothyroidism	01JAN1998		Y
	C4591001 1149 11491168	Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN2012		Y
		Infections and infestations	Pneumonia	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1149 11491171	Immune system disorders	Food allergy	01JAN1967		Y
			Rubber sensitivity	01JAN1967		Y
	C4591001 1149 11491184	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1149 11491185	Eye disorders	Eye disorder	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN1998		Y
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
			Nasal septal operation	01JAN1999	31DEC1999	N
	C4591001 1149 11491189	Gastrointestinal disorders	Haemorrhoids	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Hip surgery	01JAN1962	31DEC1962	N
			Shoulder operation	01JAN1982	31DEC1982	N
	C4591001 1149 11491190	Investigations	Blood cholesterol increased	01JAN2002		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1149 11491192	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Eye glasses therapy	01JAN2005		Y
	C4591001 1149 11491193	Endocrine disorders	Hypothyroidism	01JAN2011		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1976	31DEC1976	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Cholecystectomy	01JAN1976	31DEC1976	N
	C4591001 1149 11491195	Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
	C4591001 1149 11491196	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1149 11491199	Nervous system disorders	Nerve compression	01JAN2019		Y
		Surgical and medical procedures	Meniscus operation	01JAN1995	31DEC1996	N
	C4591001 1149 11491214	Eye disorders	Myopia	01JAN1998		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1968		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491222	Gastrointestinal disorders	Haemorrhoids	01JAN2005		Y
		Immune system disorders	Food allergy	01JAN1963		Y
		Investigations	Arthroscopy	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1149 11491224	Immune system disorders	Milk allergy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Eyeglasses therapy	01JAN2016		Y
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1149 11491225	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Knee operation	01JAN1990	31DEC2000	N
	C4591001 1149 11491226	Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1992	31DEC1992	N
			Pregnancy	01JAN1992	31DEC1992	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1149 11491229	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491231	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JUN2005		Y
			Depression	01JUN2005		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1149 11491232	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1149 11491237	Eye disorders	Hypermetropia	01JAN2001		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Lactose intolerance	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Surgical and medical procedures	Hernia repair	01JAN1995	31DEC1995	N
				01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1149 11491239	General disorders and administration site conditions	Pain	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2018	31DEC2018	N
		Nervous system disorders	Peroneal nerve palsy	01JAN2010		Y
			Sciatica	01JAN2012		Y
		Psychiatric disorders	Drug abuse	01JAN2014		Y
		Vascular disorders	Deep vein thrombosis	01JAN2018		Y
			Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491243	Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1149 11491244	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Appendectomy	01JAN1962	31DEC1962	N
			Cataract operation	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1149 11491245	Hepatobiliary disorders	Cholelithiasis	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN2014	31DEC2014	N
			Spinal fracture	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1149 11491251	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1149 11491253	Eye disorders	Hypermetropia	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
		Psychiatric disorders	Anxiety	06JAN2018		Y
			Depression	06JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
	C4591001 1149 11491257	Eye disorders	Myopia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Food allergy	01JAN1999		Y
		Infections and infestations	Bronchitis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cancer in remission	01MAY2016		Y
		Social circumstances	Menopause	01JAN2009		Y
	C4591001 1149 11491260	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
		Reproductive system and breast disorders	Prostatitis	01JAN2020	29FEB2020	N
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
	C4591001 1149 11491261	Eye disorders	Myopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Food allergy	01JAN1977		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1980		Y
			Menopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
			Cholecystectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Aortic aneurysm	01JAN2015		Y
	C4591001 1149 11491262	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Surgical and medical procedures	Fracture treatment	01JAN1970	31DEC1970	N
			Intervertebral disc operation	01JAN2014	31DEC2016	N
	C4591001 1149 11491264	Investigations	Blood urine present	01JAN1991	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2000		Y
		Renal and urinary disorders	IgA nephropathy	01JAN1991		Y
	C4591001 1149 11491267	Infections and infestations	Diverticulitis	01JAN2000	31DEC2000	N
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Keratomileusis	01JAN1998	31DEC1998	N
	C4591001 1149 11491272	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
	C4591001 1149 11491278	Infections and infestations	Osteomyelitis	01JAN1961	31DEC1967	N
		Injury, poisoning and procedural complications	Accident	01JAN1969	31DEC1969	N
			Limb injury	01JAN1969	31DEC1969	N
				01JAN2020		Y
		Metabolism and nutrition disorders	Gout	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Hypoaesthesia	01JAN1969		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1988		Y
		Surgical and medical procedures	Fracture treatment	01JAN1958	31DEC1958	N
			Prostatectomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1972	31DEC1972	N
	C4591001 1149 11491279	Investigations	Blood cholesterol increased	01JAN2018		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN1971	31DEC1971	N
				01JAN1976	31DEC1976	N
		Social circumstances	Menopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1149 11491283	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1149 11491287	Gastrointestinal disorders	Constipation	01JAN1960		Y
			Oesophagitis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Investigations	Blood cholesterol increased	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1983		Y
		Surgical and medical procedures	Mastectomy	01JAN2011	31DEC2011	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1149 11491288	Gastrointestinal disorders	Inguinal hernia	01JAN2013	31DEC2013	N
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
	C4591001 1149 11491296	Gastrointestinal disorders	Constipation	01JAN2015		Y
		Immune system disorders	Hypersensitivity	01JAN1990		Y
			Rubber sensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1975		Y
		Social circumstances	Menopause	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491297	Eye disorders	Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1149 11491298	Immune system disorders	Allergy to metals	01JAN1975		Y
			Drug hypersensitivity	01JAN1965		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma	01JAN2013	31DEC2013	N
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1986	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1149 11491299	Endocrine disorders	Goitre	01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Infections and infestations	Hepatitis A	01JAN1988	31DEC1988	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1980	31DEC1980	N
	C4591001 1149 11491300	Ear and labyrinth disorders	Hypoacusis	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
				01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Hepatitis A	01JAN1976	31DEC1976	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Nervous system disorders	Tremor	01JUL2020		Y
		Psychiatric disorders	Depression	01JAN2016		Y
			Insomnia	01AUG2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2017		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2013	31DEC2013	N
	C4591001 1149 11491301	Eye disorders	Astigmatism	01JAN1972		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
			Salivary gland resection	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1149 11491306	Ear and labyrinth disorders	Hypoacusis	01JAN2012		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		General disorders and administration site conditions	Atrophy	01JAN1944		Y
		Injury, poisoning and procedural complications	Injury	01JAN1944	31DEC1944	N
		Investigations	Blood cholesterol increased	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Surgical and medical procedures	Limb operation	01JAN1944	31DEC1956	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1149 11491309	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1992		Y
		Infections and infestations	Pneumonia	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1982		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1149 11491312	Skin and subcutaneous tissue disorders	Eczema	01JAN1972		Y
	C4591001 1149 11491313	Gastrointestinal disorders	Femoral hernia	01JAN2020	31DEC2020	N
		General disorders and administration site conditions	Hernia	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Cardiac murmur	01JAN1954		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2013		Y
			Osteoarthritis	01JAN2018		Y
		Social circumstances	Denture wearer	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1149 11491317	Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Mycobacterium tuberculosis complex test positive	01JAN1970		Y
		Nervous system disorders	Sinus headache	01JAN2000		Y
	C4591001 1149 11491318	Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1973	31DEC1973	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1975	31DEC1975	N
				01JAN1979	31DEC1979	N
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1149 11491319	Cardiac disorders	Coronary artery occlusion	01JAN1998		Y
		Investigations	Blood cholesterol increased	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1995		Y
		Surgical and medical procedures	Knee operation	01JAN2009	31DEC2009	N
			Surgery	01JAN2009	31DEC2009	N
	C4591001 1149 11491323	Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
			Inguinal hernia	01JAN2007		Y
			Umbilical hernia	01JAN2007		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Bladder operation	01JAN2010	31DEC2010	N
			Colon operation	01JAN2004	31DEC2004	N
			Ear tube insertion	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1149 11491325	Gastrointestinal disorders	Small intestinal obstruction	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995	31DEC2000	N
	C4591001 1149 11491326	Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
	C4591001 1149 11491330	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Lactose intolerance	01JAN2000		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Eye operation	01JAN2020	31DEC2020	N
			Hysterectomy	01JAN1968	31DEC1968	N
			Retinal operation	01APR2020	30APR2020	N
	C4591001 1149 11491333	Eye disorders	Hypermetropia	01JAN2004		Y
		Pregnancy, puerperium and perinatal conditions	Pregnancy	01JAN1992	31DEC1992	N
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1149 11491338	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Eye disorders	Retinal detachment	01JAN1989	31DEC1990	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000	31DEC2018	N
		Surgical and medical procedures	Eye excision	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN2002	31DEC2002	N
			Intervertebral disc operation	01JAN2004	31DEC2004	N
				01JAN2005	31DEC2005	N
			Rotator cuff repair	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1149 11491342†	Gastrointestinal disorders	Abdominal hernia	01JAN2019	31DEC2019	N
				01JUN2020	30JUN2020	N
		Infections and infestations	HIV infection	01JAN1991		Y
		Injury, poisoning and procedural complications	Scar	01FEB2019		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JAN2010		Y
	C4591001 1152 11521006	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1953		Y
		Surgical and medical procedures	Muscle operation	01JAN2010	31DEC2010	N
			Oophorectomy bilateral	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Varicose vein	01JAN2010		Y
	C4591001 1152 11521013	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1152 11521016	Surgical and medical procedures	Appendicectomy	01JAN2004	31DEC2004	N
			Vasectomy	01JAN2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1152 11521018	Cardiac disorders	Myocardial infarction	01JAN1993	31DEC1993	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2010	31DEC2010	N
	C4591001 1152 11521021	Surgical and medical procedures	Tonsillectomy	01JAN1955	31DEC1955	N
		Immune system disorders	Milk allergy	01JAN1959		Y
			Seasonal allergy	01JAN1959		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2008	31DEC2008	N
			Hand fracture	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1959		Y
		Surgical and medical procedures	Fracture treatment	01JAN1999	31DEC1999	N
				01JAN2008	31DEC2008	N
	C4591001 1152 11521023	Injury, poisoning and procedural complications	Wrist fracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN2010	31DEC2010	N
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1152 11521026	Immune system disorders	Drug hypersensitivity	01JAN1979		Y
			Food allergy	01JAN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1152 11521027	Injury, poisoning and procedural complications	Meniscus injury	01MAY2020	31MAY2020	N
		Surgical and medical procedures	Meniscus operation	01MAY2020	31MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521033	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Presbyopia	01JAN1965		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN1986		Y
				01JAN2018		Y
			Seasonal allergy	01JAN1956		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2003	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1961		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1958	31DEC1958	N
			Carpal tunnel decompression	01JAN1993	31DEC1993	N
				01JAN2006	31DEC2006	N
			Hysterectomy	19JUN2020		Y
			Rotator cuff repair	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521037	Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1152 11521041	Eye disorders	Myopia	01JAN1964		Y
			Presbyopia	01JAN1964		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Investigations	Arthroscopy	01JAN2015	31DEC2015	N
		Nervous system disorders	Sciatica	01JAN2013		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Bunion operation	01JAN2008	31DEC2008	N
			Rhinoplasty	01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1152 11521047	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Haemorrhoids	01APR2020	30JUN2020	N
		Investigations	Biopsy cervix	01JAN2008	31DEC2008	N
			Smear cervix abnormal	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
			Lithotripsy	01JAN2010	31DEC2010	N
			Thyroid operation	01JAN2012	31DEC2012	N
	C4591001 1152 11521049	Investigations	Biopsy breast	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Caesarean section	01JAN1969	31DEC1969	N
			Lipoma excision	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1152 11521050	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Infections and infestations	Pneumonia	01JAN1958	31DEC1958	N
			Sinusitis	01JAN1998	31DEC1998	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
			Bone operation	01JAN1981	31DEC1982	N
			Lymphadenectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal polypectomy	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521057	Immune system disorders	Rubber sensitivity	01JAN2018		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1998	31DEC1998	N
				01JAN2007	31DEC2007	N
			Cholecystectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1152 11521067	Injury, poisoning and procedural complications	Ligament rupture	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Surgical and medical procedures	Ligament operation	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1951	31DEC1951	N
			Uterine dilation and curettage	01JAN2015	31DEC2015	N
	C4591001 1152 11521068	Eye disorders	Myopia	01JAN1979		Y
	C4591001 1152 11521069	Gastrointestinal disorders	Dyspepsia	01JAN2003		Y
			Gastrooesophageal reflux disease	01JAN2003		Y
			Haemorrhoids	01JAN1985		Y
		Infections and infestations	Hepatitis A	01JAN1973	31DEC1973	N
			Localised infection	01JAN1971	31DEC1971	N
			Typhus	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1152 11521079	Eye disorders	Myopia	01JAN1973		Y
		Immune system disorders	Allergy to venom	01JAN2004		Y
		Infections and infestations	Pneumonia	01JAN1977	31DEC1977	N
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521080	Social circumstances	Postmenopause	01DEC2014		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1152 11521082	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
	C4591001 1152 11521083	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Psychiatric disorders	Depression	01MAR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1152 11521087	Cardiac disorders	Coronary artery disease	01JAN2019		Y
			Myocardial infarction	01JAN2019	31DEC2019	N
		Eye disorders	Cataract	01JAN2016		Y
					31JUL2020	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1974	31DEC1974	N
				01JAN1976	31DEC1976	N
			Umbilical hernia	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Ketoacidosis	01JUN2020	30JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Coronary artery bypass	01JUL2020	31JUL2020	N
			Tonsillectomy	01JAN2019	31DEC2019	N
		Endocrine disorders	Hypothyroidism	01JAN1964	31DEC1964	N
	C4591001 1152 11521088			01JAN2019		Y
		Immune system disorders	Dust allergy	01JAN1950		Y
			Food allergy	01JAN1950		Y
		Injury, poisoning and procedural complications	Patella fracture	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1965		Y
		Surgical and medical procedures	Bursa removal	01JAN2000	31DEC2000	N
			Knee operation	01JAN1965	31DEC1965	N
	C4591001 1152 11521091	Infections and infestations	Pneumonia	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendectomy	01JAN1955	31DEC1955	N
			Prostatectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1940	31DEC1940	N
			Tooth extraction	01JAN2017	31DEC2017	N
		Vascular disorders	Varicose vein	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521092	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521093	Ear and labyrinth disorders	Endolymphatic hydrops	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Food allergy	01JAN1983		Y
		Infections and infestations	Fungal skin infection	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2014		Y
			Lower oesophageal sphincter magnetic augmentation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1152 11521094	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1977	31DEC1977	N
			Umbilical hernia	01JAN1995	31DEC1995	N
		Immune system disorders	Food allergy	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995		Y
			Squamous cell carcinoma of skin	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Lithotripsy	01JAN2000	31DEC2000	N
			Renal stone removal	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Wisdom teeth removal	01JAN1978	31DEC1978	N
	C4591001 1152 11521095	Blood and lymphatic system disorders	Anaemia	01JAN2014	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Colitis	01JAN2000	31DEC2017	N
			Dyspepsia	01JAN1989		Y
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995	31DEC2007	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Osteoarthritis	01JAN1971		Y
		Psychiatric disorders	Anxiety	01JAN1972		Y
			Bipolar disorder	01JAN1972		Y
			Insomnia	01JAN2010		Y
			Mental disorder	01JAN1972	31DEC1972	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN1995		Y
		Surgical and medical procedures	Gastric bypass	01JAN2012	31DEC2012	N
			Intervertebral disc operation	01JAN2010	31DEC2010	N
				01JAN2013	31DEC2013	N
			Knee operation	01JAN1970	31DEC1970	N
				01JAN1985	31DEC1985	N
				01JAN1991	31DEC1991	N
				01JAN2015	31DEC2015	N
			Ostectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1152 11521096	Cardiac disorders	Palpitations	01JAN2018	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Thyroid mass	01JAN2005		Y
		Immune system disorders	Perennial allergy	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
			Cardiac ablation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1989		Y
		Eye disorders	Retinal detachment	01JAN2010	31DEC2011	N
	C4591001 1152 11521097	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Perennial allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Retinopexy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1152 11521099	Gastrointestinal disorders	Umbilical hernia	01JAN2018	31DEC2018	N
	C4591001 1152 11521101	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1152 11521102	Gastrointestinal disorders	Haemorrhoids	01JAN2003	31DEC2003	N
		Musculoskeletal and connective tissue disorders	Bone lesion	01JAN2018	31DEC2018	N
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN1999		Y
		Surgical and medical procedures	Bone lesion excision	01JAN2018	31DEC2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoid operation	01JAN2003	31DEC2003	N
			Keratomileusis	01JAN2001	31DEC2001	N
	C4591001 1152 11521103	Surgical and medical procedures	Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1152 11521104	Injury, poisoning and procedural complications	Ligament rupture	01JAN1985	31DEC1985	N
			Meniscus injury	01JAN1990	31DEC1990	N
				01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2003	31DEC2003	N
		Psychiatric disorders	Depression	01JAN2009		Y
		Surgical and medical procedures	Ligament operation	01JAN1985	31DEC1985	N
			Meniscus operation	01JAN1990	31DEC1990	N
				01JAN1998	31DEC1998	N
			Rotator cuff repair	01JAN2003	31DEC2003	N
			Shoulder operation	01JAN1995	31DEC1995	N
				01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521106	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2018	N
		Surgical and medical procedures	Tonsillectomy	01JAN1962	31DEC1962	N
		Vascular disorders	Hypertension	01JAN1995	31DEC1995	N
	C4591001 1152 11521107	Infections and infestations	Genital herpes	01JAN1998		Y
			Pneumonia	01JAN1961	31DEC1961	N
				01JAN1997	31DEC1997	N
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pneumothorax	01JAN1961	31DEC1961	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Thoracotomy	01JAN1961	31DEC1961	N
			Tonsillectomy	01JAN1961	31DEC1961	N
	C4591001 1152 11521109	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Hiatus hernia	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hernia hiatus repair	01JAN2009	31DEC2009	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Mastectomy	01JAN2008	31DEC2008	N
	C4591001 1152 11521119	Gastrointestinal disorders	Gastric ulcer	01JAN1984	31DEC1985	N
			Umbilical hernia	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
		Infections and infestations	Ear infection	01JAN1965		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord polyp	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN1965	31DEC1965	N
			Vocal cord polypectomy	01JAN2008	31DEC2008	N
	C4591001 1152 11521122	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Infections and infestations	Pneumonia	01JAN1955	31DEC1955	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1955	31DEC1955	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1976	31DEC1976	N
				01JAN1981	31DEC1981	N
	C4591001 1152 11521123	Immune system disorders	Drug hypersensitivity	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN1979	31DEC1979	N
			Shoulder operation	01JAN2004	31DEC2004	N
		Vascular disorders	Varicose vein	01JAN1989		Y
	C4591001 1152 11521125	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN2008	31DEC2008	N
		Renal and urinary disorders	Urinary incontinence	01JAN2010	31DEC2011	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2008		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2008	31DEC2008	N
	C4591001 1152 11521127	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2017	N
	C4591001 1152 11521128	Gastrointestinal disorders	Haemorrhoids	01JAN1971	31DEC1972	N
			Umbilical hernia	01JAN1997	31DEC1997	N
		Infections and infestations	Sepsis	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN1972	31DEC1972	N
			Tonsillectomy	01JAN1951	31DEC1951	N
			Umbilical hernia repair	01JAN1997	31DEC1997	N
	C4591001 1152 11521130	Immune system disorders	Drug hypersensitivity	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1969		Y
	C4591001 1152 11521132	Surgical and medical procedures	Caesarean section	27FEB1989	27FEB1989	N
		Injury, poisoning and procedural complications	Joint injury	01JAN2018	31DEC2018	N
		Investigations	Arthroscopy	01JAN2018	31DEC2018	N
	C4591001 1152 11521133	Surgical and medical procedures	Tonsillectomy	01JAN1965	31DEC1965	N
		Endocrine disorders	Thyroid mass	01MAR2018	31MAR2018	N
		Eye disorders	Cataract	01JAN2015	31DEC2016	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Investigations	Cardiac murmur	21AUG2020		Y
		Reproductive system and breast disorders	Prostatism	01JAN2009		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Thyroidectomy	01MAR2018	31DEC2018	N
			Tonsillectomy	01JAN1950	31DEC1950	N
	C4591001 1152 11521134	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Immune system disorders	Food allergy	01JAN2000		Y
			Perennial allergy	01JAN1975		Y
		Infections and infestations	Pneumonia	01JAN2014	31DEC2014	N
		Investigations	Cardiac murmur	21AUG2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004	N
				01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
			Caesarean section	01JAN1985	31DEC1985	N
			Cataract operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2014	31DEC2014	N
			Mastectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1955	31DEC1955	N
			Vascular disorders	Hypertension	01JAN2005	
	C4591001 1152 11521135	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1152 11521136	Cardiac disorders	Coronary artery disease	01JAN1994		Y
			Myocardial infarction	01JAN1994	31DEC1994	N
		Ear and labyrinth disorders	Meniere's disease	01JAN1992		Y
		Eye disorders	Strabismus	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1995	31DEC1995	N
		Hepatobiliary disorders	Drug-induced liver injury	01JAN1985	31DEC1985	N
		Immune system disorders	Allergy to arthropod sting	01JAN2008		Y
			Drug hypersensitivity	01JAN1985		Y
			Perennial allergy	01JAN1956		Y
		Infections and infestations	Infectious mononucleosis	01JAN1977	31DEC1977	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1982		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1984		Y
		Nervous system disorders	IVth nerve paralysis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1955		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1994	31DEC1994	N
				01JAN2012	31DEC2012	N
			Coronary artery bypass	01JAN2015	31DEC2015	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
			Micrographic skin surgery	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Strabismus correction	01JAN2015	31DEC2015	N
			Tenoplasty	01JAN2002	31DEC2002	N
			Vessel harvesting	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018	31DEC2018	N
	C4591001 1152 11521141	Blood and lymphatic system disorders	Anaemia	01JAN2020	30JUN2020	N
		Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
		General disorders and administration site conditions	Asthenia	01JAN2019	30JUN2020	N
			Fatigue	01JAN2019	30JUN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Meningitis	01JAN1998	31DEC1998	N
			Urinary tract infection	01JAN1988	31DEC2004	N
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1995	31DEC1995	N
			Hand fracture	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2019		Y
			Intervertebral disc disorder	01JAN2016	31JAN2017	N
			Osteoporosis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N
		Nervous system disorders	Sciatica	01JAN2009	31DEC2017	N
		Pregnancy, puerperium and perinatal conditions	Gestational diabetes	01JAN1977	31DEC1977	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1989		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Appendicectomy	01JAN1973	31DEC1973	N
			Caesarean section	31MAY1977	31MAY1977	N
			Female sterilisation	01JAN1984	31DEC1984	N
			Fracture treatment	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1999	31DEC1999	N
			Internal fixation of spine	01JAN2017	31JAN2017	N
			Myomectomy	01JAN1996	31DEC1996	N
			Rhinoplasty	01JAN1995	31DEC1995	N
			Spinal operation	01JAN2017	31JAN2017	N
		Vascular disorders	Hypotension	01JAN2000		Y
	C4591001 1152 11521151	Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Caesarean section	09MAR1991	09MAR1991	N
			Cholecystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Varicose vein	01JAN2010		Y
	C4591001 1152 11521152	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Elbow operation	01JAN1982	31DEC1982	N
	C4591001 1152 11521155	Congenital, familial and genetic disorders	Congenital joint malformation	01JAN1939	31DEC2018	N
		Eye disorders	Presbyopia	01JAN1950		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
			Inguinal hernia	01JAN2012	31DEC2012	N
		Injury, poisoning and procedural complications	Face injury	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Surgical and medical procedures	Arthrodesis	01JAN2018	31DEC2018	N
			Cardiac pacemaker insertion	01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN2012	31DEC2012	N
			Plastic surgery to the face	01JAN1991	31DEC1991	N
			Tonsillectomy	01JAN1950	31DEC1950	N
	C4591001 1152 11521160	Gastrointestinal disorders	Umbilical hernia	01JAN2002	31DEC2002	N
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Lithotripsy	01JAN2013	31DEC2013	N
			Muscle operation	01JAN2014	31DEC2014	N
			Umbilical hernia repair	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521161	Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN1977	31DEC1977	N
			Inguinal hernia	01JAN2005	31DEC2005	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2006	31DEC2006	N
		Immune system disorders	Mycotic allergy	01JAN1980		Y
			Perennial allergy	01JAN2012	31DEC2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1972	31DEC1975	N
			Sciatica	01JAN1973		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Colectomy total	01JAN1977	31DEC1977	N
			Ileostomy	01JAN1977		Y
			Inguinal hernia repair	01JAN2005	31DEC2005	N
				01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521162	Congenital, familial and genetic disorders	Spine malformation	(b) (6) 1954	31DEC2018	N
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Retinal detachment	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Retinopexy	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal laminectomy	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521163	Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Investigations	Arthroscopy	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1992	31DEC1992	N
		Renal and urinary disorders	Nephritis	01JAN1964	31DEC1965	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1152 11521170	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
			Fibroma	01JAN1993	31DEC1993	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2011		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Varicose vein	01JAN1970		Y
	C4591001 1152 11521171	Infections and infestations	Genital herpes	01JAN1978		Y
		Nervous system disorders	Migraine	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1152 11521172	Eye disorders	Glaucoma	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Perennial allergy	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN1977	31DEC2005	N
		Investigations	Biopsy breast	01FEB2001	28FEB2001	N
		Nervous system disorders	Sciatica	01DEC2019	31MAR2020	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Caesarean section	15MAR1977	15MAR1977	N
				18FEB1985	18FEB1985	N
			Uterine dilation and curettage	01JAN1975	31DEC1975	N
	C4591001 1152 11521174	Eye disorders	Myopia	01JAN2005		Y
			Strabismus	01JAN1960		Y
		Immune system disorders	Food allergy	01JAN1980		Y
			Seasonal allergy	01JAN1959	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Sciatica	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1956	31DEC1970	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1956	31DEC1956	N
		Surgical and medical procedures	Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521175	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Myopia	01JAN1975		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1988		Y
			Haemorrhoids	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Rubber sensitivity	01JAN1980		Y
		Infections and infestations	Genital herpes	01JAN1982		Y
			Pneumonia	01JAN1976	31DEC1976	N
				01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1986	31DEC1986	N
				01JAN2016	31DEC2016	N
			Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN1979		Y
			Sciatica	01JAN2003	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN1979		Y
			Depression	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1988	31DEC1998	N
		Surgical and medical procedures	Cheilectomy	01JAN1986	31DEC1986	N
				01JAN2016	31DEC2016	N
			Toe operation	01JAN2016	31DEC2016	N
			Tooth extraction	01JUL2020	31JUL2020	N
			Wisdom teeth removal	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521178	Gastrointestinal disorders	Haemorrhoids	01JAN1982		Y
		General disorders and administration site conditions	Fatigue	01MAR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Biopsy breast	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1981		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1984	31DEC1985	N
		Nervous system disorders	Dizziness	01JAN2000		Y
			Migraine	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Female sterilisation	01JAN1987	31DEC1987	N
			Keratomileusis	01JAN1999	31DEC1999	N
			Thyroidectomy	01JAN1984	31DEC1984	N
			Wisdom teeth removal	01JAN1974	31DEC1974	N
		Vascular disorders	Hypotension	01JAN1957		Y
			Varicose vein	01JAN2005		Y
	C4591001 1152 11521179	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1971	31DEC1971	N
	C4591001 1152 11521181	Eye disorders	Myopia	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2014		Y
		Surgical and medical procedures	Caesarean section	10MAR1998	10MAR1998	N
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1152 11521190	Immune system disorders	Perennial allergy	01JAN1970		Y
		Infections and infestations	Hepatitis A	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1152 11521191	Infections and infestations	Staphylococcal infection	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2013	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
	C4591001 1152 11521193	Gastrointestinal disorders	Umbilical hernia	01JAN2002	31DEC2002	N
		Immune system disorders	Allergy to arthropod sting	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2019		Y
			Obesity	01JAN1993		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2012	31DEC2018	N
			Osteopenia	13SEP2017		Y
		Surgical and medical procedures	Hernia repair	01JAN2002	31DEC2002	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1152 11521194	Investigations	Biopsy cervix	01JAN1988	31DEC1988	N
			Smear cervix abnormal	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN1994	31DEC1994	N
	C4591001 1152	Surgical and medical procedures	Ovarian cystectomy	01JAN1994	31DEC1994	N
	11521198	Eye disorders	Astigmatism	01JAN2002		Y
	C4591001 1152	Eye disorders	Cataract	01JAN1985	31DEC2006	N
	11521200					
		Infections and infestations	Genital herpes	01JAN2018		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2008	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2016	N
			Tendon disorder	01JAN1980	31DEC1980	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2006	31DEC2006	N
			Knee operation	01JAN1980	31DEC1980	N
			Shoulder arthroplasty	01JAN2016	31DEC2016	N
			Shoulder operation	01JAN2000	31DEC2000	N
				01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
				01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Tenoplasty	01JAN2008	31DEC2008	N
			Varicose vein operation	01JAN1987	31DEC1987	N
			Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1990		Y
			Varicose vein	01JAN1987		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521201	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2015		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Cytoreductive surgery	01JAN1988	31DEC1988	N
			Hip arthroplasty	01MAR2018	31MAR2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
			Varicose vein	01JAN2005		Y
	C4591001 1152 11521202	Gastrointestinal disorders	Peptic ulcer	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019	31DEC2019	N
	C4591001 1152 11521203	Injury, poisoning and procedural complications	Concussion	01JAN1972	31DEC1972	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN1986	31DEC1986	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1963		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1152 11521210	Ear and labyrinth disorders	Deafness	01JAN1985		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
		Investigations	Biopsy breast	01JAN2005	31DEC2005	N
				01JUN2020	30JUN2020	N
			Mammogram abnormal	01JAN2005	31DEC2005	N
				01JUN2020	30JUN2020	N
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521217	Immune system disorders	Food allergy	01JAN1970		Y
			Seasonal allergy	01JAN1965		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1152 11521233	Gastrointestinal disorders	Dyspepsia	01JAN2012	31DEC2015	N
			Haemorrhoids	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2015		Y
			Obesity	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521237	Eye disorders	Myopia	01JAN1963		Y
		Immune system disorders	Food allergy	01JAN2012		Y
			Seasonal allergy	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1152 11521238	Immune system disorders	Allergy to arthropod sting	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1978		Y
		Nervous system disorders	Migraine	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatism	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Prostatectomy	01JAN2013	31DEC2013	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1152 11521241	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2012	31DEC2012	N
		Infections and infestations	Sepsis	01JAN1983	31DEC1983	N
		Surgical and medical procedures	Hernia hiatus repair	01JAN2012	31DEC2012	N
	C4591001 1152 11521244	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Infections and infestations	Pneumonia	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Hip fracture	01NOV2019	30NOV2019	N
		Metabolism and nutrition disorders	Ketoacidosis	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	20SEP1990	20SEP1990	N
			Female sterilisation	01OCT1990	31OCT1990	N
			Fracture treatment	01NOV2019	30NOV2019	N
	C4591001 1152 11521245	Ear and labyrinth disorders	Tinnitus	01JAN1952		Y
		Eye disorders	Cataract	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Haemorrhoids	01JAN1961		Y
		Immune system disorders	Drug hypersensitivity	01JAN1952		Y
			Seasonal allergy	01JAN1952		Y
		Investigations	Arthroscopy	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Depression	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1951	31DEC1951	N
		Surgical and medical procedures	Large intestinal polypectomy	01JAN2002	31DEC2002	N
				01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1945	31DEC1945	N
			Vasectomy	01JAN1980	31DEC1980	N
			Hypertension	01JAN2018		Y
	C4591001 1152 11521246	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1152 11521247	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN1990	31DEC2005	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2005	31DEC2005	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521250	Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Constipation	01JAN1959		Y
			Dyspepsia	01JAN2015	31DEC2018	N
			Haemorrhoids	01JAN1964		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Food allergy	01JAN1990		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Histoplasmosis	01JAN1974	31DEC1974	N
			Tuberculosis	01JAN1958	31DEC1958	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypercholesterolaemia	01JAN2006		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1958		Y
		Surgical and medical procedures	Appendectomy	01JAN1958	31DEC1958	N
			Caesarean section	12NOV1982	12NOV1982	N
			Carpal tunnel decompression	01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
			Knee operation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1152 11521251	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Histoplasmosis	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2015	31MAR2020	N
			Osteopenia	01JAN2019		Y
			Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2012	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2005		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1955	31DEC1955	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Varicose vein	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521252	Infections and infestations	Septic arthritis staphylococcal	01JAN2013	31DEC2013	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Prostatism	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1946	31DEC1946	N
	C4591001 1152 11521257	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Eye disorders	Retinal scar	01JAN1995		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1963	31DEC1964	N
			Joint injury	01JAN2014	31DEC2014	N
			Ligament rupture	01JAN1967	31DEC1967	N
				01JAN1968	31DEC1968	N
			Tendon rupture	01JAN1966	31DEC1966	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC2019	N
			Squamous cell carcinoma of skin	01JAN1990	31DEC2019	N
		Nervous system disorders	Sciatica	01JAN1972		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
			Ligament operation	01JAN1967	31DEC1967	N
				01JAN1968	31DEC1968	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Retinal operation	01JAN2015	31DEC2015	N
			Tenoplasty	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN1977		Y
	C4591001 1152 11521259	Gastrointestinal disorders	Dyspepsia	01JAN1998		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1152 11521260	Gastrointestinal disorders	Hiatus hernia	01JAN1988	31DEC1988	N
		General disorders and administration site conditions	Procedural failure	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2007	31DEC2008	N
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
		Reproductive system and breast disorders	Prostatism	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1952		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1152 11521262	Gastrointestinal disorders	Food poisoning	01JAN1992	31DEC1992	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Pneumonia	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Urethritis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1996	31DEC1996	N
		Musculoskeletal and connective tissue disorders	Lower limb fracture	01JAN1996	31DEC1996	N
			Osteoarthritis	01JAN1997		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Surgical and medical procedures	Fracture treatment	01JAN1996	31DEC1996	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521265	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
	C4591001 1152 11521266	Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N
		Immune system disorders	Perennial allergy	01JAN1962		Y
			Reaction to preservatives	01JAN1980		Y
		Nervous system disorders	Migraine	01JAN1988	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
			Nasal septum deviation	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Rhinoplasty	01JAN1997	31DEC1997	N
	C4591001 1152 11521267	Cardiac disorders	Atrial fibrillation	01JAN2017	31DEC2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Palpitations	01JAN1990	31DEC2017	N
			Supraventricular tachycardia	01JAN2000	31DEC2000	N
		Immune system disorders	Perennial allergy	01JAN2000		Y
		Infections and infestations	Influenza	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Osteopenia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2000	31DEC2000	N
				01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2013	31DEC2013	N
			Open reduction of fracture	01JAN1963	31DEC1963	N
			Tonsillectomy	01JAN1967	31DEC1967	N
			Varicose vein operation	01JAN2000	31DEC2000	N
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1152 11521268	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Infections and infestations	Genital herpes	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2000		Y
		Vascular disorders	Hypotension	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521272	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1152 11521273	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2008	31DEC2008	N
			Subdural haematoma	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1991		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Surgical and medical procedures	Craniotomy	01JAN2008	31DEC2008	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1152 11521278	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
		Immune system disorders	Perennial allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1990		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Endometrial ablation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1152 11521279	Ear and labyrinth disorders	Deafness	01JAN1997		Y
		Eye disorders	Strabismus	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Colitis	01JAN2000	31DEC2015	N
			Dyspepsia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoids	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN1998	31DEC1998	N
				01JAN2019	31DEC2019	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1998	31DEC1998	N
				01JAN2019	31DEC2019	N
			Meniscus operation	01JAN2000	31DEC2000	N
			Strabismus correction	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1152 11521280	Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		General disorders and administration site conditions	Cyst	01JAN1998	31DEC1998	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1998	31DEC1998	N
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Prostatism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Limb operation	01JAN1998	31DEC1998	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinoplasty	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1152 11521281	Injury, poisoning and procedural complications	Forearm fracture	01JAN2016	31DEC2016	N
			Spinal column injury	01JAN2000	31DEC2000	N
		Investigations	Human papilloma virus test positive	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
	C4591001 1152 11521290	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521292	Gastrointestinal disorders	Inguinal hernia	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2014	31DEC2014	N
			Meniscus operation	01JAN2015	31DEC2015	N
	C4591001 1152 11521293	Eye disorders	Myopia	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Pneumonia	01JAN1973	31DEC1973	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Limb operation	01JAN2019	31DEC2019	N
	C4591001 1152 11521294	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1974	31DEC2003	N
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	01JAN1983	31DEC1983	N
				01JAN1987	31DEC1987	N
				01JAN1988	31DEC1988	N
			Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1152 11521299	Nervous system disorders	Migraine	01JAN1980		Y
		Surgical and medical procedures	Appendicectomy	01JAN1987	31DEC1987	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1152 11521301	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521303	Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Food allergy	01JAN1962		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521304	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
			Sciatica	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1152 11521305	Infections and infestations	Pneumonia	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Ligament operation	01JAN1982	31DEC1982	N
	C4591001 1152 11521306	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1152 11521307	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1152 11521310	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN1978	31DEC1978	N
				01JAN1998	31DEC1998	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC2000	N
		Surgical and medical procedures	Spinal laminectomy	01JAN1978	31DEC1978	N
				01JAN1998	31DEC1998	N
			Wisdom teeth removal	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1152 11521311	Immune system disorders	Allergy to animal	01JAN1959		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Bone lesion excision	01JAN2005	31DEC2005	N
	C4591001 1152 11521313	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1152 11521314	Surgical and medical procedures	Lithotripsy	01JAN2015	31DEC2015	N	
		Endocrine disorders	Hypothyroidism	01JAN1990		Y	
		Hepatobiliary disorders	Gallbladder disorder	01JAN2012	31DEC2012	N	
		Immune system disorders	Drug hypersensitivity	01JAN2004		Y	
			Seasonal allergy	01JAN1974		Y	
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2020		Y	
		Psychiatric disorders	Insomnia	01JAN2000		Y	
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N	
			Hysterectomy	01JAN2006	31DEC2006	N	
			Mammoplasty	01JAN2005	31DEC2005	N	
		C4591001 1152 11521315	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Psychiatric disorders	Depression	01JAN2010		Y
		C4591001 1152 11521320	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Investigations	Tuberculin test positive	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y	
			Osteoporosis	01JAN2016		Y	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N	
		Surgical and medical procedures	Breast conserving surgery	01JAN2016	31DEC2016	N	
		Vascular disorders	Hypertension	01JAN2005		Y	
	C4591001 1152 11521321	Endocrine disorders	Hypothyroidism	01JAN2014		Y	
		Eye disorders	Retinal haemorrhage	01JAN2005	31DEC2005	N	
				01JAN2007	31DEC2007	N	
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Peripheral swelling	01JAN1999		Y
		Metabolism and nutrition disorders	Hypokalaemia	01JUL2020		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	01JAN1996	31DEC1996	N
		Nervous system disorders	Cerebrovascular accident	01JAN1999	31DEC1999	N
		Reproductive system and breast disorders	Prostatism	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1152 11521326	Gastrointestinal disorders	Dyspepsia	01JAN2017	31DEC2018	N
			Inguinal hernia	01JAN2018	31DEC2018	N
			Umbilical hernia	01JAN2019	31DEC2019	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Prostatism	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Meniscus operation	01JAN1990	31DEC1990	N
			Prostatic operation	01JAN2014	31DEC2014	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
			Umbilical hernia repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521330	Immune system disorders	Seasonal allergy	01JAN1993		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Ankle operation	01JAN2000	31DEC2000	N
			Open reduction of fracture	01JAN2000	31DEC2000	N
	C4591001 1152 11521331	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1152 11521334	Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN1984	31DEC1984	N
		Investigations	Biopsy prostate	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Prostatism	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Palatal operation	01JAN2000	31DEC2000	N
			Prostatic operation	01JUL2020	31JUL2020	N
	C4591001 1152 11521337	Cardiac disorders	Mitral valve prolapse	01JAN1981		Y
			Palpitations	01JAN2016		Y
		Ear and labyrinth disorders	Deafness unilateral	01JAN2014		Y
			Meniere's disease	01JAN2014		Y
		Gastrointestinal disorders	Abdominal pain	01JAN1973	31DEC2008	N
			Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
				01JAN2005		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Joint injury	01JAN1992	31DEC2016	N
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
				01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1990	31DEC2017	N
			Squamous cell carcinoma of skin	01JAN1993	31DEC1993	N
		Nervous system disorders	Migraine with aura	01JAN2014		Y
			Neuralgia	01JAN1992	31DEC1994	N
		Reproductive system and breast disorders	Endometriosis	01JAN1997		Y
			Ovarian cyst	01JAN1973		Y
		Surgical and medical procedures	Abdominal operation	01JAN1997	31DEC1997	N
			Caesarean section	03JUN1998	03JUN1998	N
				28APR1994	28APR1994	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
			Oophorectomy	01JAN2008	31DEC2008	N
			Peripheral nerve transposition	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1152 11521342	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Eye disorders	Myopia	01JAN1972		Y
		Immune system disorders	Perennial allergy	01JAN1962		Y
		Injury, poisoning and procedural complications	Ankle fracture	16APR2009	16APR2009	N
		Investigations	Biopsy colon	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Fracture treatment	16APR2009	16APR2009	N
	C4591001 1152 11521343	Gastrointestinal disorders	Colitis	01JAN1972	31DEC1982	N
			Diarrhoea	01JAN1978	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dyspepsia	01JAN2003	31DEC2004	N
			Inguinal hernia	01JAN1998	31DEC1998	N
			Peptic ulcer	01JAN2003	31DEC2003	N
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2006	N
		Surgical and medical procedures	Gastrointestinal ulcer management	01JAN2003	31DEC2003	N
			Inguinal hernia repair	01JAN1998	31DEC1998	N
			Ligament operation	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
			Anal fissure	01JAN2007	31DEC2007	N
	C4591001 1152 11521349	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN2007	31DEC2008	N
			Inguinal hernia	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
				01JAN1961		Y
		Infections and infestations	Sinusitis	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2019	30APR2020	N
				01JUL2019	31JUL2019	N
			Osteoarthritis	01JAN2018		Y
			Rotator cuff syndrome	01DEC2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Prostatism	01JAN2013		Y
		Surgical and medical procedures	Anorectal operation	01JAN2007	31DEC2007	N
			Carpal tunnel decompression	01JAN1998	31DEC1998	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
			Rotator cuff repair	01DEC2019	31DEC2019	N
			Sinus operation	01JAN1999	31DEC1999	N
			Spinal decompression	01APR2020	30APR2020	N
				01JUL2019	31JUL2019	N
			Varicose vein operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2005		Y
			Varicose vein	01JAN2004		Y
	C4591001 1152 11521350	Immune system disorders	Perennial allergy	01JAN1960		Y
		Vascular disorders	Hypotension	01JAN1965		Y
	C4591001 1152 11521351	Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2014	31DEC2014	N
				01JAN2015	31DEC2015	N
			Inguinal hernia repair	01JAN2019	31DEC2019	N
	C4591001 1152 11521358	Eye disorders	Myopia	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521359	Cardiac disorders	Angina pectoris	01JAN2013		Y
		Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Cataract	01MAR2019	31MAR2019	N
		Gastrointestinal disorders	Abdominal pain upper	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1993		Y
			Rheumatoid arthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1991	31DEC1991	N
			Lipoma	01JAN2012	31DEC2012	N
			Malignant melanoma	01JAN1991	31DEC1991	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01FEB2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1991		Y
		Surgical and medical procedures	Cataract operation	01MAR2019	31MAR2019	N
			Cholecystectomy	01JAN2003	31DEC2003	N
			Lipoma excision	01JAN2012	31DEC2012	N
			Mastectomy	01JAN1991	31DEC1991	N
			Skin neoplasm excision	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN1991		Y
			Varicose vein	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521364	Blood and lymphatic system disorders	Anaemia	01JAN2001	31DEC2002	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN2002	31DEC2002	N
		Nervous system disorders	Neuralgia	01JAN1996	31DEC1997	N
		Psychiatric disorders	Anxiety	01JAN2015	31DEC2019	N
			Depression	01JAN2015	31DEC2019	N
		Surgical and medical procedures	Craniotomy	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2000		Y
			Varicose vein	01JAN2000		Y
	C4591001 1152 11521368	Infections and infestations	Hepatitis C	01JAN1996	31DEC2003	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
			Type 1 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Fracture treatment	01JAN1990	31DEC1990	N
			Limb operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521370	Eye disorders	Dry eye	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
			Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Thyroidectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1152 11521375	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2012	31DEC2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1998	31DEC1999	N
		Reproductive system and breast disorders	Uterine cyst	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Breast reconstruction	01JAN2000	31DEC2000	N
			Bunion operation	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Mastectomy	01JAN1998	31DEC1998	N
	C4591001 1152 11521380	Ear and labyrinth disorders	Deafness transitory	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Dyspepsia	01JAN1980		Y
			Haemorrhoids	01JAN2000	31DEC2002	N
		General disorders and administration site conditions	Peripheral swelling	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1960	31DEC2003	N
		Infections and infestations	Gonorrhoea	01JAN1968	31DEC1968	N
			Pneumonia	01JAN2003	31DEC2003	N
		Injury, poisoning and procedural complications	Spinal column injury	01JAN1998	31DEC1998	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prostate cancer	01JAN2013	31DEC2014	N
			Squamous cell carcinoma of skin	01JAN2010	31DEC2010	N
		Nervous system disorders	Monoplegia	01JAN1998	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1951	31DEC1954	N
			Nasal septum deviation	01JAN1980	31DEC1982	N
		Surgical and medical procedures	Prostatectomy	01AUG2014	31AUG2014	N
			Rhinoplasty	01JAN1982	31DEC1982	N
			Spinal fusion surgery	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2012	31JAN2020	N
	C4591001 1152 11521385	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1980		Y
			Food allergy	01JAN1960		Y
		Infections and infestations	Urinary tract infection	01JAN2017	31DEC2018	N
		Investigations	Biopsy lymph gland	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Vaginal prolapse	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31DEC2017	N
			Urinary bladder suspension	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1152 11521386	Gastrointestinal disorders	Constipation	01JAN2019		Y
			Haemorrhoids	01APR2020		Y
		Immune system disorders	Allergy to metals	01JAN1982		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Drug hypersensitivity	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Varicose vein	01JAN2006		Y
	C4591001 1152 11521387	Endocrine disorders	Hypothyroidism	01AUG2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Injury, poisoning and procedural complications	Eye injury	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1152 11521388	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521389	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Infections and infestations	Hepatitis A	01JAN1962	31DEC1962	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Rotator cuff syndrome	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatism	01JAN2013		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1152 11521392	Immune system disorders	Food allergy	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN1990	31DEC1994	N
	C4591001 1152 11521395	Immune system disorders	Seasonal allergy	01JAN1999	31DEC2015	N
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1974	31DEC1974	N
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1152 11521398	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Investigations	Cardiac murmur	08SEP2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1990	31DEC2010	N
		Surgical and medical procedures	Lithotripsy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1152 11521411	Cardiac disorders	Coronary artery disease	01JAN1997		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1997	31DEC1997	N
			Large intestine polyp	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN1951		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1994	31DEC1994	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1997	31DEC1997	N
			Large intestinal polypectomy	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder arthroplasty	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1954	31DEC1954	N
	C4591001 1152 11521417	Eye disorders	Astigmatism	01JAN2000		Y
		Gastrointestinal disorders	Haemorrhoids	01JUL2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
			Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1999		Y
			Vocal cord disorder	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Ankle arthroplasty	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
			Rotator cuff repair	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1972	31DEC1972	N
			Vocal cord operation	01JAN2009	31DEC2009	N
	C4591001 1152 11521418	Vascular disorders	Hypertension	01JAN2003		Y
		Gastrointestinal disorders	Colitis ulcerative	01JAN1976		Y
		Immune system disorders	Rubber sensitivity	01JAN1987		Y
			Seasonal allergy	01JAN1966		Y
		Infections and infestations	Genital herpes	01JAN2001		Y
		Injury, poisoning and procedural complications	Flail chest	01JAN2014	31DEC2014	N
			Rib fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papilloma	01JAN1988	31DEC1988	N
			Schwannoma	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1966		Y
			Psoriasis	01JAN1966		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN2012	31DEC2012	N
			Uvulectomy	01JAN1988	31DEC1988	N
			Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1152 11521420	Ear and labyrinth disorders	Tinnitus	01JAN1985		Y
		Eye disorders	Cataract	01MAY2020	01JUN2020 11MAY2020	N N
		Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		General disorders and administration site conditions	Drug intolerance	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Pneumonia	01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2009	31DEC2009	N
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1980	31DEC2015	N
			Sciatica	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Bursa removal	01JAN2009	31DEC2009	N
			Cataract operation	01JUN2020	01JUN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				11MAY2020	11MAY2020	N
			Inguinal hernia repair	01JAN2019	31DEC2019	N
			Meniscus removal	01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
	C4591001 1152 11521425	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Immune system disorders	Allergy to metals	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	01JAN2010		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1952	31DEC1952	N
				01JAN1958	31DEC1958	N
	C4591001 1152 11521428	Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
	C4591001 1152 11521438	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1970		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hypercholesterolaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1990	31DEC1990	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521448	Surgical and medical procedures	Shoulder operation	01JAN1990	31DEC1990	N
		Eye disorders	Amblyopia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN2009	31DEC2009	N
		Nervous system disorders	Visual field defect	01JAN1990		Y
	C4591001 1152 11521466	Surgical and medical procedures	Bone lesion excision	01JAN2010	31DEC2010	N
			Brain tumour operation	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
				01JAN1980	31DEC1980	N
	C4591001 1152 11521471			01JAN1987	31DEC1987	N
			Cholecystectomy	01JAN2018	31DEC2018	N
			Urinary bladder suspension	01JAN2019	31DEC2019	N
		Gastrointestinal disorders	Dyspepsia	01JAN2017		Y
	C4591001 1152 11521473	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Cardiac disorders	Cardiac failure congestive	01JAN2017		Y
		Surgical and medical procedures	Cardioversion	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521476	Hepatobiliary disorders	Cholelithiasis	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Food allergy	01JAN1985		Y
			Food allergy	01JAN1975		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1990	31DEC1990	N
				01JAN2005	31DEC2005	N
		Surgical and medical procedures	Breast cyst excision	01JAN1990	31DEC1990	N
				01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1152 11521484	Immune system disorders	Drug hypersensitivity	01JAN1974		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Urinary tract infection	01JAN1955		Y
		Investigations	Cardiac murmur	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1999		Y
	C4591001 1152 11521485	Immune system disorders	Allergy to animal	01JAN1949		Y
			Drug hypersensitivity	01JAN2016		Y
			Seasonal allergy	01JAN1970		Y
		Infections and infestations	Histoplasmosis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01APR2016	30APR2016	N
				01APR2019	30APR2019	N
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01SEP2016	30SEP2016	N
			Nasal turbinate hypertrophy	01SEP2016	30SEP2016	N
		Surgical and medical procedures	Bunion operation	01APR2016	30APR2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01APR2019	30APR2019	N
			Rhinoplasty	01SEP2016	30SEP2016	N
			Uterine dilation and curettage	01JAN1974	31DEC1974	N
				01JAN1975	31DEC1975	N
	C4591001 1152 11521486	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Joint swelling	01JAN2020		Y
			Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2001	N
			Tremor	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
			Knee arthroplasty	16AUG2010	16AUG2010	N
				27JUN2011	27JUN2011	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Varicose vein	01JAN1969		Y
	C4591001 1152 11521487	Infections and infestations	Histoplasmosis	01JAN1993	31DEC1993	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Sciatica	01JAN1991	31DEC2008	N
		Surgical and medical procedures	Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1152 11521488	Cardiac disorders	Atrial fibrillation	01JUN2020	30JUN2020	N
		Infections and infestations	Meningitis	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Dizziness	01JUN2020	30JUN2020	N
			Migraine	01JAN1978		Y
		Surgical and medical procedures	Cardiac ablation	01JUN2020	30JUN2020	N
	C4591001 1152 11521491	Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1152 11521494	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Eye disorders	Hypermetropia	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Intracranial aneurysm	01JAN2009	31DEC2009	N
			Sciatica	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN1972		Y
			Depression	01JAN1992		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2008	31DEC2008	N
			Intra-cerebral aneurysm operation	01JAN2009	31DEC2009	N
			Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1152 11521495	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1152 11521497	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Immune system disorders	Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1999	31DEC1999	N
		Reproductive system and breast disorders	Prostatism	01JAN2019		Y
		Surgical and medical procedures	Lithotripsy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1152 11521502	Cardiac disorders	Myocardial infarction	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Inguinal hernia	01JAN1973	31DEC1973	N
		Immune system disorders	Perennial allergy	01JAN2018		Y
		Infections and infestations	Chronic sinusitis	01JAN1955	31DEC2015	N
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN1973	31DEC1973	N
			Sinus operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1152 11521503	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1967	31DEC1967	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521507	Immune system disorders	Perennial allergy	01JAN1970		Y
		Infections and infestations	Urinary tract infection	01JAN1980		Y
		Injury, poisoning and procedural complications	Epicondylitis	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31JAN2020	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Elbow operation	01JAN1985	31DEC1985	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521510	Ear and labyrinth disorders	Deafness	01JAN2019		Y
		Eye disorders	Astigmatism	01JAN1976		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
			Food allergy	01JAN1967		Y
			Iodine allergy	01JAN1965		Y
		Infections and infestations	Peritonitis	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1982	31DEC1982	N
				01JAN2016	31DEC2016	N
		Investigations	Laparoscopy	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1999	31DEC2000	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
			Meniscus operation	01JAN1982	31DEC1982	N
				01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1967	31DEC1967	N
		Eye disorders	Myopia	01JAN1960		Y
			Strabismus	01JAN2013	31DEC2013	N
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Infections and infestations	Genital herpes	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Psychiatric disorders	Insomnia	01JAN1995		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1985	31DEC1985	N
		Surgical and medical procedures	Ovarian cystectomy	01JAN1985	31DEC1985	N
			Strabismus correction	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2019	N
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Caesarean section	21FEB1994	21FEB1994	N
				25OCT1995	25OCT1995	N
			Micrographic skin surgery	01JAN2012	31DEC2012	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
			Uterine dilation and curettage	01JAN1992	31DEC1992	N
	C4591001 1152 11521516	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Eye disorders	Blepharitis	01JAN2017		Y
			Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01MAY2020	31MAY2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
			Lipoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Migraine	01JAN1996		Y
		Surgical and medical procedures	Lipoma excision	01JAN2005	31DEC2005	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1152 11521518	Hepatobiliary disorders	Cholecystitis	01JAN1991	31DEC1991	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
				01JAN1993	31DEC1993	N
				01JAN1996	31DEC1996	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN1991	31DEC1991	N
			Gastric bypass	01JAN1999	31DEC1999	N
			Tonsillectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1152 11521523	Cardiac disorders	Palpitations	01JAN2010		Y
		Ear and labyrinth disorders	Tinnitus	01MAR2020		Y
		Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1975		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2015		Y
			Foot deformity	01JAN1993	31DEC1993	N
			Osteoarthritis	01JAN2010		Y
			Osteopenia	01JAN2015		Y
			Periarthritis	01JAN2008	31DEC2008	N
		Nervous system disorders	Headache	01JAN1965		Y
		Psychiatric disorders	Anxiety	01JAN1972		Y
			Depression	01JAN1972		Y
		Renal and urinary disorders	Pollakiuria	01JAN1990		Y
			Urinary retention	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Rhinophyma	01FEB2020		Y
		Surgical and medical procedures	Bunion operation	01JAN1993	31DEC1993	N
			Shoulder operation	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1152 11521524	Endocrine disorders	Parathyroid disorder	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Dry eye	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN1955	31DEC1955	N
			Onychomycosis	01OCT2020		Y
			Pneumonia	01DEC2019	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Appendectomy	01JAN1955	31DEC1955	N
			Parathyroidectomy	01JAN2005	31DEC2005	N
			Urinary bladder suspension	01JAN2018	31DEC2018	N
			Varicose vein operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN1995		Y
			Varicose vein	01JAN1998	31DEC1999	N
	C4591001 1152 11521525	Hepatobiliary disorders	Cholelithiasis	01JAN1992	31DEC1992	N
		Immune system disorders	Perennial allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Nervous system disorders	Neuralgia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
		Reproductive system and breast disorders	Gynaecomastia	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Abdominoplasty	01JAN2005	31DEC2005	N
			Cholecystectomy	01JAN1992	31DEC1992	N
			Gastric bypass	01JAN2005	31DEC2005	N
			Knee arthroplasty	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mastectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1972	31DEC1972	N
	C4591001 1152 11521526	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1152 11521527	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Shoulder operation	01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
	C4591001 1152 11521528	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
			Palpitations	01JAN2016		Y
		Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Pilonidal cyst	01JAN1976	31DEC1976	N
			Pneumonia	01DEC2019	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Sciatica	01JAN2010	31DEC2011	N
			Syncope	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Prostatism	01JAN2019	31MAR2020	N
		Surgical and medical procedures	Implantable defibrillator insertion	01JAN2018	31DEC2018	N
			Orchidectomy	01JAN2019	31DEC2019	N
			Pilonidal sinus repair	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521530	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1990	31DEC1990	N
			Osteoarthritis	01JAN1993		Y
		Nervous system disorders	Sciatica	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1152 11521531	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Eye disorders	Cataract	01JAN2014	31DEC2014	N
			Maculopathy	01JAN2017		Y
		Injury, poisoning and procedural complications	Splenic rupture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2007	31DEC2007	N
			Prostate cancer	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Artificial urinary sphincter implant	01JAN2014	31DEC2014	N
			Cataract operation	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Pituitary tumour removal	01JAN2007	31DEC2007	N
			Prostatectomy	01JAN2009	31DEC2009	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
	C4591001 1152 11521532	Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1980	31DEC2018	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1990	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Sciatica	01JAN2018	31DEC2019	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
	C4591001 1152 11521535	Surgical and medical procedures	Meniscus operation	01JAN1990	31DEC1990	N
		Cardiac disorders	Coronary artery disease	01JAN1995		Y
			Myocardial infarction	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
		Gastrointestinal disorders	Dyspepsia	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Abnormal loss of weight	01AUG2020	01NOV2020	N
			Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1995	31DEC1995	N
			Osteoarthritis	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Nervous system disorders	Sciatica	01JAN2000	31DEC2000	N
		Psychiatric disorders	Affective disorder	01AUG2020	01NOV2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Cough	01MAR2020	30JUN2020	N
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Bone lesion excision	01JAN1995	31DEC1995	N
			Coronary arterial stent insertion	01JAN1995	31DEC1995	N
				01JAN1998	31DEC1998	N
				01JAN2001	31DEC2001	N
				01JAN2003	31DEC2003	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
		Vascular disorders	Neovascularisation	01JAN2005		Y
	C4591001 1152 11521536	Immune system disorders	Perennial allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Ankle fracture	01NOV2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Caesarean section	26OCT1995	26OCT1995	N
				29SEP1993	29SEP1993	N
			Open reduction of fracture	01NOV2019	30NOV2019	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
			Shoulder arthroplasty	22JUL2020	22JUL2020	N
	C4591001 1152 11521538	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
	C4591001 1152 11521539	Cardiac disorders	Myocardial infarction	01MAR2020	31MAR2020	N
		Ear and labyrinth disorders	Hypoacusis	01JAN1968		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Chest pain	01MAR2020	31MAR2020	N
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN1972	31DEC1972	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAR2020	31MAR2020	N
			Elbow operation	01JAN1972	31DEC1972	N
			Haemorrhoid operation	01JAN1970	31DEC1970	N
			Skin neoplasm excision	01JAN2016	31DEC2016	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1152 11521540	Cardiac disorders	Palpitations	01JAN2000	31DEC2012	N
		Ear and labyrinth disorders	Meniere's disease	01JAN2010	31DEC2012	N
		Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Eye disorders	Anisometropia	01JAN2000		Y
		Gastrointestinal disorders	Constipation	01JAN1998	31DEC1999	N
			Dyspepsia	01JAN2015		Y
			Haemorrhoids	01JAN1999	31DEC2000	N
			Peptic ulcer	01JAN1973	31DEC1999	N
		Infections and infestations	Hepatitis A	01JAN1998	31DEC1998	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2003	31DEC2005	N
		Nervous system disorders	Dizziness	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1994	31DEC1994	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1994		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Varicose vein	01JAN2015		Y
	C4591001 1152 11521542	Ear and labyrinth disorders	Meniere's disease	01JAN1995		Y
		Eye disorders	Myopia	01JAN2010		Y
		Injury, poisoning and procedural complications	Patella fracture	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Fracture treatment	01JAN2013	31DEC2013	N
			Nervous system neoplasm surgery	01JAN2016	31DEC2016	N
	C4591001 1152 11521543	Eye disorders	Cataract	01JAN2011		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1953	31DEC1953	N
			Large intestine polyp	01JAN2013	31DEC2013	N
		Immune system disorders	Food allergy	01JAN1976		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2015	29FEB2020	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1953	31DEC1953	N
			Polypectomy	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JUN2020	31AUG2020	N
			Hypotension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521544	General disorders and administration site conditions	Drug intolerance	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2000	31DEC2000	N
			Dizziness	01JAN1990		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1960	31DEC1960	N
	C4591001 1152 11521545	Cardiac disorders	Palpitations	(b) (6) 1953		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
		Infections and infestations	Escherichia infection	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01MAR2015	31MAR2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1979	31DEC1979	N
				01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1953	31DEC1965	N
			Sinus disorder	01JAN1953		Y
	C4591001 1152 11521546	Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1993	31DEC1993	N
				01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Toe operation	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1968	31DEC1968	N
			Uterine dilation and curettage	01JAN1984	31DEC1984	N
	C4591001 1152 11521547	Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tendon rupture	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Rotator cuff syndrome	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Lower urinary tract symptoms	01JAN2016		Y
			Nephrolithiasis	01JAN2015	31DEC2016	N
		Reproductive system and breast disorders	Prostatism	01JAN2016		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Tenoplasty	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1958	31DEC1958	N
	C4591001 1152 11521548	Surgical and medical procedures	Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1152 11521550	Gastrointestinal disorders	Haemorrhoids	01JAN1983		Y
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
		Infections and infestations	Pneumonia	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
			Osteopenia	01JAN2000	31DEC2014	N
			Osteoporosis	01JAN2014		Y
	C4591001 1152 11521553	Eye disorders	Astigmatism	01JAN1965		Y
		Infections and infestations	Staphylococcal infection	01JAN2008	31DEC2008	N
		Investigations	Biopsy breast	01JAN1995	31DEC1995	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1990		Y
		Reproductive system and breast disorders	Breast mass	01JAN1990		Y
			Ovarian mass	01JAN1996	31DEC1996	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Surgical and medical procedures	Oophorectomy	01JAN1996	31DEC1996	N
			Salpingectomy	01JAN1996	31DEC1996	N
	C4591001 1152 11521554	Congenital, familial and genetic disorders	Congenital musculoskeletal anomaly	(b) (6) 1949	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Food allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
				01JAN2016	31DEC2016	N
			Biopsy breast	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Reproductive system and breast disorders	Breast mass	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1950	31DEC1980	N
		Surgical and medical procedures	Caesarean section	29JUL1988	29JUL1988	N
			Tenoplasty	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypotension	01JAN1960	31DEC1995	N
	C4591001 1152 11521555	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUN2020	30JUN2020	N
		Surgical and medical procedures	Breast conserving surgery	29JUN2020	29JUN2020	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1152 11521556	Eye disorders	Cataract	01JAN2002	31DEC2002	N
			Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cataract operation	01JAN2002	31DEC2002	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
	C4591001 1152 11521558	Hepatobiliary disorders	Gallbladder disorder	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
			Bladder cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN2008	31DEC2008	N
			Transurethral bladder resection	01JAN2008	31DEC2008	N
	C4591001 1152 11521559	Injury, poisoning and procedural complications	Ligament rupture	01JAN1991	31DEC1991	N
				01JAN2001	31DEC2001	N
			Meniscus injury	01JAN1975	31DEC1975	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Surgical and medical procedures	Ligament operation	01JAN1991	31DEC1991	N
				01JAN2001	31DEC2001	N
			Meniscus operation	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1152 11521561	Cardiac disorders	Cardiac valve disease	01JAN2017	30APR2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Hypermetropia	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Heart valve replacement	01APR2017	30APR2017	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1152 11521562	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Immune system disorders	Allergy to arthropod sting	01JAN1954		Y
			Food allergy	01JAN1954		Y
			Iodine allergy	01JAN1973		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01JAN1981	31DEC1981	N
			Foot fracture	01JAN2006	31DEC2006	N
			Road traffic accident	01JAN1981	31DEC1981	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1999	31DEC1999	N
			Osteoarthritis	01JAN2009		Y
			Osteoporosis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Bunion operation	01JAN1999	31DEC1999	N
			Cataract operation	01JAN2018	31DEC2018	N
			Fracture treatment	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2019	31DEC2019	N
			Skin neoplasm excision	01JUL2020	31JUL2020	N
			Spinal fracture treatment	01JAN1981	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521563	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Food allergy	01JAN1958		Y
			Mite allergy	01JAN1958		Y
			Seasonal allergy	01JAN1958		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2000	31DEC2000	N
			Tendon rupture	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1958		Y
		Surgical and medical procedures	Appendectomy	01JAN1958	31DEC1958	N
			Bone operation	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1973	31DEC1973	N
			Meniscus removal	01JAN1972	31DEC1972	N
				01JAN1973	31DEC1973	N
			Tenoplasty	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1152 11521564	Eye disorders	Myopia	01JAN1965		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1972	31DEC1995	N
		Surgical and medical procedures	Face lift	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Mammoplasty	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1152 11521565	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1998	31DEC1998	N
				01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1995	N
		Nervous system disorders	Migraine	01JAN2010		Y
			Thoracic outlet syndrome	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2007		Y
		Surgical and medical procedures	Abdominoplasty	01JUN2020	30JUN2020	N
			Aneurysm repair	01JAN2010	31DEC2010	N
			Caesarean section	19APR1981	19APR1981	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Mammoplasty	01JUN2020	30JUN2020	N
			Rotator cuff repair	01JAN1998	31DEC1998	N
			Shoulder operation	01JAN2008	31DEC2008	N
			Tonsillectomy	01JAN1963	31DEC1963	N
		Vascular disorders	Aortic aneurysm	01JAN2010	31DEC2010	N
	C4591001 1152 11521567	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1152 11521572	Ear and labyrinth disorders	Deafness unilateral	01JAN1964		Y
		Eye disorders	Amblyopia	01JAN1958	31DEC1958	N
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Infections and infestations	Herpes zoster	01JAN1985	31DEC2000	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1992	31DEC2003	N
		Nervous system disorders	Dizziness	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Eye operation	01JAN1958	31DEC1958	N
		Vascular disorders	Hypertension	01JAN1990	31DEC2005	N
	C4591001 1152 11521573	Blood and lymphatic system disorders	Anaemia	01JAN2013	31DEC2013	N
		Eye disorders	Astigmatism	01JAN1980		Y
			Myopia	01JAN1980		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012	31DEC2015	N
			Haemorrhoids	01JAN2018		Y
			Inguinal hernia	01JAN2010	31DEC2010	N
			Irritable bowel syndrome	01JAN2017		Y
			Umbilical hernia	01JAN2012	31DEC2012	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
				01JAN1985	31DEC1985	N
				01JAN1987	31DEC1987	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1152 11521574	Vascular disorders	Hypertension	01JAN2014		Y	
		Cardiac disorders	Mitral valve prolapse	01JAN1979		Y	
				Palpitations	01JAN1979	31DEC1998	N
		Eye disorders	Myopia	01JAN1974		Y	
		Immune system disorders	Drug hypersensitivity	01JAN2009		Y	
			Seasonal allergy	01JAN1991		Y	
		Infections and infestations	Meningitis	01JAN1991	31DEC1991	N	
		Injury, poisoning and procedural complications	Muscle rupture	01JAN2016	31DEC2016	N	
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2005		Y	
			Intervertebral disc protrusion	01JAN2009	31DEC2009	N	
			Muscle spasms	01JAN2009		Y	
			Osteoarthritis	01JAN2010		Y	
			Rotator cuff syndrome	01JAN2012	31DEC2012	N	
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N	
		Psychiatric disorders	Anxiety	01JAN1979		Y	
			Depression	01JAN1979	31DEC1983	N	
		Renal and urinary disorders	Nephrolithiasis	01JAN1978		Y	
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y	
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N	
		Intervertebral disc operation	01JAN2009	31DEC2009	N		
		Muscle operation	01JAN2016	31DEC2016	N		
		Rotator cuff repair	01JAN2012	31DEC2012	N		
	C4591001 1152 11521576	Eye disorders	Presbyopia	01JAN2005		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Milk allergy	01JAN2015		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2011	31DEC2011	N
			Osteoarthritis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2016	31DEC2017	N
				01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN1966	31DEC1966	N
			Colostomy	01JAN2016	31DEC2016	N
			Colostomy closure	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2011	31DEC2011	N
	C4591001 1152 11521578	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2010	31DEC2014	N
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1995		Y
			Haemorrhoids	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2010	31DEC2010	N
		Nervous system disorders	Sciatica	01JAN1974		Y
		Surgical and medical procedures	Ligament operation	01JAN1969	31DEC1969	N
			Splenectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1957	31DEC1957	N
	C4591001 1152 11521579	Eye disorders	Dry eye	01JUN2019		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2010	30SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dyspepsia	01JAN2010		Y
			Umbilical hernia	01JAN1956	31DEC1956	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Insomnia	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01JAN1972		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Umbilical hernia repair	01JAN1956	31DEC1956	N
	C4591001 1152 11521580	Eye disorders	Blindness unilateral	01JAN1949		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1959		Y
			Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Pneumonia	01JAN1994	31DEC1994	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Foot deformity	01JAN1990	31DEC1990	N
			Osteoarthritis	01JAN2000		Y
			Rheumatoid arthritis	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1993	31DEC1993	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1979		Y
		Surgical and medical procedures	Bunion operation	01JAN1990	31DEC1990	N
			Eye operation	01JAN1951	31DEC1951	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1955	31DEC1955	N
				01JAN1958	31DEC1958	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Toe operation	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1152 11521581	Ear and labyrinth disorders	Deafness unilateral	01JAN1970		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Myopia	01JAN1944		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1966	31DEC1990	N
			Gastric ulcer	01JAN1966	31DEC1966	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990	31OCT2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990	31DEC2019	N
		Nervous system disorders	Sciatica	01JAN2005	31DEC2016	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Tenoplasty	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1945	31DEC1945	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1152 11521582	Gastrointestinal disorders	Constipation	01JAN2002		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01FEB2020	29FEB2020	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1999	31DEC1999	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2012		Y
		Surgical and medical procedures	Bunion operation	01FEB2020	29FEB2020	N
				01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2002	31DEC2002	N
			Renal stone removal	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2019	31DEC2019	N
	C4591001 1152 11521585	Investigations	Cardiac murmur	30OCT2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01SEP2020	31DEC2020	N
		Surgical and medical procedures	Skin neoplasm excision	01SEP2020	30SEP2020	N
			Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1156 11561001	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
			Food allergy	01JAN1964		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1978	25DEC1979	N
				01JAN1996	31OCT2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008	31AUG2016	N
		Surgical and medical procedures	Hip surgery	01AUG2016	31AUG2016	N
			Shoulder operation	01JAN2017	31OCT2017	N
				01OCT2000	31OCT2000	N
				01OCT2017	31OCT2017	N
				25DEC1979	25DEC1979	N
	C4591001 1156 11561020	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2006	31DEC2017	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2013		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1156 11561022	Injury, poisoning and procedural complications	Scapula fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Overweight	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Bursitis	01JAN2016	31DEC2016	N
			Neck pain	01JAN2014		Y
			Spinal osteoarthritis	01JAN2011		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Depression	01JAN2010		Y
			Post-traumatic stress disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Chronic obstructive pulmonary disease	01JAN2012		Y
			Respiratory distress	01JAN2015	31DEC2015	N
			Sleep apnoea syndrome	01JAN2013		Y
		Social circumstances	Postmenopause	06JAN2015	06JAN2015	N
	C4591001 1156 11561024	Investigations	Cardiac murmur	05AUG2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1979		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1978	31DEC1978	N
		Nervous system disorders	Diabetic neuropathy	04JAN2019		Y
		Psychiatric disorders	Major depression	04JAN2019		Y
		Renal and urinary disorders	Chronic kidney disease	05AUG2019		Y
		Social circumstances	Postmenopause	01JAN1979	31DEC1979	N
		Surgical and medical procedures	Hysterectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1156 11561025	Gastrointestinal disorders	Gastroesophageal reflux disease	22MAY2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	11AUG2020		Y
			Type 2 diabetes mellitus	11AUG2020		Y
		Renal and urinary disorders	Haematuria	18JUL2017		Y
			Nephrolithiasis	13JUL2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1156 11561035	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Hip fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1998		Y
		Surgical and medical procedures	Hip surgery	01JAN2014	31DEC2014	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1156 11561037	Ear and labyrinth disorders	Vertigo positional	02MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Hepatic steatosis	08FEB2018		Y
		Infections and infestations	Adenoiditis	01JAN1966	31DEC1966	N
			Chronic tonsillitis	01JAN1966	31DEC1966	N
		Metabolism and nutrition disorders	Obesity	06FEB2017	01JUL2020	N
		Musculoskeletal and connective tissue disorders	Osteopenia	08FEB2018		Y
			Osteoporosis	02MAR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	08FEB2018		Y
		Psychiatric disorders	Anxiety disorder	06FEB2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	06FEB2017		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1966	31DEC1966	N
			Nasal septal operation	01JAN1982	31DEC1982	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1156 11561038	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Injury, poisoning and procedural complications	Arthropod bite	20JUL2020	26AUG2020	N
		Investigations	Mammogram abnormal	12MAY2020	28MAY2020	N
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2008	31DEC2008	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2006		Y
			Sciatica	01JAN2018		Y
			Seizure	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Reproductive system and breast disorders	Breast mass	18DEC2019	28MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Foot operation	01JAN2008	31DEC2008	N
			Gallbladder operation	01JAN2006	31DEC2006	N
	C4591001 1156 11561044	Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	25FEB2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1156 11561047	Metabolism and nutrition disorders	Type 2 diabetes mellitus	25JAN2019		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	26JUN2018		Y
			Osteopenia	13JUN2018		Y
			Osteoporosis	13JUN2018		Y
		Nervous system disorders	Parkinson's disease	25APR2018		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Aortic arteriosclerosis	25APR2018		Y
	C4591001 1156 11561051	Vascular disorders	Hypertension	25OCT2019		Y
	C4591001 1156 11561052	General disorders and administration site conditions	Pre-existing condition improved	28AUG2017	28AUG2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Nervous system disorders	Transient ischaemic attack	28AUG2017	28AUG2017	N
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561059	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2016		Y
		Infections and infestations	Furuncle	19AUG2020	24AUG2020	N
			Herpes dermatitis	11DEC2018	12JAN2019	N
			Influenza	21MAR2020	09APR2020	N
		Investigations	Occult blood positive	20OCT2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	15DEC2018		Y
			Vitamin D deficiency	30OCT2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	07DEC2016		Y
			Pain in extremity	19AUG2020		Y
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y
			Major depression	01JAN2015		Y
		Reproductive system and breast disorders	Ejaculation disorder	19AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	05JUN2019		Y
		Social circumstances	Tobacco user	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2016		Y
			Peripheral vascular disorder	25JUL2019	17SEP2019	N
	C4591001 1156 11561066	Vascular disorders	Hypertension	11JUN2020		Y
	C4591001 1156 11561067	Gastrointestinal disorders	Anal fissure	01JAN1997	31DEC1997	N
		Hepatobiliary disorders	Cholecystitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01JAN1981		Y
			Depression	01JAN1981		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Anorectal operation	01JAN1997	31DEC1997	N
			Caesarean section	11NOV1987	11NOV1987	N
			Cholecystectomy	01JAN1990	31DEC1990	N
			Female sterilisation	01JAN1989	31DEC1989	N
		Vascular disorders	Deep vein thrombosis	01DEC2016	31JAN2017	N
			Hypertension	01JAN2004		Y
	C4591001 1156 11561068	Cardiac disorders	Angina pectoris	28APR2020		Y
			Arteriosclerosis coronary artery	28APR2020		Y
		Eye disorders	Cataract	01JAN2010	31DEC2012	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	13FEB2020		Y
			Hiatus hernia	13FEB2020		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1993	31DEC1993	N
			Non-alcoholic steatohepatitis	03OCT2019	06JAN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Joint dislocation	06JUL2020		Y
		Investigations	Electrocardiogram abnormal	21APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	08AUG2019		Y
		Musculoskeletal and connective tissue disorders	Costochondritis	08JAN2020		Y
			Osteoporosis	23SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1981	31DEC1981	N
		Nervous system disorders	Carpal tunnel syndrome	08AUG2019		Y
		Reproductive system and breast disorders	Breast mass	01JAN1991	31DEC1991	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1957		Y
			Chronic obstructive pulmonary disease	01JAN2014		Y
			Pulmonary mass	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1981		Y
			Tobacco user	01JAN1970	31DEC2015	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1991	31DEC1991	N
			Cataract operation	01JAN2012	31DEC2012	N
			Cholecystectomy	01JAN1993	31DEC1993	N
			Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	08AUG2019		Y
	C4591001 1156 11561069	Gastrointestinal disorders	Inguinal hernia	01JAN1994	31DEC1994	N
				01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Limb injury	01JAN1975	31DEC1975	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	08AUG2019		Y
		Surgical and medical procedures	Amputation	01JAN1975	31DEC1975	N
			Inguinal hernia repair	01JAN1994	31DEC1994	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	08AUG2019		Y
	C4591001 1156 11561070	Gastrointestinal disorders	Constipation	01JAN1972		Y
			Gastric ulcer	01JAN2018		Y
			Haemorrhoids	01JAN2004	31DEC2004	N
		Immune system disorders	Rubber sensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Obesity	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
			Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Caesarean section	01JAN1977	31DEC1977	N
				01JAN1979	31DEC1979	N
			Haemorrhoid operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1156 11561079	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Fall	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10DEC2018		Y
		Psychiatric disorders	Insomnia	08APR2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	16FEB2017		Y
			Dyspnoea	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Tracheostomy	01JAN2010	31DEC2010	N
	C4591001 1156 11561080	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2006	N
		Nervous system disorders	Diabetic neuropathy	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Social circumstances	Postmenopause	01JAN1997		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast conserving surgery	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1156 11561083	Cardiac disorders	Bundle branch block right	01JAN2020		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2000		Y
			Spinal compression fracture	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2008		Y
			Lumbar radiculopathy	01JAN2000		Y
		Renal and urinary disorders	Albuminuria	01JAN2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1156 11561084	Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JAN1981	31DEC1981	N
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
			Trabeculectomy	01JAN2017	31DEC2017	N
	C4591001 1156 11561088	Gastrointestinal disorders	Inguinal hernia	(b) (6) 1955	30APR1965	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Accident	01JAN1978	31DEC1978	N
			Fall	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
		Surgical and medical procedures	Inguinal hernia repair	01APR1965	30APR1965	N
			Knee operation	01JAN2010	31DEC2010	N
			Nasal septal operation	01JAN1978	31DEC1978	N
	C4591001 1156 11561091	Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	14NOV2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
	C4591001 1156 11561092	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2016	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	14MAR2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	11MAY2018		Y
	C4591001 1156 11561094	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Surgical and medical procedures	Salpingectomy	01JAN2009	31DEC2009	N
	C4591001 1156 11561095	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2007		Y
			Tobacco user	01JAN1978		Y
		Surgical and medical procedures	Caesarean section	13OCT1980	13OCT1980	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1156 11561096	Metabolism and nutrition disorders	Obesity	13APR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Delivery	01JUL2006	01JUL2006	N
		Surgical and medical procedures	Caesarean section	01JUL2006	01JUL2006	N
			Contraception	01JUL2006	01JUL2006	N
			Female sterilisation	01JUL2006	01JUL2006	N
	C4591001 1156 11561098	Hepatobiliary disorders	Cholecystitis	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1156 11561099	Endocrine disorders	Hypothyroidism	01APR2017		Y
			Thyroid mass	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	28OCT2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	26AUG2020		Y
			Vitamin D deficiency	09JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	26AUG2020		Y
		Psychiatric disorders	Depression	01MAY2017		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Breast mass	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1156 11561100	Metabolism and nutrition disorders	Hyperglycaemia	01MAY2017		Y
			Hyperlipidaemia	01MAY2017		Y
		Psychiatric disorders	Major depression	19SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Pollakiuria	12JUN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15MAY2017		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	29FEB2020		Y
		Vascular disorders	Hypertension	05MAY2018		Y
	C4591001 1156 11561101	Cardiac disorders	Acute myocardial infarction	25JUL2019	25JUL2019	N
			Coronary artery disease	25JUL2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	25JUL2019		Y
		Investigations	Catheterisation cardiac	25JUL2019	25JUL2019	N
		Musculoskeletal and connective tissue disorders	Back pain	23SEP2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	25JUL2019		Y
			Coronary artery bypass	25JUL2019		Y
		Vascular disorders	Hypertension	25JUL2019		Y
	C4591001 1156 11561102	Gastrointestinal disorders	Abdominal mass	01JAN2016	31DEC2016	N
			Large intestine polyp	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2009	31DEC2016	N
			Hepatic mass	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2012		Y
		Psychiatric disorders	Major depression	01JAN2010		Y
		Social circumstances	Postmenopause	01MAR1994		Y
		Surgical and medical procedures	Cholecystectomy	01AUG2016	31DEC2016	N
			Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1156 11561103	Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Myalgia	12AUG2020		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2000	31DEC2005	N
		Surgical and medical procedures	Toe amputation	01JAN2000	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2016		Y
			Peripheral vascular disorder	01JAN2000	31DEC2005	N
	C4591001 1156 11561104	Metabolism and nutrition disorders	Hypercholesterolaemia	04MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	08AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11DEC2019		Y
		Vascular disorders	Hypertension	04MAR2020		Y
			Peripheral vascular disorder	28AUG2019		Y
	C4591001 1156 11561106	Gastrointestinal disorders	Peptic ulcer	23AUG2019		Y
		Injury, poisoning and procedural complications	Forearm fracture	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Hyperlipidaemia	22MAY2019		Y
			Hyperuricaemia	22JUL2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	12JUN2019		Y
		Surgical and medical procedures	Fracture treatment	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	14MAY2019		Y
	C4591001 1156 11561110	Cardiac disorders	Myocardial infarction	01JAN2011	31DEC2011	N
		Investigations	Prostatic specific antigen increased	22MAY2019		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2011	31DEC2011	N
			Monoplegia	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	01JAN2014		Y
			Depression	01JAN2012		Y
			Panic attack	01JAN2014		Y
		Social circumstances	Tobacco user	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1156 11561112	Gastrointestinal disorders	Gastritis	01JAN2006		Y
			Gastroesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
			Insomnia	01JAN2018		Y
			Major depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1991		Y
		Vascular disorders	Essential hypertension	01JAN2007		Y
	C4591001 1156 11561114	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2015		Y
			Rheumatoid arthritis	01JAN1974		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Arthrodesis	01JAN2015	31DEC2015	N
			Blepharoplasty	01JAN2014	31DEC2014	N
	C4591001 1156 11561116	Eye disorders	Cataract	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2002	31DEC2002	N
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypertriglyceridaemia	14MAY2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1980		Y
			Type 2 diabetes mellitus	01JAN2008		Y
			Vitamin D deficiency	14MAY2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
		Nervous system disorders	Diabetic neuropathy	27NOV2018		Y
		Psychiatric disorders	Major depression	27NOV2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2004		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Inguinal hernia repair	01JAN2002	31DEC2002	N
			Radical prostatectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Diabetic vascular disorder	27NOV2018		Y
			Hypertension	01JAN2008		Y
			Peripheral venous disease	09SEP2020		Y
	C4591001 1156 11561117	Eye disorders	Conjunctivitis allergic	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
			Insomnia	01JAN2012		Y
			Major depression	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2015		Y
		Surgical and medical procedures	Explorative laparotomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561118	Eye disorders	Cataract	01JAN2015	31DEC2018	N
		Investigations	Prostatic specific antigen increased	20JUN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Rheumatoid arthritis	01JAN2011		Y
		Psychiatric disorders	Anxiety disorder	01JAN2011		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
	C4591001 1156 11561122	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	28JUN2006		Y
	C4591001 1156 11561125	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Cataract	01JAN2009	31DEC2009	N
			Open angle glaucoma	01JAN2014		Y
		Gastrointestinal disorders	Constipation	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Nervous system disorders	Cognitive disorder	01JAN2018		Y
			Diabetic neuropathy	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
			Major depression	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1156 11561127	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1995	31DEC1995	N
	C4591001 1156 11561130	Surgical and medical procedures	Rotator cuff repair	01JAN1995	31DEC1995	N
		Cardiac disorders	Cardiac failure	01JAN2010		Y
		Eye disorders	Cataract	01JAN2016	31DEC2017	N
				01JAN2019	24MAR2020	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1984		Y
		Hepatobiliary disorders	Hepatomegaly	01JAN2018		Y
			Non-alcoholic steatohepatitis	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13JUN2017		Y
			Type 2 diabetes mellitus	01JAN1991		Y
		Reproductive system and breast disorders	Erectile dysfunction	06FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Angioplasty	01JAN2013	31DEC2013	N
				01JAN2014	31DEC2014	N
			Coronary angioplasty	01JAN2010	31DEC2010	N
			Intraocular lens implant	01JAN2017	31DEC2017	N
				24MAR2020	24MAR2020	N
		Vascular disorders	Arteriosclerosis	01JAN2010		Y
			Hypertension	13JUN2017		Y
			Peripheral vascular disorder	01JAN2011		Y
	C4591001 1156 11561133	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chronic sinusitis	01JAN2005		Y
		Injury, poisoning and procedural complications	Gun shot wound	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Vitamin D deficiency	01JAN2007		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	11MAR1993	11MAR1993	N
		Psychiatric disorders	Bipolar I disorder	01JAN2003		Y
			Depression	01JAN2003		Y
			Insomnia	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1980	31DEC1980	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1957		Y
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Caesarean section	11MAR1993	11MAR1993	N
			Explorative laparotomy	01JAN1996	31DEC1996	N
			Ovarian cystectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1156 11561138	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2015		Y
			Atrial fibrillation	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Social circumstances	Ex-tobacco user	01JAN1980	30APR2020	N
		Surgical and medical procedures	Implantable defibrillator insertion	11AUG2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1156 11561139	Hepatobiliary disorders	Hepatic steatosis	15JUL2020		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	06SEP2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01MAR2017		Y
			Type 2 diabetes mellitus	11APR2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06JUN2017		Y
				20NOV2018		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	02FEB1981	02FEB1981	N
				14SEP1985	14SEP1985	N
				17MAR1983	17MAR1983	N
		Psychiatric disorders	Major depression	16DEC2019		Y
		Surgical and medical procedures	Caesarean section	02FEB1981	02FEB1981	N
				14SEP1985	14SEP1985	N
				17MAR1983	17MAR1983	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Salpingectomy	14SEP1985	14SEP1985	N
			Sterilisation	14SEP1985		Y
		Vascular disorders	Hypertension	04NOV2016		Y
	C4591001 1156 11561140	Eye disorders	Cataract	01JAN2011	31DEC2011	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2017		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Major depression	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1156 11561141	Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	19MAR2019		Y
			Obesity	28FEB2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	13JUL2020		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	17MAY1992	17MAY1992	N
		Psychiatric disorders	Major depression	31JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	02AUG2018		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2000	31DEC2000	N
			Caesarean section	17MAY1992	17MAY1992	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	14MAR2019		Y
	C4591001 1156 11561142	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Peptic ulcer	01OCT2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1156 11561143	Congenital, familial and genetic disorders	Spina bifida	04OCT2019		Y
		Endocrine disorders	Adrenal disorder	21FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Chronic gastritis	30DEC2019		Y
			Diaphragmatic hernia	04OCT2019		Y
		Hepatobiliary disorders	Hepatic steatosis	04OCT2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04OCT2019		Y
			Type 2 diabetes mellitus	04OCT2019		Y
			Vitamin D deficiency	04OCT2019		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	04OCT2019		Y
			Osteoarthritis	04OCT2019		Y
		Nervous system disorders	Carotid artery occlusion	04OCT2019		Y
			Carotid artery stenosis	04OCT2019		Y
		Psychiatric disorders	Anxiety disorder	04OCT2019		Y
			Major depression	04OCT2019	04NOV2019	N
		Renal and urinary disorders	Urinary incontinence	04OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	04OCT2019		Y
			Emphysema	04OCT2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	04OCT2019		Y
		Vascular disorders	Essential hypertension	04OCT2019		Y
	C4591001 1156 11561144	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Intestinal obstruction	01JAN2015	31DEC2015	N
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Intestinal operation	01JAN2015	31DEC2015	N
			Intraocular lens implant	01JAN2015	31DEC2015	N
	C4591001 1156 11561150	Blood and lymphatic system disorders	Anaemia	01FEB2020		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Cataract	01JAN2017	24APR2019	N
			Diabetic retinopathy	01JAN2019		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Renal and urinary disorders	Hydronephrosis	01FEB2020		Y
		Surgical and medical procedures	Cataract operation	24APR2019	24APR2019	N
	C4591001 1156 11561151	Cardiac disorders	Atrial fibrillation	27FEB2019		Y
			Myocardial infarction	01JAN2001	31DEC2001	N
		Endocrine disorders	Hypothyroidism	01FEB2019		Y
		Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Infections and infestations	Salpingitis	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Cerebrovascular accident	27FEB2019	27FEB2019	N
		Psychiatric disorders	Anxiety	01JAN1981		Y
			Depression	04JUL1980		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Salpingectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN1972		Y
	C4591001 1156 11561152	Eye disorders	Cataract	01JAN2006	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2012		Y
			Vitamin D deficiency	07AUG2020		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008	31DEC2011	N
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
			Transurethral prostatectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1156 11561153	Blood and lymphatic system disorders	Anaemia	21APR2017		Y
		Cardiac disorders	Aortic valve stenosis	01JAN2010	24FEB2014	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	11SEP2019		Y
			Inguinal hernia	01JAN1965	31DEC1965	N
				01JAN1980	31DEC1980	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	26APR2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	27APR2020		Y
		Surgical and medical procedures	Aortic valve replacement	24FEB2014		Y
			Inguinal hernia repair	01JAN1965	31DEC1965	N
				01JAN1980	31DEC1980	N
			Valvuloplasty cardiac	24FEB2014	24FEB2014	N
		Vascular disorders	Hypertension	18NOV2016		Y
	C4591001 1156 11561157	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Injury, poisoning and procedural complications	Accident	29JUL2007	29JUL2007	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Surgical and medical procedures	Finger amputation	29JUL2007	29JUL2007	N
		Vascular disorders	Aortic arteriosclerosis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN2019		Y
	C4591001 1156 11561160†	Blood and lymphatic system disorders	Anaemia	05DEC2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	10MAY2017		Y
		Infections and infestations	HIV infection	01JAN2005		Y
			Rhinitis	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05DEC2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	08OCT2019		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	08OCT1991	08OCT1991	N
				11NOV1974	11NOV1974	N
				20DEC1983	20DEC1983	N
				31DEC1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Asthma	31JAN2018		Y
		Surgical and medical procedures	Caesarean section	08OCT1991	08OCT1991	N
				11NOV1974	11NOV1974	N
				20DEC1983	20DEC1983	N
				31DEC1987	31DEC1987	N
	C4591001 1156 11561167	Eye disorders	Open angle glaucoma	01JAN2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
				17JAN2017		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Nervous system disorders	Cognitive disorder	01JAN2016		Y
			Diabetic neuropathy	09JUL2013		Y
				29FEB2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	24JAN2014		Y
		Vascular disorders	Aortic arteriosclerosis	28JUL2016		Y
			Essential hypertension	01JAN2010		Y
			Peripheral arterial occlusive disease	31JUL2015		Y
			Peripheral venous disease	01JAN2014		Y
	C4591001 1156 11561171	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	08DEC2014	N
		Nervous system disorders	Diabetic neuropathy	01JAN2008		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1987		Y
		Surgical and medical procedures	Breast conserving surgery	08DEC2014	08DEC2014	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1156 11561173	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Gastric bypass	22MAY2017	22MAY2017	N
			Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1156 11561181	Endocrine disorders	Thyroid mass	01JAN2016		Y
		Gastrointestinal disorders	Constipation	01JAN1961		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
			Tonsillitis	01JAN1967	31DEC1967	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Osteoporosis	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Psychiatric disorders	Anxiety disorder	01JAN1965		Y
			Bipolar disorder	01JAN1966		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2016	31DEC2018	N
		Reproductive system and breast disorders	Breast cyst	01JAN1981		Y
			Ovarian cyst	01JAN1974	31DEC1974	N
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Appendectomy	01JAN1982	31DEC1982	N
			Caesarean section	26FEB1976	26FEB1976	N
			Ovarian cystectomy	01JAN1974	31DEC1974	N
			Renal stone removal	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1156 11561182	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Nervous system disorders	Lumbar radiculopathy	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1156 11561183	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		General disorders and administration site conditions	Gait disturbance	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2009		Y
			Vitamin D deficiency	01JAN2019		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2009		Y
			Lumbar radiculopathy	01JAN2017		Y
			Migraine	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Drug dependence	01JAN2018		Y
			Major depression	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
			Diabetic nephropathy	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Diabetic vascular disorder	01JAN2014		Y
			Hypertension	01JAN2010		Y
			Peripheral vascular disorder	01JAN2014		Y
			Peripheral venous disease	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561184	Injury, poisoning and procedural complications	Joint dislocation	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
			Pain in extremity	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
			Migraine	01JAN2008		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Schizophrenia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2006		Y
		Surgical and medical procedures	Knee operation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1156 11561191	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1993	31DEC1993	N
		Nervous system disorders	Migraine	01JAN2005		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
			Insomnia	01JAN2012		Y
			Major depression	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1156 11561192	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1997	31MAR2003	N
		Pregnancy, puerperium and perinatal conditions	Delivery	19DEC1982	19DEC1982	N
				19NOV1988	19NOV1988	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Skin lesion	18SEP2020		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1979	31DEC1979	N
			Caesarean section	19DEC1982	19DEC1982	N
				19NOV1988	19NOV1988	N
			Hysterectomy	01MAR2003	31MAR2003	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1156 11561193	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Cervical radiculopathy	01JAN2009		Y
			Dementia	01JAN2010		Y
			Diabetic neuropathy	01JAN2012		Y
			Lumbar radiculopathy	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1156 11561195	Cardiac disorders	Cardiac failure	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Psychiatric disorders	Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2001		Y
			Peripheral arterial occlusive disease	01MAY2018		Y
	C4591001 1156 11561197	Gastrointestinal disorders	Inguinal hernia	01JAN1970	31DEC1970	N
				22OCT2018	22OCT2018	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN1970	31DEC1970	N
				22OCT2018	22OCT2018	N
	C4591001 1156 11561202	Immune system disorders	Food allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Fall	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 1 diabetes mellitus	01JAN1952		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2017		Y
		Surgical and medical procedures	Spinal operation	01JAN2017	31DEC2017	N
	C4591001 1156 11561204	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2014	16JUL2015	N
		Surgical and medical procedures	Hysterectomy	16JUL2015	16JUL2015	N
		Vascular disorders	Hypertension	01DEC2013		Y
	C4591001 1156 11561207	Immune system disorders	Hypersensitivity	01MAR2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	17OCT2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAR2019	15APR2019	N
		Skin and subcutaneous tissue disorders	Vitiligo	01MAR2019		Y
		Surgical and medical procedures	Prostatectomy	15APR2019	15APR2019	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1156 11561211	Gastrointestinal disorders	Gastritis	29MAY2020		Y
		Vascular disorders	Essential hypertension	01JAN2018		Y
	C4591001 1156 11561212	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1156 11561215	Cardiac disorders	Hypertensive heart disease	01JAN2009		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2009		Y
		Vascular disorders	Peripheral arterial occlusive disease	01JAN2008		Y
	C4591001 1156 11561217	Cardiac disorders	Cardiac failure congestive	16NOV2018		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	01JAN1996		Y
		Ear and labyrinth disorders	Deafness neurosensory	01JAN2017		Y
		Endocrine disorders	Goitre	01JAN1992		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Psychiatric disorders	Major depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
				01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Coronary artery bypass	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1996		Y
			Peripheral vascular disorder	01JAN2000		Y
			Peripheral venous disease	01JAN2003		Y
	C4591001 1156 11561218	Eye disorders	Diabetic retinopathy	04OCT2017		Y
			Glaucoma	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04OCT2017		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Renal and urinary disorders	Chronic kidney disease	04OCT2017		Y
			Diabetic nephropathy	04OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Vascular disorders	Diabetic vascular disorder	04OCT2017		Y
			Hypertension	04OCT2017		Y
	C4591001 1156 11561219	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Seasonal allergy	07SEP2020		Y
	C4591001 1156 11561220	Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
			Sterilisation	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1156 11561221	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN1989		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1156 11561222	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Generalised anxiety disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1156 11561223	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
	C4591001 1156 11561224	Blood and lymphatic system disorders	Iron deficiency anaemia	24APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Pterygium	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2013		Y
	C4591001 1156 11561228	Gastrointestinal disorders	Constipation	01JAN2017		Y
			Hiatus hernia	26SEP2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1987	31DEC1987	N
		Injury, poisoning and procedural complications	Road traffic accident	12DEC2012	12DEC2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2014		Y
			Back pain	01JAN2015		Y
			Osteoarthritis	07FEB2019	27FEB2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1992	N
		Nervous system disorders	Epilepsy	01JAN2011		Y
		Psychiatric disorders	Major depression	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Knee arthroplasty	27FEB2019	27FEB2019	N
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561236	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Obesity	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
			Sleep apnoea syndrome	10MAR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1156 11561238	Gastrointestinal disorders	Gastroesophageal reflux disease	27AUG2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hyperlipidaemia	27AUG2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
			Osteoarthritis	01JAN1990		Y
			Spinal osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Craniotomy	01JAN2005	31DEC2005	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Haematoma	01JAN2005	31DEC2005	N
			Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561240	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2016		Y
		Eye disorders	Cataract	01FEB2019		Y
					26DEC2019	N
		Gastrointestinal disorders	Gastric fistula	01JAN2019		Y
			Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN1982	31DEC1982	N
				01JAN2015		Y
			Umbilical hernia	01JAN1982	31DEC1982	N
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
			Post procedural infection	01JAN1977	31DEC1977	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012		Y
			Bursitis	01JAN2015		Y
			Foot deformity	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
		Surgical and medical procedures	Appendicectomy	01JAN1976	31DEC1976	N
			Bunion operation	01DEC2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Cataract operation	26DEC2019	26DEC2019	N
			Colectomy	01JAN1977	31DEC1977	N
			Inguinal hernia repair	01JAN1982	31DEC1982	N
			Umbilical hernia repair	01JAN1982	31DEC1982	N
	C4591001 1156 11561241	Eye disorders	Hypermetropia	01JAN2000	31DEC2000	N
			Macular degeneration	01JAN2008		Y
			Open angle glaucoma	01JAN2008		Y
		Gastrointestinal disorders	Barrett's oesophagus	30NOV2012		Y
			Gastroesophageal reflux disease	30NOV2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	30NOV2012		Y
		Hepatobiliary disorders	Hepatic steatosis	30JUL2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	25NOV2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30JUL2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Eye operation	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Aortic arteriosclerosis	08JUL2019		Y
	C4591001 1156 11561242	Metabolism and nutrition disorders	Hypercholesterolaemia	31OCT2018		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1156 11561261	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Vascular disorders	Essential hypertension	01JAN2002		Y
	C4591001 1156 11561266	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01MAY2019	31MAY2019	N
		Surgical and medical procedures	Breast conserving surgery	01MAY2019	31MAY2019	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1156 11561267	Cardiac disorders	Angina pectoris	01JAN2017		Y
			Cardiomyopathy	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2003		Y
			Peripheral vascular disorder	01JAN2018		Y
	C4591001 1156 11561269	Cardiac disorders	Cardiovascular disorder	01JAN2011	31DEC2011	N
		Infections and infestations	Appendicitis	01JAN1995	31DEC1995	N
		Musculoskeletal and connective tissue disorders	Enthesopathy	01JAN2011		Y
		Nervous system disorders	Monoplegia	01JAN2011		Y
		Psychiatric disorders	Affective disorder	01JAN2010		Y
			Drug dependence	01JAN2011		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1156 11561271	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
			Toothache	21OCT2020		Y
		Hepatobiliary disorders	Cholelithiasis	01JUL2018	31JUL2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01APR2020		Y
			Arthropathy	01JAN1977	31DEC1977	N
		Reproductive system and breast disorders	Breast cyst	01JAN1976	31DEC1976	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1976	31DEC1976	N
			Cholecystectomy	01JUL2018	31JUL2018	N
			Wrist surgery	01JAN1977	31DEC1977	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1156 11561278	Vascular disorders	Hypertension	01JUN2019		Y
		Gastrointestinal disorders	Hiatus hernia	31OCT2016		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	03JUN2019		Y
			Hyperlipidaemia	04JUN2019		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	13MAY2019		Y
		Nervous system disorders	Amnesia	19SEP2019		Y
		Psychiatric disorders	Anxiety disorder	07NOV2018		Y
			Depression	07NOV2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07NOV2018		Y
			Vascular disorders	Hypertension	01JAN2010	
	C4591001 1156 11561279	Hepatobiliary disorders	Cholelithiasis	30OCT2017		Y
			Hepatic steatosis	30OCT2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1994		Y
		Nervous system disorders	Diabetic neuropathy	29NOV2019		Y
			Lumbar radiculopathy	01JAN1991		Y
		Psychiatric disorders	Major depression	01JAN1991		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN1968	31DEC1994	N
		Surgical and medical procedures	Mammoplasty	01JAN1994	31DEC1994	N
			Vascular disorders	Hypertension	01JAN1970	
	C4591001 1156 11561280		Peripheral vascular disorder	01JAN1985		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	08NOV2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Vascular disorders	Hypertension	07MAR2017		Y
	C4591001 1156 11561284	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
			Caesarean section	27APR1990	27APR1990	N
			Hysterectomy	01JAN2004	31DEC2004	N
			Oophorectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Essential hypertension	01JAN2016		Y
	C4591001 1157 11571005	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1157 11571007	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
	C4591001 1157 11571008	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1157 11571011	Reproductive system and breast disorders	Endometriosis	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
			Salpingectomy	01JAN1985	31DEC1985	N
	C4591001 1157 11571012	Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571014	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
			Lymphadenectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571016	Nervous system disorders	Migraine	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1157 11571018	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571022	Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1986	31DEC1986	N
				01JAN2010	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN1984		Y
		Reproductive system and breast disorders	Breast disorder	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2000	31DEC2000	N
			Cholecystectomy	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571023	Endocrine disorders	Hypogonadism	01JAN2011		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Surgical and medical procedures	Spinal operation	01JAN2019	31DEC2019	N
	C4591001 1157 11571024	Gastrointestinal disorders	Constipation	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1157 11571027	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2002		Y
			Bipolar disorder	01JAN2002		Y
			Depression	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571028	Psychiatric disorders	Depression	01JAN2019		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
	C4591001 1157 11571029	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
	C4591001 1157 11571030	Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1157 11571031	Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N
	C4591001 1157 11571033	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N
	C4591001 1157 11571035	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1157 11571036	Eye disorders	Dry eye	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1157 11571037	Cardiac disorders	Angina pectoris	01JAN1996		Y
			Cardiac failure congestive	01JAN2015		Y
			Coronary artery disease	01JAN2018		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2019	31MAY2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2019	31JAN2019	N
			Parathyroidectomy	01MAY2019	31MAY2019	N
			Vasectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1157 11571038	Endocrine disorders	Goitre	01JAN2008	31DEC2008	N
			Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2008	31DEC2008	N
			Vasectomy	01JAN1976	31DEC1976	N
	C4591001 1157 11571039	Social circumstances	Postmenopause	01JAN1999		Y
	C4591001 1157 11571041	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1157 11571044	Injury, poisoning and procedural complications	Joint injury	01OCT2019		Y
		Investigations	Arthroscopy	01JAN1995	31DEC1995	N
				01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2004	31DEC2004	N
				01JAN2011	31DEC2011	N
				01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571045	Endocrine disorders	Hypothyroidism	01JAN1975		Y
		Infections and infestations	Poliomyelitis	01JAN1951	31DEC1951	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Leg amputation	01JAN1985	31DEC1985	N
			Uterine dilation and curettage	01JAN2000	31DEC2000	N
	C4591001 1157 11571046	Endocrine disorders	Autoimmune thyroiditis	01JAN1997	31DEC1997	N
			Hypothyroidism	01JAN1997		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Radioactive iodine therapy	01JAN1997	31DEC1997	N
	C4591001 1157 11571047	Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1157 11571048	Investigations	Colonoscopy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571049	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1157 11571050	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1157 11571051	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	31DEC2018	N
		Nervous system disorders	Brachial plexopathy	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2018	31DEC2018	N
			Oophorectomy bilateral	01JAN2008	31DEC2008	N
	C4591001 1157 11571053	Endocrine disorders	Hypothyroidism	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2020		Y
			Osteoporosis	01FEB2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1157 11571055	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1157 11571058	Cardiac disorders	Atrial fibrillation	01JAN2003		Y
		Eye disorders	Dry eye	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN1998		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Chronic obstructive pulmonary disease	01JAN2008		Y
			Pulmonary fibrosis	01JAN2013		Y
		Vascular disorders	Deep vein thrombosis	01JAN2003		Y
			Hypertension	01JAN2018		Y
	C4591001 1157 11571059	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1973	31DEC1974	N
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1974	31DEC1974	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571060	Infections and infestations	Genital herpes simplex	01JAN2011		Y
			Onychomycosis	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2011	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1157 11571061	Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2010		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1157 11571062	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1157 11571063	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2004		Y
			Osteoarthritis	01JAN2009		Y
			Spinal osteoarthritis	01JAN2002	31DEC2002	N
		Nervous system disorders	Cervical radiculopathy	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal fusion surgery	01JAN2002	31DEC2002	N
	C4591001 1157 11571064	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Sjogren's syndrome	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1157 11571065	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1157 11571066	Cardiac disorders	Coronary artery disease	01JAN1994		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1994		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1994	31DEC1994	N
				01JAN2016	31DEC2016	N
			Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1157 11571067	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1157 11571068	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Radiculopathy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Spinal operation	01JAN2017	31DEC2017	N
	C4591001 1157 11571069	Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1157 11571072	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1157 11571074	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1157 11571075	Endocrine disorders	Hypothyroidism	01JAN1973		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Irritable bowel syndrome	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1157 11571076	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1992	31DEC1992	N
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1157 11571078	Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1157 11571079	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2007		Y
			Muscle spasms	01JAN2007		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1157 11571080	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1981	31DEC1981	N
		Psychiatric disorders	Depression	01JAN2014		Y
			Insomnia	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571084	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
			Irritable bowel syndrome	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1157 11571085	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
			Spinal pain	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1157 11571086	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1157 11571089	Ear and labyrinth disorders	Meniere's disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1157 11571091	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1157 11571094	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571095	Cardiac disorders	Atrial fibrillation	04NOV2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1157 11571096	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1972		Y
		Infections and infestations	Genital herpes simplex	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1157 11571097	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Mastectomy	01JAN1992	31DEC1992	N
			Oophorectomy bilateral	01JAN1998	31DEC1998	N
	C4591001 1157 11571098	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1157 11571099	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1157 11571100	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571101	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1157 11571102	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
	C4591001 1157 11571104	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Coronary angioplasty	08APR2017	08APR2017	N
			Coronary arterial stent insertion	12APR2017	12APR2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1157 11571110	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1157 11571116	Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1990		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1157 11571119	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Chronic sinusitis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2012	N
			Uterine leiomyoma	01JAN1999	31DEC2003	N
		Nervous system disorders	Neuropathy peripheral	01APR2020		Y
		Psychiatric disorders	Anxiety	01JAN2012		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2012	31DEC2012	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Lymphadenectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571120	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1157 11571123	Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1157 11571128	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	01OCT2011	31OCT2011	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
			Nephrectomy	01OCT2011	31OCT2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1157 11571131	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1157 11571133	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Surgical and medical procedures	Aortic valve replacement	01MAY2019	31DEC2019	N
			Vasectomy	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1157 11571134	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1157 11571138	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1157 11571139	Cardiac disorders	Coronary artery disease	01APR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	09APR2019		Y
		Psychiatric disorders	Panic attack	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	09APR2019	09APR2019	N
		Vascular disorders	Hypertension	09APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571142	Endocrine disorders	Hypothyroidism	01JAN1969		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1157 11571143	Musculoskeletal and connective tissue disorders	Back pain	01JAN1986		Y
		Nervous system disorders	Narcolepsy	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1157 11571144	Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN1980		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2020	02JUL2020	N
			Hypothyroidism	01JAN2005		Y
		Investigations	Biopsy cervix	01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1979	31DEC1989	N
			Uterine leiomyoma	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01DEC1995	31DEC1995	N
			Parathyroid gland operation	02JUL2020	02JUL2020	N
	C4591001 1157 11571146	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571147	Surgical and medical procedures	Salpingectomy	01JAN1980	31DEC1980	N
	C4591001 1157 11571148	Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1157 11571149	Endocrine disorders	Hypogonadism	01JAN2013		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hyperlipidaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	01JAN2010	31DEC2011	N
		Surgical and medical procedures	Chemotherapy	01JAN2010	31DEC2011	N
			Vasectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1157 11571150	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2018		Y
		Surgical and medical procedures	Salpingectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1157 11571151	Respiratory, thoracic and mediastinal disorders	Cough	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01APR2012		Y
	C4591001 1157 11571152	Immune system disorders	Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1157 11571153	Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1157 11571155	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Infections and infestations	Urinary tract infection	08OCT2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
			Prophylaxis	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1157 11571157	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1157 11571158	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1157 11571159	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN2005		Y
	C4591001 1157 11571160	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1157 11571161	Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1157 11571162	Cardiac disorders	Angina pectoris	01JAN2009		Y
			Coronary artery disease	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1157 11571163	Endocrine disorders	Hypothyroidism	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1990	N
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Depression	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1157 11571164	Cardiac disorders	Coronary artery disease	01FEB2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Coronary artery bypass	01FEB2009	28FEB2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1157 11571167	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1157 11571171	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
			Hiatus hernia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1157 11571172	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Deep vein thrombosis	01JAN2017		Y
			Hypertension	01JAN2000		Y
	C4591001 1157 11571173	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1157 11571175	Cardiac disorders	Supraventricular extrasystoles	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1157 11571177	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1157 11571178	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2011	31DEC2011	N
			Bladder cancer	01JAN2007	31DEC2009	N
			Squamous cell carcinoma	15SEP2020	15SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Post-traumatic stress disorder	01JAN1968		Y
		Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	01JAN2007		Y
		Surgical and medical procedures	Cancer surgery	15SEP2020	15SEP2020	N
			Skin neoplasm excision	01JAN2011	31DEC2011	N
			Tumour vaccine therapy	01JAN2007	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1161 11611003	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
			Seasonal allergy	01JAN1969		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1161 11611012	Endocrine disorders	Hyperthyroidism	01JAN1995		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1984		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1161 11611013	Endocrine disorders	Adrenal cyst	01JAN2015		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN1982		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Ovarian cyst	01JAN1993	31DEC1993	N
		Social circumstances	Postmenopause	01JAN1992		Y
			Tobacco user	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Aortic aneurysm	01JAN2016		Y
	C4591001 1161 11611021	Cardiac disorders	Arrhythmia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1161 11611022	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2008		Y
			Seasonal allergy	01JAN1998		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1955		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1161 11611025	Gastrointestinal disorders	Dyspepsia	01JAN2007		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1161 11611029	Gastrointestinal disorders	Constipation	01JAN2012		Y
			Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Infections and infestations	Chronic tonsillitis	01JAN2015	10JUL2017	N
		Investigations	Endoscopy upper gastrointestinal tract	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Back pain	01JAN2005		Y
			Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	06AUG2012	17FEB2020	N
			Chronic myelomonocytic leukaemia	01JAN2000		Y
			Haemangioma of skin	01JAN2010		Y
			Seborrhoeic keratosis	01JAN2010		Y
			Squamous cell carcinoma	01JAN2018	27MAY2020	N
		Renal and urinary disorders	Calculus bladder	01JAN2016	31DEC2016	N
			Chronic kidney disease	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016	31DEC2016	N
			Erectile dysfunction	01JAN2016	31DEC2017	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2012	31DEC2012	N
			Knee arthroplasty	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Penile prosthesis insertion	01JAN2017	31DEC2017	N
			Tonsillectomy	10JUL2017	10JUL2017	N
			Transurethral prostatectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1161 11611030	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01JAN1988	31DEC1988	N
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1161 11611031	Immune system disorders	Seasonal allergy	01JAN1983		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2011	31DEC2011	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1975		Y
		Surgical and medical procedures	Spinal operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1161 11611035	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2020		Y
			Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01DEC1999	01DEC1999	N
	C4591001 1161 11611036	Blood and lymphatic system disorders	Anaemia	01JAN2009	31DEC2010	N
		General disorders and administration site conditions	Oedema	01MAY2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
			Female sterilisation	01JAN1977	31DEC1977	N
	C4591001 1161 11611037	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN1959		Y
	C4591001 1161 11611038	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1960		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1161 11611042	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	15OCT2020	N
	C4591001 1161 11611043	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1161 11611044	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2018	31DEC2019	N
		Psychiatric disorders	Bipolar disorder	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621002	Metabolism and nutrition disorders	Gout	01JAN1999		Y
			Hypercholesterolaemia	01JAN2000		Y
			Hypertriglyceridaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621006	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Muscle reattachment	01JAN1995	31DEC1995	N
	C4591001 1162 11621007	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Appendicitis	01JAN1954	31DEC1954	N
			Urinary tract infection	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2011	31DEC2011	N
		Skin and subcutaneous tissue disorders	Pruritus allergic	01JAN1950		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2017	31DEC2017	N
			Urinary bladder suspension	01JAN2011	31DEC2011	N
	C4591001 1162 11621008	Surgical and medical procedures	Elbow operation	01JAN1986	31DEC1986	N
				01JAN1989	31DEC1989	N
	C4591001 1162 11621011	Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2019		Y
		Surgical and medical procedures	Knee operation	01JAN2004	31DEC2004	N
			Shoulder operation	01JAN1982	31DEC1982	N
		Vascular disorders	Deep vein thrombosis	01JAN2018		Y
			Hypertension	01JAN2017		Y
	C4591001 1162 11621012	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1162 11621013	Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
	C4591001 1162 11621014	General disorders and administration site conditions	Hernia	01JAN2020	31JAN2020	N
			Pyrexia	03AUG2020	03AUG2020	N
	C4591001 1162 11621015	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Malignant melanoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1162 11621016	Eye disorders	Dry eye	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
			Intervertebral disc protrusion	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	01JAN2003		Y
	C4591001 1162 11621017	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2018		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2015		Y
	C4591001 1162 11621020	Infections and infestations	Cellulitis	01JAN2017	31DEC2017	N
				01JUN2020	30JUN2020	N
			Pneumonia	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Obesity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	31DEC2017	N
				01JUN2018	30JUN2018	N
			Malignant melanoma of eyelid	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2009	31DEC2009	N
				01JAN2017	31DEC2017	N
				01JUN2018	30JUN2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal decompression	01JAN2005	31DEC2005	N
				01JAN2012	31DEC2012	N
	C4591001 1162 11621022	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Investigations	Blood triglycerides increased	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2013		Y
		Psychiatric disorders	Schizophrenia	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1162 11621027	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621030	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1162 11621032	Gastrointestinal disorders	Hiatus hernia	01JAN2001	31DEC2001	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2019	31OCT2019	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
			Intestinal operation	01JUL2016	31JUL2016	N
	C4591001 1162 11621036	Immune system disorders	Drug hypersensitivity	01JAN2011		Y
		Investigations	Blood triglycerides increased	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Hip arthroplasty	01OCT2014	01OCT2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip surgery	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1162 11621038	Surgical and medical procedures	Renal stone removal	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621040	Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Hiatus hernia	01NOV1977	30NOV1977	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2008	31DEC2008	N
		Psychiatric disorders	Anxiety	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2008	31DEC2008	N
			Lymphadenectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621045	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Infections and infestations	Tonsillitis	01JAN1954	31DEC1954	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1954		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1162 11621046	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
			Prostatic disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN2005	31DEC2005	N
		Social circumstances	Corrective lens user	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621047	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN1976	31DEC1976	N
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUL2020		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
			Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Splenectomy	01JAN1976	31DEC1976	N
	C4591001 1162 11621048	Eye disorders	Hypermetropia	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Surgical and medical procedures	Hip arthroplasty	01MAY2017	31MAY2017	N
			Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Prehypertension	01JAN2017		Y
	C4591001 1162 11621049	Eye disorders	Myopia	01JAN1978		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
			Gastroesophageal reflux disease	01JAN2008		Y
		Reproductive system and breast disorders	Calculus prostatic	01JAN2017		Y
	C4591001 1162 11621050	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2018		Y
		Investigations	Blood triglycerides increased	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Surgical and medical procedures	Shoulder operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1162 11621052	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Social circumstances	Corrective lens user	01JAN1968		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2005	31DEC2005	N
		Vascular disorders	Arteriosclerosis	01JAN2005		Y
			Hypertension	01JAN2005		Y
	C4591001 1162 11621053	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Artificial menopause	01JAN2010	31DEC2010	N
			Fibrocystic breast disease	01JAN1995	31DEC1995	N
		Respiratory, thoracic and mediastinal disorders	Lung cyst	01JAN2019		Y
			Pulmonary fibrosis	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Breast cyst excision	01JAN1995	31DEC1995	N
			Myomectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2018		Y
			Varicose vein	01JAN1975		Y
	C4591001 1162 11621057	Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Dyspepsia	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Investigations	Cardiac murmur	01JAN1979		Y
			Heart rate irregular	01JAN1979		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Psychiatric disorders	Schizophrenia	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1162 11621058	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Toe amputation	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621059	Eye disorders	Myopia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Social circumstances	Tobacco user	10AUG2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621060	Eye disorders	Myopia	01JAN1963		Y
		Surgical and medical procedures	Hysterectomy	01FEB2010	28FEB2010	N
	C4591001 1162 11621063	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Brachytherapy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1162 11621065	Ear and labyrinth disorders	Deafness	01JAN2017		Y
		Immune system disorders	Food allergy	01JAN1965		Y
	C4591001 1162 11621068	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Incontinence	01JUN2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Bunion operation	01JAN1988	31DEC1988	N
			Rhinoplasty	01JAN1981	31DEC1981	N
	C4591001 1162 11621069	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621071	Gastrointestinal disorders	Dyspepsia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN1965		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2005	31DEC2005	N
	C4591001 1162 11621073	Investigations	Blood triglycerides increased	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01APR2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	31DEC2002	N
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621076	Cardiac disorders	Myocardial infarction	01JAN2004	31DEC2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Spinal operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1162 11621078	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1162 11621079	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Bipolar disorder	01JAN1998		Y
				01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621082	Ear and labyrinth disorders	Deafness	01JAN2020		Y
		Eye disorders	Cataract	01JAN2007	31DEC2007	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Cataract operation	01JAN2007	31DEC2007	N
	C4591001 1162 11621087	Infections and infestations	Appendicitis	01JAN1993	31DEC1993	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621088	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
	C4591001 1162 11621089	Surgical and medical procedures	Knee operation	01FEB2020	29FEB2020	N
	C4591001 1162 11621090	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01OCT2018	31OCT2018	N
	C4591001 1162 11621095	Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2017		Y
	C4591001 1162 11621099	Immune system disorders	Drug hypersensitivity	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Heart rate irregular	01JAN1993		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1162 11621102	Eye disorders	Myopia	01JAN1987		Y
		Injury, poisoning and procedural complications	Hip fracture	01AUG1984	31AUG1984	N
				09JUL2012	09JUL2012	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Surgical and medical procedures	Hip arthroplasty	01AUG1984	31AUG1984	N
				09JUL2012	09JUL2012	N
	C4591001 1162 11621105	Endocrine disorders	Hypothyroidism	01AUG2019		Y
		Gastrointestinal disorders	Duodenal ulcer	01JUL2020		Y
			Gastric ulcer	01JUL2020		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	11SEP1991	11SEP1991	N
			Wrist surgery	01OCT2008	31OCT2008	N
				01OCT2018	31OCT2018	N
	C4591001 1162 11621109	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1162 11621113	Social circumstances	Corrective lens user	01JAN2001		Y
			Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621116	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Reaction to food additive	01JAN1980		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Investigations	Blood testosterone decreased	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Cataract operation	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN1985	31DEC1985	N
			Ligament operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621119	Reproductive system and breast disorders	Prostatic disorder	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621122	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2014		Y
			Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1162 11621123	General disorders and administration site conditions	Ulcer	01JAN2016	31DEC2016	N
		Infections and infestations	Tonsillitis	01JAN1965	31DEC1970	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2001	31DEC2001	N
				01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN2001	31DEC2001	N
				01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621125	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1968	31DEC1968	N
	C4591001 1162 11621126	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1992	31DEC1992	N
		Social circumstances	Corrective lens user	01JAN1972		Y
			Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Knee operation	01JAN1997	31DEC1997	N
			Thyroidectomy	01JAN1992	31DEC1992	N
	C4591001 1162 11621127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621134	Surgical and medical procedures	Gastric bypass	01JAN2008	31DEC2008	N
	C4591001 1162 11621136	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621138	Gastrointestinal disorders	Inguinal hernia	01JAN2019	31DEC2019	N
		Nervous system disorders	Sciatica	01JAN2015		Y
		Surgical and medical procedures	Hernia repair	01NOV2019	30NOV2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JUN2020		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621148	Injury, poisoning and procedural complications	Ligament rupture	01OCT2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Insulin resistance	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621149	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
	C4591001 1162 11621157	Endocrine disorders	Hypothyroidism	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Colitis microscopic	01JAN2018	31DEC2018	N
			Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2008	31DEC2008	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN1981	31DEC1981	N
			Urinary bladder suspension	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621160	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017	31DEC2019	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Social circumstances	Corrective lens user	01JAN1973		Y
		Surgical and medical procedures	Renal stone removal	01JAN2010	31DEC2010	N
	C4591001 1162 11621161	Gastrointestinal disorders	Rectal fissure	01JAN1992	31DEC1992	N
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Anorectal operation	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rotator cuff repair	01JAN2016	31DEC2016	N
			Wrist surgery	01JAN2014	31DEC2014	N
	C4591001 1162 11621165	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1162 11621167	Surgical and medical procedures	Appendectomy	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Foot fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Overweight	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Ex-tobacco user	01JAN1978	15JUL2020	N
		Surgical and medical procedures	Foot operation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621173	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011	31DEC2012	N
			Osteoarthritis	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN1964		Y
			Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621174	Eye disorders	Myopia	01JAN1962		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Biliary dyskinesia	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Milk allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1979		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2017		Y
		Cardiac disorders	Palpitations	01JAN2019		Y
	C4591001 1162 11621176	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Knee operation	01JAN1976	31DEC1976	N
				01JAN2005	31DEC2005	N
	C4591001 1162 11621179	Eye disorders	Myopia	01JAN1967		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
	C4591001 1162 11621184	Eye disorders	Myopia	01JAN1966		Y
		Injury, poisoning and procedural complications	Epicondylitis	06AUG2020	06AUG2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005	31DEC2005	N
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Tenoplasty	06AUG2020	06AUG2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1162 11621185	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2000	31DEC2010	N
	C4591001 1162 11621186	Ear and labyrinth disorders	Deafness	01JAN2001		Y
		Eye disorders	Cataract	01JAN2014	31DEC2019	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Investigations	Blood testosterone decreased	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1997		Y
		Nervous system disorders	Migraine	01JAN1973		Y
		Social circumstances	Corrective lens user	01JAN1969		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N
			Vasectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1162 11621189	Eye disorders	Myopia	01JAN1968		Y
		Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01MAR2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN2015	31DEC2015	N
			Arthrodesis	01JAN2000	31DEC2000	N
	C4591001 1162 11621191	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1991		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2008	31DEC2008	N
		Skin and subcutaneous tissue disorders	Rash	01JAN2007		Y
		Social circumstances	Corrective lens user	01JAN1973		Y
	C4591001 1162 11621192	Immune system disorders	Rubber sensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1980	31DEC2005	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2004	N
		Nervous system disorders	Migraine	01JAN1967		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N
			Myomectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1162 11621194	Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Bronchitis	01JAN2020	01APR2020	N
			Tonsillitis	01JAN1972	31DEC1972	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2002	31DEC2003	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2004		Y
			Rhinitis allergic	01JAN2004		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2002	31DEC2002	N
			Mammoplasty	01JAN1982	31DEC1982	N
			Oophorectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1162 11621196	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Eye disorders	Anisometropia	01JAN1954		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Fracture treatment	01DEC2016	31DEC2016	N
			Limb operation	01JAN2014	31DEC2014	N
	C4591001 1162 11621197	Gastrointestinal disorders	Inguinal hernia	01JAN1976	31DEC1976	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Injury, poisoning and procedural complications	Hip fracture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Psychiatric disorders	Anxiety	01JAN1983		Y
			Depression	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip surgery	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1162 11621198	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2012		Y
			Myopia	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2014		Y
		Infections and infestations	Hepatitis A	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1162 11621199	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Hypermetropia	01JAN1978		Y
			Myopia	01JAN1978		Y
		Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015	31DEC2015	N
		Psychiatric disorders	Anxiety	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1162 11621200	Psychiatric disorders	Insomnia	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
			Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	03DEC1986	03DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				07NOV1988	07NOV1988	N
				19JUL1985	19JUL1985	N
			Phlebectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Varicose vein	01JAN1984	31DEC1995	N
	C4591001 1162 11621201	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2015	31DEC2015	N
		Endocrine disorders	Autoimmune hypothyroidism	01JAN2015		Y
			Hypothyroidism	01JAN2008		Y
		Eye disorders	Myopia	01JAN1974		Y
		Investigations	Blood testosterone decreased	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
	C4591001 1162 11621209	Surgical and medical procedures	Lymphadenectomy	01JAN2015	31DEC2015	N
		Eye disorders	Hypermetropia	01JAN1965		Y
		Gastrointestinal disorders	Irritable bowel syndrome	17OCT1997		Y
		Metabolism and nutrition disorders	Obesity	01JAN1992		Y
			Type 2 diabetes mellitus	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	01OCT1993		Y
		Psychiatric disorders	Anxiety	01DEC2015		Y
			Depression	01DEC2015		Y
			Insomnia	01DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1982	31DEC1982	N
		Skin and subcutaneous tissue disorders	Psoriasis	01DEC2019		Y
		Surgical and medical procedures	Colectomy	17OCT1997	17OCT1997	N
			Hysterectomy	17OCT1997	17OCT1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01OCT2002		Y
	C4591001 1162 11621211	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Pneumonectomy	01JAN2018	31DEC2018	N
			Spinal operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1162 11621212	Eye disorders	Myopia	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1162 11621213	Eye disorders	Hypermetropia	01JAN1999		Y
			Myopia	27AUG1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1992	31DEC1992	N
			Arthrotomy	01JAN1993	31DEC1993	N
			Spinal laminectomy	01JAN2002	31DEC2002	N
	C4591001 1162 11621214	Injury, poisoning and procedural complications	Meniscus injury	01JAN1989	31DEC1998	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	01JAN2012		Y
		Nervous system disorders	Neuralgia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Surgical and medical procedures	Knee operation	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1162 11621215	Eye disorders	Amblyopia	01JAN1956	31DEC1960	N
		Immune system disorders	Perfume sensitivity	01JAN2000		Y
		Infections and infestations	Tonsillitis	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Humerus fracture	01JAN1974	31DEC1974	N
		Investigations	Cardiac murmur	01JAN1971		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1995	31DEC2007	N
		Nervous system disorders	Migraine	01JAN1996	31DEC2016	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	25OCT1987	25OCT1987	N
			Eye muscle operation	01JAN1960	31DEC1960	N
			Fracture treatment	01JAN1974	31DEC1974	N
			Intervertebral disc operation	01JAN1995	31DEC1995	N
				01JAN2007	31DEC2007	N
			Tonsillectomy	01JAN2000	31DEC2000	N
	C4591001 1162 11621218	Eye disorders	Myopia	01JAN1988		Y
		Infections and infestations	Tonsillitis	01JAN1968	31DEC1972	N
		Injury, poisoning and procedural complications	Ligament rupture	01DEC1989	31DEC1989	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN1989	31DEC1989	N
			Tonsillectomy	01JAN1972	31DEC1972	N
		Vascular disorders	Hypertension	01MAY2002		Y
	C4591001 1162 11621221	Eye disorders	Cataract	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Allergy to animal	01JAN1996		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Shoulder operation	01JAN1997	31DEC1997	N
				01JAN2017	31DEC2017	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
			Schizophrenia	01JAN1973		Y
	C4591001 1162 11621225	Psychiatric disorders				
		Social circumstances	Corrective lens user	01JAN2018		Y
	C4591001 1162 11621228	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1982	31DEC1982	N
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
	C4591001 1162 11621229	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Overweight	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cholelithotomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621230	Social circumstances	Corrective lens user	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621233	Infections and infestations	Tonsillitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1976	31DEC1976	N
	C4591001 1162 11621236	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Infections and infestations	Onychomycosis	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Acne	01JUN2020		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2000	31DEC2000	N
			Skin graft	01JAN2019	31DEC2019	N
			Skin operation	01JAN2019		Y
	C4591001 1162 11621237	Infections and infestations	Tonsillitis	01JAN1965	31DEC1965	N
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01MAR2015	31MAR2015	N
			Nasal septal operation	01JAN1982	31DEC1982	N
			Shoulder operation	01FEB2020	29FEB2020	N
			Surgery	01JAN1969	31DEC1969	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1162 11621238	Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Infections and infestations	Arthritis infective	01JAN1985	31DEC1985	N
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
			Obesity	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2018	31DEC2018	N
			Knee operation	01JAN1985	31DEC1985	N
			Tenoplasty	01JAN1995	31DEC1995	N
	C4591001 1162 11621240	Ear and labyrinth disorders	Deafness	01JAN2016		Y
			Tinnitus	01JAN2014		Y
		Eye disorders	Cataract	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	Bronchitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1968		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
			Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1993		Y
			Eczema	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Appendicectomy	01JAN1993	31DEC1993	N
			Cholecystectomy	01JAN2012	31DEC2012	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621241	Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Colitis ulcerative	01SEP1998	31OCT1998	N
			Diverticulum	01SEP1998		Y
			Vomiting	01JAN1956		Y
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Infections and infestations	Diverticulitis	01SEP1998	31OCT1998	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN1990		Y
		Vascular disorders	Varicose vein	01JAN1980		Y
	C4591001 1162 11621242	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Gastrointestinal disorders	Vomiting	01JAN2004		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
			Food allergy	01JAN2004		Y
		Infections and infestations	Tonsillitis	01JAN1962	31DEC1962	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2020		Y
			Spinal osteoarthritis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN1970		Y
			Pruritus allergic	01JAN2000		Y
		Surgical and medical procedures	Anorectal operation	01JAN2019	31DEC2019	N
			Appendectomy	01JAN1972	31DEC1972	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Caesarean section	05AUG1984	05AUG1984	N
			Sinus operation	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1162 11621246	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2005		Y
	C4591001 1162 11621248	Gastrointestinal disorders	Dyspepsia	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2012		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoporosis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1162 11621250	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperkalaemia	01JAN2010		Y
			Hyperlipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621253	Cardiac disorders	Cardiac failure	01DEC2018		Y
			Myocardial infarction	01JAN2017	31DEC2017	N
		Eye disorders	Myopia	01JAN1972		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1988		Y
			Drug hypersensitivity	01DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Tuberculosis	01JAN1985	31DEC1986	N
		Investigations	Blood triglycerides increased	01JAN1990		Y
			Heart rate irregular	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN2011	31DEC2014	N
			Depression	01JAN2011	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Epistaxis	01JAN1966		Y
		Surgical and medical procedures	Coronary arterial stent insertion	19NOV2019	19NOV2019	N
			Implantable defibrillator insertion	05DEC2018	05DEC2018	N
			Implantable defibrillator replacement	05DEC2018	05DEC2018	N
	C4591001 1162 11621257	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Gastrointestinal disorders	Stomatitis	01JAN2003		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Obesity	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Neuropathy peripheral	01JAN1999		Y
		Social circumstances	Corrective lens user	01JAN1995		Y
		Surgical and medical procedures	Angioplasty	01JAN2001	31DEC2001	N
		Vascular disorders	Arteriosclerosis	01JAN2001		Y
			Hypertension	01JAN2001		Y
	C4591001 1162 11621258	Eye disorders	Hypermetropia	01JAN1995		Y
			Myopia	01JAN1995		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1953		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1961		Y
				01JAN1990		Y
		Investigations	Blood triglycerides increased	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1980	31DEC1980	N
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1958		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1953		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621262	Eye disorders	Myopia	01JAN1971		Y
		Infections and infestations	Tonsillitis	01JAN1959	31DEC1960	N
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Reproductive system and breast disorders	Cervical dysplasia	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
			Hysterectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Varicose vein	01JAN2010		Y
	C4591001 1162 11621263	Endocrine disorders	Hypothyroidism	01JAN1982		Y
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621264	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
		Surgical and medical procedures	Brain tumour operation	01JAN2009	31DEC2009	N
			Renal stone removal	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1162 11621265	Ear and labyrinth disorders	Deafness	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2010	31DEC2010	N
			Ligament rupture	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1980		Y
			Asthma	01JAN1965		Y
			Nasal septum deviation	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Shoulder operation	01JAN2020	31DEC2020	N
	C4591001 1162 11621266	Eye disorders	Hypermetropia	01JAN2000		Y
			Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1979		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	20FEB1999	20FEB1999	N
	C4591001 1162 11621270	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Metabolism and nutrition disorders	Gout	01JAN1985		Y
		Surgical and medical procedures	Toe operation	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621271	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
	C4591001 1162 11621272	Surgical and medical procedures	Limb operation	01JAN1977	31DEC1977	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Infections and infestations	Diverticulitis	01JAN2014		Y
			Tonsillitis	01JAN1959	31DEC1960	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1162 11621276	Surgical and medical procedures	Tonsillectomy	01JAN1960	31DEC1960	N
		Eye disorders	Hypermetropia	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01MAR2019		Y
	C4591001 1162 11621277	Vascular disorders	Hypertension	01JAN2018		Y
		Eye disorders	Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Irritable bowel syndrome	01JAN1992		Y
		Infections and infestations	Appendicitis	01JAN1989	31DEC1989	N
			Herpes simplex	01JAN2014		Y
		Nervous system disorders	Migraine	01JAN1980	31DEC2006	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2006	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621278	Ear and labyrinth disorders	Hypoacusis	01JAN1980		Y
		Eye disorders	Myopia	01JAN1996		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Food allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1162 11621280	Eye disorders	Hypermetropia	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Blood triglycerides increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2009		Y
		Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01FEB2009		Y
	C4591001 1162 11621281	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1995		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Bone operation	01JAN2006	31DEC2006	N
			Oral surgery	01JAN2006	31DEC2006	N
	C4591001 1162 11621288	Eye disorders	Myopia	01JAN1972		Y
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621292	Eye disorders	Cataract	01JAN2019		Y
			Myopia	01JAN1981		Y
		Gastrointestinal disorders	Dental plaque	01JAN2018		Y
		Injury, poisoning and procedural complications	Facial bones fracture	01JAN1975	31DEC1975	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2000	31DEC2016	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2019		Y
		Surgical and medical procedures	Cancer surgery	01JAN2010	31DEC2010	N
			Knee operation	01JAN2016	31DEC2016	N
	C4591001 1162 11621293	Eye disorders	Myopia	01JAN1970		Y
		Psychiatric disorders	Anxiety	01JAN1979		Y
			Depression	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1970		Y
		Surgical and medical procedures	Adenoidectomy	05MAY1993	05MAY1993	N
	C4591001 1162 11621297	Cardiac disorders	Coronary artery disease	01JAN2017	31DEC2017	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN2020		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1162 11621298	Infections and infestations	Herpes simplex	01JAN2010		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
		Eye disorders	Myopia	01JAN1982		Y
	C4591001 1162 11621299	Nervous system disorders	Neuropathy peripheral	01JAN2017	31DEC2019	N
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
	C4591001 1162 11621300	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Investigations	Heart rate irregular	01AUG2000	30APR2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2000		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	(b) (6) 1953		Y
		Social circumstances	Corrective lens user	01JAN1965		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2010	31DEC2010	N
			Ligament operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1162 11621301	Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Glaucoma	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
			Herpes zoster	01JAN2018	31DEC2018	N
			Tonsillitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Caesarean section	19OCT1982	19OCT1982	N
			Cataract operation	01JAN2012	31DEC2012	N
			Colectomy	01JAN2005	31DEC2005	N
			Large intestinal polypectomy	01JAN2005	31DEC2005	N
	C4591001 1162 11621303	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Headache	01JAN2019		Y
	C4591001 1162 11621305	Cardiac disorders	Myocardial infarction	08MAR2009	08MAR2009	N
		Gastrointestinal disorders	Dyspepsia	05APR1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01OCT2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1975	31DEC1975	N
			Cholecystectomy	01JAN2017	31DEC2017	N
			Coronary arterial stent insertion	08APR2011	08APR2011	N
		Vascular disorders	Arteriosclerosis	08APR2011		Y
	C4591001 1162 11621307	Endocrine disorders	Goitre	01JAN2018	31DEC2018	N
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Thyroidectomy	01JAN2018	31DEC2018	N
	C4591001 1162 11621309	Surgical and medical procedures	Cardiac ablation	01JAN2008	31DEC2008	N
				01JAN2016	31DEC2016	N
	C4591001 1162 11621312	Eye disorders	Cataract operation Hypermetropia	01JAN2012 01JAN1975	31DEC2012	N Y
			Myopia	01JAN1975		Y
		Infections and infestations	Cellulitis	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
	C4591001 1162 11621327	Surgical and medical procedures	Appendicectomy	01JAN1979	31DEC1979	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Injury, poisoning and procedural complications	Cranio-cerebral injury	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
	C4591001 1162 11621329	Surgical and medical procedures	Hip arthroplasty	01JAN2015	31DEC2015	N
		Blood and lymphatic system disorders	Anaemia	01JAN1996		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621330	Nervous system disorders	Headache	01JAN1990	31DEC2011	N
		Social circumstances	Corrective lens user	01JAN1998		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1984	31DEC1984	N
	C4591001 1162 11621332	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN1970		Y
			Depression	01JAN1970		Y
			Insomnia	01JAN1970		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN1970		Y
			Nephrolithiasis	01JAN2005		Y
		Social circumstances	Corrective lens user	01JAN2000		Y
	C4591001 1162 11621333	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN1960	31DEC1991	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2015		Y
			Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
				01JAN1997	31DEC1997	N
			Finger amputation	01JAN1977	31DEC1977	N
	C4591001 1162 11621337	Metabolism and nutrition disorders	Obesity	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Osteoarthritis	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
			Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Spinal operation	01JAN2003	31DEC2003	N
	C4591001 1162 11621341	Eye disorders	Eyelid ptosis	01JAN2017	31DEC2017	N
			Glaucoma	01JAN2018		Y
		Surgical and medical procedures	Eyelid operation	01JAN2017	31DEC2017	N
	C4591001 1162 11621342	Blood and lymphatic system disorders	Anaemia	01JAN2011	31DEC2012	N
		Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Eye disorders	Myopia	01JAN2002		Y
		Gastrointestinal disorders	Dyspepsia	01JAN1992		Y
			Gastroesophageal reflux disease	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1983		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC2001	N
		Nervous system disorders	Headache	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1995		Y
			Insomnia	01JAN1995		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinitis allergic	01JAN1969		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1162 11621343	Metabolism and nutrition disorders	Obesity	01JAN1994		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1162 11621345	Blood and lymphatic system disorders	Anaemia	01JAN1975		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	08NOV2017	08NOV2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rash	01APR2020		Y
		Surgical and medical procedures	Caesarean section	20JUN1995	20JUN1995	N
			Female sterilisation	20JUN1995	20JUN1995	N
		Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1162 11621347	Metabolism and nutrition disorders	Obesity	10SEP2020		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1162 11621348	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Psychiatric disorders	Schizophrenia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mammoplasty	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621349	Ear and labyrinth disorders	Tinnitus	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1162 11621353	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2004		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
			Postmenopause	01JAN2004		Y
	C4591001 1162 11621357	Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
		Eye disorders	Myopia	01JAN1964		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
			Hiatus hernia	01JAN1998		Y
		Surgical and medical procedures	Knee operation	01JAN1998	31DEC1998	N
			Vasectomy	01JAN1998	31DEC1998	N
	C4591001 1162 11621359	Endocrine disorders	Hyperthyroidism	01JAN1998	31DEC1998	N
		Eye disorders	Cataract	01JAN2000		Y
			Myopia	01JAN1953		Y
		Immune system disorders	Rubber sensitivity	01JAN1946		Y
		Investigations	Blood testosterone decreased	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1978		Y
		Nervous system disorders	Seizure	01JAN1977	31DEC1981	N
		Surgical and medical procedures	Appendicectomy	01JAN1968	31DEC1968	N
			Shoulder operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	14SEP2020		Y
	C4591001 1162 11621364	Eye disorders	Presbyopia	01JAN2013		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2005		Y
		Infections and infestations	Hepatitis C	04JUL1994	07FEB2000	N
		Investigations	Heart rate irregular	01JAN2017		Y
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2013		Y
		Surgical and medical procedures	Gastric ulcer surgery	01JAN1994	31DEC1994	N
			Knee operation	01JAN2016	31DEC2016	N
			Lipoma excision	01JAN2015	31DEC2015	N
	C4591001 1162 11621365	Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621368	Ear and labyrinth disorders	Tinnitus	14SEP2020		Y
		Endocrine disorders	Hyperthyroidism	01JAN2000		Y
			Hypothyroidism	01JAN2000		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Presbyopia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Eye laser surgery	01JAN2000	31DEC2000	N
			Hip arthroplasty	24JAN2017	24JAN2017	N
			Knee operation	01JAN1981	31DEC1981	N
	C4591001 1162 11621369	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2009		Y
	C4591001 1162 11621373	Social circumstances	Corrective lens user	01JAN1990		Y
		Eye disorders	Hypermetropia	01JAN1957		Y
			Strabismus	01JAN1956	31DEC1956	N
		Gastrointestinal disorders	Hiatus hernia	01JAN1971		Y
		Immune system disorders	Drug hypersensitivity	01DEC1960		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
			Herpes zoster	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2017		Y
		Nervous system disorders	Headache	01JAN1964		Y
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1990	31DEC1990	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1960		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Eye operation	01JAN1956	31DEC1956	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Renal stone removal	01JAN2003	31DEC2003	N
	C4591001 1162 11621380	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Vascular disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1162 11621385	Metabolism and nutrition disorders	Hypertension	01JAN2013		Y
			Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Social circumstances	Corrective lens user	01JAN2002		Y
		Surgical and medical procedures	Hernia hiatus repair	01MAY2020	30JUN2020	N
	C4591001 1162 11621390	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
	C4591001 1162 11621395	Eye disorders	Presbyopia	01JAN1969		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
			Gastric ulcer	01JAN2015	31DEC2015	N
		Immune system disorders	Seasonal allergy	01JAN1993		Y
		Surgical and medical procedures	Appendectomy	01DEC2019	31DEC2019	N
			Cyst removal	01JAN2006	31DEC2006	N
			Eye operation	01JAN1994	31DEC1994	N
			Gastric bypass	01JAN2019		Y
			Knee operation	01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N
				01JAN2002	31DEC2002	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1162 11621397	Metabolism and nutrition disorders	Obesity	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621398	Eye disorders	Retinal disorder	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1957	31DEC1970	N
			Nasal septum deviation	01JAN1957		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1162 11621399	Eye disorders	Myopia	01JAN1966		Y
		Injury, poisoning and procedural complications	Spinal fracture	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Spinal operation	01JAN2016	31DEC2016	N
	C4591001 1162 11621400	Eye disorders	Myopia	01JAN1970		Y
		Infections and infestations	Herpes zoster	01JAN2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Chronic obstructive pulmonary disease	01JAN2010		Y
			Cough	01DEC2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1995	31DEC1995	N
	C4591001 1162 11621402	Metabolism and nutrition disorders	Obesity	31DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Chronic obstructive pulmonary disease	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621407	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
			Type 2 diabetes mellitus	01DEC2013		Y
		Surgical and medical procedures	Fracture treatment	01JAN1970	31DEC1970	N
	C4591001 1162 11621409	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Surgical and medical procedures	Cataract operation	01JAN2020	31JAN2020	N
			Finger amputation	01JAN1978	31DEC1978	N
			Hernia repair	01JAN1961	31DEC1961	N
	C4591001 1162 11621411	Psychiatric disorders	Schizophrenia	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
	C4591001 1162 11621412	Gastrointestinal disorders	Colitis ulcerative	01JAN2013	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Obesity	01JAN2018		Y
			Vitamin D deficiency	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Corrective lens user	01DEC2002		Y
		Surgical and medical procedures	Colectomy	01JAN2016	31DEC2016	N
			Colostomy	01JAN2016	31DEC2016	N
			Female sterilisation	16FEB1993	16FEB1993	N
			Haemorrhoid operation	01JAN2015	31DEC2015	N
			Hysterectomy	01NOV2007	30NOV2007	N
			Inguinal hernia repair	01JAN2018	31DEC2018	N
			Intestinal anastomosis	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Peripheral nerve operation	01JAN2015	31DEC2015	N
	C4591001 1162 11621415	Eye disorders	Hypermetropia	01JAN2010		Y
			Myopia	01JAN2010		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bone operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621419	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
			Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1162 11621420	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
	C4591001 1162 11621425	Eye disorders	Myopia	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000	31DEC2011	N
			Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964	31DEC1983	N
		Surgical and medical procedures	Retinal operation	01JAN2018	31DEC2018	N
	C4591001 1162 11621426	Eye disorders	Myopia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Reproductive system and breast disorders	Cervical polyp	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1162 11621428	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Obesity	01AUG2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621431	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01SEP2020		Y
		Investigations	Blood triglycerides increased	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621432	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1958	31DEC1958	N
		Injury, poisoning and procedural complications	Tibia fracture	01JAN1969	31DEC1969	N
				01JAN1984	31DEC1984	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1978		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1958		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621433	Ear and labyrinth disorders	Deafness unilateral	01JAN2000		Y
		Eye disorders	Hypermetropia	01JAN2016		Y
		Infections and infestations	Bronchitis	01JAN2020	31DEC2020	N
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Tenoplasty	01JAN2005	31DEC2005	N
	C4591001 1162 11621438	Infections and infestations	Herpes simplex	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Surgical and medical procedures	Cancer surgery	01JAN2007	31DEC2007	N
			Hernia repair	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621440	Injury, poisoning and procedural complications	Wrist fracture	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Splenectomy	01JAN1993	31DEC1993	N
	C4591001 1162 11621441	Eye disorders	Myopia	01JAN2000		Y
		Gastrointestinal disorders	Duodenogastric reflux	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Rheumatoid arthritis	01JAN2007		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1961		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1162 11621444	Injury, poisoning and procedural complications	Upper limb fracture	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Psychiatric disorders	Bipolar disorder	01JAN2012		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bone operation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1162 11621447	Eye disorders	Myopia	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1993		Y
		Psychiatric disorders	Bipolar disorder	01JAN2009		Y
			Post-traumatic stress disorder	01JAN2010		Y
		Surgical and medical procedures	Knee operation	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1162 11621449	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1162 11621465	Eye disorders	Myopia	01JAN1998		Y
	C4591001 1162 11621470	Injury, poisoning and procedural complications	Facial bones fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Social circumstances	Corrective lens user	01JAN2007		Y
		Surgical and medical procedures	Rhinoplasty	01JAN2010	31DEC2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621473	Gastrointestinal disorders	Dyspepsia	01JAN2004	31DEC2005	N
		Nervous system disorders	Migraine	01SEP2018		Y
		Psychiatric disorders	Anxiety	01JUL2015		Y
			Depression	01JUL2015		Y
	C4591001 1162 11621474	Vascular disorders	Hypertension	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1999		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
			Spinal operation	01JAN2019	31DEC2019	N
	C4591001 1162 11621475	Vascular disorders	Hypertension	01JAN1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2018	31DEC2018	N
	C4591001 1162 11621481	Vascular disorders	Hypertension	01MAR2020		Y
		Metabolism and nutrition disorders	Obesity	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1162 11621482	Eye disorders	Hypermetropia	01JAN2014		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2013		Y
	C4591001 1162 11621485	Vascular disorders	Hypertension	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621487	Injury, poisoning and procedural complications	Joint injury	01JAN1985		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1970		Y
	C4591001 1162 11621493	Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
		Nervous system disorders	Headache	01FEB2016		Y
			Migraine	01JAN2017		Y
	C4591001 1162 11621498	Metabolism and nutrition disorders	Overweight	01JAN2019		Y
	C4591001 1162 11621501	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
	C4591001 1162 11621507	Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Psychiatric disorders	Depression	01FEB2020		Y
		Social circumstances	Blood donor	10OCT2020	10OCT2020	N
			Corrective lens user	01JAN2000		Y
			Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
	C4591001 1162 11621508	Social circumstances	Corrective lens user	13OCT2010		Y
	C4591001 1162 11621509	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
	C4591001 1162 11621511	Eye disorders	Myopia	01JAN1990		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Infections and infestations	Herpes zoster	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Foot fracture	01JAN1978	31DEC1978	N
	C4591001 1162 11621512	Psychiatric disorders	Depression	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1983		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1162 11621523	Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1956		Y
	C4591001 1162 11621525	Eye disorders	Hypermetropia	01JAN2005		Y
			Myopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Psychiatric disorders	Schizophrenia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Facial operation	01JAN2011	31DEC2011	N
			Fracture reduction	01JAN2007	31DEC2007	N
			Inguinal hernia repair	01JAN2004	31DEC2004	N
	C4591001 1162 11621527	Injury, poisoning and procedural complications	Gun shot wound	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2016		Y
		Surgical and medical procedures	Removal of foreign body	01JAN1982	31DEC1982	N
	C4591001 1162 11621528	Eye disorders	Hypermetropia	01JAN2018		Y
			Myopia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vision blurred	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1162 11621529	Eye disorders	Hypermetropia	01JAN1959		Y
		Gastrointestinal disorders	Abdominal adhesions	01JAN1998	31DEC1998	N
			Dyspepsia	01JAN1990		Y
		General disorders and administration site conditions	Chest pain	01JAN2014	31DEC2014	N
		Immune system disorders	Autoinflammatory disease	01JAN1999		Y
			Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JUL2020		Y
		Injury, poisoning and procedural complications	Hand fracture	01JAN2018	31DEC2018	N
		Investigations	Liver function test increased	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN1980	31DEC1990	N
		Psychiatric disorders	Depression	01JAN2007		Y
			Insomnia	01DEC2007		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2000	N
			Ovarian cyst	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	04OCT1989	04OCT1989	N
				13MAY1991	13MAY1991	N
				23SEP1988	23SEP1988	N
			Carpal tunnel decompression	01JAN1984	31DEC1984	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Joint dislocation reduction	01JAN1988	31DEC1988	N
			Rotator cuff repair	09MAR2020	09MAR2020	N
		Vascular disorders	Aortic aneurysm	01JAN2014		Y
			Hypertension	01JAN2007		Y
	C4591001 1162 11621531	Blood and lymphatic system disorders	Anaemia	01JAN1999		Y
		Eye disorders	Glaucoma	01JAN2002		Y
		Investigations	Heart rate irregular	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
			Osteoarthritis	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN2017		Y
		Psychiatric disorders	Bipolar disorder	01JAN1999		Y
		Reproductive system and breast disorders	Endometriosis	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Hip arthroplasty	01JAN1999	31DEC1999	N
				01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1162 11621536	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Corrective lens user	01JAN2009		Y
		Surgical and medical procedures	Laparotomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621542	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Milk allergy	01JAN1997		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Autoimmune arthritis	22OCT2014		Y
			Back pain	22OCT2015		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1162 11621544	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1984	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1162 11621546	Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
	C4591001 1162 11621547	Eye disorders	Myopia	01JAN2015		Y
	C4591001 1162 11621550	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2008		Y
		Social circumstances	Corrective lens user	01JAN2018		Y
		Vascular disorders	Hypertension	01APR2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1162 11621552	Eye disorders	Cataract	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1162 11621555	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2001		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Caesarean section	01JAN1979	31DEC1979	N
				01JAN1981	31DEC1981	N
				01JAN1983	31DEC1983	N
				01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1162 11621556	Immune system disorders	Food allergy	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN2017		Y
			Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	12AUG1983	12AUG1983	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621557	Eye disorders	Myopia	01JAN1995		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN1965	31DEC1965	N
		Nervous system disorders	Cerebrovascular accident	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Peripheral nerve operation	01JAN1965	31DEC1965	N
	C4591001 1162 11621558	Eye disorders	Hypermetropia	01JAN1990		Y
			Myopia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1162 11621560	Immune system disorders	Rubber sensitivity	01JAN2000		Y
		Social circumstances	Corrective lens user	01JAN2010		Y
		Surgical and medical procedures	Cancer surgery	01JAN2014	31DEC2014	N
	C4591001 1162 11621562	Cardiac disorders	Coronary artery disease	01JAN1997		Y
		Eye disorders	Hypermetropia	01JAN2016		Y
			Myopia	01JAN2016		Y
		Gastrointestinal disorders	Anal fistula	01JAN2010	31DEC2010	N
		General disorders and administration site conditions	Chest pain	01JAN1997	31DEC1997	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2017		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2015	31DEC2015	N
			Rectal fistula repair	01JAN2010	31DEC2010	N
			Stent placement	01JAN1997	31DEC1997	N
	C4591001 1162 11621564	Eye disorders	Hypermetropia	01JAN1988		Y
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1988		Y
			Overweight	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
	C4591001 1162 11621565	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2019		Y
		Social circumstances	Corrective lens user	01JAN1996		Y
	C4591001 1162 11621567	Immune system disorders	Food allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
			Rheumatoid arthritis	01JAN2019		Y
	C4591001 1162 11621568	Surgical and medical procedures	Limb reconstructive surgery	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Limb injury	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Limb operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1162 11621578	Blood and lymphatic system disorders	Anaemia	01JAN2014	31DEC2014	N
		Eye disorders	Cataract	01JAN2014		Y
			Myopia	01DEC1975		Y
		Gastrointestinal disorders	Duodenal ulcer	01JAN2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	01JAN1974		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1975		Y
			Depression	01JAN1975		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1974	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Benign breast lump removal	01JAN1974	31DEC1974	N
				01JAN1985	31DEC1985	N
	C4591001 1162 11621581	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	04JUL2019	31JUL2019	N
		Nervous system disorders	Neuropathy peripheral	04JUL2019		Y
	C4591001 1163 11631001	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1163 11631002	Vascular disorders	Hypertension	01JUL2000		Y
	C4591001 1163 11631003	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1163 11631005	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2014		Y
	C4591001 1163 11631007	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1163 11631008	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JUL2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1163 11631009	Immune system disorders	Seasonal allergy	01JUN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP1996		Y
		Nervous system disorders	Headache	01OCT1958		Y
			Migraine	01OCT1958		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAY1968		Y
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1163 11631010	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2006		Y
		Metabolism and nutrition disorders	Fluid retention	01SEP2006		Y
			Hypercholesterolaemia	01SEP2006		Y
			Type 2 diabetes mellitus	01SEP2006		Y
		Reproductive system and breast disorders	Erectile dysfunction	12JUL2017		Y
		Surgical and medical procedures	Vascular graft	01SEP2006	30SEP2006	N
		Vascular disorders	Hypertension	01SEP2006		Y
	C4591001 1163 11631011	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2015		Y
		Psychiatric disorders	Depression	01NOV2015		Y
	C4591001 1163 11631012	Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1163 11631014	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2005		Y
			Type 2 diabetes mellitus	01JUN1998		Y
		Vascular disorders	Hypertension	01MAR2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1163 11631015	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1163 11631016	Infections and infestations	Fungal skin infection	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1163 11631017	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1163 11631018	Cardiac disorders	Coronary artery disease	01FEB2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2001		Y
		Psychiatric disorders	Bipolar disorder	01AUG2005		Y
			Depression	01OCT2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01OCT2016		Y
		Social circumstances	Tobacco user	01JAN1965	28FEB2001	N
		Surgical and medical procedures	Coronary artery bypass	01FEB2001	28FEB2001	N
		Vascular disorders	Hypertension	01OCT2015		Y
	C4591001 1163 11631019	Cardiac disorders	Coronary artery disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1163 11631020	Endocrine disorders	Hypothyroidism	01OCT2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Salivary gland cancer	01OCT2013	31AUG2014	N
	C4591001 1163 11631025	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2005		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Vascular disorders	Prostatomegaly	01JAN2012		Y
			Hypertension	01AUG2005		Y
	C4591001 1163 11631026	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	05MAR2005	05MAR2005	N
		Surgical and medical procedures	Hysterectomy	05MAR2005	05MAR2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1163 11631030	Social circumstances	Postmenopause	15MAY1999		Y
	C4591001 1163 11631031	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
		Social circumstances	Postmenopause	01JUL2005		Y
		Vascular disorders	Hypertension	01JAN2001		Y
			Lymphoedema	01DEC2000		Y
	C4591001 1163 11631032	Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JUN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01SEP2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01OCT2018		Y
	C4591001 1163 11631033	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2019		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1163 11631035	Cardiac disorders	Coronary artery disease	01FEB2012		Y
		Vascular disorders	Hypertension	01FEB2012		Y
	C4591001 1163 11631038	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2015		Y
		Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1163 11631041	Gastrointestinal disorders	Dyspepsia	01SEP2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2018		Y
		Social circumstances	Postmenopause	01OCT2008		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1163 11631043	Endocrine disorders	Hypothyroidism	01NOV2012		Y
		Immune system disorders	Seasonal allergy	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	23MAR2006	23MAR2006	N
		Social circumstances	Postmenopause	01JUL2006		Y
	C4591001 1163 11631044	Renal and urinary disorders	Urinary retention	01JUN2018		Y
	C4591001 1163 11631053	Endocrine disorders	Hypothyroidism	01MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUN1980		Y
		Metabolism and nutrition disorders	Obesity	01MAY2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2009		Y
			Fibromyalgia	01MAR2010		Y
			Osteoarthritis	01JUN2009		Y
		Psychiatric disorders	Bipolar disorder	01AUG2013		Y
			Depression	01MAY1985		Y
			Post-traumatic stress disorder	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	26DEC1985	26DEC1985	N
		Vascular disorders	Hot flush	01MAY1978		Y
			Hypertension	01FEB2017		Y
	C4591001 1163 11631055	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1163 11631058	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1163 11631062	Psychiatric disorders	Anxiety	01JUN2010		Y
			Depression	01JUN2010		Y
			Panic attack	01MAY2014		Y
		Social circumstances	Postmenopause	01SEP2014		Y
	C4591001 1163 11631065	Musculoskeletal and connective tissue disorders	Back pain	01OCT2016		Y
		Psychiatric disorders	Depression	01JAN1977		Y
		Reproductive system and breast disorders	Vaginal haemorrhage	01OCT1983	31OCT1983	N
		Surgical and medical procedures	Hysterectomy	01OCT1983	31OCT1983	N
	C4591001 1163 11631067	Nervous system disorders	Cerebellar ataxia	17JAN1957		Y
			Cerebellar atrophy	17JAN1957		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01MAR2017		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1163 11631068	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2020		Y
	C4591001 1163 11631070	Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1163 11631071	Endocrine disorders	Hypothyroidism	31JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
	C4591001 1163 11631073	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1163 11631078	Surgical and medical procedures	Hysterectomy	01APR1993	30APR1993	N
	C4591001 1163 11631079	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Hyperkalaemia	01JUL2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1163 11631080	Metabolism and nutrition disorders	Obesity	01DEC2000		Y
			Type 2 diabetes mellitus	01DEC2011		Y
		Renal and urinary disorders	Chronic kidney disease	01DEC2013		Y
		Vascular disorders	Hypertension	01DEC1995		Y
			Thrombosis	01DEC2019		Y
	C4591001 1163 11631082	Social circumstances	Postmenopause	01AUG2013		Y
	C4591001 1163 11631083	Gastrointestinal disorders	Dyspepsia	01OCT2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01DEC1990		Y
		Psychiatric disorders	Depression	01DEC2005		Y
			Insomnia	01DEC2000		Y
		Social circumstances	Tobacco user	01JAN1999	31DEC2005	N
		Surgical and medical procedures	Female sterilisation	01JUN1998	30JUN1998	N
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1163 11631084	Eye disorders	Cataract	01DEC2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1163 11631085	Skin and subcutaneous tissue disorders	Rosacea	01JUN1984		Y
		Social circumstances	Postmenopause	01JUL2009		Y
	C4591001 1163 11631086	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2013		Y
			Type 2 diabetes mellitus	01FEB2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Psychiatric disorders	Anxiety	01MAR2012		Y
		Surgical and medical procedures	Hysterectomy	23FEB2003	23FEB2003	N
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1163 11631092	Gastrointestinal disorders	Dyspepsia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	15MAY2019	15FEB2020	N
			Osteoporosis	01JAN2016		Y
		Psychiatric disorders	Alcoholism	01OCT1986	31AUG2005	N
			Bipolar disorder	01OCT1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01OCT1986		Y
			Insomnia	01OCT1986		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1163 11631094	Musculoskeletal and connective tissue disorders	Osteoporosis	31JAN2013		Y
		Psychiatric disorders	Depression	01DEC1998		Y
		Renal and urinary disorders	Hypertonic bladder	01SEP2018		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2010		Y
		Vascular disorders	Hypertension	01OCT1994		Y
	C4591001 1163 11631095	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2012		Y
		Social circumstances	Postmenopause	01APR2000		Y
		Vascular disorders	Hypertension	01NOV2019		Y
	C4591001 1163 11631097	General disorders and administration site conditions	Swelling face	10JUN2019	10JUN2019	N
		Psychiatric disorders	Insomnia	01FEB2020		Y
		Surgical and medical procedures	Hysterectomy	10JAN2000	10JAN2000	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1163 11631099	General disorders and administration site conditions	Oedema	01MAY2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR1970		Y
		Psychiatric disorders	Anxiety	01APR1988		Y
			Depression	01APR1988		Y
			Panic attack	01APR1988		Y
		Social circumstances	Postmenopause	01FEB1997		Y
			Tobacco user	01JAN1970	28FEB2007	N
		Surgical and medical procedures	Cyst removal	01MAY2018	31MAY2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypotension	01JAN1958		Y
	C4591001 1163 11631100	Cardiac disorders	Myocardial infarction	01JAN2020	31JAN2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2020	31JAN2020	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1163 11631101	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Hepatobiliary disorders	Hepatic artery stenosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	01JAN2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	01JAN2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1163 11631105	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2016		Y
		Surgical and medical procedures	Prostatectomy	01NOV2004	11JAN2005	N
	C4591001 1163 11631108	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1163 11631111	Cardiac disorders	Arrhythmia	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1163 11631115	Psychiatric disorders	Anxiety	01MAR2015		Y
			Panic attack	01MAR2015		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1163 11631118	Endocrine disorders	Hypothyroidism	01MAY2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2019		Y
	C4591001 1163 11631120	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2020		Y
		Psychiatric disorders	Depression	01FEB2018		Y
		Social circumstances	Postmenopause	01SEP2005		Y
	C4591001 1163 11631126	Endocrine disorders	Hypothyroidism	31OCT2000		Y
		Immune system disorders	Iodine allergy	01FEB1990		Y
			Rubber sensitivity	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1977		Y
			Depression	31JAN1977		Y
		Social circumstances	Postmenopause	31JUL2004		Y
	C4591001 1163 11631128	Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1163 11631130	Endocrine disorders	Hypothyroidism	01AUG1980		Y
		Psychiatric disorders	Depression	01JUN2019		Y
	C4591001 1163 11631131	Musculoskeletal and connective tissue disorders	Osteoporosis	01SEP2019		Y
		Psychiatric disorders	Depression	01JAN2009		Y
		Social circumstances	Postmenopause	01AUG2005		Y
		Vascular disorders	Hypertension	31JAN2000		Y
	C4591001 1163 11631132	Gastrointestinal disorders	Gastroesophageal reflux disease	31MAR2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Renal and urinary disorders	Hypertonic bladder	01MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	31JAN2017		Y
	C4591001 1163 11631133	Social circumstances	Postmenopause	01OCT1996		Y
		Surgical and medical procedures	Hysterectomy	01OCT1996	31OCT1996	N
		Vascular disorders	Hypertension	01FEB2012		Y
	C4591001 1163 11631134	Surgical and medical procedures	Coronary artery bypass	01AUG2017	31AUG2017	N
	C4591001 1163 11631137	Social circumstances	Postmenopause	01JUL2012		Y
		Surgical and medical procedures	Hysterectomy	01JUL2012	31JUL2012	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1163 11631141	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Multiple allergies	01DEC2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y
	C4591001 1163 11631144	Cardiac disorders	Arrhythmia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31JAN2005	N
	C4591001 1163 11631146	Cardiac disorders	Arrhythmia	01OCT1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2005		Y
		Vascular disorders	Hypertension	01MAR2005		Y
	C4591001 1163 11631147	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1163 11631148	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Nervous system disorders	Sciatica	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN1998		Y
			Depression	01JAN1998		Y
			Insomnia	01JAN2017		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1979	31JAN1979	N
		Surgical and medical procedures	Hysterectomy	01JAN1979	31JAN1979	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1163 11631149	Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1166 11661001	Cardiac disorders	Supraventricular tachycardia	01JAN2019		Y
		Eye disorders	Presbyopia	01JAN1954		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01AUG1959	31AUG1959	N
			Female sterilisation	01AUG1975	31AUG1975	N
	C4591001 1166 11661006	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2012	N
			Uterine leiomyoma	01JAN2002	31DEC2002	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2011	31DEC2011	N
			Carpal tunnel decompression	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN2002	31DEC2002	N
			Mastectomy	01JAN2011	31DEC2011	N
			Oophorectomy	01JAN2002	31DEC2002	N
	C4591001 1166 11661007	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Investigations	Cardiac murmur	01JAN1992		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2017	01FEB2017	N
		Social circumstances	Menopause	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
			Knee arthroplasty	01DEC2019	01DEC2019	N
				01MAY2020	01MAY2020	N
	C4591001 1166 11661010	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Throat cancer	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Surgical and medical procedures	Knee operation	01JAN2010	31DEC2010	N
			Rhinoplasty	01JAN2008	31DEC2008	N
			Shoulder operation	01JAN2005	31DEC2005	N
	C4591001 1166 11661012	Endocrine disorders	Hypothyroidism	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Menopause	01AUG2018		Y
	C4591001 1166 11661013	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign lung neoplasm	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Large intestinal polypectomy	01JAN2015	31DEC2015	N
			Meniscus operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1166 11661015	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1965	31DEC1965	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
	C4591001 1166 11661020	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Eye disorders	Hypermetropia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Menopause	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Endometrial ablation	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1990	31DEC1990	N
		Vascular disorders	Hot flush	01JAN2016	31DEC2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1166 11661021	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN1999	31DEC1999	N
				01JAN2005	31DEC2005	N
	C4591001 1166 11661026	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Hypermetropia	01JAN1959		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
			Food allergy	01JAN1965		Y
		Injury, poisoning and procedural complications	Clavicle fracture	01AUG2020	31AUG2020	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1166 11661027	Eye disorders	Myopia	01JAN1963		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1166 11661029	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Infections and infestations	Diverticulitis	01JAN2001		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1166 11661031	Eye disorders	Hypermetropia	01JAN2000		Y
		Surgical and medical procedures	Spinal operation	01JAN2004	31DEC2004	N
	C4591001 1166 11661034	Gastrointestinal disorders	Pancreatitis	01JAN2015	31DEC2015	N
		Investigations	Blood cholesterol increased	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Social circumstances	Corrective lens user	01JAN1964		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1166 11661038	Eye disorders	Cataract	01JAN2017		Y
			Hypermetropia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1166 11661040	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
			Shoulder operation	01JAN2010	31DEC2010	N
	C4591001 1166 11661043	Eye disorders	Presbyopia	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
		Vascular disorders	Hot flush	01JAN2010		Y
	C4591001 1166 11661045	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1957		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
				01JAN1995	31DEC1995	N
	C4591001 1166 11661050	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1966		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01APR2015	31DEC2016	N
		Surgical and medical procedures	Cancer surgery	01JAN2016	31DEC2016	N
	C4591001 1166 11661053	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Surgical and medical procedures	Knee operation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1166 11661074	Cardiac disorders	Mitral valve prolapse	01JAN1949		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1166 11661075	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Caesarean section	01JAN1990	31DEC1990	N
	C4591001 1166 11661089	Eye disorders	Myopia	01JAN1975		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01DEC2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012		Y
			Osteoporosis	01MAR2019		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1990	31DEC1990	N
	C4591001 1166 11661093	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Surgical and medical procedures	Fracture treatment	01JAN2018	31DEC2018	N
	C4591001 1166 11661098	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2016	31DEC2016	N
			Pituitary tumour	01JAN1995	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Surgical and medical procedures	Knee operation	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1166 11661100	Eye disorders	Myopia	01JAN1957		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11OCT2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Fracture treatment	01JAN2018	31DEC2018	N
			Prostatic operation	01JAN2018	31DEC2018	N
			Transurethral prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1166 11661102	Blood and lymphatic system disorders	Thrombocytopenia	01JAN2005		Y
		Gastrointestinal disorders	Rectal polyp	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Abscess drainage	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lipoma excision	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1166 11661105	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Chondroplasty	01JAN2007	31DEC2007	N
			Joint debridement	01JAN2008	31DEC2008	N
	C4591001 1166 11661107	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Postmenopausal haemorrhage	01JAN2005		Y
		Social circumstances	Menopause	01JAN2004	31DEC2005	N
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2019	31DEC2019	N
		Vascular disorders	Hot flush	01JAN2004	31DEC2005	N
	C4591001 1166 11661108	Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Dry eye	01JAN2014		Y
			Myopia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2012	31DEC2012	N
		Social circumstances	Corrective lens user	01JAN2000		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2012		Y
				01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	01JAN2012	31DEC2012	N
			Mammoplasty	01JAN2018	31DEC2018	N
			Skin lesion removal	01JAN2012	31DEC2012	N
			Wrist surgery	01JAN2013	31DEC2013	N
	C4591001 1166 11661111	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
			Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1167 11671008	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1167 11671012	Investigations	Cardiac murmur	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1167 11671014	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2003		Y
				01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2000	31DEC2000	N
			Hemiplegia	01JAN2000	31DEC2016	N
		Psychiatric disorders	Depression	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1167 11671015	Vascular disorders	Hypertension	01JAN2000		Y
		Cardiac disorders	Arteriosclerosis coronary artery	01JAN2003		Y
			Myocardial infarction	27DEC2012	27DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2006	31JAN2007	N
		Surgical and medical procedures	Coronary artery bypass	23AUG2019	23AUG2019	N
			Prostatectomy	01JAN2006	31JAN2006	N
	C4591001 1167 11671016	Vascular disorders	Hypertension	01JAN2003		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
	C4591001 1167 11671018	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
	C4591001 1167 11671024	Hepatobiliary disorders	Cholelithiasis	16OCT2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21APR2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	27SEP2018		Y
		Psychiatric disorders	Depression	15JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary granuloma	19SEP2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	09AUG2017		Y
	C4591001 1167 11671027	Blood and lymphatic system disorders	Iron deficiency anaemia	18MAR2015		Y
		Cardiac disorders	Atrial fibrillation	14JUN2014		Y
		Endocrine disorders	Hypogonadism	17MAR2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	08AUG2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16AUG2016		Y
			Type 2 diabetes mellitus	16AUG2016		Y
		Renal and urinary disorders	Chronic kidney disease	03MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21NOV2003		Y
		Skin and subcutaneous tissue disorders	Dermatitis	11NOV2019		Y
		Vascular disorders	Hypertension	02OCT2006		Y
	C4591001 1167 11671031	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
	C4591001 1167 11671033	Metabolism and nutrition disorders	Hyperlipidaemia	18SEP2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	20JAN2015		Y
		Psychiatric disorders	Nicotine dependence	01APR2014		Y
	C4591001 1167 11671037	Cardiac disorders	Palpitations	01JAN2018		Y
		Gastrointestinal disorders	Dyspepsia	10MAR2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
			Rheumatoid arthritis	01JAN2004		Y
		Psychiatric disorders	Anxiety disorder	01JAN2016		Y



16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1167 11671042	Eye disorders	Glaucoma	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	26JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
			Rhinitis allergic	01JAN1961		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1167 11671043	Metabolism and nutrition disorders	Glucose tolerance impaired	01NOV2017		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01NOV2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	26MAY2017		Y
	C4591001 1167 11671047	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Sjogren's syndrome	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN2005		Y
			Insomnia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
			Rhinitis allergic	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Raynaud's phenomenon	01JAN1995		Y
	C4591001 1167 11671048	Vascular disorders	Deep vein thrombosis	01JAN2017	31DEC2017	N
			Hypertension	01JAN2017		Y
	C4591001 1167 11671049	Cardiac disorders	Acute myocardial infarction	01SEP2002	30SEP2002	N
			Coronary artery disease	01SEP2002		Y
	C4591001 1167 11671052	Cardiac disorders	Cardiac aneurysm	01AUG2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUL2015		Y
		Infections and infestations	Onychomycosis	24JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lobular breast carcinoma in situ	01NOV2019	14FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2019		Y
	C4591001 1167 11671056	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1167 11671059	Eye disorders	Ocular hypertension	01AUG2019		Y
	C4591001 1167 11671062	Cardiac disorders	Palpitations	14FEB2012		Y
		Endocrine disorders	Goitre	01MAR2012		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	28JUL2015		Y
		General disorders and administration site conditions	Oedema	13MAY2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01SEP2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Rash	11NOV2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017	31DEC2017	N
	C4591001 1167 11671063	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
			Osteopenia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1997	31DEC1997	N
		Nervous system disorders	Memory impairment	06SEP2019		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1167 11671064	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2015	31DEC2015	N
		Nervous system disorders	Transient ischaemic attack	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Prostatic disorder	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1167 11671069	Cardiac disorders	Atrial flutter	07MAR2018		Y
			Coronary artery disease	28NOV2011		Y
		Eye disorders	Retinal detachment	14JAN2019	16JAN2021	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	29AUG2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05DEC2012		Y
			Hyperuricaemia	23FEB2017		Y
		Nervous system disorders	Neuropathy peripheral	11MAR2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	29SEP2015		Y
			Erectile dysfunction	03DEC2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	24NOV2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	29AUG2018		Y
		Vascular disorders	Aortic aneurysm	15OCT2019	15OCT2019	N
			Hypertension	13APR2015		Y
	C4591001 1167 11671074	Gastrointestinal disorders	Diverticulum	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hyperlipidaemia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1975		Y
	C4591001 1167 11671075	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1167 11671076	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Hepatitis C	01JAN1998	31DEC1999	N
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hyperlipidaemia	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
	C4591001 1167 11671077	Cardiac disorders	Cardiac failure congestive	01OCT2009		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1968		Y
		Psychiatric disorders	Anxiety	12JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	23MAY2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Vascular disorders	Sleep apnoea syndrome	01JAN2016		Y
			Arteriosclerosis	01OCT2009		Y
			Essential hypertension	01OCT2009		Y
	C4591001 1167 11671079	Ear and labyrinth disorders	Deafness unilateral	05DEC2019		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	22MAY2019		Y
			Vitamin D deficiency	08MAY2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	04MAY2017	04MAY2017	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1167 11671081	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2010		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01FEB2015		Y
		Psychiatric disorders	Anxiety	01FEB2017		Y
		Vascular disorders	Hypertension	01FEB2015		Y
	C4591001 1167 11671085	Blood and lymphatic system disorders	Iron deficiency anaemia	26AUG1998		Y
		Cardiac disorders	Arteriosclerosis coronary artery	13AUG2014		Y
			Atrial fibrillation	24OCT2012		Y
		Endocrine disorders	Hypothyroidism	10OCT2018		Y
		Eye disorders	Macular degeneration	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	08AUG2012		Y
			Haematochezia	08OCT2015	28JAN2016	N
		Metabolism and nutrition disorders	Gout	30AUG2016		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	10OCT2018		Y
			Type 2 diabetes mellitus	09MAR2017		Y
		Nervous system disorders	Dementia	28JAN2019		Y
			Lumbar radiculopathy	01JAN2010		Y
			Neuropathy peripheral	30AUG2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	10OCT2018		Y
		Vascular disorders	Hypertension	28AUG2017		Y
	C4591001 1167 11671087	Blood and lymphatic system disorders	Anaemia	22FEB2017		Y
		Cardiac disorders	Arteriosclerosis coronary artery	24MAY2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	06DEC2017		Y
		General disorders and administration site conditions	Oedema peripheral	06DEC2012		Y
		Metabolism and nutrition disorders	Gout	23FEB2009		Y
			Hyperlipidaemia	20DEC2013		Y
			Type 2 diabetes mellitus	27SEP2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	25SEP2015		Y
		Renal and urinary disorders	Chronic kidney disease	30NOV2016		Y
		Reproductive system and breast disorders	Prostatomegaly	31MAY2016		Y
	C4591001 1167 11671088	Metabolism and nutrition disorders	Gout	01JAN2016		Y
	C4591001 1167 11671090	Gastrointestinal disorders	Duodenal ulcer	18JUN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04MAR2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	02MAY2013		Y
				11AUG2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				19JUN2008		Y
			Osteopenia	13AUG2019		Y
		Psychiatric disorders	Drug dependence	02NOV2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	10DEC2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25FEB2019		Y
		Vascular disorders	Hypertension	19DEC2016		Y
	C4591001 1167 11671091	Cardiac disorders	Atrial fibrillation	15AUG2015		Y
			Coronary artery stenosis	11APR2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	02APR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23MAY2003		Y
			Impaired fasting glucose	07JUN2011		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	11APR2017		Y
		Vascular disorders	Hypertension	19NOV2014		Y
	C4591001 1167 11671093	Eye disorders	Retinal vein occlusion	01DEC2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1167 11671098	Hepatobiliary disorders	Primary biliary cholangitis	01JAN1997		Y
	C4591001 1167 11671100	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1167 11671101	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671104	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01MAY2000	31MAY2000	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1167 11671107	General disorders and administration site conditions	Oedema	01SEP1996		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01SEP1996		Y
			Vitamin B12 deficiency	01FEB2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	31OCT2018		Y
		Nervous system disorders	Hypoaesthesia	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN1999	31JAN1999	N
			Endometrial ablation	01DEC2007	31DEC2007	N
			Gastric bypass	01FEB2009	28FEB2009	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1167 11671108	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1167 11671109	Surgical and medical procedures	Carotid endarterectomy	16SEP2013	16SEP2013	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1167 11671110	Eye disorders	Glaucoma	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671115	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1167 11671116	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1167 11671121	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1982		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1167 11671122	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2014		Y
			Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1167 11671123	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1167 11671126	Ear and labyrinth disorders	Vertigo	01SEP2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	22MAY2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	30MAY2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2019		Y
		Nervous system disorders	Tension headache	01APR2019		Y
		Psychiatric disorders	Depression	04DEC2003		Y
			Drug dependence	01APR2019		Y
			Insomnia	01APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1167 11671133	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Nervous system disorders	Restless legs syndrome	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1167 11671135	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1167 11671136	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1167 11671137	Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012		Y
			Stress urinary incontinence	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1167 11671138	Cardiac disorders	Atrial fibrillation	01JAN2008		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
	C4591001 1167 11671141	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Pain in extremity	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01APR2020	30APR2020	N
			Hysterectomy	01NOV2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1167 11671143	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
	C4591001 1167 11671147	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1167 11671148	Metabolism and nutrition disorders	Iron deficiency	01FEB2020		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Vascular disorders	Aortic stenosis	01JAN2010		Y
			Hypertension	01NOV1958		Y
	C4591001 1167 11671154	Immune system disorders	Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
	C4591001 1167 11671155	Metabolism and nutrition disorders	Hyperlipidaemia	08NOV2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2017		Y
		Skin and subcutaneous tissue disorders	Eczema	02APR2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	13NOV2013		Y
	C4591001 1167 11671157	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01SEP2016	31MAY2017	N
			Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1167 11671158	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1167 11671159	Cardiac disorders	Arteriosclerosis coronary artery	17NOV2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	23JUL2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08FEB2005		Y
			Type 2 diabetes mellitus	31OCT2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	11JAN2010		Y
		Nervous system disorders	Diabetic neuropathy	01APR2014		Y
		Psychiatric disorders	Insomnia	06JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	29MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	08AUG2011		Y
		Vascular disorders	Hypertension	14JUN2012		Y
	C4591001 1167 11671161	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	20AUG2018		Y
	C4591001 1167 11671163	Endocrine disorders	Hypogonadism	30JUL2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26APR2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Erectile dysfunction	26APR2018		Y
		Vascular disorders	Hypertension	06JAN2016		Y
	C4591001 1167 11671165	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1167 11671168	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2006		Y
			Depression	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01MAR1996	31MAR1996	N
	C4591001 1167 11671171	Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01AUG2019	31AUG2019	N
	C4591001 1167 11671172	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Infections and infestations	Oral herpes	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	28DEC2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	02MAR2020		Y
		Nervous system disorders	Migraine without aura	01JAN1969		Y
		Vascular disorders	Essential hypertension	10JAN2020		Y
	C4591001 1167 11671176	Endocrine disorders	Hypothyroidism	01JAN1978		Y
	C4591001 1167 11671177	Nervous system disorders	Migraine	01JAN1980		Y
	C4591001 1167 11671180	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1167 11671182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
	C4591001 1167 11671183	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	05JAN2015		Y
		Nervous system disorders	Seizure	21FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Chronic kidney disease	03OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04OCT2016		Y
		Vascular disorders	Aortic arteriosclerosis	20MAR2020		Y
			Hypertension	01JAN2011		Y
	C4591001 1167 11671184	Nervous system disorders	Migraine	01JAN1978		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1167 11671186	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2017		Y
	C4591001 1167 11671196	General disorders and administration site conditions	Oedema peripheral	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
			Peripheral arterial occlusive disease	01JAN2014		Y
	C4591001 1167 11671197	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
	C4591001 1167 11671198	Gastrointestinal disorders	Diverticulum	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Hyperuricaemia	16MAR2017		Y
			Obesity	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	27JAN2020		Y
			Sleep apnoea syndrome	24SEP2018		Y
	C4591001 1167 11671203	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Investigations	Prostatic specific antigen increased	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Glucose tolerance impaired	07JUN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Insomnia	27AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
			Rhinitis allergic	01JAN1966		Y
			Sleep apnoea syndrome	01JAN2005		Y
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1167 11671204	Metabolism and nutrition disorders	Gout	01JUN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01SEP2012	30SEP2012	N
		Vascular disorders	Hypertension	01MAY2020		Y
			Thrombosis	01SEP2013	30SEP2014	N
	C4591001 1167 11671207	Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1167 11671209	Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
	C4591001 1167 11671215	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	24SEP2013		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1167 11671221	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1999		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Osteoarthritis	01JAN1999		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1999		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2016		Y
			Depression	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1167 11671225	Cardiac disorders	Atrioventricular block second degree	29AUG2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	29AUG2019		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	11SEP2020		Y
		Vascular disorders	Hypertension	29AUG2019		Y
	C4591001 1167 11671226	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1167 11671228	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1167 11671229	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1167 11671232	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2016		Y
	C4591001 1168 11681010	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Arthritis bacterial	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Phantom limb syndrome	01DEC2018		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
			Leg amputation	01DEC2018		Y
	C4591001 1168 11681012	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic malignant melanoma	01JAN2000	31DEC2000	N
			Prostate cancer	01JAN2013	31DEC2013	N
		Nervous system disorders	Headache	01JAN1967		Y
		Surgical and medical procedures	Pneumonectomy	01JAN2000	31DEC2000	N
			Prostatectomy	01JAN2013	31DEC2013	N
	C4591001 1168 11681015	Eye disorders	Myopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2003		Y
		Surgical and medical procedures	Knee operation	01JAN2003	31DEC2003	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1168 11681021	Eye disorders	Myopia	01JAN1960		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN1997	31DEC1997	N
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012	31DEC2012	N
			Uterine leiomyoma	01JAN1996	31DEC1996	N
		Psychiatric disorders	Panic attack	01JAN1996		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1997	31DEC1997	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1168 11681029	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
			Tonsillitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN1997		Y
			Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Tonsillectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681037	Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Blood testosterone decreased	01JAN2012		Y
		Metabolism and nutrition disorders	Gout	01JAN1990		Y
			Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN1969		Y
			Osteoarthritis	01MAR2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
			Sinus headache	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1168 11681043	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1999		Y
			Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1988		Y
		Nervous system disorders	Migraine	01JAN2014		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1168 11681044	Reproductive system and breast disorders	Menorrhagia	01JAN2018	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1168 11681049	Eye disorders	Macular degeneration	01JAN2018		Y
			Myopia	01JAN1963		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1953		Y
		Injury, poisoning and procedural complications	Upper limb fracture	30MAR2020	30MAR2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
			Uterine leiomyoma	01JAN2016	31DEC2016	N
		Nervous system disorders	Migraine	01JAN1967		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN1953		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016	31DEC2016	N
			Joint arthroplasty	30MAR2020	30MAR2020	N
			Knee arthroplasty	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1168 11681051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1168 11681055	Eye disorders	Cataract	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1992		Y
			Depression	01JAN1992		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2014	31DEC2014	N
			Neck surgery	01JAN2016	31DEC2016	N
			Spinal operation	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
	C4591001 1168 11681056	Ear and labyrinth disorders	Deafness	01JAN2010		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2019	31DEC2019	N
			Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681057	Ear and labyrinth disorders	Hypoacusis	01JAN1970		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tinnitus	01JAN1970		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Cataract	01JUN2020		Y
			Photophobia	01JAN1958		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2020		Y
			Tooth loss	01JAN1970		Y
		General disorders and administration site conditions	Pain	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Anosmia	01JAN1970		Y
			Cerebrovascular accident	01JAN2000	31DEC2000	N
			Neuropathy peripheral	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1999		Y
	C4591001 1168 11681066	Cardiac disorders	Ventricular extrasystoles	01JAN2020		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Constipation	01JAN2010		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2003		Y
			Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1168 11681067	Endocrine disorders	Hypothyroidism	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681075	Cardiac disorders	Bundle branch block right	01JAN1985		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Dyspepsia	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1168 11681082	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Sinus headache	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1965	31DEC1965	N
		Vascular disorders	Hot flush	01JAN2000		Y
			Hypertension	01JAN2015		Y
	C4591001 1168 11681083	Ear and labyrinth disorders	Tinnitus	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
			Spinal pain	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681091	Eye disorders	Astigmatism	01JAN1993		Y
			Hypermetropia	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
			Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1981	31DEC1981	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31DEC2011	N
	C4591001 1168 11681092	Cardiac disorders	Supraventricular tachycardia	01JAN2005		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2012		Y
		Gastrointestinal disorders	Abdominal hernia	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1963		Y
				01JAN2013		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Herpes zoster	01JAN2012	31DEC2012	N
			Oral herpes	01JAN1966		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2017		Y
		Surgical and medical procedures	Knee arthroplasty	01DEC2013	31DEC2013	N
				01NOV2014	30NOV2014	N
			Nephrectomy	01DEC2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1168 11681099	Immune system disorders	Seasonal allergy	01JAN1964		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681106	Eye disorders	Cataract	01JAN2010	31DEC2010	N
			Retinal detachment	01JAN2009	31DEC2009	N
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Surgical and medical procedures	Retinopexy	01JAN2009	31DEC2009	N
	C4591001 1168 11681108	Ear and labyrinth disorders	Hypoacusis	01JAN2017		Y
		Eye disorders	Cataract	01JAN2018		Y
			Hypermetropia	01JAN1993		Y
			Myopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
			Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN1986	31DEC2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01SEP2019	30SEP2019	N
		Nervous system disorders	Headache	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Mammoplasty	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1168 11681110	Cardiac disorders	Tachycardia	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Meniscus removal	01JAN1970	31DEC1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681111	Cardiac disorders	Atrial fibrillation	01MAR2019		Y
		Eye disorders	Myopia	01JAN1957		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
		Nervous system disorders	Headache	01JAN2005		Y
			Transient ischaemic attack	01JAN1997	31DEC1997	N
		Psychiatric disorders	Depression	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01MAY2019		Y
	C4591001 1168 11681113	Immune system disorders	Seasonal allergy	01JAN1964		Y
		Nervous system disorders	Headache	01JAN1964		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681119	Ear and labyrinth disorders	Deafness	01JAN2004		Y
			Tinnitus	01JAN1990		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Depression	01JAN2005		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Spinal operation	01JAN2018	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681120	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1168 11681122	Cardiac disorders	Atrial fibrillation	01JAN1982		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1168 11681123	Immune system disorders	Drug hypersensitivity	01JAN1975	31DEC1975	N
			Seasonal allergy	01JAN1971		Y
		Metabolism and nutrition disorders	Diabetic ketoacidosis	01JAN1983	31DEC1983	N
			Type 1 diabetes mellitus	01JAN1983		Y
		Nervous system disorders	Tremor	01JAN2019	01JAN2019	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31DEC2011	N
			Meniscus removal	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1168 11681124	Eye disorders	Astigmatism	01JAN1997		Y
			Hypermetropia	01JAN1997		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Rhinitis	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005	31DEC2005	N
			Back pain	01JAN2019		Y
		Nervous system disorders	Headache	01JAN1995		Y
		Surgical and medical procedures	Knee operation	01JAN2005	31DEC2005	N
	C4591001 1168 11681129	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Hernia	01JAN2010		Y
		Investigations	Blood testosterone decreased	01AUG2020		Y
		Renal and urinary disorders	Pollakiuria	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1994	31DEC1994	N
			Tonsillectomy	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1168 11681131	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Nervous system disorders	Headache	01JAN2000		Y
			Neuropathy peripheral	01JAN2009		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1168 11681133	Ear and labyrinth disorders	Deafness unilateral	01JAN1984		Y
			Tinnitus	01JAN1984		Y
		Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2004		Y
		Nervous system disorders	Migraine	01JAN2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tension headache	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
				01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681139	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
	C4591001 1168 11681140	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Eye disorders	Glaucoma	01JAN2018		Y
		Gastrointestinal disorders	Inflammatory bowel disease	01JAN2000	31DEC2000	N
			Irritable bowel syndrome	01JAN1969		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1983		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2020		Y
			Spinal osteoarthritis	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN2020	31JAN2020	N
			Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1168 11681144	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
			Seasonal allergy	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Pneumonia	01JAN1970	31DEC1970	N
		Psychiatric disorders	Depression	01JAN1994		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1997	31DEC1997	N
	C4591001 1168 11681147	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2002	31DEC2002	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Cataract operation	01JAN2005	31DEC2005	N
			Umbilical hernia repair	01JAN2002	31DEC2002	N
	C4591001 1168 11681149	Immune system disorders	Seasonal allergy	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2012	31DEC2012	N
				01JAN2014	31DEC2014	N
	C4591001 1168 11681150	Eye disorders	Hypermetropia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Infections and infestations	Tonsillitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1978		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Throat cancer	01JAN2000	31DEC2000	N
		Nervous system disorders	Headache	01JAN1980		Y
		Surgical and medical procedures	Meniscus operation	01JAN1978	31DEC1978	N
	C4591001 1168 11681151	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		General disorders and administration site conditions	Cyst	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Abdominal operation	01JAN2000	31DEC2000	N
			Gastric banding	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1168 11681152	Cardiac disorders	Bradycardia	01JAN1956		Y
		Endocrine disorders	Hyperparathyroidism	01APR2018	30APR2018	N
		Eye disorders	Cataract	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Retinopexy	01SEP2017	30SEP2017	N



16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681155	Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Eye disorders	Hypermetropia	01JAN2000		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1965		Y
		Infections and infestations	Tonsillitis	01JAN1977	31DEC1977	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01AUG2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JUN2007	30JUN2007	N
				01MAY2007	31MAY2007	N
	C4591001 1168 11681156	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01OCT2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Meniscus operation	01JAN2020	31JAN2020	N
	C4591001 1168 11681161	Cardiac disorders	Supraventricular tachycardia	01JAN2000		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
			Scoliosis	01JAN1973	31DEC1973	N
		Skin and subcutaneous tissue disorders	Acne	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN2016	31DEC2016	N
			Spinal fusion surgery	01JAN2017	31DEC2017	N
			Spinal rod insertion	01JAN1973	31DEC1973	N
			Tonsillectomy	01JAN1977	31DEC1977	N
	C4591001 1168 11681165	Ear and labyrinth disorders	Presbycusis	01JAN2020		Y
		Endocrine disorders	Autoimmune thyroiditis	01JAN1999	31DEC1999	N
		Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Hepatobiliary disorders	Cholecystitis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
				01JAN1995		Y
				01JAN2000		Y
				01JAN2005		Y
			Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2020		Y
			Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN1999	31DEC1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681170	Eye disorders	Myopia	01JAN1958		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Meniscus operation	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1168 11681171	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Nervous system disorders	Essential tremor	01JAN1990		Y
		Surgical and medical procedures	Skin graft	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1952	31DEC1952	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1168 11681172	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2010		Y
			Irritable bowel syndrome	01JAN2010		Y
			Nausea	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hysterectomy	01JAN1992	31DEC1992	N
			Spinal fusion surgery	01JAN2009	31DEC2009	N
			Thyroidectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1168 11681173	Ear and labyrinth disorders	Presbycusis	01JAN2000		Y
			Tinnitus	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1996		Y
			Seasonal allergy	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Psychogenic seizure	01JAN2011	31DEC2018	N
			Restless legs syndrome	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1168 11681174	Infections and infestations	Pneumonia	01JAN1967	31DEC1967	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01DEC2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Libido decreased	01JAN2010		Y
			Restlessness	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Mammoplasty	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1168 11681179	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Knee operation	01JAN2015	31DEC2015	N
			Spinal fusion surgery	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1168 11681180	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Muscle twitching	01JAN1945		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1168 11681181	Eye disorders	Cataract	01JAN2015	31DEC2015	N
			Hypermetropia	01JAN2015		Y
		Infections and infestations	Tonsillitis	01JAN1953	31DEC1953	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1940		Y
			Upper-airway cough syndrome	01JAN1940		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681183	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1168 11681189	Immune system disorders	Seasonal allergy	01JAN1974		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2015	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2010	31DEC2015	N
	C4591001 1168 11681191	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Cardiac murmur	(b) (6) 1957		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN1980	31DEC1980	N
	C4591001 1168 11681196	Ear and labyrinth disorders	Deafness	01JAN1950		Y
		Eye disorders	Cataract	01APR2019	30APR2019	N
			Dry eye	01APR2019		Y
			Hypermetropia	01JAN1960		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Apnoea	01JAN2009		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN1973		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1957	31DEC1957	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1168 11681199	Immune system disorders	Allergy to vaccine	01JAN1955		Y
			Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1168 11681200	Gastrointestinal disorders	Thrombosis	01JAN2012	31DEC2012	N
			Dyspepsia	01JAN2019		Y
			Large intestine polyp	01JAN1996	31DEC1996	N
		Hepatobiliary disorders	Gallbladder disorder	01JAN1996	31DEC1996	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1996	31DEC1996	N
	C4591001 1168 11681201	Cardiac disorders	Cardiac disorder	01JAN2007		Y
		Eye disorders	Hypermetropia	01JAN1968		Y
			Myopia	01JAN1968		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Investigations	Heart rate irregular	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Surgical and medical procedures	Appendicectomy	01JAN1960	31DEC1960	N
			Coronary artery bypass	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1168 11681204	Ear and labyrinth disorders	Tonsillectomy	01JAN1950	31DEC1950	N
			Deafness bilateral	01JAN2010		Y
		Gastrointestinal disorders	Tinnitus	01JAN2008		Y
			Dyspepsia	01JAN2001		Y
		Immune system disorders	Gastroesophageal reflux disease	01JAN2016		Y
			Drug hypersensitivity	01JAN2004		Y
		Metabolism and nutrition disorders	Seasonal allergy	01JAN1995		Y
			Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1987		Y
			Muscle spasms	01JAN2000		Y
			Osteoarthritis	01JAN1987		Y
		Nervous system disorders	Spinal osteoarthritis	01JAN1987		Y
			Tension headache	01JAN2000		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2017	31DEC2017	N
			Oesophageal operation	01JAN2016	31DEC2016	N
	Spinal fusion surgery		01JAN2001	31DEC2001	N	
	Tonsillectomy		01JAN1989	31DEC1989	N	
	C4591001 1168 11681205	Ear and labyrinth disorders	Deafness bilateral	01JAN2010		Y
			Tinnitus	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
	C4591001 1168 11681209	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
			Cardiac disorders	Supraventricular tachycardia	01FEB2020	
		Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inflammatory bowel disease	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Blood testosterone decreased	01JAN2018		Y
			Blood uric acid increased	01JAN2018		Y
			Heart rate irregular	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2014	31DEC2014	N
		Nervous system disorders	Restless legs syndrome	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1168 11681211	Cardiac disorders	Atrial fibrillation	01JAN1996		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN1979		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN1970		Y
		Surgical and medical procedures	Knee operation	01JAN1993	31DEC1993	N
		Vascular disorders	Deep vein thrombosis	01JAN2014	31DEC2014	N
	C4591001 1168 11681214	Endocrine disorders	Hypothyroidism	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Myopia	01JAN1953		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN1943		Y
		Infections and infestations	Prostate infection	24SEP2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2000	N
			Temporomandibular joint syndrome	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Apnoea	01JAN2015		Y
			Asthma	01JAN1943		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2010	31DEC2010	N
			Shoulder operation	01JAN2014	31DEC2014	N
	C4591001 1168 11681225	Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1168 11681230	Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1168 11681232	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Gastrointestinal disorders	Diverticular perforation	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Surgical and medical procedures	Spinal operation	01JAN1989	31DEC1989	N
	C4591001 1168 11681233	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood triglycerides increased	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Knee operation	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1168 11681235	Gastrointestinal disorders	Inguinal hernia	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2007	31DEC2007	N
	C4591001 1168 11681236	Gastrointestinal disorders	Umbilical hernia	01JAN1994	31DEC1994	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 1168 11681237	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Eye disorders	Hypermetropia	01JAN2005		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
		Nervous system disorders	Headache	01JAN1974		Y
		Psychiatric disorders	Anxiety	01JAN2004		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1168 11681240	Eye disorders	Blindness unilateral	01JAN2017		Y
			Cataract	01JAN2019	31DEC2019	N
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
			Precancerous condition	01FEB2020	29FEB2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholecystitis	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Rubber sensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Cardiac murmur	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2011	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Pulmonary embolism	01JAN1998	01JAN1998	N
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Hysterectomy	01MAY2020	31MAY2020	N
			Knee arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1169 11691003	Gastrointestinal disorders	Gastroesophageal reflux disease	03JUL2011		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	03JUL2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	31OCT2017		Y
	C4591001 1169 11691004	Metabolism and nutrition disorders	Hypercholesterolaemia	24MAR2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	09JUL2014		Y
		Psychiatric disorders	Depression	24MAR2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	23DEC2014		Y
		Vascular disorders	Hypertension	24MAR2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1169 11691005	Gastrointestinal disorders	Gastroesophageal reflux disease	24DEC2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	02FEB2018		Y
	C4591001 1169 11691006	Gastrointestinal disorders	Gastroesophageal reflux disease	18APR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29SEP2015		Y
		Psychiatric disorders	Anxiety	16OCT2015		Y
		Vascular disorders	Hypertension	03AUG2012		Y
	C4591001 1169 11691008	Endocrine disorders	Hypothyroidism	07DEC2014		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	07DEC2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	19DEC2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07DEC2014		Y
			Erectile dysfunction	29OCT2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	17DEC2014		Y
			Rhinitis allergic	21SEP2010		Y
		Vascular disorders	Hypertension	07DEC2014		Y
	C4591001 1169 11691009	Eye disorders	Vitreous detachment	08JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24DEC2014		Y
	C4591001 1169 11691013	Immune system disorders	Seasonal allergy	16NOV2018		Y
		Renal and urinary disorders	Hypertonic bladder	21AUG2017		Y
	C4591001 1169 11691015	Musculoskeletal and connective tissue disorders	Osteopenia	16AUG2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1169 11691016	Eye disorders	Glaucoma	04FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21DEC2014		Y
		Vascular disorders	Hypertension	14MAY2012		Y
	C4591001 1169 11691028	Gastrointestinal disorders	Gastroesophageal reflux disease	17DEC2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	21DEC2014		Y
		Nervous system disorders	Lumbar radiculopathy	17DEC2015		Y
		Social circumstances	Postmenopause	10SEP2018		Y
	C4591001 1169 11691032	Cardiac disorders	Atrial fibrillation	29JUL2019		Y
		Congenital, familial and genetic disorders	Type V hyperlipidaemia	29JUL2019		Y
		Gastrointestinal disorders	Defaecation disorder	05JUN2017		Y
			Gastroesophageal reflux disease	19DEC2014		Y
		Metabolism and nutrition disorders	Insulin resistance	19MAR2020		Y
			Obesity	19DEC2014		Y
			Vitamin D deficiency	22JUL2020		Y
		Renal and urinary disorders	Mixed incontinence	05JUN2017		Y
		Social circumstances	Postmenopause	29JUL2019		Y
		Vascular disorders	Hypertension	19DEC2014		Y
	C4591001 1169 11691035	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04AUG2017		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1169 11691037	Endocrine disorders	Hypothyroidism	21AUG2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01AUG2006	31AUG2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	24DEC2014		Y
	C4591001 1169 11691042	Immune system disorders	Seasonal allergy	24DEC2014		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	11NOV2019		Y
	C4591001 1169 11691045	Vascular disorders	Hypertension	30DEC2019		Y
	C4591001 1169 11691050	Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2004		Y
	C4591001 1169 11691051	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
	C4591001 1169 11691052	Congenital, familial and genetic disorders	Spina bifida	(b) (6) 1956		Y
		Infections and infestations	Chronic sinusitis	16JUN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	16JUN2020	23JUN2020	N
	C4591001 1169 11691061	Gastrointestinal disorders	Gastroesophageal reflux disease	23DEC2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	23DEC2014		Y
			Obesity	23DEC2014		Y
			Vitamin D deficiency	23DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	23DEC2014		Y
			Sleep apnoea syndrome	23DEC2014		Y
		Vascular disorders	Hypertension	23DEC2014		Y
	C4591001 1169 11691066	Endocrine disorders	Hypothyroidism	20APR2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	20APR2016		Y
			Vitamin B12 deficiency	20APR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Essential hypertension	20APR2016		Y
	C4591001 1169 11691068	Gastrointestinal disorders	Barrett's oesophagus	29JUN2016		Y
			Constipation	07JAN2019		Y
			Gastrooesophageal reflux disease	06APR2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07DEC2014		Y
			Type 2 diabetes mellitus	19DEC2014		Y
		Musculoskeletal and connective tissue disorders	Arthritis	07JAN2019		Y
		Nervous system disorders	Migraine	07DEC2014		Y
		Psychiatric disorders	Depression	07DEC2014		Y
			Generalised anxiety disorder	19DEC2014		Y
			Insomnia	19DEC2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07DEC2014		Y
			Sleep apnoea syndrome	09OCT2015		Y
		Vascular disorders	Hypertension	07DEC2014		Y
	C4591001 1169 11691070	Endocrine disorders	Androgen deficiency	07JUL2017		Y
		Gastrointestinal disorders	Acquired oesophageal web	19JUL2017		Y
			Gastrooesophageal reflux disease	21DEC2014		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	17JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21DEC2014		Y
			Sleep apnoea syndrome	21DEC2014		Y
		Vascular disorders	Hypertension	01JUL2011		Y
	C4591001 1169 11691071	Blood and lymphatic system disorders	Anaemia	21DEC2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Leukopenia	21DEC2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21DEC2014		Y
		Nervous system disorders	Trigeminal neuralgia	21DEC2014		Y
		Vascular disorders	Hypertension	21DEC2014		Y
	C4591001 1169 11691074†	Infections and infestations	HIV infection	02FEB1990		Y
		Investigations	Cardiac murmur	14JUL2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22DEC2014		Y
		Psychiatric disorders	Tobacco abuse	01JAN1965		Y
		Vascular disorders	Essential hypertension	10JAN2011		Y
	C4591001 1170 11701004	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701005	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701008	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
	C4591001 1170 11701010	Surgical and medical procedures	Coronary arterial stent insertion	01JAN2008		Y
	C4591001 1170 11701017	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2005		Y
	C4591001 1170 11701028	Cardiac disorders	Coronary artery disease	01MAR2011	31MAR2011	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1170 11701030	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Infections and infestations	Herpes simplex	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN2016		Y
	C4591001 1170 11701032	Cardiac disorders	Arrhythmia	01JAN2011		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage III	01JAN2009	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01APR2019		Y
	C4591001 1170 11701033	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1989		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2009	31DEC2010	N
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1170 11701039	Cardiac disorders	Coronary artery disease	01JAN2013		Y
	C4591001 1170 11701046	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1170 11701050	Cardiac disorders	Ventricular extrasystoles	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1170 11701056	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1170 11701058	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01NOV2019		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701061	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701062	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1170 11701066	Blood and lymphatic system disorders	Anaemia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2000		Y
	C4591001 1170 11701068	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701070	Endocrine disorders	Hypogonadism	04APR2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15FEB2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety	04APR2015		Y
		Vascular disorders	Hypertension	15OCT2013		Y
	C4591001 1170 11701071	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1170 11701078	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
		Infections and infestations	Urinary tract infection	01JAN2010		Y
	C4591001 1170 11701080	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1170 11701082	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701083	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1170 11701088	Cardiac disorders	Cardiac failure congestive	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01MAR2020		Y
	C4591001 1170 11701090	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701109	Immune system disorders	Seasonal allergy	01JAN1965		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1170 11701113	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1170 11701114	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2010		Y
			Gout	01JAN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1170 11701124	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1170 11701130	Gastrointestinal disorders	Coeliac disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
	C4591001 1170 11701133	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1170 11701141	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN1953		Y
	C4591001 1170 11701147	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701148	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701155	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2015		Y
			Coronary artery disease	01JAN2015		Y
	C4591001 1170 11701157	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	31AUG2020		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2004	31DEC2004	N
	C4591001 1170 11701160	Endocrine disorders	Hypogonadism	01JAN2010		Y
			Hypothyroidism	01JAN2010		Y
	C4591001 1170 11701161	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1170 11701168	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1170 11701169	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1968		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701172	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1170 11701173	Investigations	Blood cholesterol increased	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Nasal polyps	01JAN2015		Y
	C4591001 1170 11701175	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1170 11701176	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1979		Y
	C4591001 1170 11701177	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acrochordon	01JAN1990		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1170 11701186	Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
	C4591001 1170 11701188	Nervous system disorders	Neuropathy peripheral	13AUG2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701189	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1170 11701194	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1170 11701197	Eye disorders	Macular degeneration	01JAN2016		Y
		Immune system disorders	Sarcoidosis	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
	C4591001 1170 11701198	Endocrine disorders	Hypothyroidism	01JAN1969		Y
		Eye disorders	Macular degeneration	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006	31DEC2006	N
	C4591001 1170 11701200	Infections and infestations	Diverticulitis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lobular breast carcinoma in situ	01JAN2011		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1170 11701202	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1170 11701216	Immune system disorders	Hypersensitivity	01JAN1966		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701217	Blood and lymphatic system disorders	Immune thrombocytopenia	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Psychiatric disorders	Alcoholism	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Social circumstances	Tobacco user	01JAN1995		Y
		Vascular disorders	Deep vein thrombosis	01JAN1980		Y
			Hypertension	01JAN1998		Y
	C4591001 1170 11701218	Social circumstances	Postmenopause	01JAN2016	31DEC2016	N
	C4591001 1170 11701219	Immune system disorders	Hypersensitivity	01SEP1983		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701220	Endocrine disorders	Hypothyroidism	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1170 11701224	Immune system disorders	Seasonal allergy	01JAN1956		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1170 11701238	Investigations	Blood testosterone decreased	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2015		Y
	C4591001 1170 11701239	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1986		Y
		Social circumstances	Postmenopause	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1170 11701240	Immune system disorders	Seasonal allergy	01JAN1977		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1170 11701246	Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
	C4591001 1170 11701247	Immune system disorders	Seasonal allergy	01JAN2007		Y
	C4591001 1170 11701248	Infections and infestations	Sinusitis	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1170 11701254	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1170 11701265	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2015		Y
	C4591001 1170 11701266	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701270	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hyperlipidaemia	01JAN2000		Y
			Hypertension	01JAN2000		Y
	C4591001 1170 11701272	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Exostosis	01JUL2010		Y
			Muscle spasms	01JUL2010		Y
			Spondylitis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Skin atrophy	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1988		Y
	C4591001 1170 11701273	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1170 11701275	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1170 11701276	Immune system disorders	Seasonal allergy	01MAR1975		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701278	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701294	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
	C4591001 1170 11701295	Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1170 11701299	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1170 11701301	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Infections and infestations	Herpes simplex	01JAN2020		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1170 11701305	Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	01JAN2004	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1170 11701309	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Cardiac murmur	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Vascular disorders	Aortic stenosis	01JAN2010		Y
			Hypertension	01JAN2000		Y
	C4591001 1170 11701327	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cervical radiculopathy	01JAN1993		Y
	C4591001 1170 11701328	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2016	N
		Nervous system disorders	Myoclonus	01JAN1995		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
	C4591001 1170 11701329	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
	C4591001 1170 11701330†	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Investigations	HIV test positive	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1986		Y
			Depression	01JAN1986		Y
	C4591001 1170 11701331	Psychiatric disorders	Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1170 11701332	Ear and labyrinth disorders	Deafness bilateral	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1170 11701333	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1170 11701335	Eye disorders	Glaucoma	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	01JAN1963		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
	C4591001 1170 11701336	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
			Bipolar disorder	01JAN1995		Y
			Depression	01JAN1995		Y
		Social circumstances	Postmenopause	01DEC2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1170 11701339	Endocrine disorders	Hypothyroidism	01JAN1980		Y
	C4591001 1170 11701345†	Investigations	HIV test positive	01JAN2003		Y
		Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
	C4591001 1170 11701347	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1170 11701351†	Investigations	HIV test positive	01MAY2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	10JAN2018		Y
	C4591001 1170 11701353†	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Investigations	HIV test positive	01JAN2004		Y
	C4591001 1170 11701354	Social circumstances	Postmenopause	01JAN2010	31DEC2010	N
	C4591001 1170 11701356	Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701363	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1170 11701367	Eye disorders	Glaucoma	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2000	31DEC2000	N
	C4591001 1170 11701368	Congenital, familial and genetic disorders	Corneal dystrophy	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1170 11701369	Infections and infestations	Helicobacter infection	01JAN2018	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1170 11701371	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1170 11701409†	Immune system disorders	Seasonal allergy	01JAN2002		Y
		Investigations	HIV test positive	01JAN1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1170 11701448	Immune system disorders	Seasonal allergy	01JAN1998		Y
		Infections and infestations	Oral herpes	01JAN1974		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1170 11701454†	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2006		Y
		Immune system disorders	Seasonal allergy	01MAY2019		Y
		Investigations	HIV test positive	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
			Type 2 diabetes mellitus	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711007	Endocrine disorders	Hypothyroidism	01JAN2015		Y
	C4591001 1171 11711015	Cardiac disorders	Mitral valve prolapse	01JAN2000	31DEC2000	N
		Gastrointestinal disorders	Haemorrhoids	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2018	31DEC2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2013	31DEC2013	N
			Rotator cuff repair	01JAN2018	31DEC2018	N
	C4591001 1171 11711017	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
	C4591001 1171 11711019	Cardiac disorders	Myocardial infarction	01NOV2010	30NOV2010	N
		Surgical and medical procedures	Stent placement	13NOV2010	13NOV2010	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711022	Metabolism and nutrition disorders	Glucose tolerance impaired	01JUN2018		Y
			Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN2010	31DEC2010	N
			Cataract operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1171 11711025	Eye disorders	Cataract	01JAN1998	31DEC1998	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC2014	N
		Nervous system disorders	Migraine	01JAN1967		Y
			Neuralgia	01JAN2014	31DEC2014	N
		Psychiatric disorders	Depression	01JAN1998	31DEC2005	N
			Insomnia	01JAN2012		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2013		Y
		Surgical and medical procedures	Caesarean section	01JAN1976	31DEC1976	N
				01JAN1984	31DEC1984	N
				01JAN1985	31DEC1985	N
				01JAN1990	31DEC1990	N
			Cataract operation	01JAN1998	31DEC1998	N
			Skin neoplasm excision	01JAN1995	31DEC1995	N
				01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vascular stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1171 11711032	Gastrointestinal disorders	Peripheral vascular disorder	01FEB2015	28FEB2015	N
			Haemorrhoids	01JAN2000	31DEC2000	N
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Injury, poisoning and procedural complications	Jaw fracture	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2011	31DEC2019	N
			Migraine	01JAN2011	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2000	31DEC2017	N
	C4591001 1171 11711038	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN1963	31DEC2017	N
		Injury, poisoning and procedural complications	Fibula fracture	01MAR2020	30APR2020	N
			Tibia fracture	01MAR2020	30APR2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2014	N
		Nervous system disorders	Migraine	01JAN1979		Y
		Psychiatric disorders	Insomnia	01JAN1979		Y
		Surgical and medical procedures	Ankle operation	01APR2020	30APR2020	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Mastectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1171 11711040	Immune system disorders	Drug hypersensitivity	01JAN1965	31DEC1965	N
		Infections and infestations	Appendicitis	01JAN1987	31DEC1987	N
			Tonsillitis	01JAN1965	31DEC1965	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1987	31DEC1987	N
			Prostatectomy	01JAN2014	31DEC2014	N
			Tonsillectomy	01JAN1965	31DEC1965	N
			Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1171 11711041	Vascular disorders	Hypertension	01SEP2019		Y
		Ear and labyrinth disorders	Meniere's disease	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Cataract	01JAN2010	31OCT2015	N
		Immune system disorders	Seasonal allergy	01JAN1955		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1970		Y
			Osteopenia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Cataract operation	01OCT2015	31OCT2015	N
			Female sterilisation	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1171 11711045	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y	
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2019		Y	
		Surgical and medical procedures	Pulmonary fibrosis	17AUG2000		Y	
			Ankle arthroplasty	01JAN2017	31DEC2017	N	
			Gastrectomy	01JAN2010	31DEC2010	N	
			Gastric bypass	01OCT2019	31OCT2019	N	
			Hip arthroplasty	01JAN2010	31DEC2010	N	
			Hysterectomy	01JAN1986	31DEC1986	N	
			Shoulder arthroplasty	01JAN2013	31DEC2013	N	
			Spinal fusion surgery	01JAN2016	31DEC2016	N	
			Vascular disorders	Hot flush	01JAN1986		Y
				Hypertension	01JAN2005		Y
	C4591001 1171 11711048	Ear and labyrinth disorders	Hypoacusis	01JAN1983		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y	
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y	
		Surgical and medical procedures	Vasectomy	01JAN1982	31DEC1982	N	
	C4591001 1171 11711049	Endocrine disorders	Hypothyroidism	01JAN2010		Y	
		Immune system disorders	Seasonal allergy	01JAN2014		Y	
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y	
		Social circumstances	Postmenopause	01JAN2001		Y	
		Surgical and medical procedures	Hysterectomy	01JAN2001	31DEC2001	N	
	C4591001 1171 11711051	Immune system disorders	Seasonal allergy	01JAN1980		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Breast cyst	01JAN2006	31DEC2006	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
	C4591001 1171 11711054	Gastrointestinal disorders	Abdominal hernia	01JAN2015	31DEC2015	N
		Nervous system disorders	Sciatica	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1171 11711057	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1171 11711059	Endocrine disorders	Hypogonadism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Nocturia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1171 11711061	Immune system disorders	Seasonal allergy	01JAN1955		Y
		Vascular disorders	Hypertension	01JAN2005		Y
			Intermittent claudication	01JAN2000		Y
			Peripheral venous disease	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711063	Eye disorders	Glaucoma	01JAN2017		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
	C4591001 1171 11711064	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Infections and infestations	Appendicitis	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012	31DEC2012	N
			Osteoarthritis	07JAN2020		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
			Cholecystectomy	01JAN1988	31DEC1988	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Spinal fusion surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1171 11711078	Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010	31DEC2010	N
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Cataract operation	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cholecystectomy	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1171 11711086	Immune system disorders	Seasonal allergy	01JAN1986		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2010		Y
		Surgical and medical procedures	Vasectomy	01JUN2003	30JUN2003	N
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1171 11711090	Immune system disorders	Rubber sensitivity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01DEC2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2004	31JAN2004	N
	C4591001 1171 11711094	Eye disorders	Cataract	01JAN2015	31DEC2015	N
		Infections and infestations	Oral herpes	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01MAY2020	31MAY2020	N
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Lithotripsy	01MAY2020	31MAY2020	N
			Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1171 11711098	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2006	31DEC2006	N
		Nervous system disorders	Nerve compression	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal fusion surgery	01JAN2006	31DEC2006	N
	C4591001 1171 11711099	Cardiac disorders	Atrial fibrillation	01JAN2012	31DEC2017	N
		Eye disorders	Cataract	01JAN2000	31DEC2000	N
			Ocular hypertension	01JAN2016		Y
			Retinal detachment	01JAN2000	31DEC2000	N
		Investigations	Catheterisation cardiac	01MAR2017	31MAR2017	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cataract operation	01JAN2000	31DEC2000	N
			Micrographic skin surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1977		Y
	C4591001 1171 11711102	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Intraocular pressure increased	01JAN2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Surgical and medical procedures	Gastric banding	01JAN2007	31DEC2007	N
	C4591001 1171 11711107	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1967		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
			Seasonal allergy	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1970		Y
	C4591001 1171 11711108	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1989		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2013	31DEC2013	N
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Surgical and medical procedures	Cancer surgery	01JAN2013	31DEC2013	N
			Hysterectomy	01APR2000	30APR2000	N
	C4591001 1171 11711117	Gastrointestinal disorders	Haemorrhoids	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Vasectomy	01JAN2007	31DEC2007	N
	C4591001 1171 11711120	Cardiac disorders	Coronary artery disease	01JAN2017	31DEC2017	N
		Eye disorders	Cataract	06JUL2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
				08JUL2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1980		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1998	31DEC1998	N
			Coronary artery bypass	01OCT2017	31OCT2017	N
			Peripheral artery bypass	01JAN2013	31DEC2013	N
			Renal stone removal	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vasectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Deep vein thrombosis	01JAN2000	31DEC2000	N
			Hypertension	01JAN2017		Y
			Peripheral vascular disorder	01JAN2017		Y
	C4591001 1171 11711123	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1982		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711132	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1171 11711140	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1995	31DEC2015	N
		Nervous system disorders	Migraine with aura	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN1960		Y
		Surgical and medical procedures	Rhinoplasty	01JAN1979	31DEC1979	N
	C4591001 1171 11711148	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1171 11711149	Ear and labyrinth disorders	Hypoacusis	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Strabismus	01JAN1958	31DEC1959	N
		Immune system disorders	Seasonal allergy	01JAN1992		Y
		Infections and infestations	Ear infection viral	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Surgical and medical procedures	Strabismus correction	01JAN1959	31DEC1959	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1171 11711155	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1973	31DEC1973	N
		Surgical and medical procedures	Hysterectomy	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711157	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1171 11711160	Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1962		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2004	31DEC2004	N
			Sleep apnoea syndrome	01JAN2004		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2005	31DEC2009	N
			Varicose vein	01JAN2004		Y
	C4591001 1171 11711162	Eye disorders	Cataract	01MAY2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1171 11711165	Infections and infestations	Onychomycosis	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
	C4591001 1171 11711168	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Inguinal hernia	01JAN2013	31DEC2014	N
		Hepatobiliary disorders	Cholecystitis	01JAN2008	31DEC2008	N
		Investigations	Laparoscopy	01JAN1994	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Restless legs syndrome	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1989		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
			Hernia repair	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1171 11711170	Immune system disorders	Drug hypersensitivity	01JAN1956		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1171 11711173	Immune system disorders	Seasonal allergy	01JAN2012		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN2014	31DEC2014	N
	C4591001 1171 11711178	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Constipation	01JAN1997		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN1978		Y
				01JAN2000		Y
			Rubber sensitivity	01JAN2003		Y
			Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2007	31DEC2007	N
	C4591001 1171 11711179	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01NOV2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1171 11711180	Immune system disorders	Seasonal allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	01NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1171 11711182	Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2019	31MAY2019	N
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2019	31MAY2019	N
			Tonsillectomy	01JAN1983	31DEC1983	N
			Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1171 11711188	Vascular disorders	Hypertension	01JAN2010		Y
		Endocrine disorders	Goitre	01JAN1989	31DEC2002	N
			Hypothyroidism	01JAN2001		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2000	31DEC2000	N
			Cholelithiasis	01JAN2000	31DEC2000	N
		Infections and infestations	Urinary tract infection	01JUL2020	10JUL2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2000	31DEC2000	N
			Thyroidectomy	01JAN2002	31DEC2002	N
	C4591001 1171 11711190	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1171 11711193	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JUL2020	01JUL2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963	31DEC1969	N
	C4591001 1171 11711197	Surgical and medical procedures	Rhinoplasty	01JAN1990	31DEC1990	N
		Eye disorders	Cataract	01JAN2016		Y
		Hepatobiliary disorders	Biliary colic	01MAR2003	31MAR2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01MAR2003	31MAR2003	N
		Vascular disorders	Deep vein thrombosis	01JAN2016	31DEC2016	N
	C4591001 1171 11711199		Hypertension	01FEB2015		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN1986		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Cough	01JAN2000		Y
	C4591001 1171 11711201	Surgical and medical procedures	Intervertebral disc operation	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
			Sinus congestion	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Caesarean section	01JAN1992	31DEC1992	N
				01JAN1993	31DEC1993	N
			Female sterilisation	01JAN1994	31DEC1994	N
			Mammoplasty	01JAN1994	31DEC1994	N
	C4591001 1171 11711202	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
				01JAN1982		Y
				01JAN1991		Y
				01JAN1999		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
	C4591001 1171 11711204	Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Reproductive system and breast disorders	Polycystic ovaries	01JAN2016		Y
	C4591001 1171 11711205	Vascular disorders	Hypertension	01JAN2016		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Chronic obstructive pulmonary disease	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1171 11711208	Ear and labyrinth disorders	Deafness bilateral	01JAN2018		Y
		Eye disorders	Cataract	01JAN2010	31DEC2010	N
		Immune system disorders	Allergy to chemicals	01JAN2019		Y
			Drug hypersensitivity	01JAN1980		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Hearing aid user	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
			Pilonidal sinus repair	01JAN1962	31DEC1962	N
	C4591001 1171 11711215	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1171 11711217	Endocrine disorders	Hypogonadism	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1976		Y
				01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01JAN2006	31DEC2006	N
				01JAN2008	31DEC2008	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1171 11711218	Musculoskeletal and connective tissue disorders	Osteoporosis	01JUN2015		Y
		Nervous system disorders	Migraine	05JUN1970		Y
	C4591001 1171 11711220	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Vascular disorders	Varicose vein	01JAN2000		Y
	C4591001 1171 11711222	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Cataract	01JAN2015	31DEC2015 31DEC2018	N N
			Glaucoma	01JAN2003		Y
				01JAN2018	31DEC2018	N
			Ocular fistula	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
			Vitamin D deficiency	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1990		Y
		Surgical and medical procedures	Bladder calculus removal	01JAN2018	31DEC2018	N
			Cataract operation	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Transurethral prostatectomy	01JAN2019	31DEC2019	N
	C4591001 1171 11711227	Hepatobiliary disorders	Cholelithiasis	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
			Osteopenia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	01JAN2011	31DEC2012	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2005		Y
		Surgical and medical procedures	Cholecystectomy	01MAY2012	31MAY2012	N
			Female sterilisation	01JAN2011	31DEC2011	N
	C4591001 1171 11711230	Metabolism and nutrition disorders	Gout	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Nervous system disorders	Cubital tunnel syndrome	01JAN2011	31DEC2011	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Surgical and medical procedures	Sinuplasty	01JAN2016	31DEC2016	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1171 11711232	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
	C4591001 1171 11711233	Cardiac disorders	Coronary artery disease	01JAN2004	31AUG2005	N
		Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Infections and infestations	Soft tissue infection	01JAN2020	29FEB2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 1 diabetes mellitus	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1171 11711237	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2009		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711243	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1171 11711244	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1171 11711253	Congenital, familial and genetic disorders	Sickle cell trait	01JAN1984		Y
		Gastrointestinal disorders	Intestinal perforation	08DEC2008	08DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Breast conserving surgery	08AUG2008	08AUG2008	N
			Intestinal resection	08DEC2008	08DEC2008	N
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711254	Cardiac disorders	Arrhythmia supraventricular	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2020		Y
		Psychiatric disorders	Depression	01JAN2008		Y
	C4591001 1171 11711255	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Reproductive system and breast disorders	Breast mass	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Breast conserving surgery	01JAN1990	31DEC1990	N
	C4591001 1171 11711257	Endocrine disorders	Hypogonadism	01JUN2020		Y
	C4591001 1171 11711259	Eye disorders	Cataract	01JAN2010	31DEC2018	N
			Glaucoma	01JAN2010	31DEC2018	N
		Surgical and medical procedures	Caesarean section	16AUG1976	16AUG1976	N
			Cataract operation	01JAN2018	31DEC2018	N
			Female sterilisation	16AUG1976	16AUG1976	N
			Glaucoma surgery	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1171 11711264	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Genital herpes	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01AUG1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2013	31DEC2014	N
		Surgical and medical procedures	Breast reconstruction	01DEC2014	31DEC2014	N
			Mastectomy	01FEB2014	28FEB2014	N
	C4591001 1171 11711268	Gastrointestinal disorders	Umbilical hernia	01JAN2011	31DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Bipolar I disorder	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN2005	31DEC2005	N
			Hernia repair	01JAN2011	31DEC2011	N
	C4591001 1171 11711269	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Urethrotomy	01JAN2017	31DEC2017	N
			Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1171 11711270	Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711276	Eye disorders	Cataract	01JAN2015		Y
			Vitreous detachment	01FEB2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2013	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
			Synovitis	01JUL2020		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2015		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2018	31DEC2018	N
			Rotator cuff repair	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711277	Skin and subcutaneous tissue disorders	Psoriasis	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1171 11711282	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1993	31DEC1993	N
		Immune system disorders	Mite allergy	01JAN1995		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1999		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cholecystectomy	01JAN1993	31DEC1993	N
			Micrographic skin surgery	01JAN2019	31DEC2019	N
	C4591001 1171 11711283	Ear and labyrinth disorders	Deafness unilateral	01JAN2016		Y
		Endocrine disorders	Hypogonadism	01JAN2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN1980		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
	C4591001 1171 11711284	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Metabolism and nutrition disorders	Obesity	01JAN1982	01AUG2018	N
		Nervous system disorders	Neuralgia	01JAN2015		Y
		Surgical and medical procedures	Gastric bypass	01AUG2018	01AUG2018	N
			Hysterectomy	01JAN2005	01JAN2005	N
			Hysterosalpingo-oophorectomy	01JAN2007	01JAN2007	N
		Vascular disorders	Hypertension	01AUG2016	01AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1171 11711285	Immune system disorders	Seasonal allergy	01JAN2000		Y
				01JAN2010		Y
		Infections and infestations	Tonsillitis	01JUN1978	15JUN1978	N
		Reproductive system and breast disorders	Menorrhagia	01JAN2000	01MAR2007	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Endometrial ablation	01MAR2007	01MAR2007	N
			Tonsillectomy	15JUN1978	15JUN1978	N
	C4591001 1171 11711291	Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01FEB2020		Y
			Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Androgenetic alopecia	01FEB2020		Y
		Surgical and medical procedures	Hernia repair	01JAN1990	31DEC1990	N
	C4591001 1171 11711295	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1171 11711296	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2008		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1171 11711297	Immune system disorders	Drug hypersensitivity	01JAN1961		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1171 11711300	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1983		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2005		Y
			Hyperlipidaemia	01JAN1983		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1171 11711302	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
	C4591001 1171 11711304	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Coronary arterial stent insertion	01JAN2018	31DEC2018	N
				01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1174 11741001	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Gastrointestinal disorders	Constipation	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
			Pelvic floor repair	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN2018	31DEC2018	N
	C4591001 1174 11741002	Cardiac disorders	Mitral valve incompetence	01JAN1948	31DEC1948	N
				01JAN2016		Y
			Pericarditis	01FEB2016	29FEB2016	N
			Tachyarrhythmia	01DEC2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	01JAN2008		Y
		Surgical and medical procedures	Corneal transplant	01JAN1961	31DEC1961	N
			Spinal operation	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
				01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1945	31DEC1945	N
			Wisdom teeth removal	01JAN1956	31DEC1956	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1174 11741007	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1947	31DEC1947	N
		Vascular disorders	Aortic aneurysm	01JAN2019	31DEC2019	N
	C4591001 1174 11741009	Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Appendectomy	01JAN2003	31DEC2003	N
			Cholecystectomy	01JAN2011	31DEC2011	N
			Hernia repair	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1993	31DEC1993	N
			Wisdom teeth removal	01JAN1995	31DEC1995	N
			Contusion	01JAN1976	31DEC1976	N
	C4591001 1174 11741010	Injury, poisoning and procedural complications		01MAR2019	31MAY2019	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Intramedullary rod insertion	01APR2015	30APR2015	N
			Knee arthroplasty	01NOV2015	30NOV2015	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1174 11741012	Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
	C4591001 1174 11741014	Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Hip arthroplasty	23DEC2019	23DEC2019	N
	C4591001 1174 11741016	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Infections and infestations	Pilonidal cyst	01JAN1969	31DEC1969	N
		Investigations	Biopsy breast	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Appendectomy	01JAN1961	31DEC1961	N
			Cyst removal	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN1995	31DEC1995	N
			Thyroidectomy	01JAN2007	31DEC2007	N
			Wisdom teeth removal	01JAN1993	31DEC1993	N
	C4591001 1174 11741017	Immune system disorders	Drug hypersensitivity	01JAN1993		Y
	C4591001 1174 11741018	Cardiac disorders	Atrial fibrillation	01MAY2015	28MAY2015	N
			Atrioventricular block complete	01MAY2015	31MAY2015	N
			Cardiomyopathy	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Hepatobiliary disorders	Nonalcoholic fatty liver disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1969		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Nervous system disorders	Sciatica	01MAR2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	24APR1986	24APR1986	N
			Cardiac pacemaker insertion	28MAY2015	28MAY2015	N
			Female sterilisation	01JAN2006	31DEC2006	N
			Osteotomy	01MAR2018	01MAR2018	N
			Tenoplasty	01MAR2018	01MAR2018	N
		Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1174 11741019	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1973	31DEC1973	N
			Lymphadenectomy	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2001	31DEC2001	N
	C4591001 1174 11741021	Infections and infestations	Osteomyelitis	04NOV2019	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1975	31DEC1975	N
			Shoulder arthroplasty	01JAN2013	31DEC2013	N
		Vascular disorders	Hypertension	01JUN1999		Y
	C4591001 1174 11741022	Eye disorders	Retinal detachment	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y	
		Surgical and medical procedures	Hernia repair	01JAN1991	31DEC1991	N	
			Inguinal hernia repair	01JAN2005	31DEC2005	N	
				01JAN2015	31DEC2015	N	
		Vascular disorders	Hypertension	01JAN2005		Y	
	C4591001 1174 11741025	Cardiac disorders	Coronary artery disease	01JAN2018		Y	
		Infections and infestations	Diverticulitis	01JAN2017	31DEC2017	N	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1985		Y	
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN1989		Y	
				Intervertebral disc protrusion	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1962		Y	
		Surgical and medical procedures	Rotator cuff repair	01JAN2005	31DEC2005	N	
				Varicocele repair	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2010		Y	
	C4591001 1174 11741028	Cardiac disorders	Arrhythmia	01JAN2019	31DEC2019	N	
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010	31DEC2010	N	
		Surgical and medical procedures	Ankle operation	01JAN1969	31DEC1969	N	
				Coronary artery bypass	01JAN2020	01JAN2020	N
				Tonsillectomy	01JAN1955	31DEC1955	N
		Vascular disorders	Hypertension	01JAN2000	31DEC2000	N	
	C4591001 1174 11741029	Injury, poisoning and procedural complications	Radius fracture	01JAN1954	31DEC1954	N	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2007	31DEC2007	N	
		Social circumstances	Menopause	01JAN2001		Y	

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	01SEP2019	30SEP2019	N
			Mammoplasty	01JAN1993	31DEC1993	N
			Spinal operation	01JAN2015	31DEC2015	N
	C4591001 1174 11741035	Gastrointestinal disorders	Inguinal hernia	01JAN1972	31DEC1972	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2015	31DEC2015	N
			Caesarean section	01JAN1994	31DEC1994	N
			Hysterectomy	01OCT2015	31OCT2015	N
			Salpingo-oophorectomy bilateral	01JAN2015	31DEC2015	N
	C4591001 1174 11741036	Infections and infestations	Cellulitis	01DEC2019	31JAN2020	N
				01MAY2019	30JUN2019	N
				01SEP2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Scoliosis	(b) (6) 1943		Y
			Spinal osteoarthritis	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN1979	31DEC1979	N
				01JAN1982	31DEC1982	N
				01JAN1985	31DEC1985	N
			Knee arthroplasty	01JAN2005	31DEC2005	N
			Spinal laminectomy	01JAN1995	31DEC1995	N
	C4591001 1174 11741037	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2017	31DEC2017	N
	C4591001 1174 11741039	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Renal abscess	04APR2017	31MAY2017	N
			Urinary tract infection	01MAR2017	31MAR2017	N
		Surgical and medical procedures	Fracture treatment	01DEC2010	31DEC2010	N
				01FEB2010	28FEB2010	N
				01JAN2006	31DEC2006	N
			Keratomileusis	01JAN2006	31DEC2006	N
	C4591001 1174 11741040	Endocrine disorders	Basedow's disease	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN1975		Y
			Seasonal allergy	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1174 11741041	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN2003	31DEC2003	N
			Orchidectomy	01JAN2000	31DEC2000	N
			Wisdom teeth removal	01JAN2019	31DEC2019	N
	C4591001 1174 11741042	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2015	31JUL2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2005	31DEC2005	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Haemorrhoid operation	01JUL2020	31JUL2020	N
			Inguinal hernia repair	01AUG2019	31AUG2019	N
			Intervertebral disc operation	01JAN1980	31DEC1980	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1174 11741043	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN2010		Y
		Infections and infestations	Pneumonia	01JAN1985	31DEC1985	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
				01JAN2018	31DEC2018	N
			Cholecystectomy	01JAN2007	31DEC2007	N
			Hip arthroplasty	01JAN2017	31DEC2017	N
			Intervertebral disc operation	01JAN2011	31DEC2011	N
			Jaw operation	01JAN2010	31DEC2010	N
			Mastectomy	01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN1989	31DEC1989	N
	C4591001 1174 11741044	Nervous system disorders	Muscle contractions involuntary	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
				01JAN1987	31DEC1987	N
				01JAN1988	31DEC1988	N
			Fracture treatment	01JAN2019	31JAN2019	N
	C4591001 1174 11741047	Gastrointestinal disorders	Anal fissure	01JAN1980	31DEC1980	N
			Crohn's disease	01JAN1995		Y
			Inguinal hernia	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2008	31DEC2008	N
			Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1949	31DEC1949	N
			Cancer surgery	01JAN2018	31DEC2018	N
			Carpal tunnel decompression	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1174 11741048	Surgical and medical procedures	Breast cyst excision	01JAN1997	31DEC1997	N
			Sinus operation	01JAN2005	31DEC2005	N
				01JAN2007	31DEC2007	N
			Spinal laminectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Giant cell arteritis	01JAN2009		Y
	C4591001 1174 11741052	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01DEC2017	31DEC2017	N
				01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cardiac ablation	01JAN2005	31DEC2005	N
			Ovarian cystectomy	01JAN2005	31DEC2005	N
			Wisdom teeth removal	01JAN1985	31DEC1985	N
	C4591001 1174 11741059	Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN1985	31DEC1987	N
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Infections and infestations	Bronchitis	01MAY2020	31JUL2020	N
			Pelvic inflammatory disease	01JAN2001	31DEC2010	N
			Pneumonia	01JAN1972	31DEC1972	N
				01JAN1990	31DEC1990	N
				01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1996	31DEC1996	N
		Nervous system disorders	Migraine with aura	01JAN2020	31JUL2020	N
		Surgical and medical procedures	Appendicectomy	01JAN2001	31DEC2001	N
			Hysterectomy	01JAN2010	31DEC2010	N
			Salpingo-oophorectomy bilateral	01JAN2010	31DEC2010	N
			Sinus operation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1174 11741062	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2012	31DEC2012	N
			Knee operation	01JAN1981	31DEC1981	N
	C4591001 1174 11741064†	Infections and infestations	Pilonidal cyst	01JAN1981	31DEC1981	N
		Investigations	HIV test positive	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Surgical and medical procedures	Appendicectomy	01JAN1981	31DEC1981	N
			Tonsillectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1174 11741067	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN2020	31JAN2020	N
			Meniscus operation	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sinuplasty	01DEC2019	31DEC2019	N
	C4591001 1174 11741069	Endocrine disorders	Hyperthyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
				01JAN2018	31DEC2018	N
			Nasal septal operation	01JAN1972	31DEC1972	N
			Retinal operation	01JAN2005	31DEC2005	N
	C4591001 1177 11771002	Endocrine disorders	Hypogonadism	01JAN2017		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2010		Y
		Infections and infestations	Localised infection	02AUG2020	16AUG2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Gout	01JAN2000		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
			Vitamin D deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2012	N
		Nervous system disorders	Diabetic neuropathy	01JAN2010		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Dry skin	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771006	Gastrointestinal disorders	Tooth loss	01JAN1991	31DEC1999	N
		General disorders and administration site conditions	Drug intolerance	01JAN1963		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1994		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1975		Y
				01JAN2009		Y
			Seasonal allergy	01JAN1988		Y
		Infections and infestations	Appendicitis	01JAN1941	31DEC1941	N
			Tonsillitis	01JAN1959	31DEC1959	N
		Injury, poisoning and procedural complications	Skin laceration	01JAN2016	31DEC2016	N
			Tibia fracture	20JAN2020	20JAN2020	N
		Investigations	Cortisol increased	11JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1973		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2005		Y
			Spinal osteoarthritis	01JAN2006		Y
			Tendonitis	01JAN2012		Y
				14JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2006	31DEC2006	N
			Squamous cell carcinoma	01JUL2020	03AUG2020	N
				01MAY2018	15OCT2018	N
			Uterine cancer	01JAN1994	31DEC1994	N
			Uterine leiomyoma	01JAN1994	31DEC1994	N
		Nervous system disorders	Transient ischaemic attack	01APR2019	30APR2019	N
				01DEC2018	31DEC2018	N
		Renal and urinary disorders	Nocturia	01JAN1999		Y
			Renal failure	01JUL2012		Y
			Stress urinary incontinence	01JAN1993		Y
			Urinary incontinence	05FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Social circumstances	Postmenopause	01JAN1982		Y	
		Surgical and medical procedures	Adenoidectomy	01JAN1954	31DEC1954	N	
			Appendicectomy	01JAN1941	31DEC1941	N	
			Bone operation	20JAN2020	20JAN2020	N	
			Breast conserving surgery	01JAN2006	31DEC2006	N	
			Cancer surgery	03AUG2020	03AUG2020	N	
				15OCT2018	15OCT2018	N	
				Dental implantation	01JAN1999	31DEC1999	N
				Hand repair operation	01JAN2016	31DEC2016	N
				Hysterectomy	01JAN1994	31DEC1994	N
				Tonsillectomy	01JAN1954	31DEC1954	N
			Vascular disorders	Peripheral venous disease	01JUL2017	31DEC2017	N
	C4591001 1177 11771008		Ear and labyrinth disorders	Meniere's disease	01APR2020		Y
	C4591001 1177 11771011		Psychiatric disorders	Insomnia	01JAN2016		Y
			Gastrointestinal disorders	Gastritis	01JAN2017		Y
	C4591001 1177 11771012	Vascular disorders	Hypertension	01JAN2017		Y	
		Immune system disorders	Seasonal allergy	01JAN2005		Y	
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y	
		Vascular disorders	Arteriosclerosis	01JAN2010		Y	
	C4591001 1177 11771015	Eye disorders	Cataract	01JAN2015	31DEC2015	N	
		Gastrointestinal disorders	Large intestine polyp	01JAN2010		Y	
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y	
			Gout	01JAN2010		Y	
			Type 2 diabetes mellitus	01JAN2000		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Diffuse idiopathic skeletal hyperostosis	01JAN2010		Y
			Osteoporosis	01MAY2020		Y
		Nervous system disorders	Restless legs syndrome	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Heart valve replacement	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN2008	31DEC2008	N
		Vascular disorders	Aortic stenosis	01JAN2013	31DEC2013	N
			Hypertension	01JAN2000		Y
	C4591001 1177 11771016	Eye disorders	Strabismus	01JAN2015		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Food allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2019	28JAN2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Shoulder operation	23JAN2020	23JAN2020	N
			Strabismus correction	01JAN2015	31DEC2015	N
	C4591001 1177 11771019	Immune system disorders	Allergy to animal	01JAN1970		Y
			Mycotic allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Cardiac murmur	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2001	31DEC2001	N
			Intervertebral disc operation	01JAN2008	31DEC2008	N
			Prostatectomy	01JAN2012	31DEC2012	N
			Sinus anastomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1177 11771020	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Appendectomy	01JAN1950	31DEC1950	N
			Cataract operation	01JAN2010		Y
			Female sterilisation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771029	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1177 11771031	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Pancreatitis	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	01JAN1966		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
	C4591001 1177 11771033	Gastrointestinal disorders	Inguinal hernia	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771034	Eye disorders	Glaucoma	01JAN2016		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2019	08JUL2019	N
		General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
				01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Lipoedema	01JAN2016		Y
			Type 2 diabetes mellitus	01FEB2017		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2017		Y
		Surgical and medical procedures	Umbilical hernia repair	08JUL2019	08JUL2019	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1177 11771035	Injury, poisoning and procedural complications	Tendon rupture	01MAR2001	31MAY2001	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2019	31MAY2019	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Bone operation	01MAY2001	31MAY2001	N
			Rotator cuff repair	01MAY2019	31MAY2019	N
	C4591001 1177 11771037	Hepatobiliary disorders	Cholelithiasis	01JAN2006	31DEC2006	N
		Immune system disorders	Contrast media allergy	01JAN1987		Y
		Infections and infestations	Appendicitis	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Psychiatric disorders	Panic attack	01JAN1998		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1985	31DEC1985	N
			Infertility	01JAN1985		Y
		Surgical and medical procedures	Appendectomy	01JAN2009	31DEC2009	N
			Bone cyst excision	01JAN2015	31DEC2015	N
			Hysterectomy	01JAN1985	31DEC1985	N
			Spinal laminectomy	01JAN2015	31DEC2015	N
	C4591001 1177 11771040	Endocrine disorders	Goitre	01JAN2010		Y
			Thyroid mass	01OCT2015		Y
		Eye disorders	Chalazion	01OCT2015	18FEB2016	N
		Gastrointestinal disorders	Constipation	01JAN2019		Y
			Diverticulum	01MAY2012		Y
			Gastritis	18NOV2009		Y
			Haemorrhoids	18NOV2009		Y
			Oral disorder	01JAN2015		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2011		Y
		Injury, poisoning and procedural complications	Epicondylitis	01DEC2016	31MAR2017	N
		Metabolism and nutrition disorders	Obesity	01JAN1975	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Overweight	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	05APR2015		Y
			Osteoarthritis	01JAN1987		Y
					06APR2015	N
			Rotator cuff syndrome	01JAN1997	25FEB2009	N
			Spinal osteoarthritis	01JAN1987		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal tract adenoma	18NOV2009		Y
			Lipoma	01JAN2015		Y
				01MAR2017		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Attention deficit hyperactivity disorder	(b) (6) 1957		Y
			Autism spectrum disorder	01JAN2005		Y
			Depression	01JAN1980		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
			Urinary incontinence	01JAN2016		Y
		Reproductive system and breast disorders	Infertility	01JAN2000		Y
			Ovarian cyst	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
			Chronic obstructive pulmonary disease	01JAN2016		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Eyelid cyst removal	18FEB2016	18FEB2016	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Knee arthroplasty	01JUN2020	30JUN2020	N
				06APR2015	06APR2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				29APR2016	29APR2016	N
			Mammoplasty	01JAN2008	31DEC2008	N
			Shoulder operation	01JAN2009	31DEC2009	N
	C4591001 1177 11771041	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Inguinal hernia	01JAN2006	31DEC2006	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2006	31DEC2006	N
			Osteopenia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
				01JAN2016	31DEC2016	N
		Surgical and medical procedures	Foot operation	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN2006	31DEC2006	N
			Prostate ablation	01JAN2016	31DEC2016	N
	C4591001 1177 11771042	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Tonsillitis	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1996		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1964	31DEC1964	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771044	Endocrine disorders	Thyroid mass	01JAN1953	31DEC1953	N
		Eye disorders	Glaucoma	01JAN2000		Y
		Gastrointestinal disorders	Gastrointestinal haemorrhage	01JAN1998	31DEC1998	N
			Gastrooesophageal reflux disease	01JAN2014		Y
			Large intestine polyp	01JAN1998	31DEC1998	N
		General disorders and administration site conditions	Fatigue	01JAN2019		Y
		Injury, poisoning and procedural complications	Exposure to radiation	01JAN1953	31DEC1953	N
		Metabolism and nutrition disorders	Impaired fasting glucose	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
			Back pain	01JAN2010		Y
			Foot deformity	01JAN2016		Y
			Myalgia	01JAN2014		Y
			Polyarthrititis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Enchondromatosis	01JAN1967	31DEC1967	N
			Malignant melanoma	01FEB2020	29FEB2020	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	01JAN2014		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2010	31DEC2010	N
			Rib excision	01JAN1967	31DEC1967	N
			Skin neoplasm excision	01FEB2020	29FEB2020	N
			Tenoplasty	01JAN2005	31DEC2005	N
	C4591001 1177 11771045	Ear and labyrinth disorders	Hypoacusis	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inner ear operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1177 11771052	Endocrine disorders	Autoimmune thyroiditis	01JAN2014		Y
		Immune system disorders	Dust allergy	01JAN1962		Y
			Food allergy	01JAN1962		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1962		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2014		Y
	C4591001 1177 11771053	Surgical and medical procedures	Joint dislocation reduction	01JAN1980	31DEC1980	N
		Immune system disorders	Food allergy	01JAN2017		Y
		Injury, poisoning and procedural complications	Ligament injury	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
		Psychiatric disorders	Depression	01JAN1995	30APR1995	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2005	31DEC2005	N
			Cyst removal	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2003	31DEC2003	N
			Knee operation	01JAN2017	31DEC2017	N
				01JAN2019	31DEC2019	N
			Myomectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771055	Cardiac disorders	Stress cardiomyopathy	21FEB2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
			Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1981		Y
		Social circumstances	Postmenopause	24MAR2018		Y
		Surgical and medical procedures	Abdominoplasty	01DEC2004	31DEC2004	N
			Breast prosthesis removal	01DEC2019	31DEC2019	N
			Face lift	01DEC2004	31DEC2004	N
			Female sterilisation	20NOV1996	20NOV1996	N
			Mammoplasty	01DEC2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1177 11771059	Endocrine disorders	Hyperparathyroidism	20NOV2011		Y
		Eye disorders	Cataract	01JAN1934	31DEC2015	N
				01JAN2006	31DEC2010	N
		Hepatobiliary disorders	Cholelithiasis	30APR2020	30APR2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	08AUG2011		Y
			Impaired fasting glucose	05MAR2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009		Y
		Nervous system disorders	Carpal tunnel syndrome	15APR2013		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1177 11771060	Gastrointestinal disorders	Rectal fissure	01JAN2017	31DEC2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Cholelithiasis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Infections and infestations	Fungal infection	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1978		Y
		Surgical and medical procedures	Anorectal operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771061	Immune system disorders	Allergy to plants	01JAN1965		Y
			Mycotic allergy	01JAN1965		Y
			Seasonal allergy	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN1980	31DEC1983	N
			Pain in extremity	01JAN1983	31DEC1983	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Bunion operation	01JAN1983	31DEC1983	N
			Caesarean section	01JAN1996	31DEC1996	N
	C4591001 1177 11771062	Cardiac disorders	Atrial flutter	01JAN2016		Y
		Endocrine disorders	Hypergonadism	01JAN2012		Y
		Eye disorders	Diabetic retinopathy	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	27JUN2019		Y
		Nervous system disorders	Essential tremor	01JAN2015		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
			Microalbuminuria	27JUN2019		Y
		Reproductive system and breast disorders	Organic erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Nasal turbinate hypertrophy	01JAN2018		Y
			Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN2012	31DEC2012	N
			Intervertebral disc operation	01JAN2009	31DEC2009	N
			Knee arthroplasty	01JAN2008	31DEC2008	N
			Polypectomy	08JUL2020	08JUL2020	N
		Vascular disorders	Essential hypertension	01JAN1995		Y
	C4591001 1177 11771063	Cardiac disorders	Aortic valve incompetence	01NOV2016		Y
			Left ventricular hypertrophy	01NOV2016		Y
		Endocrine disorders	Goitre	01JAN2011		Y
		Injury, poisoning and procedural complications	Humerus fracture	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Impaired fasting glucose	01MAR2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2019	01FEB2019	N
			Parathyroid tumour benign	01JAN2012	31DEC2012	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012	31DEC2012	N	
		Surgical and medical procedures	Hip arthroplasty	01NOV2016	30NOV2016	N	
			Open reduction of fracture	01JAN1999	31DEC1999	N	
			Parathyroidectomy	01JAN2012	31DEC2012	N	
			Thyroidectomy	01JAN2011	31DEC2011	N	
			Transurethral prostatectomy	01JAN2012	31DEC2012	N	
		Vascular disorders	Aortic stenosis	01NOV2016		Y	
			Hypertension	01JAN2010		Y	
	C4591001 1177 11771064	Eye disorders	Chorioretinopathy	01JAN1994		Y	
				Conjunctivitis allergic	01JAN1964		Y
				Macular degeneration	01JAN2015		Y
				Macular fibrosis	01JAN2015		Y
			Gastrointestinal disorders	Diverticulum	01JAN2017		Y
				Gastroesophageal reflux disease	01JAN2010		Y
				Haemorrhoids	01JAN2017		Y
				Large intestine polyp	01JAN2000		Y
			Injury, poisoning and procedural complications	Fibula fracture	01JAN2010	31DEC2010	N
						01JAN2015	31DEC2015
				Foot fracture	01JAN2005	31DEC2005	N
					01JAN2013	31DEC2013	N
					01JAN2015	31DEC2015	N
				Radius fracture	01JAN2018	31DEC2018	N
				01JAN2019	31DEC2019	N	
			Tibia fracture	01JAN2015	31DEC2015	N	
		Investigations	Biopsy breast normal	01JAN1999	31DEC1999	N	
					01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1994	31DEC1995	N
			Spinal osteoarthritis	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2017	16JAN2017	N
		Nervous system disorders	Migraine	01JAN1956		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1964		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2014	31JAN2020	N
			Rosacea	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1954	31DEC1954	N
			Cervix operation	01JAN1984	31DEC1984	N
			Rotator cuff repair	01JAN1995	31DEC1995	N
			Skin neoplasm excision	16JAN2017	16JAN2017	N
			Tonsillectomy	01JAN1954	31DEC1954	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1177 11771065	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Constipation	01JAN2017		Y
			Diarrhoea	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN1999		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1999		Y
				01JAN2017		Y
		Immune system disorders	Contrast media allergy	01JAN1988		Y
		Injury, poisoning and procedural complications	Meniscus injury	01SEP2015	31JAN2020	N
		Investigations	Arthroscopy	01MAR2016	31MAR2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
			Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
			Osteoarthritis	01SEP2015	31JAN2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1999	31MAY1999	N
		Surgical and medical procedures	Finger amputation	01JAN1962	31DEC1962	N
			Hysterectomy	01MAY1999	31MAY1999	N
			Intraocular lens implant	01JAN2017	31DEC2017	N
			Knee arthroplasty	01JAN2020	31JAN2020	N
				01SEP2017	30SEP2017	N
			Meniscus operation	01JAN2020	31JAN2020	N
				01SEP2017	30SEP2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1177 11771067	Investigations	Arthroscopy	24JUN2019	24JUN2019	N
			Blood cholesterol increased	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019	24JUN2019	N
		Renal and urinary disorders	Calculus bladder	01OCT2017	31OCT2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Bladder calculus removal	31OCT2017	31OCT2017	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1177 11771068	Eye disorders	Macular degeneration	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Social circumstances	Postmenopause	01OCT2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
				01JAN1986	31DEC1986	N
	C4591001 1177 11771069	Eye disorders	Age-related macular degeneration	01JAN2015		Y
		Gastrointestinal disorders	Constipation	01JAN1956		Y
			Gastroesophageal reflux disease	01JAN2001		Y
			Hiatus hernia	01JAN2001	31DEC2003	N
		Infections and infestations	Chronic tonsillitis	01JAN1954	31DEC1955	N
			Pneumonia	01JAN1956		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1983		Y
			Glucose tolerance impaired	01NOV2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Restless legs syndrome	01JAN1999		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Bronchitis chronic	01JAN1976		Y
			Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01DEC2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	31DEC1985	N
			Oesophagogastric fundoplasty	01JAN2003	31DEC2003	N
			Tonsillectomy	01JAN1955	31DEC1955	N
	C4591001 1177 11771071	Musculoskeletal and connective tissue disorders	Synovial cyst	01JAN1962	31DEC1966	N
		Social circumstances	Postmenopause	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Synovial cyst removal	01JAN1962	31DEC1962	N
				01JAN1966	31DEC1966	N
	C4591001 1177 11771072	General disorders and administration site conditions	Hernia	01JAN1982	31DEC1982	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2014	31DEC2014	N
		Reproductive system and breast disorders	Endometriosis	01JAN1988	31DEC1988	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
			Cholecystectomy	01JAN2010	31DEC2010	N
			Hernia repair	01JAN1982	31DEC1982	N
			Hysterectomy	01JAN1988	31DEC1988	N
	C4591001 1177 11771073	Skin and subcutaneous tissue disorders	Hyperhidrosis	01JAN1955	31DEC1968	N
		Surgical and medical procedures	Sympathectomy	01JAN1968	31DEC1968	N
	C4591001 1177 11771074	Eye disorders	Cataract	01MAR2019	31MAR2019	N
		Infections and infestations	Genital herpes	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1980	31DEC2005	N
		Surgical and medical procedures	Cataract operation	01MAR2019	31MAR2019	N
	C4591001 1177 11771077	Eye disorders	Cataract	01JAN2018	31DEC2018	N
		Infections and infestations	Kidney infection	01JAN1961	31DEC1961	N
			Urinary tract infection	01JAN1961		Y
		Nervous system disorders	Migraine with aura	01JAN1965		Y
		Surgical and medical procedures	Caesarean section	21OCT1987	21OCT1987	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Cataract operation	01JAN2018	31DEC2018	N
			Ureterectomy	01JAN1961	31DEC1961	N
	C4591001 1177 11771083	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1177 11771084	Cardiac disorders	Ventricular tachycardia	01JAN2000	31DEC2015	N
		Eye disorders	Glaucoma	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Femur fracture	01NOV1972	30NOV1972	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1985		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2000	31DEC2000	N
			Fracture treatment	01NOV1972	30NOV1972	N
	C4591001 1177 11771085	Endocrine disorders	Hypothyroidism	01OCT1996		Y
		Immune system disorders	Allergy to plants	01FEB2012		Y
			Mite allergy	01FEB2012		Y
			Mycotic allergy	01FEB2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1991	31DEC1991	N
			Hodgkin's disease	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2012		Y
		Surgical and medical procedures	Caesarean section	01JAN1975	31DEC1975	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1977	31DEC1977	N
			Laparotomy	01JAN1990	31DEC1990	N
			Modified radical mastectomy	01JAN1991	31DEC1991	N
	C4591001 1177 11771089	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1177 11771091	Congenital, familial and genetic disorders	Congenital uterine anomaly	01JAN1996	31DEC1996	N
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Investigations	Human papilloma virus test positive	01JAN1999	31DEC1999	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Loop electrosurgical excision procedure	01JAN1999	31DEC1999	N
			Uterine operation	01JAN1996	31DEC1996	N
	C4591001 1177 11771094	Cardiac disorders	Mitral valve prolapse	01JAN1993		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN1996	31DEC1996	N
		Immune system disorders	Cockroach allergy	01JAN2008		Y
			Mite allergy	01JAN2008		Y
			Seasonal allergy	01JAN1996		Y
				01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2008		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1177 11771098	Injury, poisoning and procedural complications	Ankle fracture	01MAY2004	31MAY2004	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Fracture treatment	01MAY2004	31MAY2004	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771099	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010	31DEC2012	N
			Headache	01JAN1980		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Infertility	01JAN1998		Y
		Surgical and medical procedures	Appendectomy	01JAN1976	31DEC1976	N
			Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Female sterilisation	01JAN1997	31DEC1997	N
			Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1177 11771102	Eye disorders	Glaucoma	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2004	31DEC2004	N
				01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771104	Respiratory, thoracic and mediastinal disorders	Diaphragmatic paralysis	01JAN2010		Y
			Nasal congestion	01JAN1990		Y
		Surgical and medical procedures	Nasal septal operation	01JAN1990	31DEC1990	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771106	Gastrointestinal disorders	Large intestine polyp	01JAN2011		Y
		Hepatobiliary disorders	Hepatic steatosis	07OCT2019		Y
		Infections and infestations	Appendicitis	01JAN1960	31DEC1960	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2014		Y
		Surgical and medical procedures	Appendectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1177 11771107	Gastrointestinal disorders	Large intestine polyp	01JAN2012	10JAN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Metabolism and nutrition disorders	Dyslipidaemia	21FEB2013		Y
			Glucose tolerance impaired	21FEB2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	01JAN2003	31DEC2003	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2008	31DEC2009	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y
		Surgical and medical procedures	Large intestinal polypectomy	10JAN2020	10JAN2020	N
			Skin neoplasm excision	01JAN2003	31DEC2003	N
	C4591001 1177 11771108	Congenital, familial and genetic disorders	Type II hyperlipidaemia	01JAN2013		Y
		Eye disorders	Glaucoma	01JAN2013		Y
		Gastrointestinal disorders	Large intestine polyp	01JAN2010		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
				01NOV2018		Y
			Trigger finger	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2005	31DEC2005	N
		Nervous system disorders	Lumbar radiculopathy	01JAN2005	31DEC2005	N
			Transient ischaemic attack	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1177 11771109	Investigations	Cardiac murmur	01OCT2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2014		Y
			Osteopenia	01SEP2017		Y
			Spinal osteoarthritis	01AUG2013		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2016		Y
	C4591001 1177 11771110	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2001	31DEC2001	N
			Renal cancer	01JAN2016	31DEC2016	N
			Uterine leiomyoma	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Nephrectomy	01JAN2016	31DEC2016	N
			Thyroidectomy	01JAN2001	31DEC2001	N
	C4591001 1177 11771112	Immune system disorders	Drug hypersensitivity	01JAN2003		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2018	31AUG2018	N
		Surgical and medical procedures	Gastric bypass	01JAN2003	31DEC2003	N
			Hysterectomy	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1177 11771115	Hepatobiliary disorders	Hepatic steatosis	01JAN1985		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1985	31DEC1985	N
		Investigations	Hepatitis B surface antibody positive	01JAN2000		Y
			Hepatitis C antibody positive	01JAN1995		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Surgical and medical procedures	Meniscus operation	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771120	Immune system disorders	Allergy to animal	01JAN1956		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2012		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1177 11771121	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2009	31DEC2009	N
				01JUL2020		Y
			Hand fracture	01JAN2009	31DEC2009	N
			Joint dislocation	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Surgical and medical procedures	Joint dislocation reduction	01JAN1970	31DEC1970	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Open reduction of fracture	01JAN2009	31DEC2009	N
				01JAN2014	31DEC2014	N
	C4591001 1177 11771123	Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1957	31DEC1957	N
			Varicose vein operation	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
			Varicose vein	01JAN2002	31DEC2002	N
	C4591001 1177 11771125	Injury, poisoning and procedural complications	Ligament rupture	01JUN1979	30JUN1979	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Ligament operation	01JUN1979	30JUN1979	N
	C4591001 1177 11771126	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Hyperhomocysteinaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1980	31DEC1992	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2000	31DEC2014	N
		Surgical and medical procedures	Cholecystectomy	01JAN2014	31DEC2014	N
			Hip arthroplasty	01JAN1991	31DEC1991	N
				01JAN1992	31DEC1992	N
			Transurethral prostatectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1177 11771127	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				16APR2016		Y
				23MAR2017		Y
			Food allergy	01OCT2018		Y
			Reaction to food additive	01JAN1985		Y
		Metabolism and nutrition disorders	Dyslipidaemia	22SEP2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Intervertebral disc degeneration	09JAN2015		Y
			Osteoarthritis	01JAN2001	31DEC2001	N
				01JAN2017	21MAR2017	N
		Nervous system disorders	Lumbosacral radiculopathy	02MAY2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	28JAN2014		Y
			Erectile dysfunction	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1990		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2001	31DEC2001	N
				21MAR2017	21MAR2017	N
		Vascular disorders	Aortic arteriosclerosis	08AUG2017		Y
			Hypertension	05AUG2010		Y
	C4591001 1177 11771129	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2018		Y
		Renal and urinary disorders	Nephritis	01JAN1983	31DEC1995	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	14SEP1999	14SEP1999	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1177 11771130	Gastrointestinal disorders	Duodenal ulcer	01JAN1979	31AUG2010	N
		Infections and infestations	Appendicitis perforated	01JAN1990	31DEC1990	N
			Tonsillitis	01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Obesity	01JAN1999		Y
		Surgical and medical procedures	Appendectomy	01JAN1990	31DEC1990	N
			Duodenal operation	01AUG2010	31AUG2010	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1177 11771131	Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Jaw disorder	01JAN1968	31DEC1990	N
			Osteoarthritis	01JAN1999		Y
			Rotator cuff syndrome	01JAN2007	31DEC2007	N
		Nervous system disorders	Migraine	01JAN1976		Y
			Syncope	01JAN1960		Y
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1986	31DEC1986	N
				01JAN1991	31DEC1991	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
			Seborrhoeic dermatitis	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Jaw operation	01JAN1990	31DEC1990	N
			Rotator cuff repair	01JAN2007	31DEC2007	N
			Salpingostomy	01JAN1986	31DEC1986	N
				01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771132	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN1996	31DEC1996	N
				01JAN2003	31DEC2003	N
				01JAN2009	31DEC2009	N
	C4591001 1177 11771133	Injury, poisoning and procedural complications	Skin laceration	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteopenia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Finger repair operation	01JAN1990	31DEC1990	N
	C4591001 1177 11771136	Immune system disorders	Dust allergy	01JAN1970		Y
			Perfume sensitivity	01JAN1974		Y
			Seasonal allergy	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Reproductive system and breast disorders	Genital cyst	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Genitourinary operation	01JAN2008	31DEC2008	N
	C4591001 1177 11771141	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Lithotripsy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1177 11771142	Eye disorders	Cataract	01JAN2010	30SEP2012	N
		Infections and infestations	Appendicitis	01JAN1951	31DEC1951	N
			Tinea pedis	01APR2020		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01MAR2018		Y
		Reproductive system and breast disorders	Erectile dysfunction	03SEP2017		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2003	31DEC2003	N
				01NOV2016	30NOV2016	N
			Cataract operation	05SEP2012	05SEP2012	N
				12SEP2012	12SEP2012	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1177 11771143	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2003		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771144	Injury, poisoning and procedural complications	Ligament injury	01JAN1995	31DEC1995	N
			Meniscus injury	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Surgical and medical procedures	Ligament operation	01JAN1995	31DEC1995	N
			Meniscus operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771146	Eye disorders	Cataract	01JAN2000	30JUN2020	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2008	31DEC2008	N
			Skin abrasion	01JAN1971	31DEC1971	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Cataract operation	01JAN2014	31DEC2014	N
				01JUN2020	30JUN2020	N
			Meniscus operation	01JAN2008	31DEC2008	N
			Skin graft	01JAN1971	31DEC1971	N
	C4591001 1177 11771147	Gastrointestinal disorders	Large intestine perforation	01JAN2015	31DEC2015	N
		Immune system disorders	Allergy to arthropod sting	01JAN1993		Y
			Anaphylactic reaction	01JAN1993		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Glucose tolerance impaired	01JAN2014		Y
			Gout	01JAN2016		Y
		Nervous system disorders	Intention tremor	01JUN2019		Y
		Psychiatric disorders	Insomnia	01JAN2020		Y
		Surgical and medical procedures	Aneurysm repair	01JAN2012	31DEC2012	N
			Sigmoidectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Aortic aneurysm	01JAN2012	31DEC2012	N
			Hypertension	01JAN2000		Y
	C4591001 1177 11771148	Investigations	Blood cholesterol increased	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771149	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Investigations	Biopsy breast normal	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
	C4591001 1177 11771150	Vascular disorders	Hypertension	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Reproductive system and breast disorders	Infertility	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1177 11771151	Vascular disorders	Hypertension	01JAN2015		Y
		Eye disorders	Cataract	01JAN2015		Y
		Immune system disorders	Contrast media allergy	01JAN1972		Y
			Food allergy	01JAN1970		Y
		Investigations	Biopsy skin	21AUG2020	21AUG2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01JAN2002	31DEC2002	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2019	21AUG2020	N
		Surgical and medical procedures	Foot operation	01JAN2002	31DEC2002	N
	C4591001 1177 11771152	Vascular disorders	Hypertension	01JAN1983		Y
		Injury, poisoning and procedural complications	Scar	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
			Erectile dysfunction	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN1995	31DEC1995	N
			Scar excision	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771158	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1177 11771164	Cardiac disorders	Arrhythmia	01JAN2018		Y
		Endocrine disorders	Secondary hypogonadism	01JAN2009		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Umbilical hernia	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN2000	31DEC2000	N
		Vascular disorders	Arteriosclerosis	01JAN2010		Y
			Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771168	Metabolism and nutrition disorders	Dyslipidaemia	20MAY2012		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2014	N
			Osteoarthritis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Knee operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	20MAY2012		Y
	C4591001 1177 11771169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2003		Y
		Infections and infestations	Appendicitis	01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Dyslipidaemia	30MAR2004		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	14SEP2006		Y
			Vitamin D deficiency	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2018		Y
			Rotator cuff syndrome	01JAN2013	31DEC2013	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	01JAN2005	31DEC2005	N
		Nervous system disorders	Diabetic neuropathy	14SEP2006		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
		Surgical and medical procedures	Appendectomy	01JAN1968	31DEC1968	N
			Rotator cuff repair	01JAN2013	31DEC2013	N
			Skin neoplasm excision	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	25AUG2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771175	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010	31MAR2018	N
			Intervertebral disc protrusion	01JAN1968	31DEC1981	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Knee arthroplasty	01MAR2018	31DEC2018	N
			Skin neoplasm excision	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771178	Cardiac disorders	Aortic valve incompetence	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
			Rhinitis allergic	01JAN1985		Y
	C4591001 1177 11771180	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2003	31DEC2003	N
	C4591001 1177 11771189	Ear and labyrinth disorders	Tinnitus	01JAN2019		Y
			Vertigo	01JAN2016	31DEC2016	N
		Gastrointestinal disorders	Umbilical hernia	01JAN2007	31DEC2007	N
		Immune system disorders	Dust allergy	01JAN1970		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Chondroplasty	01JAN1997	31DEC1997	N
			Umbilical hernia repair	01JAN2007	31DEC2007	N
	C4591001 1177 11771190	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Infections and infestations	Appendicitis	01JAN2014	31DEC2014	N
		Investigations	Biopsy breast normal	01JAN1984	31DEC1984	N
				01JAN1989	31DEC1989	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2000		Y
	C4591001 1177 11771191	Surgical and medical procedures	Appendectomy	01JAN2014	31DEC2014	N
		Cardiac disorders	Coronary artery disease	01JAN2016		Y
			Myocardial infarction	01JAN2016	31DEC2016	N
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Coronary artery surgery	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1177 11771193	Cardiac disorders	Bundle branch block left	01OCT2018		Y
			Cardiomyopathy	01APR2020		Y
			Coronary artery disease	30AUG2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01MAR2019		Y
			Osteoarthritis	01MAR2019		Y
			Osteopenia	01AUG2015		Y
			Rotator cuff syndrome	01JAN1980	31DEC1980	N
				01JAN1990	31DEC1990	N
		Nervous system disorders	Morton's neuralgia	01JAN2017	09MAY2017	N
		Renal and urinary disorders	Renal mass	01AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	27NOV2019		Y
			Rhinitis allergic	01JAN1983		Y
			Rhinorrhoea	01JUL2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Blepharoplasty	01JAN2011	31DEC2011	N
			Neurectomy	09MAY2017	09MAY2017	N
			Rotator cuff repair	01JAN1980	31DEC1980	N
				01JAN1990	31DEC1990	N
	C4591001 1177 11771199	Eye disorders	Macular degeneration	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1985		Y
		Nervous system disorders	Transient ischaemic attack	27MAY2020	27MAY2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771201	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Wrist fracture	01AUG2018	31AUG2018	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	01JAN2008	31MAR2008	N
		Social circumstances	Breast cancer	01JAN2006	31OCT2006	N
		Surgical and medical procedures	Postmenopause	01JAN2006		Y
			Breast conserving surgery	01OCT2006	31OCT2006	N
			Craniotomy	01MAR2008	31MAR2008	N
			Open reduction of fracture	01AUG2018	31AUG2018	N
	C4591001 1177 11771202	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1177 11771203	Immune system disorders	Allergy to animal	01JAN2017		Y
			Mite allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2019	21NOV2019	N
			Vertebral osteophyte	01JAN2019	21NOV2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Spinal decompression	21NOV2019	21NOV2019	N
	C4591001 1177 11771204	Gastrointestinal disorders	Inguinal hernia	01JAN1990	31DEC1990	N
		General disorders and administration site conditions	Drug intolerance	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1990	31DEC1990	N
			Joint manipulation	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1177 11771205	Injury, poisoning and procedural complications	Ligament injury	01JAN1991	31DEC1992	N
		Surgical and medical procedures	Ligament operation	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1177 11771206	Cardiac disorders	Atrial tachycardia	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2011	31DEC2011	N
			Spinal column injury	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2008	31DEC2008	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020	18MAY2020	N
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	01JAN2015		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2008	31DEC2008	N
			Meniscus removal	01JAN2011	31DEC2011	N
			Prostatic urethral lift procedure	18MAY2020	18MAY2020	N
			Shoulder operation	01JAN2008	31DEC2008	N
			Skin neoplasm excision	01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771208	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771211	Gastrointestinal disorders	Diverticulum	01AUG2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2003		Y
	C4591001 1177 11771213	Cardiac disorders	Atrial fibrillation	01JAN2013		Y
		Ear and labyrinth disorders	Vertigo	01MAY2020		Y
		Eye disorders	Cataract nuclear	01JAN2018		Y
			Presbyopia	01JAN2018		Y
			Retinal drusen	01JAN2018		Y
			Vitreous degeneration	01JAN2018		Y
		Infections and infestations	Genital herpes simplex	01JAN2019		Y
			Tinea capitis	01JAN2010		Y
		Injury, poisoning and procedural complications	Vascular pseudoaneurysm	01JAN2015	31DEC2015	N
		Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Overweight	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteopenia	01JAN2018		Y
			Osteoporosis	01JAN2019		Y
			Plantar fascial fibromatosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2008		Y
			Lymphoma	01JAN1998	31DEC2000	N
		Nervous system disorders	Autonomic neuropathy	01JAN1995		Y
			Parkinson's disease	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2019		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Deep brain stimulation	25AUG2014	25AUG2014	N
		Vascular disorders	Hypotension	01JAN2010		Y
	C4591001 1177 11771214	Immune system disorders	Food allergy	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Parapsoriasis	01MAY2012		Y
		Surgical and medical procedures	Debridement	01NOV2016	30NOV2016	N
	C4591001 1177 11771215	Endocrine disorders	Autoimmune thyroiditis	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01OCT2003	31OCT2003	N
		Immune system disorders	Allergy to vaccine	01JAN1990		Y
			Drug hypersensitivity	01JAN1980		Y
			Food allergy	01JAN1961		Y
		Investigations	Cardiac stress test abnormal	01DEC2016	31DEC2016	N
		Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Reproductive system and breast disorders	Breast enlargement	01JAN1982	31JAN1982	N
		Social circumstances	Postmenopause	01FEB2012		Y
		Surgical and medical procedures	Cholecystectomy	01OCT2003	31OCT2003	N
			Mammoplasty	01JAN1982	31JAN1982	N
	C4591001 1177 11771217	Immune system disorders	Food allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
	C4591001 1177 11771227	Endocrine disorders	Hypothyroidism	16JUL2020		Y
		Immune system disorders	Food allergy	(b) (6) 1948		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
			Osteoporosis	01JAN2016		Y
		Surgical and medical procedures	Limb operation	01JAN2017	31DEC2017	N
				01JAN2018	31DEC2018	N
	C4591001 1177 11771229	Gastrointestinal disorders	Inguinal hernia	01NOV1990	30NOV1990	N
		Infections and infestations	Tonsillitis	01JUN1960	30JUN1960	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2005		Y
			Glucose tolerance impaired	01JUN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUL2020	31JUL2020	N
		Surgical and medical procedures	Inguinal hernia repair	01NOV1990	30NOV1990	N
			Tonsillectomy	01JUN1960	30JUN1960	N
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1177 11771230	Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
			Tendon injury	01JAN1975	31DEC1975	N
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Meniscus operation	01JAN2000	31DEC2000	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
			Tenoplasty	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1177 11771231	Congenital, familial and genetic disorders	Arteriovenous malformation	(b) (6) 1956		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	05FEB2015		Y
		Infections and infestations	Chronic sinusitis	01JAN2012		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
		Musculoskeletal and connective tissue disorders	Foot deformity	05SEP2017		Y
			Pain in extremity	09JUN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	03MAR2014		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10DEC2013		Y
		Social circumstances	Postmenopause	01MAR2008		Y
		Surgical and medical procedures	Meniscus operation	01JAN2003	31DEC2003	N
				01JAN2004	31DEC2004	N
				01JAN2006	31DEC2006	N
	C4591001 1177 11771232	Endocrine disorders	Thyroiditis	01JAN2010	31DEC2010	N
		Immune system disorders	Food allergy	01JAN1976		Y
	C4591001 1177 11771233	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2003		Y
	C4591001 1177 11771239	Gastrointestinal disorders	Hiatus hernia	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Obesity	01JAN2018		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771240	General disorders and administration site conditions	Calcinosis	01JAN1999	31DEC1999	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1991		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN1987	31DEC1987	N
			Calcific deposits removal	01JAN1999	31DEC1999	N
			Female sterilisation	01JAN1991	31DEC1991	N
	C4591001 1177 11771243	Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Bone marrow donation	01JAN1998	31DEC1998	N
			Renal stone removal	01JAN1996	31DEC1996	N
			Ureteral stent insertion	01JAN1996	31DEC1996	N
	C4591001 1177 11771244	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771247	Injury, poisoning and procedural complications	Clavicle fracture	01JAN2010	31DEC2010	N
		Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	01JAN1981	31DEC1981	N
				01JAN1987	31DEC1987	N
		Surgical and medical procedures	Bone operation	01JAN2010	31DEC2010	N
			Salpingoplasty	01JAN1991	31DEC1991	N
	C4591001 1177 11771249	Immune system disorders	Food allergy	01JAN1974	31DEC1974	N
		Renal and urinary disorders	Nephrolithiasis	01JAN1988		Y
		Surgical and medical procedures	Lithotripsy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771250	Eye disorders	Glaucoma	01JAN2015		Y
		Gastrointestinal disorders	Intestinal obstruction	01SEP2017	30SEP2017	N
		Infections and infestations	Appendicitis	01JAN2015	31JAN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Radiation proctitis	01JAN2000		Y
		Metabolism and nutrition disorders	Hypolipidaemia	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01OCT2000	31DEC2010	N
		Nervous system disorders	Migraine	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1955		Y
		Surgical and medical procedures	Appendectomy	01JAN2015	31JAN2015	N
			Intestinal resection	01SEP2017	30SEP2017	N
	C4591001 1177 11771252	Endocrine disorders	Thyroid mass	01JAN2002		Y
		Eye disorders	Dacryostenosis acquired	01JAN2011	31OCT2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Mite allergy	01JAN2011		Y
		Injury, poisoning and procedural complications	Meniscus injury	01DEC2013	31DEC2013	N
		Investigations	Arthroscopy	01DEC2013	31DEC2013	N
		Metabolism and nutrition disorders	Gluten sensitivity	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cancer surgery	01JAN2014	31DEC2014	N
			Dacryocystorhinostomy	01MAY2011	31MAY2011	N
				01OCT2011	31OCT2011	N
			Female sterilisation	01MAY1993	31MAY1993	N
	C4591001 1177 11771253	Injury, poisoning and procedural complications	Hip fracture	01JUN2005	30JUN2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2012	N
		Nervous system disorders	Nerve compression	01SEP1975	30SEP1975	N
		Surgical and medical procedures	Hip surgery	01JUN2005	30JUN2005	N
			Spinal operation	01SEP1975	30SEP1975	N
	C4591001 1177 11771255	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Reproductive system and breast disorders	Prostatitis	01JAN2004		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1177 11771256	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2010	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Mastectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1177 11771263	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Food allergy	01JAN1962		Y
		Nervous system disorders	Headache	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01AUG1974	31AUG1974	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01OCT2000	31OCT2000	N
			Nasal septal operation	01AUG1974	31AUG1974	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771264	Metabolism and nutrition disorders	Gout	01JAN1989		Y
			Type 2 diabetes mellitus	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN1979		Y
	C4591001 1177 11771268	Infections and infestations	Pilonidal cyst	01JAN1964	31DEC1964	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2007	31DEC2007	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basosquamous carcinoma of skin	01JAN2018	31AUG2019	N
			Prostate cancer	01JAN2019	31DEC2019	N
		Nervous system disorders	Cervical radiculopathy	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Pilonidal sinus repair	01JAN1964	31DEC1964	N
			Radical prostatectomy	01JAN2019	31DEC2019	N
			Spinal fusion surgery	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2017	31DEC2017	N
	C4591001 1177 11771269	Eye disorders	Cataract	01JAN2018	07JUN2018	N
		Immune system disorders	Dust allergy	01JAN1960		Y
			Mycotic allergy	01JAN1960		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2020	12FEB2020	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01MAR2020	08APR2020	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Intraocular lens implant	07JUN2018	07JUN2018	N
				22APR2018	22APR2018	N
			Rotator cuff repair	08APR2020	08APR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tenoplasty	12FEB2020	12FEB2020	N
	C4591001 1177 11771273	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma of appendix	01JAN2008	30SEP2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
			Bronchiectasis	01JAN2017		Y
			Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Abdominal hernia repair	01NOV2011	30NOV2011	N
			Appendectomy	01JUL2008	31JUL2008	N
			Chemotherapy	01SEP2008	30SEP2008	N
			Cytoreductive surgery	01SEP2008	30SEP2008	N
	C4591001 1177 11771274	Gastrointestinal disorders	Constipation	01JAN1993		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990	31DEC1996	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
			Spinal fusion surgery	01JAN1996	31DEC1996	N
	C4591001 1177 11771275	Endocrine disorders	Goitre	01JAN2010		Y
		Eye disorders	Dry eye	01JAN2019		Y
			Glaucoma	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Contrast media allergy	01JAN2010		Y
			Drug hypersensitivity	01JAN2016		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01OCT2016		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771276	Endocrine disorders	Goitre	01JAN2002	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020	31AUG2020	N
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Skin neoplasm excision	01AUG2020	31AUG2020	N
	C4591001 1177 11771277	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC2017	28FEB2018	N
		Social circumstances	Postmenopause	05MAR2018		Y
		Surgical and medical procedures	Mastectomy	01FEB2018	28FEB2018	N
	C4591001 1177 11771279	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUL2019	31JUL2019	N
		Surgical and medical procedures	Osteotomy	01JUL2019	31JUL2019	N
	C4591001 1177 11771280	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
			Food allergy	01JAN2008		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUL2018		Y
			Intervertebral disc protrusion	01JAN1986	31DEC1986	N
			Osteoarthritis	01JAN2010	31DEC2018	N
				01JUL2018	31JUL2018	N
				01JUN2017	30JUN2017	N
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2010		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1986	31DEC1986	N
			Knee arthroplasty	01JUL2018	31JUL2018	N
				01JUN2017	30JUN2017	N
	C4591001 1177 11771286	Infections and infestations	Appendicitis	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Appendectomy	01JAN2015	31DEC2015	N
			Hip arthroplasty	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2003	31DEC2003	N
	C4591001 1177 11771287	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Eye disorders	Cataract	01JAN2011	31DEC2011	N
		Gastrointestinal disorders	Gastrointestinal disorder	01JAN2017		Y
		General disorders and administration site conditions	Cyst	01JAN1998	31DEC1998	N
		Immune system disorders	Mite allergy	01JAN2013		Y
		Infections and infestations	Tonsillitis	01JAN1957	31DEC1957	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Renal and urinary disorders	Renal cyst	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2011	31DEC2011	N
			Foot operation	01JAN1998	31DEC1998	N
			Tonsillectomy	01JAN1957	31DEC1957	N
			Pyloric stenosis	01JAN1964	31DEC1964	N
	C4591001 1177 11771288	Congenital, familial and genetic disorders				
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
		Surgical and medical procedures	Pyloroplasty	01JAN1964	31DEC1964	N
	C4591001 1177 11771290	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Investigations	Arthroscopy	01JAN2010	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
	C4591001 1177 11771291	Immune system disorders	Allergy to arthropod sting	01JAN1961	31DEC1961	N
			Drug hypersensitivity	01JAN2010		Y
				08MAR2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015	12MAR2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	06JUN2017	30JUN2017	N
		Reproductive system and breast disorders	Infertility	01JAN1989		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	18MAY2012		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
			Knee arthroplasty	01MAR2016	31MAR2016	N
				12MAR2020	12MAR2020	N
		Vascular disorders	Hypertension	23SEP2009	23SEP2009	N
	C4591001 1177 11771293	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01DEC2019		Y
	C4591001 1177 11771298	Gastrointestinal disorders	Abdominal hernia	01JAN2019	31DEC2019	N
			Gastroesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2007		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2019	31DEC2019	N
			Meniscus operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1177 11771299	Endocrine disorders	Goitre	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2004		Y
				01JAN2008		Y
		Infections and infestations	Sinusitis	01JAN2009	31DEC2009	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Psychiatric disorders	Persistent depressive disorder	01JAN1985	31DEC1990	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Functional endoscopic sinus surgery	01JAN2009	31DEC2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771301	Gastrointestinal disorders	Pancreatitis	01JAN1969	31DEC1969	N
		Immune system disorders	Food allergy	01JAN1980		Y
		Infections and infestations	Tonsillitis	01JAN1952	31DEC1952	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2015	31DEC2015	N
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	08DEC1978	08DEC1978	N
				18DEC1976	18DEC1976	N
			Fracture treatment	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1952	31DEC1952	N
	C4591001 1177 11771308	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	03AUG2019	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	03SEP2020	03SEP2020	N
			Radical prostatectomy	03AUG2019	03AUG2019	N
	C4591001 1177 11771311	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016	31DEC2016	N
			Osteopenia	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2017	31DEC2017	N
			Foot operation	01JAN2016	31DEC2016	N
	C4591001 1177 11771316	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	31DEC2010		Y
		Surgical and medical procedures	Lithotripsy	01FEB2017	01FEB2017	N
				12SEP2014	12SEP2014	N
	C4591001 1177 11771317	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2010		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Food allergy	01JAN1970		Y
			Rubber sensitivity	01JAN1990		Y
		Injury, poisoning and procedural complications	Wrist fracture	27JUL2020	27JUL2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2001	31DEC2001	N
			Transient ischaemic attack	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1986	31DEC1986	N
			Sleep apnoea syndrome	01JAN1990		Y
			Vocal cord polyp	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2001	31DEC2001	N
			Fracture treatment	27JUL2020	27JUL2020	N
			Laryngeal polypectomy	01JAN1997	31DEC1997	N
			Nasal septal operation	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771325	Cardiac disorders	Coronary artery disease	01JAN2013		Y
			Myocardial infarction	01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Large intestine polyp	01JAN2012	31DEC2012	N
		Immune system disorders	Allergy to animal	01JAN1961		Y
			Dust allergy	01JAN1961		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Vitamin D deficiency	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2013	31DEC2013	N
			Polypectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1177 11771326	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2019	28FEB2019	N
		Surgical and medical procedures	Skin neoplasm excision	01FEB2019	28FEB2019	N
	C4591001 1177 11771327	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2018		Y
			Vitamin B12 deficiency	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Colectomy	01DEC2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771336	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2003		Y
		Reproductive system and breast disorders	Breast calcifications	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopausa	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771337	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1177 11771338	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771339	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1177 11771340	Infections and infestations	Appendicitis	01JAN1984	31DEC1984	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Gout	01JAN2005		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Appendectomy	01JAN1984	31DEC1984	N
			Ovarian cystectomy	01JAN1987	31DEC1987	N
	C4591001 1177 11771344	Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN2000	31DEC2000	N
				01JAN2001	31DEC2001	N
	C4591001 1177 11771349	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Gout	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
			Renal cell carcinoma	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Nephrectomy	01DEC2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prostatectomy	01DEC2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1177 11771350	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2004		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
			Rhinitis allergic	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hot flush	01DEC2004		Y
			Hypertension	01JAN1984		Y
	C4591001 1177 11771352	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Spinal fusion surgery	01JAN1997	31DEC1997	N
	C4591001 1177 11771353	Ear and labyrinth disorders	Hypoacusis	01JAN1962		Y
		Immune system disorders	Food allergy	01JAN2007		Y
			Mite allergy	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Muscle tightness	01JAN1990		Y
		Nervous system disorders	Headache	01JAN2007		Y
		Psychiatric disorders	Insomnia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2007		Y
	C4591001 1177 11771356	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Foot deformity	01JAN2001	31DEC2001	N
		Nervous system disorders	Headache	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Bunion operation	01JAN2001	31DEC2001	N
			Female sterilisation	01JAN1991	31DEC1991	N
			Mammoplasty	01JAN1986	31DEC1986	N
				01JAN2005	31DEC2005	N
			Sterilisation	01JAN1991		Y
	C4591001 1177 11771358	Hepatobiliary disorders	Cholecystitis	01JAN2003	31DEC2003	N
		Immune system disorders	Drug hypersensitivity	01JAN1967		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1177 11771359	Immune system disorders	Drug hypersensitivity	01JAN1969		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1177 11771362	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basosquamous carcinoma	01JAN2000		Y
		Renal and urinary disorders	Pelvi-ureteric obstruction	(b) (6) 1961	31DEC1997	N
		Social circumstances	Postmenopause	01JAN2016		Y
		Surgical and medical procedures	Pyeloplasty	01JAN1997	31DEC1997	N
	C4591001 1177 11771363	Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Arteriosclerosis	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771364	Immune system disorders	Food allergy	01JAN1990		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1973	31DEC1973	N
		Investigations	Colonoscopy	01JAN2010	31DEC2010	N
				01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Surgical and medical procedures	Shoulder operation	01JAN1973	31DEC1973	N
	C4591001 1177 11771365	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Face lift	01JAN1998	31DEC1998	N
			Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1177 11771370	Ear and labyrinth disorders	Vertigo	01MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Muscle rupture	01JUN2017	30JUN2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUN2017	30JUN2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Shoulder operation	01JUN2017	30JUN2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771372	Infections and infestations	Adenoiditis	01JAN1959	31DEC1959	N
			Tonsillitis	01JAN1959	31DEC1959	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	01JAN1973	31DEC1973	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1959	31DEC1959	N
			Tonsillectomy	01JAN1959	31DEC1959	N
			Uterine dilation and curettage	01JAN1973	31DEC1973	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1177 11771373	Eye disorders	Myopia	01JAN1966	31DEC1984	N
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Appendicitis	01JAN1965	31DEC1965	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1992	31DEC1992	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1986	31DEC1986	N
		Pregnancy, puerperium and perinatal conditions	Delivery	01JUN1965	01JUN1965	N
		Reproductive system and breast disorders	Endometriosis	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	01JAN1951	31DEC1951	N
		Social circumstances	Postmenopause	01JAN1986		Y
		Surgical and medical procedures	Appendicectomy	01JAN1965	31DEC1965	N
			Caesarean section	01JUN1965	01JUN1965	N
			Hysterectomy	01JAN1986	31DEC1986	N
			Keratomileusis	01JAN1984	31DEC1984	N
			Mammoplasty	01JAN1976	31DEC1976	N
			Meniscus removal	01JAN1992	31DEC1992	N
			Tonsillectomy	01JAN1951	31DEC1951	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771376	Immune system disorders	Rubber sensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Uvulopalatopharyngoplasty	01JAN2008	31DEC2008	N
	C4591001 1177 11771378	Congenital, familial and genetic disorders	Hydrocele	01JAN2010	09NOV2010	N
		Eye disorders	Glaucoma	01JAN2011	16MAR2011	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009	31DEC2019	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	24OCT2018	24OCT2018	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01OCT2013		Y
		Surgical and medical procedures	Hydrocele operation	09NOV2010	09NOV2010	N
			Micrographic skin surgery	24OCT2018	24OCT2018	N
			Trabeculectomy	16MAR2011	16MAR2011	N
	C4591001 1177 11771379	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Investigations	Colonoscopy	17AUG2020	17AUG2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
		Nervous system disorders	Seizure	01JAN2014		Y
	C4591001 1177 11771380	Eye disorders	Dry age-related macular degeneration	01JUL2019		Y
			Retinal tear	01JUL2019		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1968		Y
		Immune system disorders	Allergy to animal	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Contrast media allergy	01JUN2019		Y
		Infections and infestations	Appendicitis	01JAN1982	31DEC1982	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN2016	31DEC2016	N
			Lobular breast carcinoma in situ	01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN2011	31DEC2011	N
			Endometriosis	01JAN1994	31DEC1994	N
			Infertility	01JAN2011		Y
		Surgical and medical procedures	Appendicectomy	01JAN1982	31DEC1982	N
			Breast conserving surgery	01JAN2016	31DEC2016	N
			Endometriosis ablation	01JAN1994	31DEC1994	N
			Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1177 11771381	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1985	31DEC2010	N
	C4591001 1177 11771382	Eye disorders	Glaucoma	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1964	31DEC1964	N
		Psychiatric disorders	Anxiety	01JAN2010	31DEC2010	N
			Depression	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Appendicectomy	01JAN1964	31DEC1964	N
			Female sterilisation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771384	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Mastectomy	01DEC2014	31DEC2014	N
	C4591001 1177 11771387	Immune system disorders	Allergy to arthropod sting	01JAN2002		Y
	C4591001 1177 11771388	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2013	31MAY2017	N
		Surgical and medical procedures	Nasal septal operation	01JAN1995	31DEC1995	N
			Prostatectomy	01DEC2013	31DEC2013	N
	C4591001 1177 11771390	Cardiac disorders	Myocardial infarction	01JAN2007	31DEC2007	N
		Hepatobiliary disorders	Cholecystitis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer stage I	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
			Colectomy	01JAN2010	31DEC2010	N
			Coronary arterial stent insertion	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771395	Cardiac disorders	Arrhythmia	01JAN2004		Y
			Ventricular extrasystoles	01JAN2004	31DEC2009	N
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2004	31DEC2004	N
				01JAN2009	31DEC2009	N
	C4591001 1177 11771396	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	02JAN1995	02JAN1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Infertility	02JAN1995		Y
		Surgical and medical procedures	Hysterectomy	02JAN1995	02JAN1995	N
			Salpingo-oophorectomy bilateral	02JAN1995	02JAN1995	N
	C4591001 1177 11771398	Endocrine disorders	Autoimmune thyroiditis	01JAN2010		Y
		Infections and infestations	Appendicitis	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Infertility	01JAN2018		Y
			Menorrhagia	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Hysterectomy	01JAN2018	31DEC2018	N
	C4591001 1177 11771399	Endocrine disorders	Hypothyroidism	01JAN1981		Y
		Gastrointestinal disorders	Diverticulum intestinal	01JAN2017		Y
			Large intestine polyp	01JAN2017		Y
		Injury, poisoning and procedural complications	Head injury	01OCT2018	31OCT2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
			Back pain	01FEB2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1981	31DEC1981	N
		Nervous system disorders	Paraesthesia	01DEC2017		Y
		Psychiatric disorders	Alcohol abuse	01JAN2015		Y
			Anxiety	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN2000		Y
		Renal and urinary disorders	Nocturia	01JUL2019		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771406	Gastrointestinal disorders	Haemorrhoids	01JAN2010	31DEC2010	N
		Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Appendicectomy	01JAN1967	31DEC1967	N
			Haemorrhoid operation	01JAN2010	31DEC2010	N
			Rotator cuff repair	01JAN2017	31DEC2017	N
	C4591001 1177 11771407	Gastrointestinal disorders	Inguinal hernia	01JAN2017	31DEC2017	N
		Injury, poisoning and procedural complications	Hand fracture	01JAN1960	31DEC1960	N
			Lower limb fracture	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Obesity	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN1950	31DEC1950	N
				01JAN1960	31DEC1960	N
			Inguinal hernia repair	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771408	Cardiac disorders	Coronary artery disease	19SEP2015		Y
		Endocrine disorders	Hyperparathyroidism	01JAN1996		Y
		Eye disorders	Cataract	01JAN1994	31DEC1995	N
		Gastrointestinal disorders	Constipation	01JAN2014		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Inguinal hernia	01JAN1995	31DEC1996	N
				01JAN2007	31DEC2008	N
		Infections and infestations	Appendicitis	01JAN1950	31DEC1950	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2012		Y
			Osteopenia	01JAN2013		Y
			Spinal stenosis	01JAN2012		Y
		Surgical and medical procedures	Appendicectomy	01JAN1950	31DEC1950	N
			Inguinal hernia repair	01JAN1996	31DEC1996	N
				01JAN2008	31DEC2008	N
			Intraocular lens implant	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771409	Blood and lymphatic system disorders	Anaemia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Eye disorders	Diabetic retinopathy	01JAN1986		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1968		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2000		Y
		Renal and urinary disorders	Diabetic nephropathy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
			Vitrectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771412	Eye disorders	Pterygium	01JAN2015	31DEC2015	N
		Infections and infestations	Appendicitis	01JAN1992	31DEC1992	N

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2005	31DEC2017	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Surgical and medical procedures	Ankle arthroplasty	01JAN2017	31DEC2017	N
			Appendicectomy	01JAN1992	31DEC1992	N
			Pterygium operation	01JAN2015	31DEC2015	N
	C4591001 1177 11771413	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
				01JAN1980		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN1992	31DEC1992	N
			Upper limb fracture	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01FEB2019	28FEB2019	N
			Squamous cell carcinoma	01MAY2020	31MAY2020	N
			Squamous cell carcinoma of skin	01JAN2010	31DEC2010	N
		Reproductive system and breast disorders	Breast mass	01JAN1980	31DEC2014	N
			Endometriosis	01JAN1990	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2013		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1980	31DEC1980	N
				01JAN1985	31DEC1985	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1990	31DEC1990	N
				01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
			Endometriosis ablation	01JAN1999	31DEC1999	N
			Fracture treatment	01JAN1997	31DEC1997	N
			Micrographic skin surgery	01FEB2019	28FEB2019	N
				01JAN2010	31DEC2010	N
				01MAY2020	31MAY2020	N
			Tenoplasty	01JAN1992	31DEC1992	N
	C4591001 1177 11771414	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Scoliosis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01SEP2011	30SEP2011	N
	C4591001 1177 11771417	Eye disorders	Eye allergy	01JAN2015		Y
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2014	31DEC2014	N
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1177 11771419	Endocrine disorders	Hypogonadism	01JAN2019		Y
		Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Cholecystectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1177 11771421	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN1993		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Magnesium deficiency	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN1988		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2013		Y
		Surgical and medical procedures	Coronary artery bypass	02MAY2013	02MAY2013	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1177 11771425	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Breast operation	01JAN2018	31DEC2018	N
			Face lift	01JAN2008	31DEC2008	N
			Mammoplasty	01JAN1990	31DEC1990	N
			Neoplasm prophylaxis	01JAN2018	31DEC2018	N
			Phlebectomy	01JAN2016	31DEC2016	N
	C4591001 1177 11771426	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Hepatobiliary disorders	Cholecystitis acute	08DEC2010	08DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2019		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Cholecystectomy	08DEC2010	08DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771427	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2014		Y
			Type 1 diabetes mellitus	01JUL1996		Y
		Psychiatric disorders	Depression	01APR2014		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	22JUN1985	22JUN1985	N
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 1177 11771430	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771431	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1997		Y
			Peptic ulcer	01JAN2003	31DEC2013	N
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	27MAR2014		Y
		Infections and infestations	Sinusitis	01MAR2020	31MAY2020	N
		Investigations	Blood testosterone decreased	01MAR2020		Y
			Nasoendoscopy	23APR2020	23APR2020	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1977		Y
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2004	31DEC2004	N
			Knee operation	13MAY2018	13MAY2018	N
			Therapeutic procedure	01JAN2003	31DEC2003	N
				01JAN2006	31DEC2006	N
				01JAN2013	31DEC2013	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771436	Endocrine disorders	Hyperparathyroidism primary	01NOV2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1969		Y
				01JAN1990		Y
				01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Vitamin D deficiency	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771437	Eye disorders	Glaucoma	01JAN2018		Y
		Gastrointestinal disorders	Inguinal hernia	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholecystitis	01JAN2017	31DEC2017	N
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
				01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Cholelithotomy	01JAN2017	31DEC2017	N
			Inguinal hernia repair	01JAN2018	31DEC2018	N
			Skin neoplasm excision	01JAN2000	31DEC2000	N
	C4591001 1177 11771447	Infections and infestations	Hepatitis B	01JAN1974	31DEC1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771448	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Nervous system disorders	Spasmodic dysphonia	01JAN2012		Y
		Renal and urinary disorders	Cystitis interstitial	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1177 11771451	Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
			Vitamin D deficiency	01MAY2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1978	31DEC1978	N
			Benign neoplasm of testis	01JAN1993	31DEC1993	N
		Nervous system disorders	Tremor	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1978	31DEC1978	N
			Female sterilisation	01JAN1995	31DEC1995	N
			Orchidectomy	01JAN1993	31DEC1993	N
	C4591001 1177 11771457	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Infections and infestations	Diverticulitis	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
			Infertility	01JAN1993		Y
		Surgical and medical procedures	Colectomy	01JAN2008	31DEC2008	N
			Hysterectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1177 11771459	Eye disorders	Cataract	01JAN2015	03AUG2020	N
		Surgical and medical procedures	Cataract operation	03AUG2020	03AUG2020	N
	C4591001 1177 11771460	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Eye disorders	Cataract	01JAN2012	31DEC2012	N
			Retinal detachment	01JAN2000	31DEC2000	N
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2012	31DEC2012	N
			Retinopexy	01JAN2000	31DEC2000	N
	C4591001 1177 11771461	Eye disorders	Dry eye	01JAN2018		Y
			Glaucoma	01JAN2018		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JUL1958	31JUL1958	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1980		Y
			Gout	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Articular calcification	01JAN2012	30SEP2012	N
			Osteoporosis	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31MAR2014	N
		Surgical and medical procedures	Fracture treatment	01JUL1958	31JUL1958	N
			Renal stone removal	01MAR2014	31MAR2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Shoulder operation	01SEP2012	30SEP2012	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1177 11771462	Eye disorders	Ocular discomfort	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2019	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Nervous system disorders	Transient global amnesia	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Mammoplasty	01JAN1989	31DEC1989	N
			Sigmoidectomy	08JAN2019	08JAN2019	N
	C4591001 1177 11771467	Vascular disorders	Hypertension	01JAN1998		Y
		Infections and infestations	Appendicitis	01JAN2011	31DEC2011	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
				01JAN2006	31DEC2006	N
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
			Ligament operation	01JAN1999	31DEC1999	N
			Osteotomy	01JAN2006	31DEC2006	N
	C4591001 1177 11771468	Vascular disorders	Hypertension	01JAN2012		Y
		Injury, poisoning and procedural complications	Tendon rupture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Rotator cuff repair	01JAN2015	31DEC2015	N
			Tenoplasty	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771469	Endocrine disorders	Acromegaly	01JAN2000		Y
			Goitre	01JAN2005	31DEC2005	N
		Gastrointestinal disorders	Constipation	01JAN2000		Y
			Diverticulum oesophageal	01JAN2003	31DEC2003	N
			Gastrooesophageal reflux disease	01JAN2000		Y
			Large intestine polyp	01JAN2012		Y
		Hepatobiliary disorders	Cholecystitis	01JAN1991	31DEC1991	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000	31DEC2016	N
			Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN2004	31DEC2004	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Hip arthroplasty	01JAN2005	31DEC2005	N
				01JAN2016	31DEC2016	N
			Oesophageal operation	01JAN2003	31DEC2003	N
			Pituitary tumour removal	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771470	Ear and labyrinth disorders	Meniere's disease	01MAR2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Aortic aneurysm repair	01JAN2012	31DEC2012	N
		Vascular disorders	Aortic aneurysm	01JAN2012	31DEC2012	N
			Hypertension	01JAN2000		Y
	C4591001 1177 11771471	General disorders and administration site conditions	Drug intolerance	01JAN1970		Y
		Infections and infestations	Appendicitis	01JAN1975	31DEC1975	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
			Pain in extremity	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2003	31DEC2004	N
		Social circumstances	Postmenopause	01JAN1999		Y
		Surgical and medical procedures	Appendectomy	01JAN1975	31DEC1975	N
			Caesarean section	21OCT1998	21OCT1998	N
	C4591001 1177 11771474	Immune system disorders	Allergy to animal	01JAN1978		Y
			Seasonal allergy	01JAN1978		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2020		Y
			Tendonitis	02OCT2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	30JUN2001	N
		Nervous system disorders	Cerebrovascular accident	13AUG2016	13AUG2016	N
		Surgical and medical procedures	Myomectomy	01JUN2001	30JUN2001	N
	C4591001 1177 11771476	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771480	Immune system disorders	Food allergy	01JAN1995		Y
	C4591001 1177 11771481	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Eye disorders	Angle closure glaucoma	01JAN2003	31DEC2003	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1998		Y
		Immune system disorders	Iodine allergy	01JAN1989		Y
		Injury, poisoning and procedural complications	Ankle fracture	01JAN2006	31DEC2006	N
			Wrist fracture	01JAN1982	31DEC1982	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1990	31DEC2004	N
		Psychiatric disorders	Depression	01JAN1986		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1977	31DEC1977	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Cyst removal	01JAN1977	31DEC1977	N
			Iridotomy	01JAN2003	31DEC2003	N
			Lipoma excision	01JAN1990	31DEC1990	N
				01JAN2004	31DEC2004	N
			Open reduction of fracture	01JAN1982	31DEC1982	N
				01JAN2006	31DEC2006	N
	C4591001 1177 11771483	Eye disorders	Borderline glaucoma	01JAN2018		Y
			Dry eye	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1992		Y
			Type 2 diabetes mellitus	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	19NOV1993	19NOV1993	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1177 11771486	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer stage I	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 1177 11771489	Immune system disorders	Contrast media allergy	01JAN2000		Y
			Dust allergy	01JAN1973		Y
			Seasonal allergy	01JAN1973		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	30NOV2001	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Surgical and medical procedures	Mastectomy	01NOV2001	30NOV2001	N
	C4591001 1177 11771492	Gastrointestinal disorders	Constipation	01JAN2000		Y
			Haemorrhoids	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign small intestinal neoplasm	01JAN2017	31JAN2017	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN2002	31DEC2002	N
		Surgical and medical procedures	Intestinal operation	01JAN2017	31JAN2017	N
			Salpingo-oophorectomy bilateral	01DEC2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1177 11771495	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Food allergy	01MAR1993		Y
			Iodine allergy	01MAR1993		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Ligament sprain	01JAN1999	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Nerve compression	01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Ligament operation	01JAN1999	31DEC1999	N
			Peripheral nerve decompression	01JAN1993	31DEC1993	N
	C4591001 1177 11771498	Eye disorders	Dry eye	01JAN2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005	30JUN2020	N
			Hiatus hernia	01JUN2020	30JUN2020	N
			Inguinal hernia	01JAN2010	31DEC2010	N
		Infections and infestations	Urinary tract infection	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Gout	01AUG2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
					31AUG2019	N
					31JAN2002	N
			Spinal osteoarthritis	01JAN1980		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2019		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Hernia hiatus repair	01JUN2020	30JUN2020	N
			Hip arthroplasty	01AUG2019	31AUG2019	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Inguinal hernia repair	01JAN2010	31DEC2010	N
			Knee arthroplasty	01JAN2002	31JAN2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oesophagogastric fundoplasty	01JUN2020	30JUN2020	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1177 11771505	Surgical and medical procedures	Female sterilisation	01JAN1970	31DEC1970	N
			Ligament operation	01JAN1995	31DEC1995	N
	C4591001 1177 11771507	Infections and infestations	Appendicitis	01JAN1980	31DEC1980	N
			Pneumonia	01JAN1996	31DEC1996	N
		Investigations	Aspiration pleural cavity	01JAN1996	31DEC1996	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Nervous system disorders	Tremor	01JAN1997		Y
		Psychiatric disorders	Anxiety	01JAN1975		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01SEP2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771508	Eye disorders	Cataract	01MAY2014	31MAY2014	N
			Retinal detachment	01JAN2012	31JAN2012	N
				01SEP2011	30SEP2011	N
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01MAY2020	31MAY2020	N
		Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	01MAY2014	31MAY2014	N
			Retinal operation	01JAN2012	31JAN2012	N
				01SEP2011	30SEP2011	N
			Tenotomy	01MAY2020	31MAY2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1177 11771512	General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
		Injury, poisoning and procedural complications	Ligament rupture	01JAN1991	31DEC1991	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Surgical and medical procedures	Ligament operation	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771518	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Ear and labyrinth disorders	Exostosis of external ear canal	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018	27MAR2019	N
		Surgical and medical procedures	Hip arthroplasty	27MAR2019	27MAR2019	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1177 11771519	Musculoskeletal and connective tissue disorders	Periarthritis	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
			Squamous cell carcinoma	01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1960		Y
		Surgical and medical procedures	Cancer surgery	01JAN2005	31DEC2005	N
				01JAN2019	31DEC2019	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Skin neoplasm excision	01JAN2000	31DEC2000	N
			Toe operation	01JAN2000	31DEC2000	N
				01JAN2010	31DEC2010	N
	C4591001 1177 11771523	Eye disorders	Cataract	01JAN2012	31DEC2013	N
				01JAN2017	31DEC2018	N
			Glaucoma	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	01JAN2018		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	01JAN1978		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1177 11771527	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2011	N
		Social circumstances	Postmenopause	01JAN1993		Y
		Surgical and medical procedures	Mastectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1177 11771530	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN1963		Y
		Infections and infestations	Encephalitis	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
			Obesity	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Vitiligo	(b) (6) 1960		Y
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1177 11771535	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
			Irritable bowel syndrome	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2013		Y
			Food allergy	01JAN1961		Y
		Infections and infestations	Sinusitis	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	31AUG2017	31AUG2017	N
			Neck pain	31AUG2017	31AUG2017	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
			Rhinitis allergic	01JAN1971		Y
		Surgical and medical procedures	Mammoplasty	31AUG2017	31AUG2017	N
	C4591001 1177 11771536	Immune system disorders	Dust allergy	01JAN1998		Y
			Seasonal allergy	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Blepharoplasty	17SEP2020	17SEP2020	N
	C4591001 1177 11771538	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Sterilisation	01JAN1970		Y
			Vasectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1177 11771542	Endocrine disorders	Goitre	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Eyelid ptosis	01JAN2014	31DEC2014	N
		Gastrointestinal disorders	Leukoplakia oral	01JAN2018		Y
		Infections and infestations	Appendicitis	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1997	31DEC1997	N
			Caesarean section	10JUN2006	10JUN2006	N
			Mammoplasty	01JAN2014	31DEC2014	N
			Ptosis repair	01JAN2014	31DEC2014	N
	C4591001 1177 11771545	Gastrointestinal disorders	Inguinal hernia	01JAN2015	30SEP2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	31MAR2015	N
		Surgical and medical procedures	Inguinal hernia repair	01SEP2015	30SEP2015	N
			Transurethral prostatectomy	01MAR2015	31MAR2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1177 11771546	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2002	30APR2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
				01JAN1980	31DEC1980	N
			Hip arthroplasty	01JAN2008	31DEC2008	N
				01JAN2010	31DEC2010	N
			Hysterectomy	01APR2002	30APR2002	N
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1177 11771547	Hepatobiliary disorders	Cholecystitis	01JAN1995	31DEC1995	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
			Transurethral prostatectomy	03DEC2019	03DEC2019	N
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1177 11771553	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2006	31MAY2007	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Breast conserving surgery	01MAR2006	31MAR2006	N
	C4591001 1177 11771558	Injury, poisoning and procedural complications	Meniscus injury	01SEP2019	30SEP2019	N
		Surgical and medical procedures	Meniscus operation	01SEP2019	30SEP2019	N
	C4591001 1177 11771559	Eye disorders	Cataract	03APR2014	03APR2014	N
		Hepatobiliary disorders	Primary biliary cholangitis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Milk allergy	01JAN2000		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN1948	31DEC1948	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Reproductive system and breast disorders	Uterine prolapse	05JUL2017	05JUL2017	N
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Cataract operation	03APR2014	03APR2014	N
			Colpocleisis	05JUL2017	05JUL2017	N
			Hand amputation	01JAN1948	31DEC1948	N
	C4591001 1177 11771560	Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
			Intervertebral disc protrusion	01APR2014	31JAN2018	N
		Surgical and medical procedures	Spinal laminectomy	01JAN2018	31JAN2018	N
	C4591001 1177 11771561	Hepatobiliary disorders	Cholecystitis	01JAN2018	31DEC2018	N
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteonecrosis	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781002	Cardiac disorders	Atrial fibrillation	01JAN2017	31DEC2017	N
			Wolff-Parkinson-White syndrome	01JAN1990	31DEC1992	N
		Eye disorders	Glaucoma	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2002		Y
			Seasonal allergy	01JAN1982		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood testosterone decreased	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Reproductive system and breast disorders	Prostatomegaly	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Cardiac ablation	01JAN1992	31DEC1992	N
				01JAN2017	31DEC2017	N
			Vasectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1178 11781003	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2012		Y
	C4591001 1178 11781004	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1982		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
	C4591001 1178 11781005	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1178 11781006	Immune system disorders	Seasonal allergy	01JAN1996		Y
		Infections and infestations	Genital herpes	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01MAR2020		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Endometrial ablation	01JAN2003	31DEC2003	N
			Female sterilisation	01JAN1972	31DEC1972	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hot flush	01JAN2003		Y
	C4591001 1178 11781007	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1178 11781008	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2004	N
				01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Hip arthroplasty	01APR2019	30APR2019	N
				01NOV2018	30NOV2018	N
			Lymphadenectomy	01JAN2003	31DEC2003	N
			Mastectomy	01JAN2012	31DEC2012	N
			Oophorectomy bilateral	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781009	Cardiac disorders	Coronary artery disease	01SEP2019		Y
		Endocrine disorders	Hypogonadism	01APR2020		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2019	30SEP2019	N
	C4591001 1178 11781011	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1178 11781012	Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2007		Y
	C4591001 1178 11781015	Musculoskeletal and connective tissue disorders	Neck pain	01JAN2016		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
			Depression	01JAN1996		Y
			Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1178 11781016	Cardiac disorders	Arrhythmia	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
	C4591001 1178 11781017	Eye disorders	Glaucoma	01JAN2004		Y
		Infections and infestations	Herpes zoster	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2016		Y
	C4591001 1178 11781021	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Psychiatric disorders	Sleep disorder	01AUG2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	30JUN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781022	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Allergy to vaccine	01JAN1971		Y
			Drug hypersensitivity	01JAN1974		Y
				01JAN1977		Y
				01JAN1984		Y
				01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2014	31DEC2014	N
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Gastric bypass	01JAN2014	31DEC2014	N
			Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1178 11781023	Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1178 11781024	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN2017		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1178 11781025	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1945		Y
				01JAN1985		Y
		Infections and infestations	Diverticulitis	01JAN1989	31DEC1991	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1977	31DEC1987	N
		Surgical and medical procedures	Colectomy	01JAN1991	31DEC1991	N
			Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1178 11781027	Gastrointestinal disorders	Tooth disorder	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1988		Y
			Reaction to food additive	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	01JAN2005		Y
	C4591001 1178 11781031	Ear and labyrinth disorders	Deafness	01JAN1985		Y
		Eye disorders	Glaucoma	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2011		Y
			Osteoarthritis	01JAN1977		Y
		Reproductive system and breast disorders	Endometrial hypertrophy	01JAN2010	31DEC2012	N
		Social circumstances	Hearing aid user	01JAN1985		Y
		Surgical and medical procedures	Cochlea implant	01FEB2020		Y
			Hysterectomy	01JAN2012	31DEC2012	N
			Spinal operation	01JAN2011	31DEC2011	N
	C4591001 1178 11781032	Blood and lymphatic system disorders	Anaemia	01JAN2005		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Cataract	01JAN2003		Y
		Renal and urinary disorders	Pollakiuria	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1178 11781033	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781034	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	31DEC2001	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781035	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Endocrine disorders	Basedow's disease	01JAN1985		Y
			Hyperthyroidism	01JAN1985		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cardiac ablation	01SEP2019	30SEP2019	N
	C4591001 1178 11781037	Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1178 11781039	Ear and labyrinth disorders	Deafness bilateral	01JAN2015		Y
		Eye disorders	Cataract	01JUN2019	30JUN2019	N
			Dry eye	01JAN2010		Y
			Macular degeneration	01MAY2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Surgical and medical procedures	Cataract operation	01JUL2019	31JUL2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Prostatectomy	01JAN2004	31DEC2004	N
			Vasectomy	01JAN1972	31DEC1972	N
	C4591001 1178 11781042	Psychiatric disorders	Anxiety	01DEC2018		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1178 11781045	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1986		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1985		Y
		Nervous system disorders	Epilepsy	01JAN1959		Y
		Renal and urinary disorders	Urge incontinence	01JAN1989		Y
		Social circumstances	Postmenopause	01JAN1986		Y
	C4591001 1178 11781047	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1969		Y
	C4591001 1178 11781048	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Bipolar disorder	01JAN2010		Y
			Depression	01JAN2011		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1178 11781049	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Immune system disorders	Drug hypersensitivity	01MAR2018		Y
			Seasonal allergy	01JAN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Osteoporosis	01JAN1990		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2002	31DEC2002	N
	C4591001 1178 11781057	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Renal and urinary disorders	Urge incontinence	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1178 11781059	Investigations	Blood cholesterol increased	01JAN2017		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1178 11781060	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Carotid endarterectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Investigations	Cardiac murmur	01JAN1970		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma stage I	01JAN2015	31DEC2015	N
			Prostate cancer	01JAN2018	30SEP2019	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2010		Y
			Essential tremor	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2000		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1178 11781064	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01AUG2020		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1178 11781066	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
	C4591001 1178 11781068	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1178 11781071	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Otitis media	01JAN2019	31DEC2019	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Myringotomy	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781075	Immune system disorders	Drug hypersensitivity	01JAN1966		Y
	C4591001 1178 11781076	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cancer surgery	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781080	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Vascular disorders	Raynaud's phenomenon	01JAN1990		Y
	C4591001 1178 11781081	Cardiac disorders	Arrhythmia	01JAN1994	31DEC1994	N
		Eye disorders	Glaucoma	01DEC2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Nervous system disorders	Neuralgia	01JAN2016		Y
		Surgical and medical procedures	Cardioversion	01JAN1994	31DEC1994	N
			Vasectomy	01JAN1993	31DEC1993	N
	C4591001 1178 11781085	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1178 11781086	Cardiac disorders	Arrhythmia	01APR2018		Y
		Ear and labyrinth disorders	Deafness bilateral	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2012		Y
		Surgical and medical procedures	Cardiac ablation	13JUL2020	13JUL2020	N
			Cardiac pacemaker insertion	01APR2018	30APR2018	N
			Vasectomy	01JAN1978	31DEC1978	N
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1178 11781088	Cardiac disorders	Atrial fibrillation	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Eye disorders	Glaucoma	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Spinal stenosis	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Panic attack	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781090	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Infections and infestations	Rhinitis	01JAN2010		Y
		Metabolism and nutrition disorders	Gout	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Renal and urinary disorders	Urinary retention	01JAN2019		Y
	C4591001 1178 11781091	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Vascular disorders	Hot flush	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781093	Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1178 11781094	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
		Psychiatric disorders	Depression	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781099	Eye disorders	Cataract	01JAN1987		Y
					31DEC1987	N
			Glaucoma	01JAN1987		Y
			Iritis	01JAN1987		Y
		Infections and infestations	Poliomyelitis	01JUL1954		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
		Reproductive system and breast disorders	Uterine malposition	01JAN1987	31DEC1987	N
		Surgical and medical procedures	Cataract operation	01JAN1987	31DEC1987	N
			Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1178 11781101	Cardiac disorders	Arrhythmia	01JAN2015		Y
			Myocardial infarction	01JAN2015	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Infections and infestations	Genital herpes	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1975		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2016		Y
		Renal and urinary disorders	Proteinuria	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
	C4591001 1178 11781102	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1178 11781103	Congenital, familial and genetic disorders	Thalassaemia	01JAN1963		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN1990		Y
		Infections and infestations	Herpes simplex	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1178 11781108	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN1999		Y
	C4591001 1178 11781109	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	31DEC2015	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Mastectomy	01JAN2015	31DEC2015	N
	C4591001 1178 11781111	Eye disorders	Macular degeneration	31AUG2020		Y
		Gastrointestinal disorders	Crohn's disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
	C4591001 1178 11781112	Eye disorders	Dry eye	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1178 11781115	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Investigations	Cardiac murmur	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2006		Y
			Obesity	01JAN1965		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1178 11781117	Eye disorders	Macular degeneration	01JAN2017		Y
		Immune system disorders	Allergy to metals	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1178 11781118	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781119	Immune system disorders	Drug hypersensitivity	01JAN1958		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1999	31DEC1999	N
			Breast cancer recurrent	01JAN2007	31DEC2007	N
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2007	31DEC2007	N
			Mastectomy	01JAN1999	31DEC1999	N
	C4591001 1178 11781122	Cardiac disorders	Atrial fibrillation	01JAN2020		Y
			Cardiomyopathy	01JAN2008		Y
			Left ventricular hypertrophy	01JAN2008		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN1947		Y
		Investigations	Prostatic specific antigen increased	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01FEB2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781123	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Psychiatric disorders	Depression	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781124	Immune system disorders	Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1178 11781125	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781126	Cardiac disorders	Coronary artery disease	01FEB2020		Y
		Gastrointestinal disorders	Diverticulum	01FEB2020		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	01AUG2020		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1178 11781132	Immune system disorders	Drug hypersensitivity	01JAN1977		Y
			Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN2002	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2006		Y
			Urge incontinence	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1178 11781134	Cardiac disorders	Coronary artery disease	01JAN1994		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mitral valve prolapse	01JAN1994		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1988		Y
		Nervous system disorders	Neuralgia	01JAN1994		Y
		Social circumstances	Postmenopause	01JAN1974		Y
		Surgical and medical procedures	Hysterectomy	01JAN1974	31DEC1974	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1178 11781136	Cardiac disorders	Atrial fibrillation	01FEB2020		Y
			Ventricular extrasystoles	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1967		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Skin neoplasm excision	01JAN2011	31DEC2011	N
	C4591001 1178 11781138	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1178 11781139	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
			Hypersensitivity	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Plantar fasciitis	01JAN2018		Y
		Nervous system disorders	Headache	01JAN1990		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1977	31DEC1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1178 11781140	Vascular disorders	Hot flush	01JAN2017		Y
	C4591001 1178 11781142	Gastrointestinal disorders	Inguinal hernia	01JAN2018		Y
	C4591001 1178 11781143	Immune system disorders	Allergy to vaccine	01JAN1965		Y
		Infections and infestations	Herpes simplex	01JAN2012		Y
		Nervous system disorders	Headache	01JAN2000		Y
	C4591001 1178 11781146	Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
			Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Epicondylitis	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1988	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hot flush	01JAN2005		Y
	C4591001 1178 11781147	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Prehypertension	01MAY2020		Y
	C4591001 1178 11781148	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781151	Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2016		Y
		Nervous system disorders	Seizure	01JAN1986		Y
		Respiratory, thoracic and mediastinal disorders	Atelectasis	01JAN2012	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2001		Y
		Surgical and medical procedures	Thoracotomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1178 11781152	Eye disorders	Cataract	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN1973		Y
	C4591001 1178 11781157	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2013		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781158	Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1972		Y
		Infections and infestations	Oral herpes	01JAN1996		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1998	31DEC2001	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01AUG2001	31AUG2001	N
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1178 11781159	Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1178 11781160	Immune system disorders	Drug hypersensitivity	01JAN1962		Y
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Haemochromatosis	01JAN1995		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1985		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1178 11781164	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
			Depression	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1178 11781165	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN1990		Y
			Depression	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2019		Y
	C4591001 1178 11781166	Ear and labyrinth disorders	Deafness bilateral	01JAN2000		Y
		Eye disorders	Cataract	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
			Prostatomegaly	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN1980	31DEC1980	N
	C4591001 1178 11781167	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2020	31MAR2020	N
		Surgical and medical procedures	Skin lesion removal	01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781169	Gastrointestinal disorders	Inguinal hernia	28AUG2020	28AUG2020	N
		Surgical and medical procedures	Inguinal hernia repair	28AUG2020	28AUG2020	N
	C4591001 1178 11781172	Investigations	Blood cholesterol increased	01JAN1991		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y
	C4591001 1178 11781173	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
			Seasonal allergy	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Menorrhagia	01JAN2002	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2004	31DEC2004	N
	C4591001 1178 11781174	Nervous system disorders	Restless legs syndrome	01JAN1979		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1962		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1178 11781176	Eye disorders	Cataract	01JUN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2018		Y
	C4591001 1178 11781177	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1178 11781178	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN1995		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781180	Immune system disorders	Drug hypersensitivity	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1178 11781184	Infections and infestations	Herpes simplex	01JAN2013		Y
	C4591001 1178 11781191	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
	C4591001 1178 11781192	Ear and labyrinth disorders	Deafness unilateral	01JAN2015		Y
		Infections and infestations	Hepatitis C	01JAN2020	31AUG2020	N
	C4591001 1178 11781193	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
	C4591001 1178 11781195	Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2013		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Injury, poisoning and procedural complications	Cartilage injury	01MAR2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2006		Y
		Nervous system disorders	Diabetic neuropathy	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Insomnia	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1178 11781196	Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
	C4591001 1178 11781199	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1984		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1178 11781200	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1994		Y
		Infections and infestations	Appendicitis	01JAN1994	31DEC1994	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Appendicectomy	01JAN1994	31DEC1994	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1178 11781201	Psychiatric disorders	Bipolar II disorder	01JAN2001		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1178 11781202	Immune system disorders	Seasonal allergy	01JAN1975		Y
		Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1178 11781203	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1178 11781204	Eye disorders	Cataract	01JAN2005	31DEC2005	N
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Psychiatric disorders	Panic attack	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1178 11781205	Surgical and medical procedures	Cataract operation	01JAN2005	31DEC2005	N	
		Endocrine disorders	Hypothyroidism	01JAN2000		Y	
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y	
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y	
			Seasonal allergy	01JAN2005		Y	
		Infections and infestations	Folliculitis	28JUL2020		Y	
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2012		Y	
		Social circumstances	Postmenopause	01JAN2003		Y	
		C4591001 1178 11781206	Cardiac disorders	Atrial fibrillation	01JAN2015	31DEC2015	N
			Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
	C4591001 1178 11781207	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y	
			Type 2 diabetes mellitus	01JAN2010		Y	
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N	
		Vascular disorders	Hypertension	01JAN2005		Y	
		Cardiac disorders	Arrhythmia	01JAN2018		Y	
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y	
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2019		Y	
		Psychiatric disorders	Depression	01JAN2018		Y	
		Renal and urinary disorders	Urge incontinence	01JAN2017		Y	
		Reproductive system and breast disorders	Endometriosis	01JAN1980	31DEC1990	N	
	C4591001 1178 11781212	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N	
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y	
		Hepatobiliary disorders	Hepatic steatosis	01JAN2015		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Lung disorder	01SEP2019		Y
			Sleep apnoea syndrome	01JAN2008		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1178 11781215	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1178 11781220	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		General disorders and administration site conditions	Fatigue	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1966		Y
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1178 11781225	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1178 11781229	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1178 11781231	Gastrointestinal disorders	Diverticulum	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Nervous system disorders	Migraine	01JAN1985		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1178 11781232	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN1991		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
			Osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV2015	30NOV2015	N
		Psychiatric disorders	Depression	01JAN2018		Y
		Surgical and medical procedures	Breast conserving surgery	01NOV2015	30NOV2015	N
	C4591001 1178 11781238	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Investigations	Cardiac murmur	01JAN1965		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN1979	31DEC1980	N
		Reproductive system and breast disorders	Uterine prolapse	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Thyroidectomy	01JAN1980	31DEC1980	N
	C4591001 1178 11781240	Cardiac disorders	Cardiovascular disorder	01JAN2014		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
			Blood testosterone decreased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1178 11781241	Cardiac disorders	Coronary artery disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781242	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1988		Y
	C4591001 1178 11781243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2004		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1178 11781246	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
	C4591001 1178 11781250	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1992		Y
			Pain in extremity	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1178 11781252	Eye disorders	Dry eye	01JAN1996		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1974		Y
		Immune system disorders	Drug hypersensitivity	01JAN2008		Y
				01JAN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Polycystic ovaries	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1178 11781255	Immune system disorders	Hypersensitivity	01JAN1995		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1178 11781256	Gastrointestinal disorders	Coeliac disease	01JAN2000		Y
		Hepatobiliary disorders	Hepatitis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01APR2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2010		Y
	C4591001 1178 11781259	Metabolism and nutrition disorders	Insulin resistance	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1178 11781261	Immune system disorders	Drug hypersensitivity	01JAN1978		Y
		Investigations	Blood cholesterol increased	01JAN1988		Y
		Psychiatric disorders	Depression	01JAN2002		Y
	C4591001 1178 11781264	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Eye disorders	Iridocyclitis	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1970		Y
				01JAN1973		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1980		Y
				01JAN1990		Y
				01JAN1999		Y
				01JAN2013		Y
			Sarcoidosis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1178 11781265	Endocrine disorders	Thyroid mass	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1178 11781272	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Eye disorders	Retinal detachment	01JAN2019	30JUN2019	N
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
			Seasonal allergy	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Surgical and medical procedures	Retinopexy	01JUN2019	30JUN2019	N
			Vasectomy	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1178 11781273	Gastrointestinal disorders	Gastric ulcer	01JAN1982	31DEC1982	N
			Inguinal hernia	01JAN2007	31DEC2007	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2002	31DEC2002	N
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Infections and infestations	Hepatitis B	01JAN1982	31DEC1982	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hepatitis C	01JAN2006	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2002	31DEC2002	N
			Gastric ulcer surgery	01JAN1982	31DEC1982	N
			Inguinal hernia repair	01JAN2007	31DEC2007	N
	C4591001 1178 11781274	Endocrine disorders	Hypothyroidism	01JAN1989		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1987		Y
		Immune system disorders	Drug hypersensitivity	01JAN1992		Y
			Seasonal allergy	01JAN2019		Y
		Metabolism and nutrition disorders	Fluid retention	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Knee operation	01JAN2018	31DEC2018	N
	C4591001 1178 11781276	Gastrointestinal disorders	Diarrhoea	01FEB2020		Y
			Gastroesophageal reflux disease	01JAN1998		Y
			Hiatus hernia	01JAN1998		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Depression	01JAN2013		Y
		Renal and urinary disorders	Urge incontinence	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1178 11781278	Gastrointestinal disorders	Gastrointestinal ulcer	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN1984	31DEC2018	N
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1178 11781280	Immune system disorders	Allergy to arthropod sting	01JAN1992		Y
	C4591001 1178 11781281	Psychiatric disorders	Depression	01JAN2002		Y
	C4591001 1178 11781282	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Nervous system disorders	Migraine	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1178 11781283	Investigations	Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018		Y
			Nerve compression	01JAN2016	31DEC2016	N
		Psychiatric disorders	Depression	01MAY2020		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
			Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sinus congestion	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Spinal operation	01JAN2016	31DEC2016	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781287	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1178 11781289	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
	C4591001 1178 11781292	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
			Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1178 11781293	Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Eye disorders	Visual impairment	01JAN2009	31DEC2010	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1980		Y
			Inguinal hernia	01JAN2000	31DEC2000	N
		Infections and infestations	Diverticulitis	01JAN2009	31DEC2009	N
			Herpes simplex	01JAN1975		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hip arthroplasty	01JAN2011	31DEC2011	N
			Ileectomy	01JAN2009	31DEC2009	N
			Inguinal hernia repair	01JAN2000	31DEC2000	N
			Keratomileusis	01JAN2010	31DEC2010	N
			Thyroidectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1178 11781294	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1996		Y
			Type 2 diabetes mellitus	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Prehypertension	01JAN1996		Y
	C4591001 1178 11781297	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1178 11781299	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1993		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1999		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2016		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1993	31DEC1993	N
			Spinal fusion surgery	01JAN1997	31DEC1997	N
			Vasectomy	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1178 11781302	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
			Staphylococcal infection	01JAN2008	31DEC2008	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2015	31DEC2015	N
		Nervous system disorders	Complex regional pain syndrome	01JAN2015	31DEC2018	N
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Attention deficit hyperactivity disorder	01JAN2008		Y
		Surgical and medical procedures	Incisional drainage	01JAN2008	31DEC2008	N
			Meniscus operation	01JAN2015	31DEC2015	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1178 11781303	Endocrine disorders	Androgen deficiency	01JAN2015		Y
			Hypothyroidism	01APR2020		Y
		Infections and infestations	Bronchitis	01JAN2018		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2018	31DEC2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2012	31DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2012	31DEC2012	N
			Meniscus operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1178 11781304	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1998	31DEC1998	N
			Squamous cell carcinoma	01JAN2005	31DEC2005	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1998	31DEC1998	N
				01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1178 11781305	Gastrointestinal disorders	Abdominal hernia	01JAN2006	31DEC2006	N
			Gastroesophageal reflux disease	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2007	31DEC2007	N
		Immune system disorders	Drug hypersensitivity	01JAN1972		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Reproductive system and breast disorders	Endometriosis	01JAN1986	31DEC1986	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Pruritus	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Hernia repair	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1178 11781306	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1178 11781307	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Cataract	01MAR2020	31MAY2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Upper limb fracture	01JAN1997	31DEC1997	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2001	31DEC2001	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1998		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Cataract operation	01MAR2020	31MAR2020	N
				01MAY2020	31MAY2020	N
			Fracture treatment	01JAN1997	31DEC1997	N
			Meningioma surgery	01JAN2001	31DEC2001	N
	C4591001 1178 11781308	Blood and lymphatic system disorders	Lymphadenopathy	01JAN2015	31DEC2015	N
		Eye disorders	Dry eye	01MAY2016		Y
		Infections and infestations	Appendicitis	01JAN1973	31DEC1973	N
			Tonsillitis	01JAN1981	31DEC1981	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JUL2014	30NOV2016	N
		Psychiatric disorders	Depression	01JUL2014		Y
			Insomnia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1988	31DEC1988	N
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Axillary lymphadenectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Blepharoplasty	01JAN2003	31DEC2003	N
			Mastectomy	01JUL2014	31JUL2014	N
			Rhinoplasty	01JAN1988	31DEC1988	N
			Tonsillectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JUL2013		Y
	C4591001 1178 11781313	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Immune system disorders	Drug hypersensitivity	01JAN1962		Y
				01JAN1976		Y
				01JAN1996		Y
			Seasonal allergy	01JAN2001		Y
		Infections and infestations	Genital herpes simplex	01JAN1980		Y
			Urinary tract infection	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2001		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1178 11781315	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Gastrointestinal disorders	Abdominal pain upper	01JAN2019		Y
			Constipation	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1179 11791001	Musculoskeletal and connective tissue disorders	Osteoarthritis	05JUN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791003	Infections and infestations	Endocarditis	13MAY2010	11SEP2014	N
		Renal and urinary disorders	Renal cyst	04MAR1976		Y
	C4591001 1179 11791004	Endocrine disorders	Thyroid cyst	05MAY2010		Y
		Gastrointestinal disorders	Haemorrhoids	21MAY1990		Y
		Psychiatric disorders	Depression	04FEB2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	14SEP1980		Y
		Vascular disorders	Essential hypertension	08AUG2000		Y
	C4591001 1179 11791005	Infections and infestations	Hepatitis C	05JUN1969	02FEB2017	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	17OCT2016	09SEP2017	N
	C4591001 1179 11791006	Congenital, familial and genetic disorders	Factor V Leiden mutation	(b) (6) 1957		Y
		Gastrointestinal disorders	Pancreatitis	03JUN2013	03JUL2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2006	31DEC2006	N
			Migraine	01JAN2015		Y
		Renal and urinary disorders	Nephrolithiasis	03FEB2016	04JUN2019	N
	C4591001 1179 11791007	Blood and lymphatic system disorders	Thrombocytopenia	10AUG2020	14AUG2020	N
		Hepatobiliary disorders	Hepatic steatosis	01SEP2019		Y
		Investigations	Vitamin B12 decreased	01FEB2020		Y
		Vascular disorders	Hypertension	05AUG2018		Y
	C4591001 1179 11791011	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Psychiatric disorders	Generalised anxiety disorder	01JAN2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791013	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1179 11791015	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1987		Y
		Renal and urinary disorders	Renal cyst	01JAN2019	31DEC2019	N
		Vascular disorders	Arteriosclerosis	01JAN1997		Y
	C4591001 1179 11791016	Ear and labyrinth disorders	Vertigo	01JAN2017	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015	31DEC2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
	C4591001 1179 11791017	Blood and lymphatic system disorders	Polycythaemia	01JAN2018		Y
		Endocrine disorders	Hypogonadism	01JAN2018		Y
			Hypothyroidism	01JAN2000		Y
		Eye disorders	Borderline glaucoma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1179 11791018	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
	C4591001 1179 11791019	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1996		Y
	C4591001 1179 11791020	Vascular disorders	Hypertension	01JAN1990		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1179 11791022	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2020		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1179 11791024	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2006		Y
			Hyperlipidaemia	01JAN2006		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2006	31DEC2006	N
		Vascular disorders	Deep vein thrombosis	01JAN2006	31DEC2006	N
	C4591001 1179 11791025	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1179 11791026	Cardiac disorders	Bradycardia	01JAN1980		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1998		Y
			Female sterilisation	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791029	Immune system disorders	Sarcoidosis	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1179 11791031	Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1179 11791032	Infections and infestations	Cytomegalovirus infection	01JAN1984		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Surgical and medical procedures	Hernia repair	01DEC2019	31DEC2020	N
			Prostatectomy	01JAN2015		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1179 11791034	Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010		Y
	C4591001 1179 11791035	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1179 11791036	Eye disorders	Glaucoma	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1179 11791037	Investigations	Vitamin B12 decreased	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2010	N
		Nervous system disorders	Carotid artery stenosis	01JAN2000		Y
	C4591001 1179 11791038	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN1990	31DEC1994	N
		Nervous system disorders	Carotid artery stenosis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1179 11791039	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	04SEP2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1179 11791040	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2013		Y
		Surgical and medical procedures	Female sterilisation	01JAN2000		Y
	C4591001 1179 11791041	Surgical and medical procedures	Vasectomy	01JAN2000		Y
	C4591001 1179 11791043	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1179 11791044	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1179 11791045	Endocrine disorders	Autoimmune thyroiditis	01JAN1976		Y
		Infections and infestations	Hepatitis C	01JAN2015	31DEC2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01JAN1998	31DEC2004	N
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1179 11791046	Endocrine disorders	Hypothyroidism	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1179 11791047	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1995		Y
	C4591001 1179 11791049	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2019	N
			Squamous cell carcinoma	01JAN2018	31DEC2019	N
		Social circumstances	Postmenopause	01JAN1998		Y
	C4591001 1179 11791051	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1179 11791052	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1179 11791053	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Spinal operation	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1179 11791055	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
	C4591001 1179 11791056	Social circumstances	Postmenopause	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791057	Cardiac disorders	Coronary artery disease	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1179 11791059	Gastrointestinal disorders	Diverticulum	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN1990		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2008		Y
	C4591001 1179 11791060	Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1179 11791062	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1976		Y
			Gout	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Rash	01MAR2020	31DEC2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1179 11791063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
	C4591001 1179 11791065	Infections and infestations	Tinea infection	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018	31DEC2019	N
		Renal and urinary disorders	Hypertonic bladder	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791068	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1179 11791070	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Epilepsy	01JAN2019		Y
	C4591001 1179 11791071	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN1995		Y
	C4591001 1179 11791072	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01FEB2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1179 11791073	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1179 11791074	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1179 11791077	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1179 11791078	Cardiac disorders	Supraventricular tachycardia	01JAN2016		Y
		Psychiatric disorders	Bipolar I disorder	01JAN2015		Y
	C4591001 1179 11791080	Endocrine disorders	Hypothyroidism	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Viral cardiomyopathy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01JAN2019	30JUN2019	N
		Surgical and medical procedures	Hysterectomy	01JUN2019		Y
			Vertebroplasty	01DEC2019	31AUG2020	N
	C4591001 1179 11791084	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1179 11791088	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Transient ischaemic attack	01MAY2020	31MAY2020	N
	C4591001 1179 11791089	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998		Y
	C4591001 1179 11791094	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2018	N
			Coronary artery stent removal	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1179 11791095	Congenital, familial and genetic disorders	Antithrombin III deficiency	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1179 11791096	Infections and infestations	Genital herpes	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1995		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1179 11791102	Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1179 11791103	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1179 11791105	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1179 11791110	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1179 11791111	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2003	31DEC2004	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1179 11791113	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1179 11791116	Cardiac disorders	Cardiac failure congestive	01JAN2004		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018	31DEC2019	N
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2008	31DEC2009	N
	C4591001 1179 11791120	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1179 11791121	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
	C4591001 1179 11791127	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2013	N
	C4591001 1179 11791128	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	01JAN2016	31DEC2017	N
			Meningioma	01JAN2008	31DEC2009	N
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1179 11791129	Metabolism and nutrition disorders	Gout	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1179 11791132	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2010	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1179 11791134	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1179 11791135	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2006	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1179 11791140	Endocrine disorders	Basedow's disease	01JAN2006	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1179 11791141	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2004	31DEC2006	N
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1179 11791142	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1999	31DEC2000	N
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1179 11791155	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
	C4591001 1179 11791157	Social circumstances	Postmenopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1179 11791163	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2008		Y
	C4591001 1179 11791164	Investigations	Blood bilirubin increased	01JAN1967		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
	C4591001 1179 11791168	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1179 11791169	Cardiac disorders	Arrhythmia	01JAN2006		Y
		Ear and labyrinth disorders	Vertigo	01JAN2008		Y
	C4591001 1179 11791171	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1179 11791172	Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1185 11851001	Social circumstances	Celibacy	01JAN2010		Y
		Surgical and medical procedures	Gastric bypass	01JAN2016		Y
	C4591001 1185 11851003	Endocrine disorders	Hypothyroidism	01JAN1980		Y
	C4591001 1185 11851004	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Social circumstances	Menopause	01JAN2005		Y
	C4591001 1185 11851007	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
		Surgical and medical procedures	Vasectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1185 11851016	Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1185 11851027	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1185 11851031	Surgical and medical procedures	Salpingectomy	01JAN2003	31DEC2003	N
	C4591001 1185 11851035	Social circumstances	Celibacy	01OCT2020		Y
	C4591001 1185 11851042	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1185 11851044	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1185 11851046	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Celibacy	01OCT2020		Y
	C4591001 1185 11851047	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2000	01JAN2000	N
	C4591001 1185 11851057	Cardiac disorders	Coronary artery disease	01MAY2008		Y
		Nervous system disorders	Ischaemic stroke	30APR2004	30APR2004	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1185 11851058	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
		Psychiatric disorders	Depression	01JAN1980		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1185 11851061	Surgical and medical procedures	Salpingectomy	01DEC2013	01DEC2013	N
			Thyroidectomy	05DEC2003	05DEC2003	N
	C4591001 1185 11851062	Skin and subcutaneous tissue disorders	Neurodermatitis	(b) (6) 1963		Y
		Social circumstances	Celibacy	01JAN2020		Y
	C4591001 1185 11851065	Surgical and medical procedures	Glaucoma surgery	07JAN2020	07JAN2020	N
	C4591001 1194 11941001	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Immune system disorders	Allergy to animal	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Seasonal allergy	01JAN1985		Y
	C4591001 1194 11941002	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1194 11941006	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2004		Y
		Social circumstances	Ex-tobacco user	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1194 11941007	Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y
		Eye disorders	Conjunctivitis allergic	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2005		Y
			Varicose vein	01JAN2000		Y
	C4591001 1194 11941008	Cardiac disorders	Bundle branch block right	09DEC2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1970		Y
			Osteoarthritis	01JAN2016	15MAY2018	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Vascular disorders	Hypertension	01MAR2017		Y
	C4591001 1194 11941011	Social circumstances	Tobacco user	01JAN1975		Y
	C4591001 1194 11941013	Cardiac disorders	Coronary artery disease	01JAN2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	15JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2011		Y
			Peripheral arterial occlusive disease	01OCT2014		Y
	C4591001 1194 11941015	Infections and infestations	Pneumonia	13JUN2019	28JUN2019	N
	C4591001 1194 11941017	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	22MAR2011		Y
	C4591001 1194 11941018	Cardiac disorders	Atrial fibrillation	01JAN2013	31DEC2019	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2009		Y
		Nervous system disorders	Amnesia	01JAN2016	29FEB2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
			Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1194 11941021	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1194 11941022	Eye disorders	Conjunctivitis allergic	01JAN1971		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971		Y
		Social circumstances	Ex-tobacco user	01JAN1971		Y
		Vascular disorders	Hypertension	01MAR2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1194 11941027	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1991	31DEC1992	N
	C4591001 1194 11941028	Infections and infestations	Chronic sinusitis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2007		Y
		Surgical and medical procedures	Nasal polyps	01JAN2001		Y
	C4591001 1194 11941029	Immune system disorders	Hysterectomy	01JAN1997	31DEC1997	N
		Respiratory, thoracic and mediastinal disorders	Drug hypersensitivity	01JAN1990		Y
	C4591001 1194 11941035	Social circumstances	Nasal polyps	01JAN1995		Y
	C4591001 1194 11941036	Immune system disorders	Postmenopause	01JAN2013		Y
			Allergy to animal	01JAN2000		Y
			Dust allergy	01JAN2000		Y
			Sarcoidosis	01JAN1985		Y
			Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1194 11941037	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1194 11941038	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1194 11941039	Cardiac disorders	Coronary artery disease	01JUN2012		Y
			Myocardial infarction	01JUN2012	30JUN2012	N
		Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 1194 11941040	Cardiac disorders	Sinus bradycardia	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Macular degeneration	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2018	30JUN2018	N
	C4591001 1194 11941042	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1194 11941049	Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Internal fixation of fracture	01JAN1998		Y
	C4591001 1194 11941050	Immune system disorders	Allergy to metals	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1194 11941055	Social circumstances	Postmenopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1194 11941059	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1194 11941060	Eye disorders	Conjunctivitis allergic	01JAN1960		Y
		Vascular disorders	Subclavian artery thrombosis	01JAN2018	30APR2018	N
	C4591001 1194 11941063	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1194 11941064	Cardiac disorders	Coronary artery disease	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1194 11941068	Eye disorders	Conjunctivitis allergic	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2012	31DEC2012	N
	C4591001 1194 11941073†	Vascular disorders	Hypertension	01JAN2009		Y
		Investigations	HIV test positive	01JAN1973		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2009		Y
	C4591001 1194 11941074	Vascular disorders	Hypertension	01JAN2009		Y
		Cardiac disorders	Bundle branch block right	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1194 11941075	Vascular disorders	Peripheral arterial occlusive disease	01JAN2015		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN1989	31DEC1989	N
			Gastroesophageal reflux disease	01JAN1989		Y
		Infections and infestations	Diverticulitis	01MAR2017	31MAR2017	N
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1194 11941076	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012	30JUN2013	N
	C4591001 1194 11941078	Vascular disorders	Hypertension	01JAN2005		Y
		Immune system disorders	Allergy to arthropod sting	01JAN2018		Y
	C4591001 1194 11941079	Social circumstances	Postmenopause	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2018		Y
	C4591001 1194 11941084	Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1194 11941085	General disorders and administration site conditions	Drug intolerance	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1194 11941094	Cardiac disorders	Aortic valve incompetence	01JAN2000		Y
		Endocrine disorders	Hypothyroidism	01SEP2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1998		Y
			Thrombosis	01MAY2017	31MAY2017	N
	C4591001 1194 11941095	Cardiac disorders	Aortic valve incompetence	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	01JAN2006	31DEC2006	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010	31DEC2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1945		Y
			Chronic obstructive pulmonary disease	01JAN2015		Y
		Surgical and medical procedures	Prostatectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1194 11941099	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Surgical and medical procedures	Sterilisation	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1194 11941102	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1195 11951006	Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1195 11951007	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Endometrial hyperplasia	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1195 11951011	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	01JAN1958		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1195 11951012	Immune system disorders	Seasonal allergy	01JAN1998		Y
	C4591001 1195 11951014	Metabolism and nutrition disorders	Hypercholesterolaemia	29OCT2014		Y
		Musculoskeletal and connective tissue disorders	Spinal stenosis	14MAY2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Arteriosclerosis	20JAN2014		Y
	C4591001 1195 11951016	Cardiac disorders	Left ventricular hypertrophy	11SEP2012		Y
		Hepatobiliary disorders	Cholecystitis chronic	11AUG2004		Y
			Cholelithiasis	01JAN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02JAN2008		Y
			Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	28JUL2008		Y
			Osteoarthritis	09JAN2008		Y
			Spinal disorder	01APR2008		Y
		Vascular disorders	Hypertension	17NOV2008		Y
	C4591001 1195 11951025	Cardiac disorders	Ventricular extrasystoles	30NOV2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
			Peripheral arterial occlusive disease	30NOV2018		Y
	C4591001 1195 11951028	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1195 11951031	Immune system disorders	Mite allergy	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1195 11951033	Musculoskeletal and connective tissue disorders	Spinal disorder	03JUL2012		Y
		Nervous system disorders	Migraine	06JAN2000		Y
			Tremor	09JUN2020		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1195 11951034	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
			Spinal disorder	18MAR2004		Y
	C4591001 1195 11951036	Metabolism and nutrition disorders	Hypercholesterolaemia	11NOV2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	04JUL2005		Y
			Periarthritis	14JAN2003		Y
			Spinal disorder	08SEP2004		Y
				15OCT2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1195 11951037	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1195 11951038	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1195 11951044	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Nervous system disorders	Cerebrovascular accident	01MAY2016	31MAY2016	N
			Diabetic neuropathy	01JUL2016		Y
		Psychiatric disorders	Depression	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1195 11951045	Immune system disorders	Seasonal allergy	01JAN2000		Y
	C4591001 1195 11951046	Gastrointestinal disorders	Gastroesophageal reflux disease	16DEC2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	26SEP2019		Y
		Psychiatric disorders	Depression	23APR2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	09OCT2015		Y
	C4591001 1195 11951049	Cardiac disorders	Coronary artery disease	01JAN2016		Y
		Endocrine disorders	Thyroiditis	29APR2003		Y
		Gastrointestinal disorders	Chronic gastritis	03JUN2004		Y
		Metabolism and nutrition disorders	Hyperuricaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	08APR2011		Y
			Intervertebral disc protrusion	01JUL2011		Y
			Osteoporosis	05AUG2015		Y
			Spinal stenosis	25JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	07JUN2013		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	08OCT2010		Y
			Respiratory failure	07OCT2010		Y
		Vascular disorders	Hypertension	07OCT2010		Y
	C4591001 1195 11951050	Metabolism and nutrition disorders	Hyperuricaemia	17OCT2018		Y
			Obesity	24OCT2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	24OCT2018		Y
		Vascular disorders	Hypertension	17OCT2018		Y
			Peripheral arterial occlusive disease	30NOV2012		Y
	C4591001 1195 11951052	Gastrointestinal disorders	Gastroesophageal reflux disease	25JUL2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	25JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30AUG2011		Y
			Spinal disorder	14JUN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	25JAN2011		Y
		Vascular disorders	Hypertension	15JAN2015		Y
	C4591001 1195 11951057	Immune system disorders	Seasonal allergy	04APR2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	31JAN2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	19JAN2012		Y
			Scoliosis	03JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	08JUL2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	19JUL2010		Y
	C4591001 1195 11951058	Endocrine disorders	Goitre	30JUN2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	20AUG2011		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	15APR2010		Y
	C4591001 1195 11951059	Vascular disorders	Hypertension	05MAY2010		Y
		Nervous system disorders	Carpal tunnel syndrome	25MAY2009		Y
	C4591001 1195 11951078	Vascular disorders	Hypertension	07SEP2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	26MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	28AUG2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1195 11951086	Musculoskeletal and connective tissue disorders	Rheumatic disorder	01JAN2005		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
	C4591001 1195 11951087	Vascular disorders	Hypertension	01JAN2014		Y
		Psychiatric disorders	Sleep disorder	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1195 11951088	Vascular disorders	Hypertension	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1195 11951094	Vascular disorders	Hypertension	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	16MAR2017		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hypercholesterolaemia	16MAR2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1195 11951095	Cardiac disorders	Arrhythmia	16JUN2016		Y
			Atrial fibrillation	02APR2020		Y
		Musculoskeletal and connective tissue disorders	Joint range of motion decreased	27AUG2020		Y
		Renal and urinary disorders	Renal failure	22APR2020		Y
		Vascular disorders	Hypertension	10FEB2020		Y
	C4591001 1195 11951096	Endocrine disorders	Hyperthyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	07MAR2018		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Vascular disorders	Hypertension	11JUL2016		Y
	C4591001 1195 11951097	Cardiac disorders	Angina pectoris	11JAN2002	11JAN2002	N
			Coronary artery disease	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	14FEB2007		Y
			Type 2 diabetes mellitus	23OCT2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	06DEC2013		Y
			Intervertebral disc protrusion	30MAR2011		Y
			Osteoarthritis	14MAY2002		Y
		Psychiatric disorders	Anxiety disorder	23DEC2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	12MAY2016		Y
		Vascular disorders	Hypertension	11JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1195 11951102	Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1195 11951103	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1195 11951110	Cardiac disorders	Coronary artery disease	10APR2013		Y
		Endocrine disorders	Goitre	06MAR2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	03APR2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	31JUL2014		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	25JUL2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
			Chronic obstructive pulmonary disease	10JAN2013		Y
			Sleep apnoea syndrome	09JUL2018		Y
	C4591001 1195 11951111	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1195 11951112	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1195 11951121	Cardiac disorders	Bundle branch block left	29JAN2016		Y
		Endocrine disorders	Autoimmune thyroiditis	19APR2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	28NOV2005		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	04APR2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1195 11951122	Ear and labyrinth disorders	Meniere's disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	02FEB2004		Y
			Hyperkalaemia	07JUL2020		Y
			Hyperuricaemia	04MAR2003		Y
			Type 2 diabetes mellitus	24MAR2020		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	02MAR2006		Y
			Osteochondrosis	02MAR2006		Y
			Polymyalgia rheumatica	14MAY2016		Y
			Spinal osteoarthritis	23MAR2010		Y
		Psychiatric disorders	Depression	05JAN2012		Y
		Renal and urinary disorders	Hypertensive nephropathy	14MAY2016		Y
		Vascular disorders	Aortic aneurysm	12NOV2015		Y
			Hypertension	01JUL2009		Y
	C4591001 1195 11951124	Immune system disorders	Food allergy	14MAR2008		Y
			Seasonal allergy	14MAR2008		Y
		Musculoskeletal and connective tissue disorders	Exostosis	07MAY2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	07MAY2008		Y
	C4591001 1195 11951125	Cardiac disorders	Aortic valve incompetence	01JAN2018		Y
			Atrial fibrillation	28JAN2012		Y
			Cardiac failure chronic	10MAY2001		Y
			Mitral valve incompetence	13JUL2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	16FEB2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	26AUG2018		Y
		Infections and infestations	Bronchopulmonary aspergillosis allergic	01APR2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	09JUL2014		Y
			Hyperuricaemia	02AUG2004		Y
		Musculoskeletal and connective tissue disorders	Back pain	26NOV2002		Y
			Foot deformity	12OCT2017		Y
			Intervertebral disc protrusion	01OCT2000		Y
			Osteoarthritis	01JAN1999		Y
			Osteoporosis	26AUG2018		Y
			Spinal osteoarthritis	05OCT2010		Y
				10JUN2002		Y
		Nervous system disorders	Cerebellar infarction	27JUN2014	27JUN2014	N
			Cervicobrachial syndrome	01OCT1998		Y
		Psychiatric disorders	Sleep disorder	29AUG2002		Y
		Renal and urinary disorders	Renal failure	06AUG2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12JUL2012		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01OCT1998		Y
		Vascular disorders	Hypertension	01OCT1998		Y
			Varicose vein	01JAN2001		Y
	C4591001 1195 11951126	Cardiac disorders	Atrial fibrillation	27SEP2018		Y
			Hypertensive heart disease	19OCT2006		Y
			Supraventricular tachycardia	03FEB2004		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	06JUL2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	31OCT2005		Y
			Type 2 diabetes mellitus	16AUG2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	02OCT2012		Y
			Intervertebral disc protrusion	26APR2004		Y
			Osteochondrosis	16MAY2009		Y
			Osteoporosis	13MAY2015		Y
			Spinal osteoarthritis	29MAY2019		Y
		Psychiatric disorders	Depression	15MAR2004		Y
			Sleep disorder	15FEB2013		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	27JUL2018		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Vascular disorders	Hypertension	29JUN2005		Y
	C4591001 1195 11951127	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Gastrointestinal disorders	Chronic gastritis	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	02OCT2019		Y
			Type 2 diabetes mellitus	25NOV2019		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Vascular disorders	Hypertension	02OCT2019		Y
	C4591001 1195 11951128	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1195 11951129	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01AUG2014		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN1962		Y
			Intervertebral disc protrusion	01APR2018		Y
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2019		Y
		Psychiatric disorders	Sleep disorder	01DEC2016		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1195 11951130	Endocrine disorders	Goitre	17JUN2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	17JUN2004		Y
			Type 2 diabetes mellitus	27MAY2004		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	04JAN2005		Y
		Renal and urinary disorders	Chronic kidney disease	07NOV2017		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	12JUL2005		Y
	C4591001 1195 11951131	Gastrointestinal disorders	Gastroesophageal reflux disease	12OCT2015		Y
			Umbilical hernia	30APR2020	11MAY2020	N
		Immune system disorders	Seasonal allergy	01OCT1999		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	24OCT2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	11DEC2017		Y
			Scoliosis	30AUG2018		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01OCT1999		Y
		Social circumstances	Postmenopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01APR2000		Y
	C4591001 1195 11951132	Endocrine disorders	Goitre	01JAN1997		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1195 11951133	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1996		Y
		Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1195 11951143	Social circumstances	Postmenopause	01JAN2007		Y
	C4591001 1195 11951145	Endocrine disorders	Autoimmune thyroiditis	20APR2010		Y
		Infections and infestations	Sinobronchitis	18FEB2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	08JUL2008		Y
		Musculoskeletal and connective tissue disorders	Osteochondrosis	13JUN2019		Y
			Osteopenia	13JUN2019		Y
		Vascular disorders	Hypertension	25APR2008		Y
	C4591001 1195 11951149	Cardiac disorders	Myocardial infarction	01JAN2009	31DEC2009	N
				01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2019		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1195 11951150	Endocrine disorders	Hypothyroidism	15AUG2017		Y
		Gastrointestinal disorders	Diverticulum	21NOV2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	03NOV2004		Y
			Hyperuricaemia	24JUN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	08MAY2014		Y
			Osteoarthritis	29APR2020		Y
				29JUN2016		Y
		Nervous system disorders	Migraine	12JAN2004		Y
		Psychiatric disorders	Depression	03NOV2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	08OCT2007		Y
		Vascular disorders	Hypertension	17MAR2011		Y
	C4591001 1195 11951151	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1195 11951152	Immune system disorders	Mite allergy	01JAN1985		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1982		Y
	C4591001 1195 11951156	Vascular disorders	Thrombosis	01JAN2019	31JAN2019	N
	C4591001 1197 11971002	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1197 11971004	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN1964		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN1976		Y
			Vitamin B12 deficiency	01JAN2014		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Psychiatric disorders	Sleep disorder	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1964		Y
		Surgical and medical procedures	Metabolic surgery	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01SEP2020		Y
	C4591001 1197 11971006	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
	C4591001 1197 11971008	Gastrointestinal disorders	Ileus	02JUN2012	07JUN2012	N
		Hepatobiliary disorders	Hepatic steatosis	30JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	31JUL2009		Y
		Renal and urinary disorders	Renal cyst	30JAN2012		Y
		Vascular disorders	Hypertension	28DEC2009		Y
	C4591001 1197 11971009	Gastrointestinal disorders	Gastroesophageal reflux disease	09FEB2009		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	28MAY2020		Y
			Osteoarthritis	04DEC2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	28NOV2017		Y
		Vascular disorders	Aortic arteriosclerosis	14APR2020		Y
			Varicose vein	15JUL2019		Y
	C4591001 1197 11971010	Metabolism and nutrition disorders	Type 2 diabetes mellitus	14APR2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	04JAN2012		Y
		Vascular disorders	Arteriosclerosis	01JAN2010		Y
			Hypertension	01JAN1994		Y
	C4591001 1197 11971011	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1197 11971012	Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
	C4591001 1197 11971013	Endocrine disorders	Hypothyroidism	25APR2014		Y
	C4591001 1197 11971016	Cardiac disorders	Atrial fibrillation	01SEP2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	23NOV1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	31MAR1994		Y
			Hyperuricaemia	10AUG1995		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1969		Y
		Vascular disorders	Hypertension	20FEB1995		Y
	C4591001 1197 11971021	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Diverticulum	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Nervous system disorders	Carotid arteriosclerosis	01MAR2017		Y
		Surgical and medical procedures	Anticoagulant therapy	01JAN2001		Y
			Varicose vein operation	01JAN2016	31DEC2016	N
		Vascular disorders	Thrombosis	01JAN1985	31DEC2001	N
			Varicose vein	01JAN1985		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971022	Gastrointestinal disorders	Gastritis	10JUL2020		Y
			Large intestine polyp	10JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
	C4591001 1197 11971023	Gastrointestinal disorders	Gastritis	05NOV2012		Y
		Hepatobiliary disorders	Cholelithiasis	03DEC2012	22AUG2013	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	07MAY2019		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	17FEB2020	05MAR2020	N
		Vascular disorders	Aortic arteriosclerosis	10JUN2013		Y
			Hypertension	11MAY1998		Y
	C4591001 1197 11971024	Metabolism and nutrition disorders	Hypercholesterolaemia	22AUG1996		Y
			Hyperuricaemia	22AUG1996		Y
			Obesity	01JAN1993		Y
		Vascular disorders	Arteriosclerosis	10JUL2012		Y
			Hypertension	28MAR1994		Y
	C4591001 1197 11971025	Metabolism and nutrition disorders	Hypercholesterolaemia	08JAN2016		Y
			Type 2 diabetes mellitus	22AUG2013		Y
		Nervous system disorders	Carotid arteriosclerosis	08JAN2016		Y
		Vascular disorders	Aortic arteriosclerosis	08JAN2016		Y
			Hypertension	01JAN2013		Y
	C4591001 1197 11971027	Endocrine disorders	Thyroiditis	18NOV2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2016	31MAY2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Amenorrhoea	01JAN2013		Y
	C4591001 1197 11971030	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
	C4591001 1197 11971033	Gastrointestinal disorders	Diverticulum	01JAN2015		Y
			Gastric ulcer	23SEP2020		Y
			Hiatus hernia	23SEP2020		Y
		Investigations	Lipase increased	06JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	26MAY2015		Y
			Hyperlipidaemia	26MAY2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Paraproteinaemia	01JAN2017		Y
		Nervous system disorders	Carotid arteriosclerosis	01OCT2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	08OCT2019		Y
	C4591001 1197 11971034	Endocrine disorders	Hypothyroidism	01JAN1972		Y
		Gastrointestinal disorders	Oesophagitis	01JAN2005		Y
		Hepatobiliary disorders	Cholelithiasis	22MAY2012		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	05JUL2017		Y
	C4591001 1197 11971036	Gastrointestinal disorders	Diverticulum	20JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01MAY2017		Y
		Vascular disorders	Peripheral arterial occlusive disease	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thrombosis	02SEP2020		Y
	C4591001 1197 11971037	Endocrine disorders	Androgen deficiency	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1197 11971038	Hepatobiliary disorders	Hepatic steatosis	15APR1994		Y
		Metabolism and nutrition disorders	Hyperuricaemia	04SEP2001		Y
			Obesity	08NOV1994		Y
			Type 2 diabetes mellitus	08OCT1999		Y
		Musculoskeletal and connective tissue disorders	Spinal disorder	30MAR2016		Y
				31OCT1996		Y
		Renal and urinary disorders	Renal failure	04SEP2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	28FEB2009		Y
			Erectile dysfunction	24JUN2009		Y
		Vascular disorders	Hypertension	06MAY1996		Y
	C4591001 1197 11971043	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JUN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Nervous system disorders	Carotid artery stenosis	21SEP2020		Y
		Vascular disorders	Hypertension	28APR2018		Y
	C4591001 1197 11971044	Cardiac disorders	Coronary artery disease	01MAY2015		Y
		Hepatobiliary disorders	Hepatic cyst	19MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018		Y
		Nervous system disorders	Carotid arteriosclerosis	23SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Sleep disorder	01JAN2000		Y
		Vascular disorders	Hypertension	29SEP2020		Y
	C4591001 1197 11971046	Gastrointestinal disorders	Oesophagitis	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	03JUL2018		Y
		Vascular disorders	Hypertension	16AUG2011		Y
	C4591001 1197 11971047	Renal and urinary disorders	Renal failure	11OCT2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	09DEC2013		Y
		Surgical and medical procedures	Nephrectomy	01JAN2005		Y
		Vascular disorders	Aortic aneurysm	01JAN2018		Y
			Arteriosclerosis	01JAN2005		Y
			Hypertension	01JAN1985		Y
	C4591001 1197 11971048	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2000		Y
	C4591001 1197 11971049	Endocrine disorders	Goitre	01JUL2013		Y
		Gastrointestinal disorders	Diverticulum	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	15AUG2017		Y
	C4591001 1197 11971050	Gastrointestinal disorders	Chronic gastritis	05DEC2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05OCT2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2005		Y
		Renal and urinary disorders	Renal failure	20FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	14JUL2015		Y
	C4591001 1197 11971051	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
			Emphysema	01JAN2019		Y
	C4591001 1197 11971052	Vascular disorders Metabolism and nutrition disorders	Hypertension Hypercholesterolaemia	01JAN2005 19NOV2014		Y Y
		Nervous system disorders	Cerebral microangiopathy	16MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	16MAR2018		Y
	C4591001 1197 11971054	Metabolism and nutrition disorders	Hypercholesterolaemia	07MAR1994		Y
		Renal and urinary disorders	Renal cyst	26NOV2019		Y
		Vascular disorders	Aortic arteriosclerosis	07DEC2017		Y
	C4591001 1197 11971055	Vascular disorders	Varicose vein	01JAN2007		Y
	C4591001 1197 11971056	Cardiac disorders	Cardiac failure chronic	20NOV2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	07MAR2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	31OCT2016		Y
		Vascular disorders	Hypertension	06MAR2006		Y
	C4591001 1197 11971057	Metabolism and nutrition disorders	Hypercholesterolaemia	11NOV2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1995		Y
	C4591001 1197 11971061	Eye disorders	Glaucoma	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971062	Gastrointestinal disorders	Oesophagitis	27APR2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	22MAR2011		Y
		Vascular disorders	Hypertension	09MAY2009		Y
	C4591001 1197 11971063	Endocrine disorders	Hypothyroidism	01JAN1976		Y
		Injury, poisoning and procedural complications	Meniscus injury	19JUN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	21MAY2012		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1197 11971065	Eye disorders	Glaucoma	10JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01FEB2018		Y
		Surgical and medical procedures	Glaucoma surgery	01JAN2018	31DEC2018	N
			Meniscus removal	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1197 11971066	Infections and infestations	Diverticulitis	08AUG2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	26MAY1994		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12NOV2015		Y
		Vascular disorders	Aortic arteriosclerosis	12NOV2015		Y
	C4591001 1197 11971067	Musculoskeletal and connective tissue disorders	Back pain	01JAN2008		Y
	C4591001 1197 11971070	Gastrointestinal disorders	Oesophagitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	08NOV2012		Y
			Type 2 diabetes mellitus	01JAN2004		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Back pain	09JAN2013		Y
			Osteoarthritis	04APR2011	06JAN2012	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	26MAY2016		Y
		Surgical and medical procedures	Cataract operation	01DEC2018	31DEC2018	N
				01JAN2017	22NOV2017	N
			Oophorectomy bilateral	01JAN2018		Y
		Vascular disorders	Essential hypertension	06JAN2012		Y
	C4591001 1197 11971071	Gastrointestinal disorders	Oesophagitis	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21JUN2018		Y
		Vascular disorders	Aortic aneurysm	04NOV2011		Y
			Hypertension	10FEB2012		Y
	C4591001 1197 11971072	Metabolism and nutrition disorders	Fructose intolerance	05OCT2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	02MAY2018	19JUN2018	N
		Vascular disorders	Aortic arteriosclerosis	22DEC2017		Y
			Hypertension	27JUL1998		Y
	C4591001 1197 11971073	Metabolism and nutrition disorders	Hypercholesterolaemia	14NOV2006		Y
		Nervous system disorders	Carotid arteriosclerosis	11DEC2016		Y
		Vascular disorders	Aortic arteriosclerosis	11DEC2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971074	Metabolism and nutrition disorders	Hypercholesterolaemia	17JAN1994		Y
		Skin and subcutaneous tissue disorders	Nail dystrophy	01OCT2018		Y
		Vascular disorders	Hypertension	25APR1994		Y
	C4591001 1197 11971075	Metabolism and nutrition disorders	Hyperuricaemia	05MAY1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	25MAR2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	25JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Vascular disorders	Hypertension	17DEC2012		Y
	C4591001 1197 11971076	Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostatic adenoma	01JAN2012		Y
		Renal and urinary disorders	Renal cyst	01JAN2001		Y
		Surgical and medical procedures	Vasectomy	01JAN2004		Y
	C4591001 1197 11971080	Gastrointestinal disorders	Constipation	12SEP1993		Y
		Nervous system disorders	Migraine	01JAN1976		Y
			Paraplegia	19OCT1993		Y
			Polyneuropathy	12SEP1993		Y
		Renal and urinary disorders	Incontinence	12SEP1993		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1197 11971081	Congenital, familial and genetic disorders	Developmental hip dysplasia	01JAN2001		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1994		Y
		Vascular disorders	Hypertension	09DEC2013		Y
	C4591001 1197 11971082	Cardiac disorders	Coronary artery disease	16JAN2015		Y
		Hepatobiliary disorders	Hepatic steatosis	18MAY2004		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	16JAN2015		Y
			Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Periarthritis	09JUL2020		Y
		Vascular disorders	Aortic arteriosclerosis	12FEB2019		Y
			Hypertension	11AUG2003		Y
	C4591001 1197 11971083	Gastrointestinal disorders	Gastritis	20JUN2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	14APR1994		Y
		Vascular disorders	Hypertension	10MAY1994		Y
	C4591001 1197 11971084	Musculoskeletal and connective tissue disorders	Spinal disorder	01JAN2001		Y
		Nervous system disorders	Carotid arteriosclerosis	16APR2015		Y
			Cerebrovascular accident	22FEB2018	22FEB2018	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1197 11971085	Endocrine disorders	Basedow's disease	01JAN1993		Y
		Gastrointestinal disorders	Oesophagitis	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
	C4591001 1197 11971086	Eye disorders	Cataract	22NOV2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Hepatic cyst	20MAY2016		Y
			Hepatic steatosis	07AUG2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12AUG2016		Y
			Type 2 diabetes mellitus	12AUG2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2015		Y
		Renal and urinary disorders	Renal failure	12AUG2016		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1197 11971087	Cardiac disorders	Coronary artery disease	01JAN2001		Y
			Ventricular fibrillation	02NOV2018	02NOV2018	N
		Eye disorders	Glaucoma	01SEP2012		Y
			Visual impairment	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01OCT2020		Y
		Nervous system disorders	Cerebrovascular accident	18JAN2018	18JAN2018	N
			Polyneuropathy	01JAN2018		Y
		Renal and urinary disorders	Renal failure	27FEB2018		Y
		Surgical and medical procedures	Implantable defibrillator insertion	06NOV2018	06NOV2018	N
		Vascular disorders	Hypertension	01SEP2012		Y
	C4591001 1197 11971089	Cardiac disorders	Atrial fibrillation	01JAN2016		Y
		Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN1978		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostatic adenoma	01JUN2014		Y
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1197 11971090	Cardiac disorders	Cardiac failure	16OCT2016		Y
		Endocrine disorders	Goitre	06APR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Eye disorders	Glaucoma	16OCT2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	10MAR2011		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	24JAN2017		Y
			Type 2 diabetes mellitus	01AUG2005		Y
		Nervous system disorders	Carotid arteriosclerosis	23AUG2005		Y
		Renal and urinary disorders	Renal failure	15NOV2006		Y
		Vascular disorders	Hypertension	28SEP1997		Y
	C4591001 1197 11971091	Endocrine disorders	Goitre	01JAN2003		Y
		Eye disorders	Glaucoma	01JAN2013		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2000		Y
			Hiatus hernia	01JAN2000		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2017		Y
			Vitamin D deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JUL2020		Y
		Vascular disorders	Varicose vein	01JAN2008		Y
	C4591001 1197 11971097	Blood and lymphatic system disorders	Anaemia	09OCT2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	08JAN2020		Y
			Hyperuricaemia	08JAN1998		Y
			Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	22MAR2017		Y
		Renal and urinary disorders	Renal failure	26SEP2010		Y
		Vascular disorders	Hypertension	10SEP2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1197 11971098	Hepatobiliary disorders	Hepatic steatosis	01JAN2006		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Vascular disorders	Type 2 diabetes mellitus	01JAN1994		Y
	C4591001 1197 11971099	Gastrointestinal disorders	Hypertension	01JAN1994		Y
		Gastrointestinal disorders	Irritable bowel syndrome	21MAY2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	21JAN2017		Y
		Vascular disorders	Hypertension	21FEB2019		Y
	C4591001 1197 11971100	Gastrointestinal disorders	Oesophagitis	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1197 11971101	Gastrointestinal disorders	Chronic gastritis	01JAN1990		Y
			Diverticulum	01JAN2013		Y
			Hiatus hernia	01JAN1990		Y
		Metabolism and nutrition disorders	Obesity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Nervous system disorders	Carotid arteriosclerosis	01JAN2015		Y
		Vascular disorders	Aortic aneurysm	01JAN2018		Y
			Hypertension	01JAN2000		Y
	C4591001 1202 12021001	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1202 12021002	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2004		Y
	C4591001 1202 12021003	Eye disorders	Glaucoma	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1202 12021004	Cardiac disorders	Bundle branch block left	01JAN2011		Y
			Congestive cardiomyopathy	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1202 12021006	Ear and labyrinth disorders	Vertigo	14OCT2020		Y
	C4591001 1202 12021008	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1202 12021012	Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
	C4591001 1203 12031002	Immune system disorders	Seasonal allergy	01JAN1968		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
			Rhinitis allergic	01JAN1968		Y
		Social circumstances	Menopause	01JAN2005	31DEC2005	N
	C4591001 1203 12031003	Nervous system disorders	Dizziness	01JAN1970		Y
		Surgical and medical procedures	Adenoidectomy	01JAN1951	31DEC1951	N
			Hysterectomy	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1203 12031006	Injury, poisoning and procedural complications	Ankle fracture	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Stillbirth	01JAN1973	31DEC1973	N
		Social circumstances	Aborted pregnancy	01JAN1998	31DEC1998	N
			Menopause	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Caesarean section	01JAN1975	31DEC1975	N
			Umbilical hernia repair	01JAN1956	31DEC1956	N
	C4591001 1203 12031007	Social circumstances	Menopause	01JAN2006	31DEC2006	N
	C4591001 1203 12031009	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2019	N
	C4591001 1203 12031011	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2000		Y
		Social circumstances	Menopause	01JUN2006	30JUN2006	N
	C4591001 1203 12031012	Social circumstances	Menopause	01JAN1994	31DEC1994	N
		Surgical and medical procedures	Fracture treatment	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2007	31DEC2007	N
				01JAN2017	31DEC2017	N
			Nasal septal operation	01JAN1970	31DEC1970	N
			Ovarian cystectomy	01JAN1991	31DEC1991	N
			Tenoplasty	01JAN2016	31DEC2016	N
	C4591001 1203 12031013	Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Eye disorders	Glaucoma	01JAN2014		Y
		Social circumstances	Menopause	01JAN2004	31DEC2004	N
	C4591001 1203 12031014	Gastrointestinal disorders	Diverticulum	01JAN2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Herpes zoster	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Social circumstances	Menopause	01JAN1994	31DEC1994	N
	C4591001 1203 12031016	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Social circumstances	Menopause	01JAN1989	31DEC1989	N
	C4591001 1203 12031018	Infections and infestations	Hepatitis A	01JAN1978	31DEC1978	N
			Pneumonia	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
			Skin neoplasm excision	01JAN1998	31DEC2010	N
	C4591001 1203 12031022	Vascular disorders	Varicose vein	01JAN1992		Y
	C4591001 1203 12031025	Immune system disorders	Allergy to animal	(b) (6) 1958		Y
			Drug hypersensitivity	01JAN1991		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2010		Y
		Social circumstances	Menopause	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Hysterectomy	01JAN2005	31DEC2005	N
	C4591001 1203 12031027	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Social circumstances	Menopause	01JAN2010	31DEC2010	N
		Vascular disorders	Essential hypertension	01JAN1995		Y
	C4591001 1203 12031029	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN1975	31DEC1975	N
		Surgical and medical procedures	Cholecystectomy	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Essential hypertension	01JAN2005		Y
	C4591001 1203 12031038	Renal and urinary disorders	Nocturia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
	C4591001 1203 12031039	Injury, poisoning and procedural complications	Abdominal injury	01JAN1984	31DEC1984	N
			Chest injury	01JAN1984	31DEC1984	N
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Adjustment disorder with depressed mood	01JAN2016	31DEC2018	N
		Social circumstances	Menopause	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1203 12031040	Social circumstances	Menopause	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
		Vascular disorders	Varicose vein	01JAN2001		Y
	C4591001 1203 12031043	Social circumstances	Menopause	01JAN1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1203 12031050	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1203 12031054	Cardiac disorders	Myocardial infarction	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Coronary arterial stent insertion	15JAN2020	15JAN2020	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1203 12031055	Social circumstances	Menopause	01JAN1999	31DEC1999	N
		Vascular disorders	Essential hypertension	01JAN2017		Y
			Varicose vein	01JAN2005		Y
	C4591001 1203 12031061	Immune system disorders	Mite allergy	01JAN2005		Y
		Surgical and medical procedures	Nasal septal operation	01JAN2010	31DEC2010	N
	C4591001 1204 12041002	Cardiac disorders	Atrial fibrillation	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1204 12041003	Metabolism and nutrition disorders	Vitamin D deficiency	16AUG2010		Y
	C4591001 1204 12041007	Musculoskeletal and connective tissue disorders	Trigger finger	25JUN2020		Y
	C4591001 1204 12041014	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	01JAN2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1938		Y
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1204 12041016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Bladder operation	01JAN2000	31DEC2000	N
			Foot operation	25AUG2017	25AUG2017	N
			Rotator cuff repair	25APR2020	25APR2020	N
		Vascular disorders	Hypertension	25AUG2017		Y
	C4591001 1204 12041022	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041024	General disorders and administration site conditions	Oedema peripheral	01JAN1980		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN1990	31DEC1990	N
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1990		Y
		Surgical and medical procedures	Ligament operation	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1204 12041028	Ear and labyrinth disorders	Meniere's disease	01SEP2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Muscle strain	01FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01SEP2017		Y
	C4591001 1204 12041032	Metabolism and nutrition disorders	Hyperlipidaemia	03SEP2010		Y
	C4591001 1204 12041035	Investigations	Laparoscopy	01JAN1982	31DEC1982	N
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01FEB2018		Y
	C4591001 1204 12041036	Surgical and medical procedures	Spinal laminectomy	01DEC2019	31DEC2019	N
	C4591001 1204 12041037	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1204 12041042	Immune system disorders	Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN1976	31DEC1979	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016	31MAY2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2011	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2010	31DEC2010	N
			Hip arthroplasty	01JAN2016	31DEC2016	N
			Knee operation	01JAN1979	31DEC1979	N
	C4591001 1204 12041050	Investigations	Blood cholesterol increased	01JAN2000		Y
		Surgical and medical procedures	Debridement	01JAN2018	31DEC2018	N
			Spinal laminectomy	01JAN1993	31DEC1993	N
	C4591001 1204 12041053	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	11NOV2011	11NOV2013	N
		Social circumstances	Postmenopause	11NOV2011		Y
	C4591001 1204 12041054	Congenital, familial and genetic disorders	Thalassaemia	01FEB2017		Y
		Immune system disorders	Seasonal allergy	01JAN2016		Y
		Vascular disorders	Hypertension	01FEB2017		Y
	C4591001 1204 12041056	Cardiac disorders	Coronary artery disease	08SEP2001		Y
		Investigations	Blood cholesterol increased	08SEP2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tonsil cancer	08SEP2015	20MAY2016	N
		Vascular disorders	Hypertension	08SEP2008		Y
	C4591001 1204 12041057	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2007	31DEC2007	N
			Knee operation	01JAN2017	31DEC2017	N
			Open reduction of fracture	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1204 12041068	Cardiac disorders	Acute myocardial infarction	01JAN2020	06JAN2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	09DEC2010	09JAN2011	N
		Social circumstances	Postmenopause	09SEP2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
			Metabolic surgery	01JAN2017	31DEC2017	N
			Thrombectomy	01JAN2010	31DEC2010	N
			Hyperlipidaemia	01JAN2005		Y
	C4591001 1204 12041069	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Internal fixation of fracture	01FEB2000	29FEB2000	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1204 12041083	Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
	C4591001 1204 12041087	Endocrine disorders	Goitre	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Nervous system disorders	Migraine	01JAN1968		Y
		Social circumstances	Postmenopause	10SEP2010		Y
		Surgical and medical procedures	Caesarean section	01JUL1999	01JUL1999	N
			Intervertebral disc operation	01JAN2012	31DEC2012	N
	C4591001 1204 12041104	Infections and infestations	Pilonidal cyst	01JAN1979	31DEC1979	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	15SEP2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1977	31DEC1977	N
			Meniscus operation	01JAN2011	31DEC2011	N
				01JAN2017	31DEC2017	N
			Sinus operation	01JUN2020	31DEC2020	N
			Varicocele repair	01JAN2009	31DEC2009	N
			Biopsy breast	01JAN2010	31DEC2010	N
	C4591001 1204 12041106	Investigations				
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Social circumstances	Postmenopause	15SEP2007		Y
	C4591001 1204 12041109	Gastrointestinal disorders	Gastrooesophageal reflux disease	16SEP2012		Y
		Nervous system disorders	Morton's neuralgia	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	16SEP2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Ovarian cystectomy	01JAN1981	31DEC1981	N
	C4591001 1204 12041115	Metabolism and nutrition disorders	Gout	01JAN2007		Y
			Hypercholesterolaemia	01JAN1999		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1953	31DEC1953	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1204 12041117	Metabolism and nutrition disorders	Hypercholesterolaemia	17SEP2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	17MAY2009	03JUN2009	N
		Social circumstances	Postmenopause	17SEP2009		Y
		Surgical and medical procedures	Mastectomy	01JAN2009	31DEC2009	N
			Ventricular septal defect repair	01JAN2018	31DEC2018	N
	C4591001 1204 12041119	Surgical and medical procedures	Bunion operation	01JAN2008	31DEC2008	N
			Tenoplasty	01JAN1997	31DEC1997	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041126	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	04SEP2020		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	18SEP1987		Y
		Social circumstances	Postmenopause	18SEP2015		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1977	31DEC1977	N
	C4591001 1204 12041130	Surgical and medical procedures	Abdominal hernia repair	01JAN2010	31DEC2010	N
	C4591001 1204 12041142	Immune system disorders	Food allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1954	31DEC1954	N
			Hysterectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1204 12041146	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Social circumstances	Postmenopause	23SEP2003		Y
		Surgical and medical procedures	Bunion operation	01JAN2005	31DEC2005	N
			Caesarean section	01JAN1997	31DEC1997	N
			Cardiac ablation	01JAN2010	31DEC2018	N
				01JAN2018	31DEC2018	N
			Face lift	01JAN1996	31DEC1996	N
				01JAN2008	31DEC2008	N
				01JAN2018	31DEC2018	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Limb operation	01JAN2014	31DEC2014	N
				01MAR2019	31MAR2019	N
				01MAY2020	31MAY2020	N
			Open reduction of fracture	01JAN2017	31DEC2017	N
	C4591001 1204 12041151	Psychiatric disorders	Anxiety	01JAN2012		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01JAN2017	31DEC2017	N
			Retinopexy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1204 12041159	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Social circumstances	Postmenopause	24SEP1993		Y
		Surgical and medical procedures	Caesarean section	01JAN1966	31DEC1966	N
				01JAN1968	31DEC1968	N
				01JAN1973	31DEC1973	N
			Lipectomy	01JAN1993	31DEC1993	N
			Ovarian cystectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1204 12041162†	Gastrointestinal disorders	Inguinal hernia	01JAN2000	31DEC2000	N
		Investigations	HIV test positive	24SEP2004		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Knee operation	01JAN2011	31DEC2011	N
				01JAN2014	31DEC2014	N
	C4591001 1204 12041169	Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041171	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	15JUL2020		Y
	C4591001 1204 12041172†	Cardiac disorders	Cardiac failure congestive	01JAN2018		Y
		Investigations	HIV test positive	01JAN1998		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN1996		Y
		Surgical and medical procedures	Foot operation	01AUG2020	31AUG2020	N
				01SEP2020	30SEP2020	N
			Toe amputation	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1204 12041173†	Investigations	HIV test positive	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	28SEP2015		Y
		Vascular disorders	Hypertension	28SEP2018		Y
	C4591001 1204 12041175	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1966	31DEC1966	N
	C4591001 1204 12041196	Endocrine disorders	Hypothyroidism	01JAN1987		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1204 12041198	Surgical and medical procedures	Hernia repair	01JAN1964	31DEC1964	N
	C4591001 1204 12041200†	Investigations	Blood triglycerides increased	01JAN1994		Y
			HIV test positive	01JAN1994		Y
		Nervous system disorders	Sciatica	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1988		Y
			Depression	01JAN1988		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1204 12041201	Musculoskeletal and connective tissue disorders	Osteoporosis	01MAR2019		Y
		Surgical and medical procedures	Fracture treatment	01JAN2011	31DEC2011	N
			Knee operation	01JAN2011	31DEC2011	N
			Renal stone removal	01NOV2019	30NOV2019	N
			Tenoplasty	01JAN1997	31DEC1997	N
	C4591001 1204 12041211	Infections and infestations	Pilonidal cyst	01JAN2002	31DEC2002	N
		Reproductive system and breast disorders	Breast cyst	01JAN2002	31DEC2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Social circumstances	Postmenopause	15JUN2017		Y
		Surgical and medical procedures	Bunion operation	01JAN2006	31DEC2006	N
			Keratomileusis	01JAN2000	31DEC2000	N
			Mammoplasty	01JAN2002	31DEC2002	N
	C4591001 1204 12041212	Cardiac disorders	Atrial flutter	03AUG2020		Y
			Cardiac amyloidosis	01JAN2005	31DEC2006	N
		Gastrointestinal disorders	Diverticulum	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1204 12041213	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN2015	31DEC2015	N
			Rotator cuff repair	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1204 12041219	Social circumstances	Postmenopause	25JUN2005		Y
	C4591001 1204 12041223	Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Urticaria	01AUG2018		Y
		Surgical and medical procedures	Fracture treatment	01JAN2008	31DEC2008	N
	C4591001 1204 12041224	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Nervous system disorders	Carotid artery disease	01JAN2016		Y
		Surgical and medical procedures	Appendicectomy	15MAY1958	15MAY1958	N
			Radical prostatectomy	01JAN2016	31DEC2016	N
			Skin neoplasm excision	15JUN2018	15JUN2018	N
	C4591001 1204 12041225	Injury, poisoning and procedural complications	Meniscus injury	01JAN1985	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Knee operation	01JAN1990	31DEC1990	N
			Shoulder operation	01JAN2000	31DEC2000	N
	C4591001 1204 12041226	Social circumstances	Postmenopause	15JUN2011		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	01JAN2019	N
	C4591001 1204 12041229	Infections and infestations	Ear infection	01JAN1967	31DEC1967	N
		Reproductive system and breast disorders	Breast calcifications	14DEC2018	31JAN2019	N
		Social circumstances	Postmenopause	01OCT2018		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2019	31JAN2019	N
			Tonsillectomy	01JAN1967	31DEC1967	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1204 12041230	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma	01JAN1986	31DEC1986	N
			Prostate cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Arterial therapeutic procedure	01JAN1986	31DEC1986	N
			Prostatic operation	01JAN2005	31DEC2005	N
	C4591001 1204 12041231	Ear and labyrinth disorders	Sudden hearing loss	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Rheumatic fever	01JAN1972	31DEC1972	N
		Reproductive system and breast disorders	Ovarian cyst	01JAN1981	31DEC1981	N
		Social circumstances	Postmenopause	15JUN2013		Y
		Surgical and medical procedures	Oophorectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1204 12041244	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2014	31DEC2014	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	15OCT2006		Y
		Social circumstances	Postmenopause	15OCT2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
				01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01SEP2020		Y
	C4591001 1204 12041245	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Seasonal affective disorder	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Surgical and medical procedures	Hip arthroplasty	01AUG2011	31AUG2011	N
				01AUG2016	31AUG2016	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1204 12041249	Injury, poisoning and procedural complications	Back injury	01JAN1982	31DEC2010	N
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Intervertebral disc operation	01JAN2010	31DEC2010	N
	C4591001 1204 12041250	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JAN2010	31DEC2010	N
		Social circumstances	Postmenopause	30JUN2015		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2010	31DEC2010	N
	C4591001 1204 12041251	Injury, poisoning and procedural complications	Ankle fracture	01JAN1990	31DEC1990	N
			Femur fracture	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Bone operation	01JAN1990	31DEC1990	N
	C4591001 1204 12041254	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Diverticulitis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2002	N
				01JAN2009	31DEC2009	N
			Renal cell carcinoma	01JAN1998	31DEC1998	N
		Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1974	31DEC2010	N
		Social circumstances	Postmenopause	30JUN2002		Y
		Surgical and medical procedures	Colectomy	01JAN2011	31DEC2011	N
			Mole excision	01JAN2002	31DEC2002	N
				01JAN2009	31DEC2009	N
			Nephrectomy	01JAN1998	31DEC1998	N
	C4591001 1204 12041266	Cardiac disorders	Atrial fibrillation	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Cardiac ablation	01JAN2013	31DEC2013	N
	C4591001 1204 12041282	Cardiac disorders	Coronary artery disease	01JAN2001	31DEC2001	N
			Myocardial infarction	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Inguinal hernia	01JAN2006	31DEC2006	N
		Investigations	Blood cholesterol increased	01JAN2001		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2001	31DEC2001	N
			Hernia repair	01JAN2006	31DEC2006	N
			Hip arthroplasty	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1204 12041289	Cardiac disorders	Mitral valve incompetence	01JAN2013	31DEC2013	N
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Mitral valve repair	01JAN2013	31DEC2013	N
	C4591001 1204 12041291	Infections and infestations	Appendicitis	01APR1975	02APR1975	N
		Social circumstances	Postmenopause	01MAR2010		Y
		Surgical and medical procedures	Appendicectomy	02APR1975	02APR1975	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1205 12051001	Metabolism and nutrition disorders	Hyperlipidaemia	09MAR2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	11FEB2013		Y
		Vascular disorders	Hypertension	20JUL2016		Y
	C4591001 1205 12051002	Metabolism and nutrition disorders	Hyperlipidaemia	10FEB2009		Y
		Surgical and medical procedures	Open reduction of fracture	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1205 12051005	Investigations	Gamma-glutamyltransferase abnormal	01JAN2010		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	01JAN2012	N
	C4591001 1205 12051006	Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1205 12051007	Surgical and medical procedures	Appendicectomy	01JAN2014	01JAN2014	N
			Urethral operation	01JAN2019	01JAN2019	N
	C4591001 1205 12051008	Surgical and medical procedures	Thyroidectomy	01JAN2013	01JAN2013	N
	C4591001 1205 12051009	Cardiac disorders	Arteriosclerosis coronary artery	01JAN1983		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Surgical and medical procedures	Sinus operation	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1205 12051018	Cardiac disorders	Coronary artery disease	01JAN2000		Y
			Myocardial infarction	01JAN2000	31DEC2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hyperthyroidism	01JAN2004		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN1990		Y
	C4591001 1205 12051019	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1205 12051020	Surgical and medical procedures	Abdominal hernia repair	01JAN2017	31DEC2017	N
			Caesarean section	01JAN1982	31DEC1982	N
				01JAN1983	31DEC1983	N
			Thyroid cystectomy	01JAN1970	31DEC1970	N
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1205 12051031	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1205 12051037	Cardiac disorders	Coronary artery disease	01AUG2015		Y
			Myocardial infarction	01AUG2015	31AUG2015	N
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2015	31AUG2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1205 12051038	Social circumstances	Menopause	01JAN2003		Y
	C4591001 1205 12051039	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1205 12051045	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	01JAN2012		Y
	C4591001 1205 12051046	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	01JAN2010	31DEC2010	N
			Vascular stent insertion	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1205 12051053	Social circumstances	Menopause	01JAN2009		Y
	C4591001 1205 12051055	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2002	31DEC2002	N
	C4591001 1205 12051056	Cardiac disorders	Coronary artery disease	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1205 12051057	Cardiac disorders	Coronary artery disease	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1205 12051058	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	01JAN2015	N
	C4591001 1205 12051059	Social circumstances	Menopause	01JAN2013		Y
	C4591001 1205 12051070	Psychiatric disorders	Anxiety disorder	01JAN2015		Y
	C4591001 1205 12051072	Cardiac disorders	Tachycardia	01JAN2015		Y
		Social circumstances	Menopause	01JAN1984		Y
	C4591001 1205 12051076	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1207 12071001	Gastrointestinal disorders	Gastritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1207 12071004	Vascular disorders	Hypertension	12OCT2019		Y
	C4591001 1207 12071017	Endocrine disorders	Hypothyroidism	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1207 12071019	Surgical and medical procedures	Coronary arterial stent insertion	01JAN2010		Y
	C4591001 1207 12071020	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1207 12071022	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Hypertriglyceridaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1207 12071029	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1207 12071030	Endocrine disorders	Autoimmune thyroiditis	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1207 12071031	Surgical and medical procedures	Coronary arterial stent insertion	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1207 12071034	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2017		Y
	C4591001 1207 12071043	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1207 12071055	Hepatobiliary disorders	Hepatic cirrhosis	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2005	31DEC2005	N
	C4591001 1207 12071056	Investigations	Blood cholesterol increased	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1207 12071063	Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1207 12071068	Cardiac disorders	Arrhythmia	06NOV2015		Y
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1207 12071069	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1208 12081006	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1208 12081014	Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1995		Y
	C4591001 1208 12081015	Cardiac disorders	Atrial fibrillation	01JAN2019		Y
		Endocrine disorders	Hyperthyroidism	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1208 12081036	Metabolism and nutrition disorders	Insulin resistance	01MAY2019		Y
	C4591001 1208 12081041	Investigations	Blood cholesterol increased	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1208 12081055	Gastrointestinal disorders	Colitis ulcerative	01JAN2005	31DEC2005	N
	C4591001 1209 12091005	Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1209 12091012	Endocrine disorders	Hypothyroidism	01JAN1995		Y
	C4591001 1210 12101003	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1210 12101004	Investigations	Blood cholesterol increased	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1210 12101043	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1210 12101044	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1210 12101062	Infections and infestations	Pyelonephritis	01JAN1980	31DEC1980	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Surgical and medical procedures	Nephrectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1212 12121021†	Investigations	HIV test positive	01FEB2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
	C4591001 1212 12121030	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1212 12121033	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1213 12131007	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2000		Y
			Hypercholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Prostatectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1213 12131009	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1989	31DEC1989	N
			Meniscus operation	01JAN1997	31DEC1997	N
	C4591001 1213 12131017	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
	C4591001 1213 12131020	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1213 12131022	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1213 12131027	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1213 12131029	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1213 12131030	Nervous system disorders	Migraine	01JAN2012		Y
	C4591001 1213 12131049	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1213 12131058	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1214 12141002	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Injury, poisoning and procedural complications	Decompression sickness	01JAN2006	31DEC2006	N
		Nervous system disorders	Paraparesis	01JAN2006		Y
		Surgical and medical procedures	Gastric operation	01JAN2000	31DEC2000	N
	C4591001 1214 12141003	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1214 12141006	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1214 12141010	Metabolism and nutrition disorders	Metabolic syndrome	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1214 12141011	Cardiac disorders	Atrial fibrillation	01JAN2020		Y
		Psychiatric disorders	Insomnia	01JAN2006		Y
		Surgical and medical procedures	Aneurysm repair	01JAN2005	31DEC2005	N
			Appendicectomy	01JAN1982	31DEC1982	N
			Inguinal hernia repair	01JAN1979	31DEC1979	N
			Intervertebral disc operation	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1214 12141026	Cardiac disorders	Sinus tachycardia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1214 12141028	Cardiac disorders	Myocardial infarction	01JAN2003	31DEC2003	N
		Metabolism and nutrition disorders	Gout	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1214 12141032	Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1214 12141033	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN2018	31DEC2018	N
	C4591001 1214 12141035	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1214 12141046	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1214 12141050	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Embolic arterial	07NOV2020	07NOV2020	N
			Hypertension	01JAN2002		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1217 12171004	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1217 12171006	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1217 12171007	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1217 12171024	Psychiatric disorders	Anxiety	01JAN2018		Y
	C4591001 1217 12171025	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JUN2020	30JUN2020	N
	C4591001 1217 12171026	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1217 12171027	Investigations	Blood cholesterol increased	01JAN2019		Y
		Vascular disorders	Arteriosclerosis	01JAN2019		Y
			Hypertension	01JAN2019		Y
	C4591001 1217 12171029	Investigations	Blood cholesterol increased	01JAN2019		Y
	C4591001 1217 12171033	Cardiac disorders	Coronary artery disease	01JAN2009		Y
		Investigations	Blood cholesterol increased	01JAN2009		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1217 12171043	Endocrine disorders	Hypothyroidism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1217 12171057	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
	C4591001 1217 12171058	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
	C4591001 1217 12171060	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1218 12181002	Ear and labyrinth disorders	Deafness neurosensory	09AUG2018		Y
		Injury, poisoning and procedural complications	Eyeball avulsion	01JAN1977		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	11SEP2019		Y
		Vascular disorders	Essential hypertension	01JAN2010		Y
	C4591001 1218 12181020	Cardiac disorders	Coronary artery disease	01JAN2014		Y
			Myocardial infarction	01JAN2014	31JAN2014	N
		Gastrointestinal disorders	Splenic artery aneurysm	15MAY2018	31MAY2018	N
		Immune system disorders	Drug hypersensitivity	09AUG2019		Y
			Seasonal allergy	01JAN2006		Y
		Infections and infestations	Urinary tract infection	01AUG2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	23MAY2019		Y
			Vitamin B12 deficiency	23MAY2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Nervous system disorders	Migraine	12NOV1997	31DEC2019	N
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Nephrectomy	22JAN2019	22JAN2019	N
			Skin neoplasm excision	13SEP2007	13SEP2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal laminectomy	01JAN2005	31JAN2005	N
	C4591001 1218 12181021	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Lip swelling	01JAN1979		Y
		Immune system disorders	Drug hypersensitivity	01JAN1979		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1983	31DEC2010	N
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN1979		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
	C4591001 1218 12181024	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	15OCT2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	11JUL2016		Y
			Sjogren's syndrome	08JUL2008		Y
		Nervous system disorders	Migraine	19FEB2009		Y
		Psychiatric disorders	Depression	10AUG2017		Y
		Reproductive system and breast disorders	Uterine prolapse	08JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1218 12181033	Gastrointestinal disorders	Gastroesophageal reflux disease	02APR2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2007		Y
		Infections and infestations	Pyelonephritis	13FEB2020	16MAR2020	N
		Investigations	Blood cholesterol increased	03JUL2019	16NOV2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Diabetes mellitus	04DEC1999		Y
			Obesity	18NOV2008		Y
			Vitamin D deficiency	20NOV2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
			Sinus disorder	17APR2014		Y
		Surgical and medical procedures	Umbilical hernia repair	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	17APR2014		Y
	C4591001 1218 12181056	Metabolism and nutrition disorders	Obesity	24APR2001		Y
		Surgical and medical procedures	Appendectomy	01JAN1985	31DEC1985	N
			Finger amputation	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	23JUL2013		Y
	C4591001 1219 12191005	Infections and infestations	Oral herpes	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Nervous system disorders	Migraine	01JAN2008		Y
		Skin and subcutaneous tissue disorders	Drug eruption	01JUN2020	30JUN2020	N
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Endometriosis ablation	01JAN2006	31DEC2006	N
			Neurosurgery	01JAN2017	31DEC2017	N
	C4591001 1219 12191008	Infections and infestations	Urinary tract infection	01JAN2015	31DEC2016	N
			Vaginitis chlamydial	01JAN2000	31DEC2000	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Urethral cyst	01JAN2015	31DEC2016	N
		Surgical and medical procedures	Urethral operation	01JAN2016	31DEC2016	N
	C4591001 1219 12191009	Cardiac disorders	Atrial fibrillation	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1219 12191010	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2013	31DEC2017	N
	C4591001 1219 12191011	Metabolism and nutrition disorders	Gout	01JAN2015	31DEC2015	N
			Type 2 diabetes mellitus	01JAN2014	31DEC2015	N
		Renal and urinary disorders	Chronic kidney disease	01JAN2010		Y
		Social circumstances	Alcohol use	01JAN1991	31DEC1994	N
		Surgical and medical procedures	Female sterilisation	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1219 12191012	Cardiac disorders	Atrial fibrillation	01JAN2010		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1219 12191015	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JUL1988	31JUL1988	N
	C4591001 1219 12191018	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Abscess limb	01JUN2015	30JUN2015	N
			Herpes zoster	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Oral herpes	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1990		Y
		Social circumstances	Menopause	01JAN2014		Y
		Surgical and medical procedures	Cataract operation	01JAN2013	31DEC2013	N
			Retinopexy	01JAN2002	31DEC2002	N
	C4591001 1219 12191020	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Gallbladder disorder	01DEC2000	31JAN2001	N
		Immune system disorders	Seasonal allergy	01JAN2010	31MAY2020	N
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1990	31DEC1999	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2016	29FEB2016	N
		Surgical and medical procedures	Arthrodesis	01JAN1999	31DEC1999	N
			Cholecystectomy	01JAN2001	31JAN2001	N
			Spinal laminectomy	01FEB2016	29FEB2016	N
	C4591001 1219 12191021	Endocrine disorders	Hyperthyroidism	01JAN2014	31DEC2015	N
		General disorders and administration site conditions	Pain	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2018		Y
	C4591001 1219 12191025	Metabolism and nutrition disorders	Gout	01JAN2012		Y
			Hyperlipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012	31DEC2013	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)	
	C4591001 1219 12191027	Vascular disorders	Hypertension	01JAN2014		Y	
		Endocrine disorders	Hypothyroidism	01JAN2005		Y	
		Hepatobiliary disorders	Cholelithiasis	01JAN1997	31DEC1997	N	
		Immune system disorders	Seasonal allergy	01JAN1990		Y	
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y	
			Type 2 diabetes mellitus	01JAN2005		Y	
		Nervous system disorders	Paraesthesia	01JUL2020		Y	
		Psychiatric disorders	Depression	01JAN1990		Y	
		Social circumstances	Menopause	01JAN2015		Y	
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N	
	Cholelithotomy		01JAN1997	31DEC1997	N		
	C4591001 1219 12191031	Vascular disorders	Hypertension	01JAN2014		Y	
		Blood and lymphatic system disorders	Anaemia	01JAN2017	31MAR2018	N	
			Endocrine disorders	Hypothyroidism	01JAN1975	31DEC1985	N
		Gastrointestinal disorders	Gastric ulcer	01JAN1985	31DEC1985	N	
		Hepatobiliary disorders	Gallbladder disorder	01JAN2007	31DEC2009	N	
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y	
					01JAN1995		Y
				Seasonal allergy	01JAN1995		Y
		Injury, poisoning and procedural complications	Chest injury	01JAN1985	31DEC1985	N	
			Femur fracture	01JAN2017	31DEC2017	N	
	Musculoskeletal and connective tissue disorders	Multiple fractures	01JAN1985	31DEC1985	N		
		Road traffic accident	01JAN1985	31DEC1985	N		
		Osteoporosis	01JAN2017		Y		

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lip and/or oral cavity cancer	01FEB2018	30APR2018	N
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2009	31DEC2009	N
			Dental implantation	01FEB2018	31MAR2018	N
			Fracture treatment	01JAN2017	31DEC2017	N
			Knee operation	01JAN1986	31DEC1986	N
			Tracheostomy	01JAN1985	31DEC1985	N
			Leukopenia	01JAN2001	22SEP2015	N
	C4591001 1219 12191032	Blood and lymphatic system disorders				
		Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01OCT2001	31MAY2002	N
		Renal and urinary disorders	Urinary retention	01JAN2015		Y
	C4591001 1219 12191036	Blood and lymphatic system disorders	Anaemia	01JAN1990	31DEC1992	N
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01OCT2014		Y
	C4591001 1219 12191037	Eye disorders	Macular hole	01NOV1987		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Urinary tract infection	01JAN2014	31DEC2014	N
		Injury, poisoning and procedural complications	Injury	01NOV1987	30NOV1987	N
			Multiple fractures	01NOV1987	30NOV1987	N
			Road traffic accident	01NOV1987	31DEC1987	N
		Nervous system disorders	Subarachnoid haemorrhage	01JAN2014	31DEC2014	N
		Renal and urinary disorders	Urinary incontinence	01JAN1993	31DEC2008	N
		Surgical and medical procedures	Bladder repair	01JAN2014	31DEC2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lipoma excision	01JAN2019	31DEC2019	N
			Surgery	01NOV1987	31JAN1988	N
	C4591001 1219 12191038	Ear and labyrinth disorders	Deafness unilateral	01JAN2010		Y
		Infections and infestations	Otitis media	14NOV2020		Y
	C4591001 1219 12191041	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		General disorders and administration site conditions	Injection site swelling	01JAN1970	31DEC1970	N
		Infections and infestations	Latent tuberculosis	01JAN1992	31DEC1993	N
		Psychiatric disorders	Depression	01JAN2002		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1980		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Fracture treatment	01JAN2012	31DEC2012	N
			Open reduction of fracture	01JAN2016	31DEC2016	N
	C4591001 1219 12191043	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
					30APR2018	N
		Psychiatric disorders	Depression	01JAN1997		Y
		Surgical and medical procedures	Hip arthroplasty	01APR2016	30APR2016	N
				01APR2018	30APR2018	N
	C4591001 1219 12191045	Ear and labyrinth disorders	Deafness unilateral	01JAN1955		Y
			Tympanic membrane perforation	01JAN1955	31DEC1960	N
		Immune system disorders	Seasonal allergy	01JAN2013		Y
		Infections and infestations	Syphilis	01JAN1968	31DEC1968	N
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2015		Y
			Arthralgia	01AUG2020		Y
			Back pain	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2014		Y
			Restrictive pulmonary disease	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Social circumstances	Alcohol use	01JAN1980	31DEC2000	N
		Surgical and medical procedures	Ear operation	01JAN1960	31DEC1960	N
			Fracture treatment	01JAN1995	31DEC1995	N
	C4591001 1219 12191052	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
	C4591001 1219 12191055	Gastrointestinal disorders	Coeliac disease	01JAN2019		Y
			Irritable bowel syndrome	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1984		Y
				01JAN1988		Y
			Seasonal allergy	01JAN1980		Y
		Infections and infestations	Latent tuberculosis	01JAN1968	31DEC1968	N
		Injury, poisoning and procedural complications	Head injury	01JAN1968	31DEC1968	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1985	31DEC1985	N
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Antibiotic prophylaxis	01JAN1968	31DEC1968	N
			Cataract operation	01JAN1988	31DEC1988	N
			Nasal septal operation	01JAN1987	31DEC1987	N
			Rhinoplasty	01JAN1986	31DEC1986	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal laminectomy	01JAN1985	31DEC1985	N
			Strabismus correction	01JAN1988	31DEC1988	N
	C4591001 1219 12191057	Ear and labyrinth disorders	Tympanic membrane perforation	01JAN1957	31DEC2005	N
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Injury, poisoning and procedural complications	Exposure to communicable disease	01JAN1957	31DEC1957	N
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN2016	31DEC2017	N
		Surgical and medical procedures	Lung operation	01JAN1966	31DEC1966	N
			Tympanoplasty	01JAN2005	31DEC2005	N
	C4591001 1219 12191060	Cardiac disorders	Cardiac failure congestive	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
				01JAN1990		Y
			Food allergy	01JAN2015		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN1989		Y
		Nervous system disorders	Migraine	01JAN1973		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Cataract operation	01JAN2016	31DEC2016	N
			Female sterilisation	01JAN1985		Y
			Umbilical hernia repair	01JAN1973	31DEC1973	N
			Uterine polypectomy	01JAN2016	31DEC2016	N
	C4591001 1220 12201006	Endocrine disorders	Thyroid disorder	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Gallbladder disorder	01JAN1990	31DEC1990	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Investigations	Blood cholesterol increased	02DEC2019		Y
			Blood triglycerides increased	02DEC2019		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Female sterilisation	01JAN1985	31DEC1985	N
			Sterilisation reversal	01JAN1988	31DEC1988	N
			Uterine dilation and curettage	01JAN1991	31DEC1991	N
	C4591001 1220 12201008	Ear and labyrinth disorders	Deafness neurosensory	01JAN2014		Y
			Vertigo	01NOV2019	29FEB2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Gallbladder disorder	01JAN2017	21SEP2017	N
		Investigations	Blood cholesterol increased	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01DEC2018		Y
		Nervous system disorders	Headache	01JAN2012	31DEC2016	N
		Psychiatric disorders	Depression	01JAN1979		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	21SEP2017	21SEP2017	N
			Plastic surgery	01JAN2010	31DEC2010	N
	C4591001 1220 12201014	Blood and lymphatic system disorders	Anaemia	01NOV2009	31AUG2017	N
		Eye disorders	Glaucoma	01JAN2013	31DEC2020	N
		Investigations	Blood cholesterol increased	11AUG2017		Y
			Hepatic enzyme increased	21AUG2017	29JAN2018	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2017		Y
		Psychiatric disorders	Alcohol abuse	01JAN1977	31DEC2001	N
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1220 12201034	Immune system disorders	Food allergy	01JAN1962		Y
			Seasonal allergy	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1980	31DEC2010	N
		Psychiatric disorders	Alcohol use disorder	01JAN1980	31DEC2018	N
			Depression	01JAN2000	31DEC2018	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Alcohol rehabilitation	01JAN2018	30APR2018	N
			Metabolic surgery	01FEB2015	28FEB2015	N
	C4591001 1220 12201038	Blood and lymphatic system disorders	Anaemia	01JAN2006	31DEC2006	N
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Injury, poisoning and procedural complications	Nerve injury	01MAR2020		Y
			Road traffic accident	01MAR2020	31MAR2020	N
		Investigations	Biopsy breast	01JAN2005	31DEC2005	N
			Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2020	31OCT2020	N
		Nervous system disorders	Headache	01MAR2020		Y
		Psychiatric disorders	Anxiety	01MAY2020	30SEP2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
			Thyroidectomy	01OCT2018	31OCT2018	N
	C4591001 1220 12201040	Ear and labyrinth disorders	Deafness	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
			Colonoscopy	15JAN2020	15JAN2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2008	31AUG2013	N
	C4591001 1220 12201049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Pancreatitis	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Hepatic steatosis	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1977		Y
				01JAN1998		Y
			Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2020		Y
		Nervous system disorders	Carpal tunnel syndrome	01NOV2019		Y
			Headache	01NOV2019	31OCT2020	N
			Migraine	01JAN2000	31DEC2000	N
		Renal and urinary disorders	Urinary incontinence	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01MAR2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2020		Y
		Social circumstances	Menopause	01DEC2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2007	31DEC2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1220 12201054	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Chlamydial infection	01JAN2000	31DEC2000	N
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Bladder repair	01JAN2017	31DEC2017	N
	C4591001 1220 12201055	Immune system disorders	Drug hypersensitivity	01JAN1997		Y
			Seasonal allergy	01JAN1996		Y
		Infections and infestations	Herpes zoster	01JAN2016	31DEC2016	N
		Investigations	Blood cholesterol increased	01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1220 12201058	Immune system disorders	Sarcoidosis	01JAN1978	31DEC1979	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	01JAN1978		Y
		Investigations	Biopsy lymph gland	01JAN1978	31DEC1978	N
			Mediastinoscopy	01JAN1978	31DEC1978	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1970		Y
			Tendon disorder	01JAN2013		Y
		Nervous system disorders	Tremor	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
			Tendon sheath incision	01JAN2016	31DEC2016	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Thyroidectomy	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1962	31DEC1962	N
	C4591001 1220 12201060	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2016		Y
			Back pain	01JAN2011		Y
			Fibromyalgia	01JAN2016		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Vascular disorders	Venous thrombosis limb	01JAN2016	31DEC2018	N
	C4591001 1221 12211001	Surgical and medical procedures	Hysterectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1221 12211004	Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN2018		Y
	C4591001 1221 12211009	Eye disorders	Cataract	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1978		Y
		Infections and infestations	Chlamydial infection	01JAN1976	31DEC1976	N
			Herpes virus infection	01JAN1976		Y
	C4591001 1221 12211015	Hepatobiliary disorders	Gallbladder disorder	01MAR1988	30SEP1988	N
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Infections and infestations	Cellulitis	01DEC2010	31DEC2010	N
			Clostridium difficile infection	01JAN2017	31JAN2017	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
				01JAN2018		Y
				01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01SEP1988	31DEC1988	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Debridement	01DEC2010	31DEC2010	N
			Knee arthroplasty	01JUN2016	30JUN2016	N
	C4591001 1221 12211016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN1998		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1996		Y
		Skin and subcutaneous tissue disorders	Eczema	01APR2016		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1221 12211017	Endocrine disorders	Hypothyroidism	07AUG2000		Y
		Eye disorders	Cataract	04JUN2019		Y
		Psychiatric disorders	Depression	28AUG2015		Y
	C4591001 1221 12211018	Blood and lymphatic system disorders	Thrombocytopenia	26MAR2019		Y
		Gastrointestinal disorders	Diverticulum	06JUN2018		Y
			Haemorrhoids	06JUN2018		Y
		General disorders and administration site conditions	Precancerous condition	12JAN2017	12JAN2017	N
		Hepatobiliary disorders	Hepatic cirrhosis	12JAN2017		Y
		Immune system disorders	Seasonal allergy	01JAN1972		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2005		Y
		Nervous system disorders	Headache	01MAR2020		Y
		Surgical and medical procedures	Cholecystectomy	12JAN2017	12JAN2017	N
			Large intestinal polypectomy	06JUN2018	06JUN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1221 12211021	Hepatobiliary disorders	Cholelithiasis	01AUG2020		Y
		Infections and infestations	Epididymitis	01JUL2020	31AUG2020	N
		Nervous system disorders	Migraine	01JAN2012		Y
		Renal and urinary disorders	Nephrolithiasis	01AUG2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
	C4591001 1221 12211027	Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
	C4591001 1221 12211028	Gastrointestinal disorders	Diverticulum	10OCT2013		Y
			Gastroesophageal reflux disease	10JUN2014		Y
		Infections and infestations	Herpes zoster	20JUL2011		Y
		Investigations	Tuberculin test positive	01JAN1989	31DEC1990	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	10OCT2010	10OCT2010	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2010	N
		Surgical and medical procedures	Rotator cuff repair	10NOV2019	10NOV2019	N
	C4591001 1221 12211039	Cardiac disorders	Myocardial infarction	08JAN2018	08JAN2018	N
		Congenital, familial and genetic disorders	Factor V Leiden mutation	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	08JAN2018	08JAN2018	N
			Hip surgery	15APR2010	15APR2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Neck surgery	08JAN2008	08JAN2008	N
		Vascular disorders	Deep vein thrombosis	01JAN2013	31DEC2018	N
	C4591001 1221 12211048	Immune system disorders	Seasonal allergy	01JAN1993		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Exostosis	01JAN2010	17JAN2012	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Surgical and medical procedures	Bone lesion excision	17JAN2012	17JAN2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1221 12211049	Cardiac disorders	Pulmonary valve incompetence	20AUG2020		Y
		Ear and labyrinth disorders	Vertigo	30JAN2018		Y
		Immune system disorders	Food allergy	01JAN2020		Y
			Seasonal allergy	01JAN2019		Y
		Infections and infestations	Herpes zoster	01SEP2020	30SEP2020	N
			Otitis externa fungal	17AUG2020		Y
		Investigations	Blood cholesterol increased	14AUG2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	20AUG2020		Y
		Nervous system disorders	Facial paralysis	14AUG2020		Y
	C4591001 1221 12211050	Immune system disorders	Multiple allergies	01JAN2018		Y
		Renal and urinary disorders	Urinary incontinence	01JAN1985	30APR2011	N
	C4591001 1221 12211051	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2020		Y
		Immune system disorders	Allergy to chemicals	01JAN1969		Y
		Psychiatric disorders	Depression	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1221 12211052	Nervous system disorders	Migraine	01JAN1985		Y
		Renal and urinary disorders	Nephrolithiasis	01OCT2000	31DEC2002	N
		Surgical and medical procedures	Hysterotomy	01AUG2015	31AUG2015	N
	C4591001 1221 12211057	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		Immune system disorders	Contrast media allergy	29JUN2016		Y
			Milk allergy	01JAN1990		Y
			Rubber sensitivity	29JUN2016		Y
			Seasonal allergy	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	01JAN1980		Y
	C4591001 1221 12211058	Immune system disorders	Seasonal allergy	01JAN2019		Y
		Surgical and medical procedures	Oophorectomy	19MAY2010	19MAY2010	N
	C4591001 1221 12211059	Injury, poisoning and procedural complications	Femur fracture	13MAY2016	01JUN2016	N
			Patella fracture	13MAY2016	01JUN2016	N
			Skin laceration	13MAY2016	01JUN2016	N
			Tibia fracture	13MAY2016	01JUN2016	N
		Surgical and medical procedures	Knee arthroplasty	01MAR2018	31MAR2018	N
	C4591001 1221 12211061	Infections and infestations	Hepatitis C	01JAN2010	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN1984		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007	31DEC2010	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1221 12211063	Infections and infestations	Tuberculosis	01JAN1969	31DEC1970	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1221 12211066	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1968		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Sinus disorder	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01JAN1976		Y
		Surgical and medical procedures	Tenoplasty	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2018		Y
			Varicose vein	01JAN1990		Y
	C4591001 1221 12211075	Hepatobiliary disorders	Gallbladder disorder	01JAN1977	31DEC1977	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	08SEP2020		Y
		Nervous system disorders	Diabetic neuropathy	08SEP2020	01OCT2020	N
		Surgical and medical procedures	Hysterotomy	01JAN2010	31DEC2010	N
		Vascular disorders	Thrombosis	01JUN2002	31DEC2002	N
	C4591001 1221 12211076	Hepatobiliary disorders	Gallbladder disorder	01JAN2013	31DEC2013	N
	C4591001 1221 12211077	Hepatobiliary disorders	Gallbladder disorder	01JAN2006	31DEC2006	N
	C4591001 1221 12211084	Infections and infestations	Chlamydial infection	01JAN1985	31DEC1985	N
		Nervous system disorders	Migraine	01JAN1973		Y
		Psychiatric disorders	Depression	01JAN1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1221 12211085	Investigations	Blood cholesterol increased	01NOV2016		Y
		Metabolism and nutrition disorders	Diabetes mellitus	01AUG2020		Y
		Vascular disorders	Hypertension	01OCT2017		Y
	C4591001 1221 12211086	Hepatobiliary disorders	Gallbladder disorder	01MAY2002	31MAY2002	N
		Infections and infestations	Herpes zoster	22NOV2010	31DEC2010	N
	C4591001 1221 12211091	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2019		Y
		Psychiatric disorders	Depression	01MAR2013		Y
	C4591001 1221 12211092	Eye disorders	Cataract	01JAN2015		Y
		Gastrointestinal disorders	Intestinal polyp	01JAN2014	30JUN2016	N
		Investigations	Blood cholesterol increased	01JAN2017	30NOV2017	N
		Metabolism and nutrition disorders	Diabetes mellitus	01JAN2011		Y
		Vascular disorders	Hypertension	01AUG2011		Y
	C4591001 1221 12211093	Hepatobiliary disorders	Cholelithiasis	01JAN2011		Y
		Infections and infestations	Urinary tract infection	01JUL2011	31JUL2011	N
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011	31DEC2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2018		Y
		Nervous system disorders	Migraine	01SEP2020		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1223 12231006	Immune system disorders	Seasonal allergy	01JAN2010		Y
				01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
	C4591001 1223 12231007	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1223 12231009	Endocrine disorders	Autoimmune thyroiditis	01AUG2000		Y
	C4591001 1223 12231010	Cardiac disorders	Arrhythmia	01JAN2018		Y
			Cardiac failure congestive	01JAN2016		Y
		Metabolism and nutrition disorders	Gout	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Aortic aneurysm repair	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1223 12231011	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1223 12231012	Cardiac disorders	Myocardial infarction	01JAN1997	31DEC1997	N
			Ventricular extrasystoles	01JAN2009	31DEC2009	N
		Infections and infestations	Rhinitis	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2013		Y
	C4591001 1223 12231013	Endocrine disorders	Hypothyroidism	01JAN1970		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231015	Social circumstances	Menopause	01JAN2016		Y
		Surgical and medical procedures	Sterilisation	01JAN1994	31DEC1994	N
	C4591001 1223 12231017	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1223 12231019	Renal and urinary disorders	Chronic kidney disease	16APR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2017		Y
	C4591001 1223 12231020	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1223 12231021	Cardiac disorders	Myocardial infarction	01JAN2001	31DEC2001	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1994		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2013	31DEC2013	N
	C4591001 1223 12231023	Renal and urinary disorders	Neurogenic bladder	01NOV2019		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Anal fistula repair	01JAN2016	31DEC2016	N
	C4591001 1223 12231029	Eye disorders	Glaucoma	01MAR2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2010		Y
			Type 2 diabetes mellitus	01MAY2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231032	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01FEB2015		Y
	C4591001 1223 12231033	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
	C4591001 1223 12231037	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1223 12231038	Infections and infestations	Tooth infection	24AUG2020		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2018	31DEC2018	N
	C4591001 1223 12231039	Gastrointestinal disorders	Crohn's disease	01JAN2007	31DEC2012	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01FEB2018		Y
	C4591001 1223 12231040	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Eye disorders	Dry age-related macular degeneration	01JAN2010		Y
			Neovascular age-related macular degeneration	01JAN2010		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2015		Y
		Infections and infestations	Oral candidiasis	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal cancer	01JAN1993	31DEC1993	N
		Nervous system disorders	Tension headache	01JAN2008		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2000		Y
		Surgical and medical procedures	Laryngectomy	01JAN1993	31DEC1993	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231042	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1999		Y
		Nervous system disorders	Migraine	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999		Y
	C4591001 1223 12231043	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1223 12231046	Endocrine disorders	Hypothyroidism	01JAN2018		Y
	C4591001 1223 12231047	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1223 12231049	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
	C4591001 1223 12231052	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1989		Y
		Nervous system disorders	Migraine with aura	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN1989		Y
	C4591001 1223 12231056	Endocrine disorders	Hypothyroidism	01MAY2004		Y
	C4591001 1223 12231058	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2020		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1980		Y
	C4591001 1223 12231059	Social circumstances	Menopause	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231060	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Bipolar II disorder	01JAN2010		Y
	C4591001 1223 12231065	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Skin and subcutaneous tissue disorders	Dermatitis	01JAN2019		Y
	C4591001 1223 12231067	Eye disorders	Glaucoma	01JAN1990		Y
		Infections and infestations	Sinusitis	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Psychiatric disorders	Insomnia	01JAN1980		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2019		Y
	C4591001 1223 12231068	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1223 12231070	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231076	Eye disorders	Age-related macular degeneration	01JAN2010		Y
	C4591001 1223 12231078	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1223 12231080	Skin and subcutaneous tissue disorders	Granuloma annulare	01MAR2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231081	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1223 12231085	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	01JAN2004		Y
		Psychiatric disorders	Depression	01JAN2008		Y
			Insomnia	01JAN2008		Y
		Social circumstances	Menopause	01JAN2003		Y
	C4591001 1223 12231089	Endocrine disorders	Hyperthyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1223 12231091	Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01NOV2019		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1223 12231096	Cardiac disorders	Myocardial infarction	01JAN2000	31DEC2000	N
		Endocrine disorders	Hypothyroidism	01MAY2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1223 12231097	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
			Coronary artery disease	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1223 12231098	Cardiac disorders	Ventricular extrasystoles	01JAN2000		Y
		Immune system disorders	Multiple allergies	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999		Y
	C4591001 1223 12231102	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1223 12231103	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1223 12231104	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1993		Y
	C4591001 1223 12231106	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01AUG2020		Y
	C4591001 1223 12231107	Social circumstances	Menopause	01JAN2016		Y
	C4591001 1223 12231108	Respiratory, thoracic and mediastinal disorders	Asthma	01FEB1995		Y
		Vascular disorders	Hypertension	01MAY2020		Y
	C4591001 1223 12231109	Cardiac disorders	Atrial flutter	01FEB2020		Y
		Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	01JAN2019		Y
	C4591001 1223 12231114	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	01JAN2009		Y
	C4591001 1223 12231115	Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
	C4591001 1223 12231123	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1223 12231124	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1223 12231125	Nervous system disorders	Tremor	01JAN2017		Y
	C4591001 1223 12231126	Eye disorders	Cataract	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
		Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1223 12231129	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231130	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
		Psychiatric disorders	Alcohol abuse	01JAN2015		Y
			Depression	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1223 12231132	Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1223 12231134	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
	C4591001 1223 12231136	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Herpes virus infection	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1223 12231138	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01AUG2020		Y
	C4591001 1223 12231139	Immune system disorders	Multiple allergies	01AUG2010		Y
		Investigations	Intraocular pressure test	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231140	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1223 12231142	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012	31DEC2015	N
	C4591001 1223 12231143	Ear and labyrinth disorders	Hypoacusis	01JAN2005		Y
		Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1223 12231149	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1223 12231155	Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAY2020		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1223 12231156	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
	C4591001 1223 12231158	Immune system disorders	Multiple allergies	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2004	31DEC2004	N
			Malignant melanoma	01JAN2008		Y
			Squamous cell carcinoma	01JAN2019	31DEC2019	N
		Nervous system disorders	Migraine	01JAN2000		Y
			Transient ischaemic attack	01JAN2006		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2008		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1223 12231159	Ear and labyrinth disorders	Eustachian tube dysfunction	01JAN2017		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2002		Y
			Irritable bowel syndrome	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
			Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	17AUG2020		Y
			Malignant melanoma	01JAN2007	31DEC2007	N
		Social circumstances	Menopause	01JAN1998		Y
		Surgical and medical procedures	Prophylaxis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1223 12231178	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1223 12231182	Cardiac disorders	Atrial fibrillation	01JAN1998		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2017		Y
			Gastrooesophageal reflux disease	01JAN2001		Y
		Infections and infestations	Diverticulitis	01JAN2019		Y
		Injury, poisoning and procedural complications	Joint dislocation	01JAN1966	31DEC1967	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231193	Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Postmenopause	01FEB2017		Y
	C4591001 1223 12231194	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231198	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1223 12231203	Investigations	Blood cholesterol increased	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1223 12231206	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1223 12231207	Psychiatric disorders	Drug dependence	01JAN1980	31DEC1999	N
	C4591001 1223 12231209	Infections and infestations	Hepatitis C	01JAN2015	31DEC2018	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Depression	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231218	Nervous system disorders	Sciatica	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2011		Y
			Depression	01JAN2012		Y
			Drug dependence	01JAN1983		Y
			Psychotic disorder	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
	C4591001 1223 12231227	Endocrine disorders	Basedow's disease	01JAN2004	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
	C4591001 1223 12231228	Eye disorders	Glaucoma	01JAN1992		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma of eyelid	01AUG2019	30SEP2019	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JUL2020		Y
	C4591001 1223 12231235	Eye disorders	Glaucoma	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Nervous system disorders	Carotid artery stenosis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1223 12231240	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN1990	31DEC1990	N
			Tongue neoplasm malignant stage unspecified	01JAN2015	31DEC2015	N
	C4591001 1223 12231248	Metabolism and nutrition disorders	Gout	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1223 12231254	Musculoskeletal and connective tissue disorders	Myalgia	01SEP2020		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN1985		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1223 12231255	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1223 12231257	Cardiac disorders	Acute myocardial infarction	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231259	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1223 12231261	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1223 12231262	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Reproductive system and breast disorders	Vulvovaginal dryness	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990		Y
	C4591001 1223 12231263	Infections and infestations	Hepatitis C	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1223 12231266	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01SEP2020		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1224 12241001	Psychiatric disorders	Depression	01MAY2020		Y
		Vascular disorders	Deep vein thrombosis	01JAN2016	31DEC2016	N
				01JAN2020	31JAN2020	N
			Hypertension	01JAN2010		Y
	C4591001 1224 12241002	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Hypertriglyceridaemia	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1224 12241003	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1993		Y
		Metabolism and nutrition disorders	Hypophosphataemia	01JAN1985		Y
		Surgical and medical procedures	Cholecystectomy	01NOV2019	30NOV2019	N
			Hysterectomy	01JAN1993	31DEC1993	N
			Keratomileusis	01JAN2011	31DEC2011	N
	C4591001 1224 12241004	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN1997		Y
			Vitamin D deficiency	09NOV2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1224 12241006	Infections and infestations	Herpes zoster	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2018		Y
			Osteoarthritis	01JAN1966		Y
		Nervous system disorders	Seizure	01JAN2017		Y
			Trigeminal neuralgia	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2016		Y
			Nephrolithiasis	01JAN1978	31DEC1978	N
				01JAN2016	31DEC2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1224 12241007	Cardiac disorders	Myocardial infarction	01JAN2018	31DEC2018	N
		Infections and infestations	Staphylococcal infection	01JAN1998	31DEC1998	N
		Nervous system disorders	Ischaemic stroke	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2018	31DEC2018	N
	C4591001 1224 12241011	Endocrine disorders	Hypothyroidism	01JAN2013		Y
			Thyroid atrophy	01JAN2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Insomnia	07FEB2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2013		Y
	C4591001 1224 12241012	Vascular disorders	Hypertension	01JAN1982		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Nervous system disorders	Parkinson's disease	01JAN1990		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y
			Insomnia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1224 12241013	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1224 12241014	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1999		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
			Depression	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01NOV2017	30NOV2017	N
			Hip arthroplasty	01MAY2008	31MAY2008	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1224 12241015	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241016	Surgical and medical procedures	Endodontic procedure	09JUL2020	09JUL2020	N
		Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Eye disorders	Cataract	01JAN2018	31JAN2020	N
		Injury, poisoning and procedural complications	Mallet finger	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
	C4591001 1224 12241018	Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
		Surgical and medical procedures	Cataract operation	01JAN2020	31JAN2020	N
			Mastectomy	01JAN2009	31DEC2009	N
		Cardiac disorders	Cardiac failure congestive	01JAN2012		Y
		General disorders and administration site conditions	Pain	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Rheumatic fever	01JAN1964	31DEC1964	N
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
	C4591001 1224 12241019	Surgical and medical procedures	Aortic valve replacement	01JAN1977	31DEC1977	N
				01JAN1988	31DEC1988	N
				01JAN1999	31DEC1999	N
				01JAN2012	31DEC2012	N
				01JAN2003	31DEC2003	N
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	14AUG2018	14AUG2018	N	



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Squamous cell carcinoma	21FEB2019	21FEB2019	N
		Surgical and medical procedures	Adenoidectomy	01JAN1964	31DEC1964	N
			Keratomileusis	01JAN2002	31JAN2002	N
			Skin neoplasm excision	07APR2017	07APR2017	N
			Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1224 12241020	Infections and infestations	Tonsillitis	01DEC1958	31DEC1958	N
		Investigations	Laparoscopy	01JUL1990	31JUL1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lipoma	01JAN2010	22JAN2021	N
		Surgical and medical procedures	Hysterectomy	01JUL1998	31JUL1998	N
			Tonsillectomy	01DEC1958	31DEC1958	N
	C4591001 1224 12241022	Gastrointestinal disorders	Inguinal hernia	01JAN2006		Y
		General disorders and administration site conditions	Oedema peripheral	01JAN2012		Y
		Infections and infestations	Chronic sinusitis	01JAN2012		Y
			Subcutaneous abscess	01JAN2012	31DEC2012	N
		Investigations	C-reactive protein increased	01JAN2018		Y
			Lipoprotein (a) increased	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1224 12241023	Cardiac disorders	Cardiac failure congestive	01JUN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2011		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Psychiatric disorders	Depression	01FEB2016		Y
		Social circumstances	Menopause	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1224 12241025	Cardiac disorders	Coronary artery disease	01OCT2014		Y
			Myocardial infarction	01OCT2013	31OCT2013	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2014		Y
		Psychiatric disorders	Anxiety	01NOV2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01OCT2014		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT2013	31OCT2013	N
		Vascular disorders	Hypertension	01OCT2014		Y
	C4591001 1224 12241028	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1976		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01MAY2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1224 12241029	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Knee arthroplasty	05DEC2018	05DEC2018	N
	C4591001 1224 12241030	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
			Vitamin D deficiency	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1224 12241033	Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241035	Cardiac disorders	Acute myocardial infarction	01JAN2015	31DEC2015	N
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Gastrointestinal disorders	Constipation	01JAN2014		Y
			Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Oral herpes	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN1998		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1998		Y
			Back pain	01JAN1998		Y
			Spondylitis	01JAN1998		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1224 12241036	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
			Knee arthroplasty	01SEP2018	30SEP2018	N
			Spinal operation	01JAN1990	19JUL2020	N
	C4591001 1224 12241037	Cardiac disorders	Cardiac failure congestive	01SEP2019		Y
			Myocardial infarction	01OCT2019	31OCT2019	N
				01SEP2019	30SEP2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Arthroscopy	01DEC1990	31DEC1990	N
				01JUN2001	30JUN2001	N
				01OCT2010	31OCT2010	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2019		Y
		Psychiatric disorders	Depression	01SEP2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT2019	31OCT2019	N
			Implantable defibrillator replacement	31DEC2019	31DEC2019	N
			Knee operation	01APR1982	30APR1982	N
	C4591001 1224 12241038	Gastrointestinal disorders	Constipation	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1224 12241039	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		General disorders and administration site conditions	Stenosis	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
			Scoliosis	01JAN2000		Y
			Spinal osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Social circumstances	Menopause	01JAN1989		Y
		Surgical and medical procedures	Hip arthroplasty	01NOV2018	30NOV2018	N
				20NOV2016	20NOV2016	N
			Rotator cuff repair	01JAN2014	31JAN2014	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01MAR2000	31MAR2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1224 12241040	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
				01JAN2018	31DEC2018	N
		Psychiatric disorders	Depression	01JAN2014		Y
		Social circumstances	Menopause	01JAN2003		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2003	31DEC2003	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241041	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2013		Y
		Immune system disorders	Hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Heart valve replacement	01JAN2005	31DEC2005	N
	C4591001 1224 12241042	Endocrine disorders	Hypothyroidism	01MAY2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUN2005		Y
		Nervous system disorders	Cerebrovascular accident	10JUN2015	10JUN2015	N
		Psychiatric disorders	Anxiety	01JUL2015		Y
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Caesarean section	10DEC1980	10DEC1980	N
	C4591001 1224 12241043	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Anxiety	01OCT2018		Y
		Social circumstances	Menopause	01JAN2012	31DEC2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1224 12241044	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2020		Y
			Type 2 diabetes mellitus	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1224 12241045	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01MAY2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Fibromyalgia	01JAN2006		Y
			Rheumatoid arthritis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
			Insomnia	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2009		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1224 12241046	Cardiac disorders	Coronary artery disease	02FEB2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2007		Y
		Surgical and medical procedures	Coronary arterial stent insertion	02FEB2010	02FEB2010	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1224 12241047	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1990		Y
		Metabolism and nutrition disorders	Gout	01JAN1995		Y
			Hyperlipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2012		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN1992		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1988		Y
		Surgical and medical procedures	Spinal fusion surgery	01JAN2005	31DEC2005	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1224 12241048	Infections and infestations	Appendicitis	01JAN1967	31DEC1967	N
				01JAN1968	31DEC1968	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JUL1998		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Spinal osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Keratomileusis	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1987	31DEC1987	N
	C4591001 1224 12241049	Endocrine disorders	Hypothyroidism	01JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Appendicectomy	01JAN1975	31DEC1975	N
			Caesarean section	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1962	31DEC1962	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUN2000		Y
	C4591001 1224 12241050	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1224 12241051	Cardiac disorders	Angina pectoris	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN1995	31DEC1995	N
			Tenoplasty	01JAN1966	31DEC1966	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1224 12241052	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Abdominal pain	01MAY2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2020		Y
			Hyperlipidaemia	01JAN2019		Y
			Vitamin D deficiency	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2020		Y
			Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1224 12241054	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1224 12241055	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Sinusitis bacterial	01FEB2014	28FEB2014	N
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Surgical and medical procedures	Knee arthroplasty	01NOV2018	30NOV2018	N
			Paranasal sinus polypectomy	01JAN1980	28FEB2014	N
			Sinus operation	01FEB2014	28FEB2014	N
	C4591001 1224 12241057	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Vascular disorders	Hypertension	12AUG2019		Y
	C4591001 1224 12241059	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1224 12241061	Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1224 12241062	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1224 12241063	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2009		Y
		Psychiatric disorders	Insomnia	01JAN2004		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241064	Social circumstances	Menopause	01JAN2017		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2015		Y
			Dyspepsia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1995		Y
		Infections and infestations	Oral herpes	01JAN2010		Y
		Injury, poisoning and procedural complications	Cartilage injury	01OCT2007	31OCT2007	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01JUL2019	31JUL2019	N
		Reproductive system and breast disorders	Vaginal prolapse	01JAN2014		Y
		Surgical and medical procedures	Bunion operation	01NOV2009	30NOV2009	N
			Female sterilisation	01JAN1999	31JAN1999	N
			Joint manipulation	01JAN2020	31DEC2020	N
			Synovial cyst removal	01JAN1959	31DEC1959	N
			Tonsillectomy	01JAN1964	31DEC1964	N
		C4591001 1224 12241070	Cardiac disorders	Cardiac failure congestive	01JAN2019	
	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y	
		Type 2 diabetes mellitus	01JAN2013		Y	
	Vascular disorders	Hypertension	01JAN2013		Y	
		Thrombosis	01JAN2015		Y	
	C4591001 1224 12241071	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	Gastrointestinal disorders	Colitis	21AUG2020		Y	
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1224 12241073	Endocrine disorders	Hypothyroidism	01JAN1997		Y
	Psychiatric disorders	Depression	01JAN2010		Y	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2018	31DEC2018	N
			Spinal fusion surgery	01JAN2015	31DEC2015	N
	C4591001 1224 12241076	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1224 12241077	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1224 12241080	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Eyelid infection	21AUG2018	21AUG2018	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1955		Y
	C4591001 1224 12241082	Eye disorders	Glaucoma	01JAN2006		Y
		Gastrointestinal disorders	Constipation	01JAN2006		Y
			Gastroesophageal reflux disease	01JAN2006		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2002		Y
			Intervertebral disc degeneration	01JAN2006	31DEC2019	N
			Pain in extremity	01JAN2002		Y
			Rotator cuff syndrome	01JAN2004	31DEC2004	N
		Psychiatric disorders	Insomnia	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2004	31DEC2004	N
			Spinal decompression	01JAN2006	31DEC2006	N
				01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1224 12241087	Cardiac disorders	Angina pectoris	01JAN2007	31DEC2008	N
			Arteriosclerosis coronary artery	01JAN2010		Y
			Coronary artery disease	01JAN2007		Y
			Mitral valve incompetence	01JAN2008		Y
		Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN2005		Y
		Eye disorders	Cataract	01JAN2017		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2008		Y
		Immune system disorders	Seasonal allergy	01JAN2008		Y
		Injury, poisoning and procedural complications	Pelvic fracture	01JAN2008	31DEC2008	N
			Tibia fracture	01JAN2014	31DEC2014	N
			Upper limb fracture	01JAN1999	31DEC1999	N
			Wrist fracture	01JAN1999	31DEC1999	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1969		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1999		Y
			Pain in extremity	01JAN2017		Y
		Nervous system disorders	Restless legs syndrome	01JAN2004		Y
		Psychiatric disorders	Insomnia	01JAN1959		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN2000		Y
		Social circumstances	Menopause	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Intermittent claudication	01JAN2005		Y
	C4591001 1224 12241089	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Dry mouth	01JAN1980		Y
			Gastroesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1224 12241094	Immune system disorders	Seasonal allergy	01JAN1965		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1965		Y
		Social circumstances	Menopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1224 12241095	Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Appendectomy	01JAN1980	31DEC1980	N
			Hysterosalpingo-oophorectomy	01JAN2004	31DEC2004	N
	C4591001 1224 12241097	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Social circumstances	Menopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1224 12241099	Cardiac disorders	Angina pectoris	01JAN2010		Y
			Myocardial infarction	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1224 12241100	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN1995		Y
		Social circumstances	Menopause	01JAN1999		Y
		Surgical and medical procedures	Caesarean section	01JAN1986	31DEC1986	N
				01JAN1990	31DEC1990	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1224 12241101	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1224 12241102	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010	10FEB2017	N
		Surgical and medical procedures	Hip arthroplasty	10FEB2017	10FEB2017	N
			Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1224 12241103	Social circumstances	Menopause	01JAN2005		Y
	C4591001 1224 12241106	Metabolism and nutrition disorders	Hyperlipidaemia	01AUG2020		Y
		Social circumstances	Menopause	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241107	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Herpes zoster	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Social circumstances	Menopause	01JAN1999		Y
		Surgical and medical procedures	Hysterectomy	31OCT1983	31OCT1983	N
			Knee arthroplasty	01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1224 12241108	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Surgical and medical procedures	Appendicectomy	01JAN1975	31DEC1975	N
			Spinal laminectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1224 12241109	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01SEP2018		Y
		Social circumstances	Menopause	01JAN1990		Y
	C4591001 1224 12241110	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Renal and urinary disorders	Hypertonic bladder	01AUG2020		Y
		Surgical and medical procedures	Appendicectomy	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1224 12241111	Surgical and medical procedures	Cataract operation	01NOV2017	30NOV2017	N
	C4591001 1224 12241112	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Nervous system disorders	Dysgeusia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241113	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Infections and infestations	Urinary tract infection	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01MAY2020		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1224 12241115	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1224 12241116	Cardiac disorders	Coronary artery disease	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
			Erectile dysfunction	01JAN2019		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2015	31DEC2015	N
			Knee arthroplasty	01JAN2007	31DEC2007	N
			Meniscus operation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1224 12241120	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Type 2 diabetes mellitus	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1224 12241122	Ear and labyrinth disorders	Meniere's disease	01JAN1990		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017		Y
			Osteoarthritis	01JAN1997		Y
		Surgical and medical procedures	Chondroplasty	01JAN2017	31DEC2017	N
			Shoulder arthroplasty	01JAN2018	31DEC2018	N
			Varicose vein operation	01JAN2019	31DEC2019	N
		Vascular disorders	Varicose vein	01JAN2019	31DEC2019	N
	C4591001 1224 12241127	Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Menopause	01JAN1988		Y
	C4591001 1224 12241129	Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1988	31DEC1988	N
		Injury, poisoning and procedural complications	Nerve injury	01NOV2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2010		Y
		Psychiatric disorders	Depression	01NOV2010		Y
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	02SEP2010		Y
	C4591001 1224 12241130	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1224 12241140	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241142	Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
	C4591001 1224 12241145	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1968		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Social circumstances	Postmenopause	01JAN2012		Y
	C4591001 1224 12241148	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Acne cystic	01JAN2019		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1999	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1224 12241149	Gastrointestinal disorders	Irritable bowel syndrome	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
			Sleep apnoea syndrome	01JAN2016		Y
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN1996		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1224 12241153	Metabolism and nutrition disorders	Hyperlipidaemia	01SEP2020		Y
			Vitamin D deficiency	22APR2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30JUL2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	30JUL2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	09JUL2014		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
	C4591001 1224 12241157	Cardiac disorders	Coronary artery disease	01AUG2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Nephropathy	01MAR2020		Y
			Renal failure	01JAN2007		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
			Erectile dysfunction	01JAN2012		Y
		Surgical and medical procedures	Renal transplant	01JAN2012	31DEC2012	N
			Stent placement	01FEB2018	31DEC2018	N
	C4591001 1224 12241159	Social circumstances	Postmenopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241163	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1224 12241164	Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1226 12261009	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Social circumstances	Menopause	01JAN1999	31DEC1999	N
	C4591001 1226 12261023	Cardiac disorders	Coronary artery insufficiency	01SEP2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
			Glucose tolerance impaired	01JAN2015		Y
		Surgical and medical procedures	Vascular stent insertion	01SEP2015		Y
		Vascular disorders	Aortic stenosis	01SEP2015		Y
			Hypertension	01JAN2005		Y
	C4591001 1226 12261033	Musculoskeletal and connective tissue disorders	Femoroacetabular impingement	01JAN1999		Y
	C4591001 1226 12261034	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Menopause	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01DEC1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261035	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1226 12261039	Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1226 12261040	Metabolism and nutrition disorders	Obesity	01JAN1995		Y
	C4591001 1226 12261042	Cardiac disorders	Sinus tachycardia	01JAN1995		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasm	01JAN1999	31DEC1999	N
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Intestinal resection	01JAN2015	31DEC2015	N
			Mastectomy	01JAN1999	31DEC1999	N
	C4591001 1226 12261046	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Social circumstances	Menopause	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261050	Surgical and medical procedures	Vasectomy	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261053	Social circumstances	Menopause	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1226 12261059	Gastrointestinal disorders	Gastritis	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1226 12261062	Endocrine disorders	Hypothyroidism	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1226 12261063	Eye disorders	Glaucoma	01JAN2006		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2002	N
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1226 12261064	Infections and infestations	Diverticulitis	01OCT2019	31OCT2019	N
		Musculoskeletal and connective tissue disorders	Neck pain	01DEC2019		Y
		Social circumstances	Menopause	01JAN1991		Y
		Surgical and medical procedures	Intestinal resection	01OCT2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261070	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1226 12261077	Cardiac disorders	Acute myocardial infarction	01JAN2012	31DEC2012	N
			Coronary artery insufficiency	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2019		Y
			Oesophagitis	01JUL2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Surgical and medical procedures	Vascular stent insertion	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261090	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer in situ	01JAN2007	31DEC2007	N
	C4591001 1226 12261095	Social circumstances	Menopause	01JAN2007		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma of colon	01JAN2000	31DEC2000	N
			Basal cell carcinoma	01JAN2017	31DEC2017	N
			Lymphoma	01JAN1997	31DEC1997	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Sigmoidectomy	01JAN2000	31DEC2000	N
			Splenectomy	01JAN1997	31DEC1997	N
	C4591001 1226 12261098	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Social circumstances	Menopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1226 12261101	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1226 12261128	Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261141	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2001		Y
		Nervous system disorders	Headache	01JAN1981		Y
		Psychiatric disorders	Insomnia	01JAN1986		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
	C4591001 1226 12261142	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2018		Y
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1226 12261143	Injury, poisoning and procedural complications	Epicondylitis	01JUN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261145	Cardiac disorders	Arrhythmia	01JAN2017		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	01MAY1987	31MAY1987	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Obesity	01JAN2010		Y
		Nervous system disorders	Monoparesis	01MAY1987		Y
			Muscle spasticity	01JAN1987		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2005		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2012	31DEC2012	N
	C4591001 1226 12261162	Cardiac disorders	Arrhythmia	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2015		Y
			Osteoarthritis	01JAN2015		Y
		Social circumstances	Menopause	01JAN1997		Y
	C4591001 1226 12261169	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1226 12261171	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Nervous system disorders	Cluster headache	01JAN1980		Y
	C4591001 1226 12261173	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Hyperuricaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261181	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261187	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261195	Social circumstances	Menopause	01JAN1996		Y
		Vascular disorders	Hypotension	01JAN2010		Y
	C4591001 1226 12261198	Psychiatric disorders	Depression	01JAN2018		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN2010	31DEC2010	N
	C4591001 1226 12261209	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1226 12261211	Vascular disorders	Hypertension	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Menopause	01JAN1996		Y
	C4591001 1226 12261212	Gastrointestinal disorders	Gastroesophageal reflux disease	01FEB2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Menopause	01JAN1995		Y
	C4591001 1226 12261219	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2012		Y
	C4591001 1226 12261221	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2010		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1226 12261222	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Deep vein thrombosis	01NOV2016	30NOV2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261225	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1226 12261252	Cardiac disorders	Angina unstable	01APR2012	30APR2012	N
			Coronary artery insufficiency	01APR2012		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01APR2012		Y
			Type 2 diabetes mellitus	01APR2012		Y
		Surgical and medical procedures	Vascular stent insertion	01APR2012	30APR2012	N
		Vascular disorders	Hypertension	01APR2012		Y
	C4591001 1226 12261253	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1226 12261255	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261268	Congenital, familial and genetic disorders	Congenital cerebrovascular anomaly	01JAN1991	31DEC1991	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN2014		Y
		Surgical and medical procedures	Cerebrovascular operation	01JAN1991	31DEC1991	N
			Vasectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261281	Cardiac disorders	Arrhythmia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261283	Gastrointestinal disorders	Dyspepsia	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Nervous system disorders	Headache	01JAN2017		Y
		Surgical and medical procedures	Female sterilisation	01JAN1985	01JAN1985	N
	C4591001 1226 12261284	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1999		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261286	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2020		Y
	C4591001 1226 12261289	Gastrointestinal disorders	Lumbar hernia	01JAN2019		Y
		Infections and infestations	Labyrinthitis	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2012		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261297	Metabolism and nutrition disorders	Obesity	19AUG2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
	C4591001 1226 12261309	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000		Y
	C4591001 1226 12261310	Hepatobiliary disorders	Cholelithiasis	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Obesity	01JAN1976	31DEC2007	N
		Surgical and medical procedures	Cholecystectomy	01JAN2011	31DEC2011	N
			Metabolic surgery	01JAN2007	31DEC2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Varicose vein	01JAN1976	31DEC2011	N
	C4591001 1226 12261311	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261316	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Surgical and medical procedures	Salpingectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1226 12261317	Infections and infestations	Appendicitis	01JAN1969	31DEC1969	N
		Musculoskeletal and connective tissue disorders	Arthropathy	01JAN2013		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Appendicectomy	01JAN1969	31DEC1969	N
			Oophorectomy bilateral	01JAN2015	31DEC2015	N
	C4591001 1226 12261318	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2019		Y
	C4591001 1226 12261320	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261329	Cardiac disorders	Arrhythmia	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1226 12261334	Gastrointestinal disorders	Diverticulum	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Vasectomy	01JAN1984		Y
	C4591001 1226 12261335	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12261339	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Glucose tolerance impaired	01OCT2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261342	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Glucose tolerance impaired	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2016		Y
	C4591001 1226 12261346	Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1226 12261353	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Nervous system disorders	Cervicobrachial syndrome	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y
			Varicose vein	01JAN2010		Y
	C4591001 1226 12261366	Hepatobiliary disorders	Cholelithiasis	01MAY2019	30JUN2019	N
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	17JUN2019	17JUN2019	N
			Vasectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261367	Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1226 12261368	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012		Y
			Hypercholesterolaemia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
			Insomnia	01JAN2014		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1226 12261370	Social circumstances	Menopause	01JAN2010		Y
	C4591001 1226 12261371	Cardiac disorders	Acute myocardial infarction	01JAN2010	31DEC2010	N
	C4591001 1226 12261374	Metabolism and nutrition disorders	Obesity	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1226 12261378	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1976	31DEC1995	N
		Psychiatric disorders	Depression	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261381	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261386	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1226 12261388	Skin and subcutaneous tissue disorders	Cutaneous amyloidosis	01JAN2017		Y
		Social circumstances	Menopause	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261398	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261401	Social circumstances	Menopause	01JUN2014		Y
	C4591001 1226 12261402	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261419	Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1226 12261438	Ear and labyrinth disorders	Tinnitus	01JAN2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Social circumstances	Menopause	01JAN1992		Y
		Surgical and medical procedures	Fracture treatment	01JAN2016	31DEC2016	N
	C4591001 1226 12261446	Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01MAY2020		Y
	C4591001 1226 12261450	Social circumstances	Menopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12261453	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperuricaemia	01JAN2016		Y
			Obesity	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1226 12261458	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Depression	01APR2020		Y
	C4591001 1226 12261461	Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261462	Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2011	31DEC2014	N
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261464	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2003	31DEC2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01DEC1999	31DEC1999	N
		Surgical and medical procedures	Hysterectomy	01DEC1999	31DEC1999	N
	C4591001 1226 12261467	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Glucose tolerance impaired	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261473	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1226 12261477	Musculoskeletal and connective tissue disorders	Inclusion body myositis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261481	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Renal and urinary disorders	Stress urinary incontinence	01JAN2010		Y
		Social circumstances	Menopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2005		Y
			Varicose vein	01JAN1979		Y
	C4591001 1226 12261487	Social circumstances	Menopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261499	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010		Y
			Overweight	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2009	N
		Social circumstances	Menopause	01JAN1993		Y
		Surgical and medical procedures	Mastectomy	01JAN2004	31DEC2004	N
	C4591001 1226 12261506	Social circumstances	Menopause	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261510	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261513	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261523	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
	C4591001 1226 12261527	Endocrine disorders	Hypothyroidism	01JAN1994		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Hyperuricaemia	01AUG2020		Y
			Obesity	01JAN2014		Y
		Social circumstances	Menopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261534	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12261536	Surgical and medical procedures	Vision correction operation	01JAN2005	31DEC2005	N
	C4591001 1226 12261537	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1969		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261539	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1226 12261541	Reproductive system and breast disorders	Endometriosis	01JAN2000	31DEC2004	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2004	31DEC2004	N
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1226 12261550	Reproductive system and breast disorders	Endometriosis	01JAN1990	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1993	31DEC1993	N
			Oophorectomy	01JAN1993	31DEC1993	N
			Oophorectomy bilateral	01JAN1993	31DEC1993	N
	C4591001 1226 12261552	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2010		Y
		Surgical and medical procedures	Coronary revascularisation	01JAN2010	31DEC2010	N
	C4591001 1226 12261556	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Obesity	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2004	31DEC2004	N
			Metabolic surgery	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12261558	Gastrointestinal disorders	Gastritis	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1226 12261565	Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261573	Cardiac disorders	Arrhythmia	01MAR2019		Y
		Surgical and medical procedures	Dental implantation	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1968	31DEC1968	N
			Vasectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261580	Endocrine disorders	Goitre	01JAN2004	31DEC2005	N
			Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
			Tendonitis	01JAN2011		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1226 12261589	Surgical and medical procedures	Vasectomy	01JAN2013	31DEC2013	N
	C4591001 1226 12261605	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
	C4591001 1226 12261608	Cardiac disorders	Arrhythmia	01JAN2013		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1226 12261613	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1226 12261617	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1995	31DEC1996	N
		Social circumstances	Menopause	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1226 12261626	Metabolism and nutrition disorders	Obesity	01JAN1990		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261635	Infections and infestations	Labyrinthitis	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Social circumstances	Menopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261638	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2005		Y
			Varicose vein	01JAN2010		Y
	C4591001 1226 12261639	Psychiatric disorders	Anxiety disorder	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261640	Cardiac disorders	Coronary artery insufficiency	01AUG2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Glucose tolerance impaired	01JAN2020		Y
		Surgical and medical procedures	Coronary arterial stent insertion	16SEP2019	16SEP2019	N
	C4591001 1226 12261642	Metabolism and nutrition disorders	Hyperuricaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12261652	Metabolism and nutrition disorders	Obesity	01JAN2003		Y
		Surgical and medical procedures	Vasectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261658	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Obesity	01JAN2010		Y
		Nervous system disorders	Peroneal nerve palsy	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261662	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1968		Y
	C4591001 1226 12261663	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1226 12261671	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12261678	Cardiac disorders	Coronary artery insufficiency	01SEP2004		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2004		Y
			Type 2 diabetes mellitus	01JAN1997		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2020		Y
		Social circumstances	Tobacco user	01JAN1971	31OCT2004	N
		Surgical and medical procedures	Coronary artery bypass	01OCT2004	31OCT2004	N
		Vascular disorders	Hypertension	01SEP2004		Y
	C4591001 1226 12261700	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261727	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261735	Social circumstances	Menopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261744	Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2019		Y
	C4591001 1226 12261755	Metabolism and nutrition disorders	Hyperglycaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261774	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
		Social circumstances	Menopause	01JAN2014		Y
		Vascular disorders	Hypertension	01FEB2020		Y
	C4591001 1226 12261785	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1226 12261786	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261787	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Infections and infestations	Erysipelas	26AUG2020	10SEP2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis	11SEP2020		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1226 12261788	Cardiac disorders	Acute myocardial infarction	01JAN2016	31DEC2016	N
			Coronary artery insufficiency	01JAN2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2016	31DEC2016	N
	C4591001 1226 12261799	Cardiac disorders	Arrhythmia	01JAN2015		Y
		Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2015	31DEC2015	N
			Metabolic surgery	01JAN2014	31DEC2014	N
	C4591001 1226 12261814	Social circumstances	Menopause	01JAN2013		Y
	C4591001 1226 12261816	Metabolism and nutrition disorders	Obesity	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1226 12261817	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Surgical and medical procedures	Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1226 12261822	Infections and infestations	Labyrinthitis	01MAY2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
	C4591001 1226 12261825	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Psychiatric disorders	Anxiety disorder	01JAN1981		Y
		Surgical and medical procedures	Vasectomy	01JAN2008	31DEC2008	N
	C4591001 1226 12261829	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1226 12261837	Immune system disorders	Food allergy	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2010		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1226 12261861	Gastrointestinal disorders	Gastritis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JUN2019		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2010		Y
		Social circumstances	Menopause	01JAN1997		Y
	C4591001 1226 12261862	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Menopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12261872	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1226 12261883	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Obesity	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2012	01NOV2018	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Nephrectomy	01NOV2011	01NOV2011	N
	C4591001 1226 12261891	Renal and urinary disorders	Nephrolithiasis	01JAN1999		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261903	Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1226 12261913	Blood and lymphatic system disorders	Thrombocytopenia	01JAN1990		Y
		Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1226 12261915	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2019		Y
			Glucose tolerance impaired	01MAR2019		Y
		Musculoskeletal and connective tissue disorders	Chondromalacia	01SEP2019		Y
		Social circumstances	Menopause	01JAN2007	31DEC2007	N
	C4591001 1226 12261916	Psychiatric disorders	Anxiety	01JAN1990		Y
	C4591001 1226 12261921	Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1226 12261949	Social circumstances	Menopause	01JAN2010		Y
	C4591001 1226 12261955	Psychiatric disorders	Depression	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1226 12261965	Congenital, familial and genetic disorders	Heart disease congenital	01JAN2000		Y
	C4591001 1226 12261969	Endocrine disorders	Hypothyroidism	01JAN1977		Y
		Nervous system disorders	Migraine	01JAN2018		Y
		Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Sterilisation	27DEC1995	27DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12261977	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12261979	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
		Social circumstances	Menopause	01JAN1996		Y
	C4591001 1226 12261984	Endocrine disorders	Hypothyroidism	01JAN2013		Y
		Gastrointestinal disorders	Gastritis	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1226 12261990	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Social circumstances	Menopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12261991	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1226 12261993	Injury, poisoning and procedural complications	Nerve root injury lumbar	01JAN1985		Y
			Road traffic accident	01JAN1985	31DEC1985	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262004	Gastrointestinal disorders	Haemorrhoids	01JAN2001	10FEB2021	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1226 12262005	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12262009	Surgical and medical procedures	Vasectomy	01JAN2004	31DEC2004	N
	C4591001 1226 12262025	Metabolism and nutrition disorders	Overweight	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1983		Y
	C4591001 1226 12262031	Gastrointestinal disorders	Constipation	01JAN2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Nervous system disorders	Headache	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1226 12262032	Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1226 12262033	Social circumstances	Menopause	01JAN1996	31DEC1996	N
	C4591001 1226 12262043	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262053	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Social circumstances	Menopause	01JAN2014	31DEC2014	N
	C4591001 1226 12262054	Endocrine disorders	Hypothyroidism	01JAN2019		Y
		Infections and infestations	Osteomyelitis	01JAN2016	31DEC2016	N
		Injury, poisoning and procedural complications	Lower limb fracture	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2019		Y
			Overweight	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017		Y
		Surgical and medical procedures	Limb operation	01JAN2016	31DEC2016	N
	C4591001 1226 12262055	Infections and infestations	Labyrinthitis	01JAN2011		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Obesity	01JAN2005		Y
		Social circumstances	Menopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1226 12262057	Surgical and medical procedures	Vasectomy	01JAN2009	31DEC2009	N
	C4591001 1226 12262061	Psychiatric disorders	Anxiety	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000		Y
			Chronic obstructive pulmonary disease	01JAN2012		Y
		Social circumstances	Menopause	01JAN2006		Y
			Tobacco user	01JAN1972		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262066	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Social circumstances	Menopause	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1226 12262069	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2008		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1226 12262074	Gastrointestinal disorders	Oesophagitis	01JAN2014		Y
		Metabolism and nutrition disorders	Overweight	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Nervous system disorders	Headache	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal septum deviation	01JAN1990		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1226 12262077	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Nervous system disorders	Carotid artery dissection	01JAN2020	31JAN2020	N
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1226 12262082	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JUN2014	30NOV2014	N
		Surgical and medical procedures	Penile prosthesis insertion	01JAN2018	31DEC2018	N
			Radical prostatectomy	01NOV2014	30NOV2014	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12262088	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262098	Cardiac disorders	Atrial fibrillation	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Nervous system disorders	Dementia	01JAN2018		Y
		Psychiatric disorders	Depression	01APR2020		Y
		Social circumstances	Menopause	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1226 12262100	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	01JAN2005	31DEC2005	N
		Nervous system disorders	Dizziness	01MAR2020		Y
			Headache	01MAR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12262102	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Glucose tolerance impaired	01JAN2015		Y
		Social circumstances	Menopause	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12262109	Cardiac disorders	Cardiac disorder	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Prostatism	01JAN2017		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2018	31MAY2018	N
			Vasectomy	01JAN1985	31DEC1985	N



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1226 12262118	Metabolism and nutrition disorders	Obesity	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Oophorectomy bilateral	01JAN2015	31DEC2015	N
	C4591001 1226 12262139	Gastrointestinal disorders	Gastritis	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Obesity	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1226 12262147	Cardiac disorders	Arrhythmia	01JAN2014		Y
		Endocrine disorders	Thyroid cyst	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1987	31DEC1988	N
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1226 12262150	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Social circumstances	Menopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1226 12262155	Gastrointestinal disorders	Inguinal hernia	01JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2018		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1226 12262156	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
			Hypercholesterolaemia	01JAN2018		Y
			Obesity	01JAN2015		Y
		Social circumstances	Menopause	01JAN2003		Y
	C4591001 1226 12262158	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1226 12262160	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Osteopenia	01JAN2013		Y
			Spinal osteoarthritis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1987		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1226 12262161	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1990		Y
	C4591001 1226 12262171	Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N
	C4591001 1226 12262173	Social circumstances	Menopause	01JAN2012	31DEC2012	N
	C4591001 1226 12262174	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1226 12262177	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2007		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperuricaemia	01JAN2007		Y
			Obesity	01MAR2020		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1226 12262202	Endocrine disorders	Adrenal mass	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Glucose tolerance impaired	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Menopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1226 12262203	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Renal and urinary disorders	Renal impairment	01JAN2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1226 12262207	Psychiatric disorders	Depression	01JAN2016		Y
	C4591001 1226 12262210	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Hepatobiliary disorders	Cholecystitis chronic	01JAN2017	28FEB2019	N
			Cholelithiasis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN1991	31DEC1991	N
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Cholecystectomy	01FEB2019	28FEB2019	N
			Thyroidectomy	01JAN1991	31DEC1991	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262214	Hepatobiliary disorders	Cholelithiasis	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Hyperuricaemia	01JAN2014		Y
			Obesity	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01SEP2012	30SEP2012	N
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Nephrectomy	01SEP2012	30SEP2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262215	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2018		Y
		Social circumstances	Menopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1226 12262222	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Glaucoma	01JAN2014	31MAY2019	N
		Injury, poisoning and procedural complications	Injury corneal	01JAN2018	31MAY2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Corneal transplant	01MAY2019	31MAY2019	N
	C4591001 1226 12262235	Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1226 12262238	Endocrine disorders	Hypothyroidism	01JAN1979		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262240	Endocrine disorders	Hypothyroidism	01OCT1999		Y
		Injury, poisoning and procedural complications	Femur fracture	01NOV2019	29FEB2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01OCT2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01NOV2019		Y
		Social circumstances	Menopause	01JAN1993		Y
		Vascular disorders	Hypertension	01OCT2005		Y
	C4591001 1226 12262248	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2004		Y
	C4591001 1226 12262250	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
	C4591001 1226 12262253	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
			Obesity	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1226 12262254	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01JAN2012		Y
		Social circumstances	Menopause	01JAN2004		Y
	C4591001 1226 12262257	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262264	Gastrointestinal disorders	Dyspepsia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001		Y
	C4591001 1226 12262265	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pharyngeal neoplasm	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Pharyngeal operation	01JAN2010	31DEC2010	N
	C4591001 1226 12262266	Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1977		Y
		Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1226 12262271	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1226 12262277	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostatic adenoma	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262281	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2016		Y
		Psychiatric disorders	Anxiety disorder	01JAN1998		Y
		Social circumstances	Menopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262288	Gastrointestinal disorders	Dyspepsia	01JAN1987		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
			Glucose tolerance impaired	01JAN2019		Y
			Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Anxiolytic therapy	01JAN2010		Y
			Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1226 12262296	Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2000		Y
		Social circumstances	Menopause	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262302	Metabolism and nutrition disorders	Gout	01JAN1983		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1226 12262305	Metabolism and nutrition disorders	Obesity	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Myalgia	01APR2020		Y
		Social circumstances	Menopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1226 12262306	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01DEC2015		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1226 12262308	Gastrointestinal disorders	Gastritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JUN2020		Y
			Type 2 diabetes mellitus	01JUN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
		Social circumstances	Menopause	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1226 12262310	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1226 12262312	Gastrointestinal disorders	Gastritis	01JAN2013		Y
		Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1226 12262323	Social circumstances	Menopause	01JAN2014		Y
	C4591001 1226 12262324	Endocrine disorders	Hypothyroidism	01OCT2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01OCT2000		Y
		Nervous system disorders	Migraine	01OCT2010		Y
		Psychiatric disorders	Insomnia	01OCT2015		Y
		Social circumstances	Menopause	01OCT2018		Y
	C4591001 1226 12262325	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1994	31DEC1994	N
		Nervous system disorders	Cerebrovascular accident	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN1994	31DEC1994	N
			Oophorectomy	01JAN1994	31DEC1994	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1226 12262328	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2020		Y
			Obesity	01JAN2015		Y
		Psychiatric disorders	Obsessive-compulsive disorder	01JAN2018		Y
	C4591001 1226 12262332	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1226 12262336	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Vasectomy	01JAN1985	31DEC1985	N
	C4591001 1226 12262342	Reproductive system and breast disorders	Premature menopause	01JAN1990		Y
	C4591001 1226 12262344	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1980		Y
			Obesity	01JAN1990		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	31DEC1988	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1226 12262345	Injury, poisoning and procedural complications	Post procedural hypothyroidism	01DEC2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01NOV2011	31DEC2011	N
		Surgical and medical procedures	Thyroidectomy	01DEC2011		Y
	C4591001 1226 12262355	Metabolism and nutrition disorders	Overweight	01JAN2010		Y
		Social circumstances	Menopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN1981	31DEC1981	N
			Metabolic surgery	01JAN2015	31DEC2015	N
	C4591001 1226 12262358	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperuricaemia	01JAN2013		Y
			Overweight	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1229 12291003	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1960		Y
		Social circumstances	Menopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1229 12291005	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1986		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1229 12291014	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1229 12291017	Metabolism and nutrition disorders	Gout	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2003		Y
	C4591001 1229 12291018	Musculoskeletal and connective tissue disorders	Arthritis	01JAN1992		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1229 12291023	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2006		Y
	C4591001 1229 12291026	Nervous system disorders	Epilepsy	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2009		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1229 12291028	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
	C4591001 1229 12291034	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1229 12291036	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1229 12291038	Gastrointestinal disorders	Umbilical hernia	01JAN2018		Y
		Infections and infestations	Tinea versicolour	01SEP2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1229 12291040	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1229 12291041	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1229 12291044	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1229 12291050	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2014		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1229 12291054	Renal and urinary disorders	Chronic kidney disease	09SEP2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1229 12291056	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Social circumstances	Menopause	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1984	31DEC1984	N
				01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1229 12291060	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990		Y
		Surgical and medical procedures	Cataract operation	01FEB2018		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1229 12291067	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1229 12291068	Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2016		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291069	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1992		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN1993	31DEC1993	N
	C4591001 1229 12291071	Social circumstances	Menopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1229 12291074	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Social circumstances	Menopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1229 12291075	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1977		Y
		Social circumstances	Menopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1229 12291076†	Infections and infestations	HIV infection	01JAN1999		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1229 12291080	Infections and infestations	Upper respiratory tract infection	25SEP2020	05OCT2020	N
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Caesarean section	01JAN2015	31DEC2015	N
	C4591001 1229 12291084	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Social circumstances	Menopause	01JAN1988		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1229 12291085	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291087	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1229 12291089†	Infections and infestations	HIV infection	01JAN2008		Y
		Social circumstances	Menopause	01JAN2003		Y
	C4591001 1229 12291097	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2009		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1229 12291102†	Infections and infestations	HIV infection	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Nervous system disorders	Epilepsy	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1229 12291106	Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
	C4591001 1229 12291111	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Caesarean section	01JAN1980		Y
			Female sterilisation	01JAN1987		Y
		Vascular disorders	Hypertension	01JAN1972		Y
	C4591001 1229 12291120	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
		Social circumstances	Menopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN1987		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291121	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Menopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN1986		Y
	C4591001 1229 12291123	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Nervous system disorders	Trigeminal neuralgia	01JAN2019		Y
		Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1229 12291125	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1229 12291129	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2016		Y
		Social circumstances	Menopause	01JAN2009		Y
	C4591001 1229 12291137	Surgical and medical procedures	Limb operation	01JAN1985	31DEC1985	N
	C4591001 1229 12291144	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Social circumstances	Menopause	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1229 12291147	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1229 12291148	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1229 12291150	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Social circumstances	Menopause	01JAN2005		Y
	C4591001 1229 12291162	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1229 12291163	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1229 12291164	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Social circumstances	Menopause	01JAN2009		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1229 12291183	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1229 12291191	Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Obesity	01JAN2012		Y
	C4591001 1229 12291203†	Infections and infestations	HIV infection	01JAN2003		Y
		Social circumstances	Menopause	01JAN2016		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1229 12291206	Gastrointestinal disorders	Peptic ulcer	01JAN1987	31DEC1987	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2019		Y
		Surgical and medical procedures	Gastrointestinal ulcer management	01JAN1987	31DEC1987	N
	C4591001 1229 12291208	Ear and labyrinth disorders	Hypoacusis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Social circumstances	Menopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1229 12291210†	Infections and infestations	HIV infection	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1230 12301003	Gastrointestinal disorders	Hiatus hernia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
		Surgical and medical procedures	Intraocular lens implant	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2019	31DEC2019	N
			Tonsillectomy	01JAN1945	31DEC1945	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1230 12301007	Eye disorders	Myopia	01JAN1989		Y
		Injury, poisoning and procedural complications	Jaw fracture	01MAR1993	31MAR1993	N
			Rib fracture	01MAR1983	31MAR1983	N
		Surgical and medical procedures	Fracture treatment	01JAN1993	31DEC1993	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01MAR1983	31MAR1983	N
			Tonsillectomy	01JAN1973	31DEC1973	N
	C4591001 1230 12301014	Eye disorders	Cataract	01AUG2018		Y
			Dry eye	01AUG2018		Y
		Gastrointestinal disorders	Constipation	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Insomnia	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2012		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	01JAN2018		Y
	C4591001 1230 12301025	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastric cancer	01OCT2014	27OCT2014	N
		Surgical and medical procedures	Abdominal operation	27OCT2014	27OCT2014	N
			Chemotherapy	01FEB2015	31DEC2016	N
			Inguinal hernia repair	01JAN1995	31DEC1995	N
				01JAN2005	31DEC2005	N
			Intraocular lens implant	01JAN2010	31DEC2010	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1230 12301027	Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Pregnancy, puerperium and perinatal conditions	Delivery	01JUN1995	01JUN1995	N
				06JAN1990	06JAN1990	N
				25FEB1993	25FEB1993	N
				25MAR1984	25MAR1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1230 12301059	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1230 12301076	Musculoskeletal and connective tissue disorders	Kyphosis	01JAN2009		Y
			Osteoporosis	01AUG2009		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyoma	01JAN1986	31DEC1986	N
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
	C4591001 1230 12301096	Vascular disorders	Hypertension	01JAN2015		Y
		Social circumstances	Tobacco user	01JAN2010		Y
	C4591001 1230 12301098	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Caesarean section	01JAN1971	31DEC1971	N
				01JAN1973	31DEC1973	N
			Coronary arterial stent insertion	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1975	31DEC1975	N
			Tonsillectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1970		Y
	C4591001 1230 12301111	Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2010		Y
	C4591001 1230 12301119	Injury, poisoning and procedural complications	Skull fracture	01APR1992	30APR1992	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Nervous system disorders	Coma	01APR1992	30APR1992	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Pregnancy, puerperium and perinatal conditions	Delivery	13JUL1985	13JUL1985	N
				16JUN1993	16JUN1993	N
		Social circumstances	Menopause	01JAN2014		Y
			Tobacco user	01JAN1976		Y
		Surgical and medical procedures	Bone operation	01APR1992	30APR1992	N
			Open reduction of fracture	01APR2014	30APR2014	N
			Pituitary tumour removal	01JAN1978	31DEC1978	N
	C4591001 1230 12301120	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
	C4591001 1230 12301127	Endocrine disorders	Hypothyroidism	01JAN1992		Y
		Metabolism and nutrition disorders	Gout	01JAN2015		Y
			Obesity	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Reproductive system and breast disorders	Dysfunctional uterine bleeding	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01MAR2017		Y
	C4591001 1230 12301128	Surgical and medical procedures	Caesarean section	15SEP1994	15SEP1994	N
	C4591001 1230 12301155	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1230 12301167	Surgical and medical procedures	Vasectomy	01JAN1983	31DEC1983	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JUL2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUL2010		Y
	C4591001 1230 12301168	Surgical and medical procedures	Caesarean section	12JUL1996	12JUL1996	N
				26JUL1999	26JUL1999	N
			Female sterilisation	26JUL1999	26JUL1999	N
			Salpingectomy	26JUL1999	26JUL1999	N
			Tonsillectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JUL2020		Y
	C4591001 1230 12301169	Ear and labyrinth disorders	Deafness unilateral	01JAN2017		Y
	C4591001 1230 12301178	Infections and infestations	Appendicitis	01JAN1974	31DEC1974	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1974	31DEC1974	N
			Hysterectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1230 12301179	Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
		Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
			Tendon sheath incision	01JAN2005	31DEC2005	N
	C4591001 1231 12311007	Reproductive system and breast disorders	Benign prostatic hyperplasia	30NOV2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311014	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1995	31DEC2005	N
	C4591001 1231 12311015	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	T-cell lymphoma	01JUN2017	31DEC2018	N
		Surgical and medical procedures	Chemotherapy	01JUN2017	31DEC2018	N
			Transplant	01JUN2018	31DEC2018	N
	C4591001 1231 12311020	Respiratory, thoracic and mediastinal disorders	Asthma	02MAR2013		Y
	C4591001 1231 12311028	Congenital, familial and genetic disorders	Factor XI deficiency	18AUG2018		Y
	C4591001 1231 12311037	Vascular disorders	Hypertension	15JAN2010		Y
	C4591001 1231 12311044	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN1988		Y
		Eye disorders	Presbyopia	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2016		Y
	C4591001 1231 12311050	Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1231 12311056	Nervous system disorders	Ischaemic stroke	01MAY2017	01MAY2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12311059	Cardiac disorders	Congestive cardiomyopathy	01AUG2015		Y
		Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12311060	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUN2004		Y
		Vascular disorders	Hypertension	14AUG2014		Y
	C4591001 1231 12311061	Respiratory, thoracic and mediastinal disorders	Lung disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311063	Vascular disorders	Hypertension	10JAN2016		Y
	C4591001 1231 12311090	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Vascular disorders	Hypertension	10AUG2000		Y
	C4591001 1231 12311106	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG1998		Y
		Nervous system disorders	Diabetic neuropathy	15FEB2019		Y
	C4591001 1231 12311132	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
	C4591001 1231 12311139	Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2015		Y
		Vascular disorders	Hypertension	27JUN2004		Y
	C4591001 1231 12311148	Infections and infestations	Diverticulitis	19JUL1979	20JUL1979	N
		Surgical and medical procedures	Appendicectomy	12JUN1968	14JUN1968	N
	C4591001 1231 12311150	Endocrine disorders	Hyperthyroidism	01JAN2012		Y
	C4591001 1231 12311155	Cardiac disorders	Mitral valve prolapse	15JUL1990		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	11FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01AUG2000		Y
	C4591001 1231 12311163	Gastrointestinal disorders	Haemorrhoids	01NOV2019		Y
	C4591001 1231 12311165	Cardiac disorders	Arrhythmia	31MAY2018	20DEC2018	N
	C4591001 1231 12311173	Nervous system disorders	Migraine	01DEC2019		Y
		Vascular disorders	Hypertension	23FEB2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311174	Metabolism and nutrition disorders	Hypertriglyceridaemia	01DEC2019		Y
		Vascular disorders	Hypertension	01JUL2002		Y
	C4591001 1231 12311182	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2015		Y
		Vascular disorders	Hypertension	10AUG2005		Y
	C4591001 1231 12311184	Vascular disorders	Hypertension	01JUN2002		Y
	C4591001 1231 12311197	Gastrointestinal disorders	Internal hernia	01MAR2012	13MAR2012	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Surgical and medical procedures	Intestinal anastomosis	01MAR2012	13MAR2012	N
			Intestinal resection	01MAR2012	13MAR2012	N
	C4591001 1231 12311201	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12311209	Metabolism and nutrition disorders	Type 2 diabetes mellitus	07OCT2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	23AUG2012	18AUG2015	N
	C4591001 1231 12311213	Vascular disorders	Hypertension	10OCT2010		Y
	C4591001 1231 12311225	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12311227	Vascular disorders	Hypertension	24OCT2000		Y
	C4591001 1231 12311228	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2010		Y
		Vascular disorders	Hypertension	01AUG2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311234	Endocrine disorders	Hypothyroidism	01MAR2010		Y
		Gastrointestinal disorders	Diverticulum	04MAR2016		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1231 12311235	Surgical and medical procedures	Gastric bypass	22AUG2015		Y
	C4591001 1231 12311236	Endocrine disorders	Hypothyroidism	10APR2001		Y
		Gastrointestinal disorders	Coeliac disease	13OCT2015		Y
			Gastrointestinal polyp	01JUL2012		Y
			Gastroesophageal reflux disease	01AUG2001		Y
	C4591001 1231 12311240	Cardiac disorders	Coronary artery disease	01APR2004	05MAY2004	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01OCT2000		Y
		Renal and urinary disorders	Chronic kidney disease	29NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	08MAY2014		Y
			Emphysema	01JAN2008		Y
		Surgical and medical procedures	Coronary artery bypass	01APR2004	05MAY2004	N
	C4591001 1231 12311249	Musculoskeletal and connective tissue disorders	Tendonitis	02MAY2020		Y
		Vascular disorders	Hypertension	14AUG2010		Y
	C4591001 1231 12311250	Endocrine disorders	Hypothyroidism	01AUG2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1231 12311253	Endocrine disorders	Hypothyroidism	01JUL2010		Y
		Social circumstances	Andropause	01AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311254	Endocrine disorders	Hypothyroidism	12JUL2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12JUN2017		Y
	C4591001 1231 12311258	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2000		Y
	C4591001 1231 12311262	Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12311271	Immune system disorders	Drug hypersensitivity	02SEP2003	02SEP2003	N
		Skin and subcutaneous tissue disorders	Drug eruption	02SEP2003	02SEP2003	N
	C4591001 1231 12311278	Endocrine disorders	Autoimmune thyroiditis	06SEP2016		Y
		Vascular disorders	Hypertension	11MAR2009		Y
	C4591001 1231 12311280	Congenital, familial and genetic disorders	Renal hypoplasia	01MAR2008		Y
		Gastrointestinal disorders	Gastrointestinal polyp	01MAR2017	01JUN2018	N
	C4591001 1231 12311292	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2002		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAR2018		Y
	C4591001 1231 12311300	Immune system disorders	Hypersensitivity	01AUG2012		Y
	C4591001 1231 12311310	Investigations	Biopsy breast	15SEP2000	15SEP2000	N
		Surgical and medical procedures	Appendectomy	08AUG1972	08AUG1972	N
			Cholecystectomy	09AUG1996	09AUG1996	N
		Vascular disorders	Hypertension	02JUN2018		Y
	C4591001 1231 12311316	Cardiac disorders	Acute myocardial infarction	01NOV2009	05NOV2009	N
	C4591001 1231 12311318	Metabolism and nutrition disorders	Type 2 diabetes mellitus	14MAY2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	14MAY2015		Y
		Vascular disorders	Hypertension	14MAY2015		Y
	C4591001 1231 12311323	Surgical and medical procedures	Caesarean section	14FEB1994	14FEB1994	N
	C4591001 1231 12311324	Injury, poisoning and procedural complications	Head injury	01JAN2015	10JAN2015	N
	C4591001 1231 12311326	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
	C4591001 1231 12311329	Endocrine disorders	Hypothyroidism	13MAY2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Foot deformity	13MAR2013	13MAR2013	N
		Psychiatric disorders	Generalised anxiety disorder	01JAN2017		Y
		Surgical and medical procedures	Adenotonsillectomy	10JUN1966	10JUN1966	N
			Hysterectomy	14JUN2006	14JUN2006	N
	C4591001 1231 12311363	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Liposarcoma	12JAN2006	10JUL2011	N
	C4591001 1231 12311379	Investigations	Prostatic specific antigen increased	12AUG2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12311382	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2019		Y
			Peripheral venous disease	03JUN2010		Y
	C4591001 1231 12311390	Endocrine disorders	Hypothyroidism	01OCT2000		Y
		Vascular disorders	Hypertension	01MAR2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311394	Musculoskeletal and connective tissue disorders	Osteoarthritis	20SEP2018		Y
	C4591001 1231 12311400	Nervous system disorders	Carotid artery occlusion	01OCT2010		Y
	C4591001 1231 12311404	Gastrointestinal disorders	Hiatus hernia	01OCT1980		Y
		Renal and urinary disorders	Nephrolithiasis	01JUL2015		Y
		Surgical and medical procedures	Varicose vein operation	01MAY1990	01MAY2012	N
	C4591001 1231 12311407	Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 1231 12311415	Ear and labyrinth disorders	Meniere's disease	13NOV2013		Y
		Gastrointestinal disorders	Irritable bowel syndrome	11AUG2010		Y
		Psychiatric disorders	Depression	24JUN2010	01AUG2019	N
		Reproductive system and breast disorders	Breast mass	17NOV2005	17NOV2005	N
	C4591001 1231 12311416	Endocrine disorders	Hypothyroidism	01JUN1995		Y
		Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 1231 12311419	Gastrointestinal disorders	Pancreatitis	10JAN2019	20JAN2019	N
	C4591001 1231 12311424	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal cancer	01FEB2016	01AUG2016	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1231 12311426	Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1231 12311434	Vascular disorders	Hypertension	22JUN2012		Y
	C4591001 1231 12311437	Vascular disorders	Hypertension	02AUG2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311442	Injury, poisoning and procedural complications	Dislocation of vertebra	10OCT2019		Y
			Humerus fracture	15OCT2015	23OCT2015	N
		Metabolism and nutrition disorders	Insulin resistance	15AUG2013		Y
			Obesity	21APR2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	21SEP1990		Y
		Surgical and medical procedures	Knee arthroplasty	14APR2010		Y
		Vascular disorders	Deep vein thrombosis	10DEC2010	24DEC2010	N
	C4591001 1231 12311450	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG1980		Y
	C4591001 1231 12311456	Metabolism and nutrition disorders	Hypercholesterolaemia	15AUG2000		Y
		Vascular disorders	Hypertension	13AUG2015		Y
	C4591001 1231 12311471	Cardiac disorders	Acute myocardial infarction	01APR2012	01APR2012	N
	C4591001 1231 12311477	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
	C4591001 1231 12311478	Vascular disorders	Hypertension	18AUG2010		Y
	C4591001 1231 12311488	Injury, poisoning and procedural complications	Nerve injury	01JAN2010		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1231 12311498	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2018		Y
			Type 2 diabetes mellitus	01FEB2002		Y
		Vascular disorders	Hypertension	01MAR2012		Y
	C4591001 1231 12311500	Blood and lymphatic system disorders	Anaemia	01JAN1980	01JAN2016	N
		Infections and infestations	Peritonitis	01AUG2015	01AUG2015	N

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12311510	Metabolism and nutrition disorders	Dyslipidaemia	06JUL2014		Y
		Renal and urinary disorders	Nephrolithiasis	06JUL2011		Y
		Vascular disorders	Hypertension	06JUL2014		Y
	C4591001 1231 12311512	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2000		Y
		Psychiatric disorders	Anxiety	01JUL2018		Y
	C4591001 1231 12311514	Cardiac disorders	Sinus tachycardia	01JAN2010		Y
		Endocrine disorders	Hypothyroidism	01JUN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01APR2014		Y
		Psychiatric disorders	Insomnia	01JUN2018		Y
	C4591001 1231 12311515	Gastrointestinal disorders	Dyspepsia	13SEP2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	16FEB2000		Y
		Vascular disorders	Hypertension	16MAR2010		Y
	C4591001 1231 12311517	Ear and labyrinth disorders	Deafness unilateral	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
	C4591001 1231 12311533	Ear and labyrinth disorders	Meniere's disease	20DEC2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12311542	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y
			Type 2 diabetes mellitus	01AUG2015		Y
	C4591001 1231 12311549	Gastrointestinal disorders	Dental caries	01SEP2018	01MAR2019	N
		Surgical and medical procedures	Tooth extraction	01MAR2019	01MAR2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1231 12311554	Endocrine disorders	Hypothyroidism	11JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	11AUG2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01AUG2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	04AUG2010		Y
		Vascular disorders	Hypertension	09AUG2010		Y
	C4591001 1231 12311561	Gastrointestinal disorders	Hiatus hernia	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	14OCT2010		Y
		Vascular disorders	Hypertension	09JUN2010		Y
	C4591001 1231 12311563	Psychiatric disorders	Depression	14FEB2015		Y
	C4591001 1231 12311564	Gastrointestinal disorders	Gastritis	01JUN2020		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12311574	Nervous system disorders	Restless legs syndrome	01JUN2015		Y
	C4591001 1231 12311576	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	12MAR2018	01JUN2018	N
		Skin and subcutaneous tissue disorders	Vitiligo	01JAN2019		Y
	C4591001 1231 12311583	Endocrine disorders	Hypothyroidism	14JUL2010		Y
	C4591001 1231 12311586	Metabolism and nutrition disorders	Type 2 diabetes mellitus	20MAY2010		Y
		Vascular disorders	Hypertension	19JUL2005		Y
	C4591001 1231 12311589	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUL2017		Y
		Renal and urinary disorders	Hypercalciuria	26JUN2017		Y
	C4591001 1231 12311603	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer in situ	01FEB2002	01OCT2002	N
		Surgical and medical procedures	Hysterectomy	18OCT2000	22OCT2000	N
		Vascular disorders	Hypertension	01MAY1994		Y
	C4591001 1231 12311610	Metabolism and nutrition disorders	Hypercholesterolaemia	08AUG2000		Y
			Type 2 diabetes mellitus	11AUG2010		Y
		Vascular disorders	Hypertension	08AUG2000		Y
	C4591001 1231 12311612	Endocrine disorders	Hypothyroidism	06JUL2000		Y
		Infections and infestations	Erysipelas	06JUL1995		Y
		Metabolism and nutrition disorders	Obesity	01JAN1990		Y
			Type 2 diabetes mellitus	06JUL2010		Y
		Vascular disorders	Hypertension	06JUL2017		Y
	C4591001 1231 12311613	Psychiatric disorders	Insomnia	10APR2020		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12311620	Surgical and medical procedures	Phlebectomy	03MAY1984	03MAY1984	N
		Vascular disorders	Phlebitis	20APR1984	03MAY1984	N
	C4591001 1231 12311639	Cardiac disorders	Mitral valve prolapse	01JAN1990		Y
	C4591001 1231 12311657	Metabolism and nutrition disorders	Type 2 diabetes mellitus	17AUG2018		Y
		Vascular disorders	Hypertension	16AUG2016		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311667	Metabolism and nutrition disorders	Type 2 diabetes mellitus	15AUG2011		Y
		Surgical and medical procedures	Hysterectomy	28SEP1984	28SEP1984	N
		Vascular disorders	Hypertension	23JUN2016		Y
	C4591001 1231 12311672	Eye disorders	Angle closure glaucoma	01JAN2020	18SEP2020	N
			Narrow anterior chamber angle	02FEB2020	07SEP2020 14SEP2020	N N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2017		Y
	C4591001 1231 12311675	Nervous system disorders	Carotid arteriosclerosis	01FEB2017		Y
	C4591001 1231 12311677	Vascular disorders	Hypertension	12JUN2000		Y
	C4591001 1231 12311680	Respiratory, thoracic and mediastinal disorders	Asthma	06SEP1998		Y
	C4591001 1231 12311688	Metabolism and nutrition disorders	Type 1 diabetes mellitus	08AUG1990		Y
		Vascular disorders	Hypertension	07AUG2012		Y
	C4591001 1231 12311699	Congenital, familial and genetic disorders	Arteriovenous malformation	01MAY2020	20JAN2021	N
	C4591001 1231 12311706	Metabolism and nutrition disorders	Dyslipidaemia	26AUG2008		Y
			Gout	29AUG1990		Y
	C4591001 1231 12311707	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2006		Y
	C4591001 1231 12311709	Nervous system disorders	Carotid arteriosclerosis	01JUN2014		Y
		Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 1231 12311713	Endocrine disorders	Hypothyroidism	02APR2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01FEB1997	02APR1997	N
	C4591001 1231 12311716	Endocrine disorders	Hypothyroidism	01AUG2002		Y
	C4591001 1231 12311717	Metabolism and nutrition disorders	Dyslipidaemia	06APR2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	02AUG2010		Y
	C4591001 1231 12311720	Metabolism and nutrition disorders	Hypercholesterolaemia	12MAY2010		Y
	C4591001 1231 12311723	Endocrine disorders	Hypothyroidism	01JUN1985		Y
		Infections and infestations	Onychomycosis	01JAN2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2017		Y
		Psychiatric disorders	Depression	01JAN2017		Y
	C4591001 1231 12311725	Psychiatric disorders	Depression	01MAY2006		Y
		Vascular disorders	Hypertension	01SEP2001		Y
	C4591001 1231 12311727	Gastrointestinal disorders	Coeliac disease	(b) (6) 1944		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Osteoporosis	01JUN2010		Y
		Vascular disorders	Hypertension	01MAR2017		Y
	C4591001 1231 12311728	Metabolism and nutrition disorders	Hypercholesterolaemia	15AUG2017		Y
		Psychiatric disorders	Sleep disorder	19AUG2014		Y
	C4591001 1231 12311729	Metabolism and nutrition disorders	Metabolic syndrome	06AUG2015		Y
			Obesity	01MAY2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Anxiety disorder	03AUG2005		Y
		Vascular disorders	Hypertension	10AUG2005		Y
	C4591001 1231 12311732	Cardiac disorders	Acute myocardial infarction	15AUG2001	15AUG2001	N
	C4591001 1231 12311737	Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12311742	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	16DEC2016	02FEB2017	N
	C4591001 1231 12311743	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JUL2007		Y
	C4591001 1231 12311744	Vascular disorders	Hypertension	01OCT2010		Y
	C4591001 1231 12311745	Metabolism and nutrition disorders	Hypercholesterolaemia	12MAR2005		Y
	C4591001 1231 12311753	Metabolism and nutrition disorders	Type 2 diabetes mellitus	05FEB2000		Y
		Vascular disorders	Hypertension	08APR2000		Y
	C4591001 1231 12311758	Cardiac disorders	Myocardial ischaemia	15OCT2013	18OCT2013	N
	C4591001 1231 12311762	Cardiac disorders	Supraventricular tachycardia	01JUN2001	01AUG2001	N
	C4591001 1231 12311767	Endocrine disorders	Hypothyroidism	10AUG2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostatic adenoma	10AUG2010		Y
	C4591001 1231 12311772	Musculoskeletal and connective tissue disorders	Fibromyalgia	12OCT2005		Y
		Surgical and medical procedures	Salpingectomy	01JAN1990	31DEC1990	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311775	Metabolism and nutrition disorders	Hypercholesterolaemia	12AUG2010		Y
	C4591001 1231 12311781	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2010		Y
			Metabolic syndrome	01JUN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2012		Y
	C4591001 1231 12311785	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12311798	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2014		Y
	C4591001 1231 12311803	Cardiac disorders	Extrasystoles	01AUG2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2011		Y
	C4591001 1231 12311808	Respiratory, thoracic and mediastinal disorders	Asthma	18AUG2000		Y
		Vascular disorders	Hypertension	02AUG2016		Y
	C4591001 1231 12311810	Cardiac disorders	Mitral valve prolapse	01JAN1996		Y
	C4591001 1231 12311814	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01AUG2000		Y
		Vascular disorders	Hypertension	01AUG1990		Y
	C4591001 1231 12311815	Infections and infestations	Meningitis	01JAN1966	14JAN1966	N
		Nervous system disorders	Demyelination	01JAN1966		Y
			Paraesthesia	01JAN1966		Y
		Social circumstances	Tobacco user	01JAN1982		Y
	C4591001 1231 12311826	Cardiac disorders	Tachycardia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1231 12311840	Psychiatric disorders	Depression	10AUG2010		Y
	C4591001 1231 12311848	Endocrine disorders	Hypothyroidism	03OCT2010		Y
	C4591001 1231 12311853	Metabolism and nutrition disorders	Type 1 diabetes mellitus	24SEP1990		Y
	C4591001 1231 12311856	Vascular disorders	Hypertension	01MAY2015		Y
	C4591001 1231 12311864	Ear and labyrinth disorders	Deafness	01JAN1997		Y
		Endocrine disorders	Hyperthyroidism	01JAN2012	01JAN2013	N
		Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Infections and infestations	Tuberculous pleurisy	01JAN1995	09OCT1995	N
		Injury, poisoning and procedural complications	Thoracic vertebral fracture	01JUN1978	01NOV1978	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	28FEB2001	31DEC2016	N
		Surgical and medical procedures	Thyroidectomy	01JAN2013	01JAN2013	N
	C4591001 1231 12311872	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1231 12311873	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2019		Y
	C4591001 1231 12311878	Endocrine disorders	Hypothyroidism	14JUN2010		Y
	C4591001 1231 12311880	Cardiac disorders	Ventricular extrasystoles	01MAR2015		Y
		Reproductive system and breast disorders	Menopausal symptoms	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311891	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2010		Y
	C4591001 1231 12311909	Gastrointestinal disorders	Hiatus hernia	01JAN2002		Y
		Metabolism and nutrition disorders	Gout	01JAN2008		Y
			Hypercholesterolaemia	01JAN2001		Y
		Surgical and medical procedures	Varicose vein operation	01JAN2020	27OCT2020	N
		Vascular disorders	Hypertension	01JAN2008		Y
			Varicose vein	14JAN2020		Y
	C4591001 1231 12311914	Cardiac disorders	Arrhythmia	08MAY2010	28MAY2010	N
		Vascular disorders	Deep vein thrombosis	02DEC2016	02FEB2018	N
	C4591001 1231 12311927	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	02OCT2018		Y
	C4591001 1231 12311931	Psychiatric disorders	Depression	01APR2017		Y
	C4591001 1231 12311935	Injury, poisoning and procedural complications	Tibia fracture	05JAN2018	05JAN2018	N
		Social circumstances	Ex-tobacco user	03APR2003	03MAY2018	N
	C4591001 1231 12311936	Metabolism and nutrition disorders	Type 2 diabetes mellitus	11AUG2016		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1231 12311937	Metabolism and nutrition disorders	Hyperuricaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01FEB2019		Y
		Vascular disorders	Hypertension	03AUG2010		Y
	C4591001 1231 12311946	Vascular disorders	Hypertension	02JUL2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12311948	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12311956	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12311959	Endocrine disorders	Autoimmune thyroiditis	01AUG1995		Y
	C4591001 1231 12311960	Vascular disorders	Hypertension	26AUG2008		Y
	C4591001 1231 12311963	Cardiac disorders	Acute myocardial infarction	02JUN2011	15JUN2011	N
		Gastrointestinal disorders	Hiatus hernia	25AUG2010		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01AUG1995		Y
		Vascular disorders	Peripheral vascular disorder	04APR2018		Y
	C4591001 1231 12311970	Eye disorders	Glaucoma	01JUN2018		Y
		Infections and infestations	Atypical pneumonia	15MAY2018	30MAY2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
		Surgical and medical procedures	Coronary artery bypass	19DEC2018		Y
		Vascular disorders	Hypertension	10MAR2000		Y
	C4591001 1231 12311978	Psychiatric disorders	Panic attack	01AUG2016		Y
	C4591001 1231 12311979	Respiratory, thoracic and mediastinal disorders	Emphysema	01JUN1990		Y
	C4591001 1231 12311993	Vascular disorders	Hypertension	14MAR2018		Y
	C4591001 1231 12311995	Vascular disorders	Hypertension	05OCT2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312000	Gastrointestinal disorders	Irritable bowel syndrome	01FEB2014		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01SEP2014	01MAY2015	N
	C4591001 1231 12312012	Vascular disorders	Hypertension	20AUG2017		Y
	C4591001 1231 12312014	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
	C4591001 1231 12312016	Vascular disorders	Deep vein thrombosis	15JUL1992	31JUL1992	N
			Hypertension	15JUN2018		Y
	C4591001 1231 12312018	Infections and infestations	Tuberculosis	01OCT1970	27NOV1971	N
		Vascular disorders	Hypertension	20APR2016		Y
	C4591001 1231 12312023	Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1231 12312026	Metabolism and nutrition disorders	Hypercholesterolaemia	30JUL2008		Y
	C4591001 1231 12312040	Metabolism and nutrition disorders	Hypercholesterolaemia	03MAR2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	03MAR2016		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12312054	Metabolism and nutrition disorders	Gout	01JAN2016		Y
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1231 12312057	Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1231 12312058	Cardiac disorders	Arrhythmia	10AUG2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	10AUG2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2010		Y
	C4591001 1231 12312060	Eye disorders	Cataract	01JUN2020		Y
	C4591001 1231 12312070	Eye disorders	Glaucoma	01JAN1978		Y
	C4591001 1231 12312072	Cardiac disorders	Ventricular extrasystoles	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12312081	Cardiac disorders	Acute myocardial infarction	01SEP2003	03SEP2003	N
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2003	03SEP2003	N
		Vascular disorders	Hypertension	01SEP2003		Y
	C4591001 1231 12312082	Eye disorders	Glaucoma	18AUG2000		Y
	C4591001 1231 12312084	Metabolism and nutrition disorders	Dyslipidaemia	16AUG1990		Y
	C4591001 1231 12312085	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1231 12312091	Gastrointestinal disorders	Dental caries	01JAN2011	17SEP2020	N
	C4591001 1231 12312092	Cardiac disorders	Acute myocardial infarction	28JAN2018	28JAN2018	N
		Nervous system disorders	Essential tremor	01JAN2010		Y
	C4591001 1231 12312098	Cardiac disorders	Acute myocardial infarction	01SEP2009	01OCT2009	N
		Ear and labyrinth disorders	Vertigo positional	01MAR1987		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01SEP2009	01OCT2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312100	Cardiac disorders	Coronary artery disease	10MAY2012		Y
	C4591001 1231 12312104	Metabolism and nutrition disorders	Dyslipidaemia	29AUG2017		Y
		Nervous system disorders	Ischaemic stroke	29AUG2017	06SEP2017	N
		Vascular disorders	Hypertension	29AUG2017		Y
	C4591001 1231 12312106	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
		Psychiatric disorders	Depression	01AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2018		Y
		Vascular disorders	Arteriosclerosis	01AUG2010		Y
			Hypertension	01JAN2014		Y
	C4591001 1231 12312108	Endocrine disorders	Hypothyroidism	18AUG1995		Y
		Infections and infestations	Herpes ophthalmic	18NOV2019	18JAN2020	N
	C4591001 1231 12312112	Psychiatric disorders	Insomnia	23AUG2016		Y
	C4591001 1231 12312114	Cardiac disorders	Acute myocardial infarction	01AUG2015	01SEP2015	N
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2015	01SEP2015	N
	C4591001 1231 12312122	Eye disorders	Cataract	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12312130	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2010		Y
		Vascular disorders	Hypertension	01JAN1981		Y
	C4591001 1231 12312131	Nervous system disorders	Ischaemic stroke	10SEP2012	25SEP2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2008		Y
	C4591001 1231 12312144	Metabolism and nutrition disorders	Dyslipidaemia	05AUG2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	03AUG2019		Y
	C4591001 1231 12312145	Endocrine disorders	Hypothyroidism	02AUG1985		Y
		Gastrointestinal disorders	Gastritis	12JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2017		Y
		Psychiatric disorders	Insomnia	01AUG2020		Y
		Vascular disorders	Hypertension	01AUG1999		Y
	C4591001 1231 12312148	Surgical and medical procedures	Coronary artery bypass	01JAN2003	07JAN2003	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1231 12312151	Metabolism and nutrition disorders	Type 2 diabetes mellitus	12AUG2012		Y
	C4591001 1231 12312156	Cardiac disorders	Coronary artery disease	23MAR2017	24MAR2017	N
				31OCT2019	01NOV2019	N
		Metabolism and nutrition disorders	Gout	01JAN2000		Y
			Type 2 diabetes mellitus	03SEP2008		Y
		Surgical and medical procedures	Coronary arterial stent insertion	24JAN2017	25JAN2017	N
			Vascular stent insertion	23MAR2017	24MAR2017	N
				31OCT2019	01NOV2019	N
		Vascular disorders	Hypertension	18APR2006		Y
	C4591001 1231 12312158	Vascular disorders	Hypertension	01JAN2017		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12312161	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2010		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2010		Y
	C4591001 1231 12312162	Metabolism and nutrition disorders	Hypercholesterolaemia	13AUG2010		Y
	C4591001 1231 12312163	Endocrine disorders	Hypothyroidism	01DEC2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	06JAN2012	03MAR2013	N
		Psychiatric disorders	Insomnia	01JUN2017		Y
		Surgical and medical procedures	Thyroidectomy	01DEC2012	04DEC2012	N
	C4591001 1231 12312178	Metabolism and nutrition disorders	Dyslipidaemia	02MAR2018		Y
	C4591001 1231 12312182	Metabolism and nutrition disorders	Hypercholesterolaemia	21JUN2016		Y
		Vascular disorders	Hypertension	16JUN2016		Y
	C4591001 1231 12312197	Cardiac disorders	Coronary artery disease	15AUG2007		Y
	C4591001 1231 12312199	Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1231 12312209	Endocrine disorders	Hypothyroidism	01JAN1986		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2001	01DEC2001	N
	C4591001 1231 12312217	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
		Social circumstances	Tobacco user	01JAN1972	31DEC2017	N
		Vascular disorders	Hypertension	10JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312220	Vascular disorders	Hypertension	01AUG1996		Y
	C4591001 1231 12312223	Gastrointestinal disorders	Large intestine polyp	06JAN2020	28NOV2020	N
		Surgical and medical procedures	Polypectomy	06JAN2020	06JAN2020	N
	C4591001 1231 12312229	Nervous system disorders	Epilepsy	07DEC1993		Y
	C4591001 1231 12312230	Psychiatric disorders	Depression	03JAN2018		Y
	C4591001 1231 12312232	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12312233	Gastrointestinal disorders	Dental caries	01FEB2020		Y
		Vascular disorders	Hypertension	01MAR1998		Y
	C4591001 1231 12312234	Infections and infestations	Genital herpes	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUN2013		Y
	C4591001 1231 12312237	Nervous system disorders	Migraine with aura	19AUG1974		Y
	C4591001 1231 12312240	Endocrine disorders	Hypothyroidism	20MAY1950		Y
	C4591001 1231 12312241	Musculoskeletal and connective tissue disorders	Trigger finger	01MAR2019		Y
		Nervous system disorders	Carotid arteriosclerosis	03FEB2020		Y
	C4591001 1231 12312248	Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAR2020		Y
		Psychiatric disorders	Anxiety	01MAR2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312250	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12312253	Endocrine disorders	Hypothyroidism	01JAN2016		Y
	C4591001 1231 12312256	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG1964	31AUG1964	N
		Psychiatric disorders	Bruxism	02JAN2018		Y
	C4591001 1231 12312261	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2012		Y
		Nervous system disorders	Transient ischaemic attack	01NOV2014	01NOV2014	N
		Vascular disorders	Deep vein thrombosis	01JAN2010	01APR2010	N
	C4591001 1231 12312262	Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12312265	Eye disorders	Cataract	01JAN2018	15NOV2020	N
		Gastrointestinal disorders	Dyspepsia	01JAN2018		Y
			Gastritis	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JUN2020		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1231 12312273	Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1967		Y
	C4591001 1231 12312277	Vascular disorders	Hypertension	01JAN2018	01DEC2018	N
	C4591001 1231 12312278	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1231 12312279	Endocrine disorders	Hypothyroidism	02APR2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	04MAY2010		Y
		Vascular disorders	Hypertension	01APR2015		Y
	C4591001 1231 12312285	Nervous system disorders	Tension headache	07JUN2018		Y
	C4591001 1231 12312290	Metabolism and nutrition disorders	Type 2 diabetes mellitus	09AUG2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	04AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	10AUG1970		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12312293	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01AUG2009	02AUG2010	N
	C4591001 1231 12312301	Vascular disorders	Hypertension	11FEB2008		Y
	C4591001 1231 12312328	Ear and labyrinth disorders	Deafness bilateral	01FEB2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1973		Y
		Psychiatric disorders	Insomnia	01JAN1973		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR1995		Y
		Vascular disorders	Hypertension	01JUN1995		Y
	C4591001 1231 12312337	Social circumstances	Tobacco user	01AUG2015		Y
	C4591001 1231 12312345	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2012		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1231 12312347	Cardiac disorders	Arrhythmia	10FEB2013		Y
		Nervous system disorders	Carotid arteriosclerosis	02MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	02JAN2015		Y
	C4591001 1231 12312354	Respiratory, thoracic and mediastinal disorders	Asthma	01AUG1973		Y
	C4591001 1231 12312377	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2008		Y
	C4591001 1231 12312380	Respiratory, thoracic and mediastinal disorders	Asthma	31AUG2001	29AUG2006	N
	C4591001 1231 12312383	Respiratory, thoracic and mediastinal disorders	Asthma	03JAN2018		Y
	C4591001 1231 12312387	Metabolism and nutrition disorders	Dyslipidaemia	10AUG2010		Y
	C4591001 1231 12312392	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	12AUG2013	22AUG2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	02AUG1965		Y
		Surgical and medical procedures	Mastectomy	12AUG2013	22AUG2017	N
	C4591001 1231 12312393	Endocrine disorders	Hyperparathyroidism	01MAR2020		Y
		Metabolism and nutrition disorders	Hypercalcaemia	01MAR2020		Y
			Type 2 diabetes mellitus	06MAR2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01MAR2020	03APR2020	N
		Surgical and medical procedures	Nephrectomy	01MAR2020	03APR2020	N
	C4591001 1231 12312416	Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12312423	Metabolism and nutrition disorders	Type 2 diabetes mellitus	08AUG2019		Y
		Renal and urinary disorders	Urinary incontinence	01DEC2019		Y
		Vascular disorders	Hypertension	08AUG2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312431	Cardiac disorders	Arrhythmia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12312432	Cardiac disorders	Arrhythmia	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1231 12312440	Surgical and medical procedures	Carotid endarterectomy	19AUG2015	30AUG2015	N
		Vascular disorders	Hypertension	19AUG2005		Y
	C4591001 1231 12312450	Metabolism and nutrition disorders	Dyslipidaemia	02APR2018		Y
		Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1231 12312453	Gastrointestinal disorders	Coeliac disease	01NOV2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03APR2000		Y
	C4591001 1231 12312459	Psychiatric disorders	Anxiety	01FEB2020		Y
	C4591001 1231 12312463	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JUN2002		Y
	C4591001 1231 12312465	Nervous system disorders	Migraine	01JAN2000		Y
	C4591001 1231 12312470	Psychiatric disorders	Anxiety disorder	01MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Sinus polyp	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01OCT2015		Y
	C4591001 1231 12312484	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10JUN2005		Y
			Vitamin D deficiency	07AUG2020		Y
	C4591001 1231 12312485	Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12312490	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10MAY2015		Y
	C4591001 1231 12312492	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seminoma	01JUN2012	01DEC2017	N
		Surgical and medical procedures	Orchidectomy	01DEC2012	01DEC2012	N
	C4591001 1231 12312496	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2019		Y
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1231 12312497	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostatic adenoma	04APR2018	04APR2018	N
	C4591001 1231 12312498	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2012		Y
			Obesity	03JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01MAY2014	14JUN2014	N
		Surgical and medical procedures	Nephrectomy	14JUN2014	14JUN2014	N
	C4591001 1231 12312504	Endocrine disorders	Hypothyroidism	01MAR2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312505	Metabolism and nutrition disorders	Metabolic syndrome	10OCT2010		Y
		Vascular disorders	Hypertension	10OCT2010		Y
	C4591001 1231 12312508	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12312511	Endocrine disorders	Hypothyroidism	12JUN2012		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	26JUN2013		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	15SEP2016		Y
		Surgical and medical procedures	Uterine prolapse repair	07MAR2014	09MAR2014	N
	C4591001 1231 12312515	Psychiatric disorders	Panic attack	16JAN2014	23JAN2014	N
	C4591001 1231 12312526	Endocrine disorders	Hypothyroidism	01JUL2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
		Vascular disorders	Hypertension	01JUL2017		Y
	C4591001 1231 12312527	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	06NOV2006	06NOV2006	N
	C4591001 1231 12312541	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2015		Y
	C4591001 1231 12312549	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1993		Y
	C4591001 1231 12312551	Metabolism and nutrition disorders	Dyslipidaemia	10JAN2010		Y
	C4591001 1231 12312556	Vascular disorders	Arteriosclerosis	01SEP2014		Y
	C4591001 1231 12312558	Metabolism and nutrition disorders	Type 2 diabetes mellitus	20AUG2018		Y
		Vascular disorders	Hypertension	10AUG2009		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12312564	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10FEB2018		Y
	C4591001 1231 12312565	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01FEB2014		Y
	C4591001 1231 12312567	Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1231 12312568	Cardiac disorders	Atrial fibrillation	26DEC2011	27DEC2011	N
		Vascular disorders	Hypertension	27DEC2011		Y
	C4591001 1231 12312569	Endocrine disorders	Hypothyroidism	01JUN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR1992	01MAR1993	N
	C4591001 1231 12312571	Cardiac disorders	Myocardial infarction	24DEC2012	25DEC2012	N
		Surgical and medical procedures	Stent placement	25DEC2012	25DEC2012	N
	C4591001 1231 12312574	Renal and urinary disorders	Acute kidney injury	01FEB2000	01MAR2000	N
		Vascular disorders	Hypertension	01FEB2000		Y
	C4591001 1231 12312579	Psychiatric disorders	Bipolar disorder	01AUG2008		Y
	C4591001 1231 12312590	Surgical and medical procedures	Hysterectomy	01JUN2003	01JUN2003	N
	C4591001 1231 12312595	Infections and infestations	Tinea versicolour	02FEB1985		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12312598	Nervous system disorders	Cerebrovascular accident	31JAN2019	07FEB2019	N
		Vascular disorders	Hypertension	01JUN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312599	Psychiatric disorders	Sleep disorder	01JAN1990		Y
	C4591001 1231 12312604	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12312614	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2017		Y
	C4591001 1231 12312619	Endocrine disorders	Hypothyroidism	09SEP2004		Y
	C4591001 1231 12312625	Psychiatric disorders	Depression	15AUG1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUL2010		Y
	C4591001 1231 12312631	Vascular disorders	Obesity	01AUG2010		Y
		Vascular disorders	Hypertension	01JUL2010		Y
	C4591001 1231 12312631	Gastrointestinal disorders	Gastritis	01JUL2012		Y
	C4591001 1231 12312635	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01SEP2015		Y
	C4591001 1231 12312637	Vascular disorders	Hypertension	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2010		Y
	C4591001 1231 12312646	Gastrointestinal disorders	Hiatus hernia	15OCT2012		Y
	C4591001 1231 12312650	Metabolism and nutrition disorders	Dyslipidaemia	08AUG2012		Y
		Nervous system disorders	Paraesthesia	01JUN2019		Y
		Vascular disorders	Transient ischaemic attack	20MAR2017	20MAR2017	N
	C4591001 1231 12312650	Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1231 12312650	Vascular disorders	Hypertension	01JUN2000		Y
	C4591001 1231 12312657	Infections and infestations	Herpes dermatitis	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01FEB2009		Y
		Nervous system disorders	Migraine	01JAN1979		Y
	C4591001 1231 12312661	Vascular disorders	Hypertension	01JUN1996		Y
	C4591001 1231 12312667	Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2015		Y
	C4591001 1231 12312668	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1231 12312682	Infections and infestations	Urinary tract infection	19MAR2020	04MAY2020	N
		Renal and urinary disorders	Calculus urinary	19MAR2020	04MAY2020	N
	C4591001 1231 12312689	Endocrine disorders	Hypothyroidism	18AUG2005		Y
		Gastrointestinal disorders	Gastritis	21AUG1980		Y
		Infections and infestations	Oral herpes	01JAN1990		Y
	C4591001 1231 12312691	Endocrine disorders	Hypothyroidism	16FEB2000		Y
	C4591001 1231 12312692	Gastrointestinal disorders	Gastritis	01AUG1970		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2010		Y
		Psychiatric disorders	Anxiety disorder	01AUG1970		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12312699	Endocrine disorders	Hypothyroidism	01AUG2005		Y
	C4591001 1231 12312700	Vascular disorders	Hypertension	16SEP2015		Y
	C4591001 1231 12312703	Eye disorders	Glaucoma	01SEP1994		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312706	Investigations	Smooth muscle antibody	02AUG1983		Y
	C4591001 1231 12312722	Gastrointestinal disorders	Dental caries	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1980		Y
	C4591001 1231 12312733	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG1990		Y
		Vascular disorders	Peripheral venous disease	01JAN2020		Y
	C4591001 1231 12312745	Vascular disorders	Hypertension	12AUG2010		Y
	C4591001 1231 12312749	Metabolism and nutrition disorders	Dyslipidaemia	05APR2017		Y
			Hyperuricaemia	04DEC2018		Y
	C4591001 1231 12312756	Metabolism and nutrition disorders	Hyperuricaemia	17AUG2005		Y
			Insulin resistance	18AUG2010		Y
		Psychiatric disorders	Insomnia	25MAR2020		Y
		Vascular disorders	Hypertension	17AUG2005		Y
	C4591001 1231 12312764	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12312766	Psychiatric disorders	Insomnia	01FEB2015		Y
	C4591001 1231 12312767	Congenital, familial and genetic disorders	Congenital cystic kidney disease	17OCT2007		Y
	C4591001 1231 12312799	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2015		Y
	C4591001 1231 12312808	Metabolism and nutrition disorders	Dyslipidaemia	25MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	12NOV2017		Y
			Sleep apnoea syndrome	08AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312816	Vascular disorders	Hypertension	27AUG2014		Y
	C4591001 1231 12312817	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2005		Y
		Surgical and medical procedures	Cholecystectomy	01SEP1988	01OCT1988	N
			Vascular graft	01MAY2016	01DEC2016	N
			Vocal cord polypectomy	01DEC1990	18DEC1990	N
		Vascular disorders	Hypertension	01AUG1990		Y
			Peripheral venous disease	20APR2016		Y
	C4591001 1231 12312818	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01AUG2009	02DEC2017	N
	C4591001 1231 12312820	Ear and labyrinth disorders	Meniere's disease	01OCT2016		Y
		Endocrine disorders	Hypothyroidism	01OCT2015		Y
		Eye disorders	Glaucoma	01OCT2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	02JAN2017		Y
	C4591001 1231 12312828	Vascular disorders	Hypertension	08FEB2018		Y
	C4591001 1231 12312832	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG1985		Y
		Vascular disorders	Hypertension	02JAN2020		Y
	C4591001 1231 12312834	Metabolism and nutrition disorders	Dyslipidaemia	18OCT2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	21AUG2015		Y
	C4591001 1231 12312837	Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1231 12312841	Vascular disorders	Hypertension	03APR2008		Y
	C4591001 1231 12312863	Metabolism and nutrition disorders	Hypercholesterolaemia	10MAY2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Bruxism	01JUL2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14AUG2007		Y
		Vascular disorders	Nasal septum deviation	01JAN1980		Y
		Metabolism and nutrition disorders	Hypertension	08MAR2008		Y
	C4591001 1231 12312872	Metabolism and nutrition disorders	Type 1 diabetes mellitus	04AUG2008		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	13AUG2017		Y
	C4591001 1231 12312878	Cardiac disorders	Arrhythmia	01JAN2015		Y
		Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01NOV2015		Y
	C4591001 1231 12312881	Vascular disorders	Hypertension	04APR2008		Y
	C4591001 1231 12312885	Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1231 12312887	Endocrine disorders	Autoimmune thyroiditis	10OCT2001		Y
		Gastrointestinal disorders	Barrett's oesophagus	15AUG2012		Y
			Hiatus hernia	16NOV2007		Y
	C4591001 1231 12312893	Blood and lymphatic system disorders	Polycythaemia	01MAR2020		Y
		Vascular disorders	Hypertension	06JUN2003		Y
	C4591001 1231 12312902	Reproductive system and breast disorders	Cystocele	01FEB2019		Y
		Surgical and medical procedures	Metabolic surgery	13JUL2013	13JUL2013	N
			Rotator cuff repair	18AUG2018	18AUG2018	N
	C4591001 1231 12312908	Endocrine disorders	Hypothyroidism	12JUN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312909	Metabolism and nutrition disorders	Type 2 diabetes mellitus	22AUG1990		Y
		Vascular disorders	Hypertension	29AUG2002		Y
	C4591001 1231 12312915	Endocrine disorders	Hypothyroidism	01NOV2019		Y
		Eye disorders	Cataract	01JUN2019	31AUG2020	N
				12DEC2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2015		Y
			Peptic ulcer	12DEC2012		Y
	C4591001 1231 12312935	Nervous system disorders	Parkinson's disease	01MAY2019		Y
	C4591001 1231 12312945	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2010		Y
	C4591001 1231 12312950	Endocrine disorders	Hypothyroidism	21AUG2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	21AUG2010		Y
		Psychiatric disorders	Insomnia	21AUG2015		Y
	C4591001 1231 12312961	Cardiac disorders	Left ventricular hypertrophy	10AUG1994		Y
	C4591001 1231 12312963	Gastrointestinal disorders	Haemorrhoids	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	06AUG2020		Y
		Vascular disorders	Hypertension	09AUG2010		Y
	C4591001 1231 12312967	Cardiac disorders	Arrhythmia	16AUG2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	11DEC2019		Y
		Vascular disorders	Hypertension	04AUG2010		Y
	C4591001 1231 12312970	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12312973	Surgical and medical procedures	Bladder polypectomy	01AUG2015	01AUG2016	N
	C4591001 1231 12312978	Metabolism and nutrition disorders	Dyslipidaemia	21AUG2016		Y
	C4591001 1231 12312980	Vascular disorders	Hypertension	21AUG2017		Y
	C4591001 1231 12312993	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	01JAN1998		Y
	C4591001 1231 12312997	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2017		Y
			Type 2 diabetes mellitus	01JUN2017		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1231 12312998	Endocrine disorders	Hypothyroidism	01AUG2014		Y
	C4591001 1231 12312999	Psychiatric disorders	Anxiety disorder	08AUG2020		Y
	C4591001 1231 12313000	Cardiac disorders	Angina pectoris	09APR2016	10APR2016	N
		Investigations	Catheterisation cardiac	09APR2016	10APR2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	04APR2016		Y
		Vascular disorders	Hypertension	09FEB2010		Y
	C4591001 1231 12313004	Endocrine disorders	Hypothyroidism	01JAN2000		Y
	C4591001 1231 12313010	Psychiatric disorders	Adjustment disorder with depressed mood	07AUG2014		Y
		Vascular disorders	Hypertension	04AUG2005		Y
	C4591001 1231 12313016	Nervous system disorders	Paralysis	(b) (6) 1964	02JAN1990	N
	C4591001 1231 12313017	Cardiac disorders	Mitral valve stenosis	01FEB1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313024	Endocrine disorders	Hypothyroidism	17JUN2005		Y
	C4591001 1231 12313029	Blood and lymphatic system disorders	Polycythaemia	01MAR1985		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	10AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	12AUG1997		Y
		Vascular disorders	Hypertension	10AUG2000		Y
	C4591001 1231 12313039	Vascular disorders	Hypertension	01FEB2006		Y
	C4591001 1231 12313052	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	10AUG2016	10OCT2016	N
	C4591001 1231 12313053	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2000		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12313055	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12313057	Psychiatric disorders	Insomnia	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1231 12313060	Cardiac disorders	Myocardial infarction	12SEP2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Polycythaemia vera	01JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2020		Y
		Surgical and medical procedures	Stent placement	12SEP2017		Y
	C4591001 1231 12313072	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2015	01JAN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313077	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12313081	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2007		Y
			Type 2 diabetes mellitus	08FEB2020		Y
	C4591001 1231 12313089	Cardiac disorders	Arteriospasm coronary	01JUN2016		Y
		Endocrine disorders	Hypothyroidism	12APR1990		Y
		Gastrointestinal disorders	Chronic gastritis	01MAR2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	12AUG2015		Y
		Renal and urinary disorders	Hypercalciuria	12JUL2015		Y
	C4591001 1231 12313090	Metabolism and nutrition disorders	Dyslipidaemia	03JUL2018		Y
	C4591001 1231 12313094	Gastrointestinal disorders	Irritable bowel syndrome	12APR2010		Y
		Psychiatric disorders	Anxiety	01AUG2014		Y
	C4591001 1231 12313103	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2012		Y
			Hyperuricaemia	01JUN2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	30SEP2015	30SEP2015	N
		Vascular disorders	Arterial occlusive disease	30JUL2015		Y
			Hypertension	01JUN2010		Y
	C4591001 1231 12313114	Cardiac disorders	Acute myocardial infarction	01JUN2016	01JUN2016	N
		Gastrointestinal disorders	Dental caries	01MAR2020	03SEP2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2016		Y
		Psychiatric disorders	Anxiety	01JUN2016		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y
		Social circumstances	Tobacco user	01JAN1960	01JUN2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Stent placement	02JUN2016	02JUN2016	N
	C4591001 1231 12313119	Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12313121	Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1231 12313126	Gastrointestinal disorders	Gastritis	01AUG2015		Y
	C4591001 1231 12313131	Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1963		Y
	C4591001 1231 12313133	Endocrine disorders	Hypothyroidism	01SEP2009		Y
	C4591001 1231 12313154	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01AUG2000	01AUG2000	N
		Psychiatric disorders	Anxiety disorder	01AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01AUG2016		Y
		Surgical and medical procedures	Hysterectomy	01AUG2000	01AUG2000	N
	C4591001 1231 12313159	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2015		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12313169	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2011		Y
	C4591001 1231 12313171	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
		Vascular disorders	Hypertension	01DEC2019		Y
	C4591001 1231 12313173	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2000		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12313185	Vascular disorders	Hypertension	04AUG2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313187	Vascular disorders	Hypertension	01MAR2019		Y
	C4591001 1231 12313208	Respiratory, thoracic and mediastinal disorders	Asthma	20MAR1975		Y
	C4591001 1231 12313221	Respiratory, thoracic and mediastinal disorders	Asthma	03APR1963		Y
	C4591001 1231 12313222	Endocrine disorders	Hypothyroidism	08AUG2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	11AUG2009		Y
		Nervous system disorders	Cerebrovascular accident	07JAN2009	11AUG2009	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15AUG2018		Y
		Vascular disorders	Hypertension	12AUG2009		Y
	C4591001 1231 12313230	Endocrine disorders	Hypothyroidism	14JUN2010		Y
	C4591001 1231 12313234	Gastrointestinal disorders	Lumbar hernia	01JAN2016	22JAN2021	N
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2002	31DEC2003	N
		Surgical and medical procedures	Nephrectomy	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	20JAN2007		Y
	C4591001 1231 12313239	Metabolism and nutrition disorders	Hypercholesterolaemia	10AUG2010		Y
	C4591001 1231 12313241	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2020		Y
	C4591001 1231 12313242	Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2013	01JUL2015	N
				01JUL2011	01JUL2013	N
		Vascular disorders	Hypertension	01JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313252	Endocrine disorders	Hypothyroidism	07AUG2013		Y
		Gastrointestinal disorders	Gastritis	01JUN2015	01APR2017	N
	C4591001 1231 12313254	Nervous system disorders	Migraine without aura	01MAR1975		Y
	C4591001 1231 12313261	Cardiac disorders	Acute myocardial infarction	20APR1992	20APR1992	N
		Endocrine disorders	Hypothyroidism	11AUG2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	20APR1992		Y
		Nervous system disorders	Carpal tunnel syndrome	01JUN2018	01OCT2020	N
		Surgical and medical procedures	Coronary angioplasty	20APR1992	20APR1992	N
	C4591001 1231 12313262	Vascular disorders	Hypertension	11AUG2010		Y
	C4591001 1231 12313267	Immune system disorders	Drug hypersensitivity	29AUG2010		Y
	C4591001 1231 12313275	Immune system disorders	Drug hypersensitivity	(b) (6) 1961		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Vascular disorders	Hypertension	16AUG2005		Y
	C4591001 1231 12313279	Endocrine disorders	Hypothyroidism	01JAN1988		Y
		Psychiatric disorders	Depression	01NOV2019		Y
	C4591001 1231 12313295	Cardiac disorders	Ventricular extrasystoles	19SEP2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	10AUG2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	15MAR2020		Y
			Squamous cell carcinoma	15MAR2020		Y
		Surgical and medical procedures	Skin neoplasm excision	02MAY2018	08JUL2018	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				18APR2000	01JUN2000	N
	C4591001 1231 12313309	Vascular disorders	Hypertension	01FEB2012		Y
	C4591001 1231 12313320	Cardiac disorders	Arrhythmia	15JUL2010		Y
		Vascular disorders	Hypertension	05JUL2010		Y
	C4591001 1231 12313323	Respiratory, thoracic and mediastinal disorders	Dysphonia	01MAR2020		Y
	C4591001 1231 12313328	Vascular disorders	Hypertension	02MAR2020		Y
	C4591001 1231 12313331	Cardiac disorders	Arrhythmia	01JAN1998		Y
		Surgical and medical procedures	Cardiac ablation	01FEB2001	08FEB2001	N
	C4591001 1231 12313344	Social circumstances	Tobacco user	02AUG1972		Y
		Vascular disorders	Hypertension	18AUG2015		Y
	C4591001 1231 12313346	Endocrine disorders	Hypothyroidism	18JUN1970		Y
		Psychiatric disorders	Anxiety disorder	27AUG2019		Y
	C4591001 1231 12313347	Respiratory, thoracic and mediastinal disorders	Emphysema	30AUG2013		Y
	C4591001 1231 12313352	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Rhinitis	01SEP2010		Y
		Social circumstances	Tobacco user	01JAN1970	19MAR2010	N
	C4591001 1231 12313354	Blood and lymphatic system disorders	Iron deficiency anaemia	02AUG2019		Y
	C4591001 1231 12313359	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2012		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	23SEP2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cluster headache	01AUG2020		Y
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1231 12313362	Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1231 12313366	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC2018	01MAR2019	N
	C4591001 1231 12313371	Metabolism and nutrition disorders	Dyslipidaemia	03JUL2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	03AUG2018	03AUG2018	N
				03OCT2000	03OCT2000	N
		Vascular disorders	Hypertension	03MAR2015		Y
	C4591001 1231 12313377	Metabolism and nutrition disorders	Dyslipidaemia	04AUG2014		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12313379	Cardiac disorders	Angina pectoris	01SEP2004		Y
		Infections and infestations	Furuncle	05OCT2019		Y
	C4591001 1231 12313380	Vascular disorders	Hypertension	01JUN2011		Y
	C4591001 1231 12313382	Endocrine disorders	Hypothyroidism	02MAR2003		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	02MAY2006		Y
			Type 2 diabetes mellitus	02APR2006		Y
	C4591001 1231 12313391	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2015		Y
	C4591001 1231 12313397	Psychiatric disorders	Sleep disorder	15MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	28AUG2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313403	Immune system disorders	Drug hypersensitivity	01AUG1984		Y
		Reproductive system and breast disorders	Erectile dysfunction	22SEP2017		Y
	C4591001 1231 12313411	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	07JAN2020	12FEB2020	N
				18MAY2019	12FEB2020	N
	C4591001 1231 12313418	Metabolism and nutrition disorders	Obesity	10JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15MAR2015		Y
		Surgical and medical procedures	Metabolic surgery	16FEB2016	16FEB2016	N
	C4591001 1231 12313420	Endocrine disorders	Hypothyroidism	15AUG1990		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN1985		Y
		Vascular disorders	Hypertension	01AUG1985		Y
	C4591001 1231 12313423	Endocrine disorders	Hypothyroidism	01FEB2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2013		Y
		Surgical and medical procedures	Cardiac ablation	01FEB2000		Y
	C4591001 1231 12313424	Cardiac disorders	Cardio-respiratory arrest	01JUN1992	06JUN1992	N
		Injury, poisoning and procedural complications	Cervical vertebral fracture	11NOV2011	01FEB2012	N
			Chemical poisoning	01JUN1992	06JUN1992	N
			Hip fracture	01JUN1990	01SEP1990	N
			Neck injury	11NOV2011	01FEB2012	N
		Nervous system disorders	Ischaemic stroke	01JUL2008	01OCT2008	N
			Trigeminal neuralgia	01JUN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313426	Metabolism and nutrition disorders	Hypercholesterolaemia	04JUL2010		Y
	C4591001 1231 12313436	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02FEB2005		Y
		Surgical and medical procedures	Cardiac ablation	01JUN2015	02JUN2015	N
	C4591001 1231 12313447	Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12313453	Cardiac disorders	Acute myocardial infarction	01JUN2009	10JUN2009	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JUN2009		Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1231 12313457	Vascular disorders	Hypertension	04FEB2019		Y
	C4591001 1231 12313458	Cardiac disorders	Myocardial infarction	23AUG2009	28AUG2009	N
		Surgical and medical procedures	Stent placement	23AUG2009	28AUG2009	N
	C4591001 1231 12313461	Vascular disorders	Hypertension	20OCT2015		Y
	C4591001 1231 12313464	Endocrine disorders	Hypothyroidism	02MAR1970		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01MAR2010		Y
		Surgical and medical procedures	Cochlea implant	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01MAR2010		Y
	C4591001 1231 12313468	Gastrointestinal disorders	Dental caries	01MAY2020		Y
			Tooth disorder	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	02FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1974		Y
	C4591001 1231 12313472	Endocrine disorders	Hypothyroidism	06JUN2002		Y
	C4591001 1231 12313477	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2017		Y
		Psychiatric disorders	Depression	02AUG2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01AUG2012		Y
			Cough	05JUL2020		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1231 12313478	Psychiatric disorders	Insomnia	14MAY2012		Y
	C4591001 1231 12313485	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	20DEC1993	02JUL2000	N
		Surgical and medical procedures	Hysterectomy	02JUL2000	07JUL2000	N
	C4591001 1231 12313495	Social circumstances	Tobacco user	10OCT1973		Y
	C4591001 1231 12313502	Cardiac disorders	Acute myocardial infarction	25MAR2010	30MAR2010	N
		Metabolism and nutrition disorders	Dyslipidaemia	25MAR2010		Y
	C4591001 1231 12313511	Gastrointestinal disorders	Gastritis	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2005		Y
	C4591001 1231 12313522	Reproductive system and breast disorders	Benign prostatic hyperplasia	31MAR2017		Y
	C4591001 1231 12313524	Cardiac disorders	Atrial fibrillation	18AUG2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	02FEB2014		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	18AUG2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	02FEB2014		Y
	C4591001 1231 12313530	Vascular disorders	Hypertension	01AUG1990		Y
	C4591001 1231 12313531	Nervous system disorders	Cerebrovascular accident	24FEB2017	03MAR2017	N
	C4591001 1231 12313536	Cardiac disorders	Arrhythmia	01JAN1970		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1231 12313538	Vascular disorders	Hypertension	01APR2020		Y
	C4591001 1231 12313545	Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1231 12313549	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2011	01JAN2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12313550	Cardiac disorders	Acute myocardial infarction	14OCT2019	16OCT2019	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	09MAR2009		Y
		Nervous system disorders	Haemorrhagic stroke	09MAR2009	09MAR2009	N
		Psychiatric disorders	Depression	11MAY2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	13AUG2018		Y
		Surgical and medical procedures	Coronary artery bypass	16OCT2019	16OCT2019	N
	C4591001 1231 12313552	Endocrine disorders	Hypothyroidism	04APR2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	20JUL2015		Y
		Vascular disorders	Hypertension	20JUL2007		Y
	C4591001 1231 12313568	Metabolism and nutrition disorders	Dyslipidaemia	02FEB2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	01FEB2016		Y
		Psychiatric disorders	Insomnia	01MAR2018		Y
	C4591001 1231 12313573	Metabolism and nutrition disorders	Dyslipidaemia	03AUG2020		Y
	C4591001 1231 12313577	Infections and infestations	Rhinitis	31AUG2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	31AUG2016		Y
			Type 2 diabetes mellitus	31AUG2016		Y
	C4591001 1231 12313582	Cardiac disorders	Arrhythmia	15AUG2016		Y
		Gastrointestinal disorders	Irritable bowel syndrome	07AUG2004		Y
		Metabolism and nutrition disorders	Dyslipidaemia	04APR2013		Y
			Hyperuricaemia	04APR2016		Y
			Type 2 diabetes mellitus	15DEC2013		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JUL2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01APR2007	07JUL2007	N
		Psychiatric disorders	Depression	07JUL2020		Y
		Vascular disorders	Hypertension	12DEC2001		Y
	C4591001 1231 12313584	Gastrointestinal disorders	Hiatus hernia	08AUG2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	14JUN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	20DEC2013	20DEC2018	N
		Vascular disorders	Hypertension	20MAY2008		Y
	C4591001 1231 12313585	Infections and infestations	Pulmonary tuberculosis	16JUL1990	09DEC1990	N
		Metabolism and nutrition disorders	Dyslipidaemia	02FEB2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	06FEB2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	17DEC2014	17DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	14AUG1991		Y
			Chronic obstructive pulmonary disease	01JUN1991		Y
		Vascular disorders	Hypertension	13APR2010		Y
	C4591001 1231 12313586	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2006		Y
	C4591001 1231 12313597	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1231 12313599	Endocrine disorders	Hypothyroidism	15AUG2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	05AUG2015		Y
			Osteoporosis	01JAN2015		Y
		Vascular disorders	Hypertension	29AUG2018		Y
	C4591001 1231 12313600	Ear and labyrinth disorders	Vertigo	01NOV2016		Y
	C4591001 1231 12313602	Endocrine disorders	Hyperthyroidism	10JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	10JAN2017		Y
	C4591001 1231 12313603	Endocrine disorders	Hypothyroidism	15JUN1990		Y
		Vascular disorders	Hypertension	11AUG2010		Y
	C4591001 1231 12313604	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12313608	Endocrine disorders	Hypothyroidism	08AUG2013		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Hyperuricaemia	10AUG2014		Y
		Musculoskeletal and connective tissue disorders	Chondropathy	01JAN2009		Y
		Surgical and medical procedures	Meniscus operation	01JAN2009	31DEC2009	N
	C4591001 1231 12313610	Cardiac disorders	Atrial fibrillation	04APR2012		Y
		Vascular disorders	Hypertension	04APR2012		Y
	C4591001 1231 12313611	Eye disorders	Glaucoma	15JAN2015		Y
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 1231 12313615	Metabolism and nutrition disorders	Hyperuricaemia	01JAN2000		Y
	C4591001 1231 12313626	Gastrointestinal disorders	Oesophagitis	01JAN2012		Y
	C4591001 1231 12313627	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01AUG2001		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12313628	Gastrointestinal disorders	Haemorrhoids	23JAN2001		Y
		Immune system disorders	Seasonal allergy	01SEP2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2010		Y
		Surgical and medical procedures	Haemorrhoid operation	10OCT2012	10OCT2012	N
				12JUN2002	12JUN2002	N
		Vascular disorders	Hypertension	01MAR2010		Y
	C4591001 1231 12313642	Vascular disorders	Hypertension	12JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313645	Gastrointestinal disorders	Coeliac disease	01JUN2000		Y
	C4591001 1231 12313648	Endocrine disorders	Hypothyroidism	20JUL2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	20JUL2010		Y
	C4591001 1231 12313649	Endocrine disorders	Hypothyroidism	24AUG1995		Y
		Psychiatric disorders	Generalised anxiety disorder	24AUG2019		Y
	C4591001 1231 12313650	Cardiac disorders	Angina pectoris	06OCT1993		Y
		Endocrine disorders	Hypothyroidism	23JUN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	14SEP2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	20AUG2018		Y
		Vascular disorders	Hypertension	12JUL2012		Y
	C4591001 1231 12313651	Investigations	Blood pressure increased	01MAR2020		Y
	C4591001 1231 12313652	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2000		Y
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12313654	Metabolism and nutrition disorders	Dyslipidaemia	03MAR2015		Y
			Type 2 diabetes mellitus	03MAR2015		Y
		Vascular disorders	Hypertension	02FEB2000		Y
	C4591001 1231 12313674	Musculoskeletal and connective tissue disorders	Sjogren's syndrome	07JUL1977		Y
		Psychiatric disorders	Insomnia	07JUL1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hip arthroplasty	19DEC2018	19DEC2018	N
	C4591001 1231 12313676	Gastrointestinal disorders	Coeliac disease	01JAN1989		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1231 12313678	Vascular disorders	Hypertension	02AUG2017		Y
	C4591001 1231 12313687	Eye disorders	Glaucoma	01JAN2012		Y
	C4591001 1231 12313690	Vascular disorders	Hypertension	01DEC1991		Y
	C4591001 1231 12313691	Endocrine disorders	Hypothyroidism	20AUG1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01MAY2018	31MAY2018	N
		Psychiatric disorders	Insomnia	18DEC2018		Y
		Surgical and medical procedures	Hysterectomy	10APR2000	31DEC2000	N
			Lung lobectomy	31MAY2018	31MAY2018	N
		Vascular disorders	Hypertension	21OCT1995		Y
	C4591001 1231 12313692	Musculoskeletal and connective tissue disorders	Osteoarthritis	17JUL2010		Y
	C4591001 1231 12313708	Endocrine disorders	Hypothyroidism	01OCT2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01OCT2016		Y
			Type 1 diabetes mellitus	01JAN2013		Y
		Psychiatric disorders	Depression	01OCT2016		Y
		Vascular disorders	Hypertension	01OCT2016		Y
	C4591001 1231 12313712	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	03FEB2002	03FEB2007	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313719	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2007		Y
	C4591001 1231 12313728	Vascular disorders	Hypertension	01MAR2004		Y
	C4591001 1231 12313730	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2008		Y
	C4591001 1231 12313736	Endocrine disorders	Hypothyroidism	01JUN1992		Y
	C4591001 1231 12313740	Cardiac disorders	Ventricular extrasystoles	06JUN2012		Y
	C4591001 1231 12313741	Metabolism and nutrition disorders	Type 2 diabetes mellitus	27MAY2010		Y
	C4591001 1231 12313744	Endocrine disorders	Hypothyroidism	01JUL2006		Y
	C4591001 1231 12313745	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	15JAN2011		Y
	C4591001 1231 12313748	Metabolism and nutrition disorders	Hypercholesterolaemia	21MAY2020		Y
	C4591001 1231 12313751	Reproductive system and breast disorders	Benign prostatic hyperplasia	13JUN2018		Y
		Vascular disorders	Hypertension	20APR2000		Y
	C4591001 1231 12313753	Vascular disorders	Hypertension	08AUG2014		Y
	C4591001 1231 12313754	Metabolism and nutrition disorders	Obesity	12MAR1995		Y
	C4591001 1231 12313755	Cardiac disorders	Palpitations	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01NOV2013	01FEB2014	N
			Breast cancer	01MAR2012	01MAR2017	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313760	Endocrine disorders	Hypothyroidism	02MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	06MAR2015	19APR2015	N
	C4591001 1231 12313763	Endocrine disorders	Hypothyroidism	03APR2014		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	03APR2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	05JUN2000	03JUN2006	N
		Surgical and medical procedures	Myomectomy	03JUN2003	03JUN2003	N
		Vascular disorders	Hypertension	03MAY2016		Y
	C4591001 1231 12313768	Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 1231 12313770	Endocrine disorders	Hypothyroidism	24AUG2004		Y
		Metabolism and nutrition disorders	Dyslipidaemia	24AUG2004		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	24AUG2019		Y
	C4591001 1231 12313775	Vascular disorders	Hypertension	01JUN1991		Y
	C4591001 1231 12313779	Vascular disorders	Hypertension	01JUL2016		Y
	C4591001 1231 12313783	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	15JUN2020		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2013		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1961		Y
		Surgical and medical procedures	Spinal operation	06DEC2013	06DEC2013	N
		Vascular disorders	Hypertension	01JAN2012		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1231 12313784	Cardiac disorders	Coronary artery disease	20AUG2004		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	24AUG2004		Y
	C4591001 1231 12313791	Endocrine disorders	Hypothyroidism	05JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	10AUG2010		Y
		Social circumstances	Menopause	07OCT2010		Y
		Vascular disorders	Hypertension	02JUN2020		Y
	C4591001 1231 12313792	Endocrine disorders	Hypothyroidism	01JUN1999		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2015		Y
	C4591001 1231 12313796	Cardiac disorders	Coronary artery disease	10AUG2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	10AUG2013	17AUG2013	N
	C4591001 1231 12313799	Metabolism and nutrition disorders	Type 2 diabetes mellitus	08AUG2016		Y
	C4591001 1231 12313813	Endocrine disorders	Hypothyroidism	01NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	10OCT2018	31OCT2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAY2018	09AUG2020	N
		Surgical and medical procedures	Prostatectomy	09AUG2020	09AUG2020	N
			Thyroidectomy	31OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12313817	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	10MAR2007		Y
		Nervous system disorders	Transient ischaemic attack	01JAN2018	01JAN2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313829	Vascular disorders	Hypertension	25AUG2016		Y
	C4591001 1231 12313833	Respiratory, thoracic and mediastinal disorders	Pneumothorax	24JUL2003	05SEP2003	N
		Vascular disorders	Hypertension	02FEB2017		Y
	C4591001 1231 12313834	Vascular disorders	Hypertension	02SEP2010		Y
	C4591001 1231 12313835	Psychiatric disorders	Major depression	15JUN2017		Y
	C4591001 1231 12313838	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2014		Y
		Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12313839	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12313844	Endocrine disorders	Hypothyroidism	01JUN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2013		Y
		Vascular disorders	Hypertension	01JUN2013		Y
	C4591001 1231 12313845	Eye disorders	Cataract	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1231 12313849	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1979		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12313850	Cardiac disorders	Coronary artery occlusion	01OCT2011		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01OCT2011		Y
		Vascular disorders	Hypertension	01JUL1998		Y
	C4591001 1231 12313852	Skin and subcutaneous tissue disorders	Psoriasis	01JUN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12313855	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2016		Y
		Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1231 12313858	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12313860	Metabolism and nutrition disorders	Obesity	02MAR1996	03OCT2010	N
		Surgical and medical procedures	Gastric bypass	02MAR1996	03OCT2010	N
	C4591001 1231 12313867	Metabolism and nutrition disorders	Hypercholesterolaemia	07JUN2019		Y
	C4591001 1231 12313874	Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2000		Y
	C4591001 1231 12313880	Cardiac disorders	Acute myocardial infarction	30OCT2013	30OCT2013	N
		Metabolism and nutrition disorders	Dyslipidaemia	05MAY2013		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	30OCT2013		Y
		Surgical and medical procedures	Coronary artery bypass	30OCT2013	30OCT2013	N
		Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1231 12313883	Metabolism and nutrition disorders	Hyperuricaemia	23NOV2017		Y
			Obesity	05MAR2018		Y
			Type 2 diabetes mellitus	10JUN2019		Y
		Vascular disorders	Hypertension	08AUG2019		Y
	C4591001 1231 12313891	Endocrine disorders	Hypothyroidism	11AUG2000		Y
		Vascular disorders	Hypertension	05AUG2010		Y
	C4591001 1231 12313894	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	08AUG2010		Y
		Vascular disorders	Hypertension	08AUG1995		Y
	C4591001 1231 12313897	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2019		Y
		Renal and urinary disorders	Hypercalciuria	01OCT2019		Y
		Reproductive system and breast disorders	Ovarian cyst	10JAN2010	25MAR2010	N
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	25MAR2010	25MAR2010	N
	C4591001 1231 12313899	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	10OCT2009	16OCT2011	N
		Surgical and medical procedures	Hysterectomy	16NOV2011	16NOV2011	N
	C4591001 1231 12313918	Gastrointestinal disorders	Gastroesophageal reflux disease	04MAR2010		Y
	C4591001 1231 12313920	Endocrine disorders	Thyroid mass	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	02JUN2010		Y
	C4591001 1231 12313926	Reproductive system and breast disorders	Benign prostatic hyperplasia	11AUG2005		Y
	C4591001 1231 12313928	Vascular disorders	Hypertension	15MAR2018		Y
	C4591001 1231 12313929	Ear and labyrinth disorders	Tinnitus	01MAR2018		Y
		Endocrine disorders	Hypothyroidism	11SEP2008		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01MAR2008		Y
	C4591001 1231 12313940	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN1998		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12313947	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01AUG2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN1989	31DEC1989	N
	C4591001 1231 12313950	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
	C4591001 1231 12313951	Skin and subcutaneous tissue disorders	Dermal cyst	(b) (6) 1960		Y
		Vascular disorders	Hypertension	11AUG2014		Y
	C4591001 1231 12313952	Psychiatric disorders	Anxiety	01OCT2010		Y
		Vascular disorders	Hypertension	01OCT2008		Y
	C4591001 1231 12313954	Endocrine disorders	Hypothyroidism	02APR1994		Y
	C4591001 1231 12313958	Vascular disorders	Hypertension	01JUN2006		Y
	C4591001 1231 12313961	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1231 12313962	Reproductive system and breast disorders	Benign prostatic hyperplasia	02JAN2018		Y
	C4591001 1231 12313972	Vascular disorders	Hypertension	03MAR2017		Y
	C4591001 1231 12313976	Skin and subcutaneous tissue disorders	Vitiligo	01AUG1969		Y
		Vascular disorders	Hypertension	14SEP2010		Y
	C4591001 1231 12313980	Cardiac disorders	Arrhythmia	01JAN2018		Y

16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age						
Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2018		Y
	C4591001 1231 12313982	Endocrine disorders	Hypothyroidism	05APR1997		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05JUL2020		Y
	C4591001 1231 12313983	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 1954		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2010		Y
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12313990	Cardiac disorders	Cardiovascular disorder	01JUN2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	08APR2010		Y
			Type 2 diabetes mellitus	24JUL2014		Y
		Vascular disorders	Hypertension	15JUN2010		Y
	C4591001 1231 12313992	Metabolism and nutrition disorders	Dyslipidaemia	12JUN2017		Y
	C4591001 1231 12313997	Congenital, familial and genetic disorders	Bicuspid aortic valve	(b) (6) 1959		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2007		Y
	C4591001 1231 12314001	Endocrine disorders	Hypothyroidism	25AUG2010		Y
		Reproductive system and breast disorders	Adnexa uteri cyst	07OCT2014	21OCT2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2019		Y
			Asthmatic crisis	01JUL2019	01JUL2019	N
			Rhinitis allergic	01JAN2015		Y
		Surgical and medical procedures	Oophorectomy bilateral	01OCT2014	31OCT2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salpingo-oophorectomy bilateral	21OCT2014	21OCT2014	N
	C4591001 1231 12314003	Injury, poisoning and procedural complications	Spinal column injury	01JUN1998	01JUL2016	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01MAY2020		Y
		Psychiatric disorders	Insomnia	01MAY2015		Y
		Surgical and medical procedures	Foraminotomy	01JAN1999	31DEC1999	N
			Intervertebral disc operation	01JAN1998	31DEC1998	N
				01JAN2014	31DEC2014	N
			Spinal laminectomy	01JAN2016	31DEC2016	N
	C4591001 1231 12314015	Respiratory, thoracic and mediastinal disorders	Asthma	01JUL1980		Y
	C4591001 1231 12314019	Gastrointestinal disorders	Dyspepsia	23MAR2005		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12314025	Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1231 12314026	Psychiatric disorders	Depression	01FEB2013		Y
		Vascular disorders	Hypertension	01NOV2009		Y
	C4591001 1231 12314027	Eye disorders	Cataract	01MAR2019		Y
					01NOV2019	N
		Surgical and medical procedures	Cataract operation	01NOV2019	01NOV2019	N
		Vascular disorders	Hypertension	01JUN2005		Y
	C4591001 1231 12314029	Endocrine disorders	Hypothyroidism	21MAY2013		Y
		Metabolism and nutrition disorders	Dyslipidaemia	20MAR2012		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	16OCT2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cerebrovascular accident	16JUL2013	20JUL2013	N
		Psychiatric disorders	Persistent depressive disorder	16SEP2014		Y
		Vascular disorders	Hypertension	18APR2012		Y
	C4591001 1231 12314035	Cardiac disorders	Acute myocardial infarction	21SEP2018	23SEP2018	N
		Gastrointestinal disorders	Gastrointestinal ulcer haemorrhage	01JAN1998	31DEC1998	N
		Infections and infestations	Diverticulitis	01APR2018	15APR2018	N
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2018		Y
		Social circumstances	Tobacco user	01JAN1975	31DEC2007	N
		Surgical and medical procedures	Colectomy	15APR2018	15APR2018	N
			Vascular stent insertion	21SEP2018	21SEP2018	N
		Vascular disorders	Hypertension	23SEP2018		Y
	C4591001 1231 12314036	Gastrointestinal disorders	Hiatus hernia	23MAR2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01FEB2015		Y
		Vascular disorders	Hypertension	25AUG2015		Y
	C4591001 1231 12314039	Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUL2008		Y
		Vascular disorders	Hypertension	01JUL2008		Y
	C4591001 1231 12314040	Surgical and medical procedures	Breast conserving surgery	12AUG1998	31AUG1998	N
			Cholecystectomy	08AUG1982	31AUG1982	N
	C4591001 1231 12314041	Vascular disorders	Hypertension	01JUL2013		Y
	C4591001 1231 12314051	Gastrointestinal disorders	Gastroesophageal reflux disease	26SEP2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	06AUG1995		Y
		Vascular disorders	Hypertension	17FEB2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314054	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign muscle neoplasm	01AUG2015		Y
		Surgical and medical procedures	Hysterectomy	01AUG2015		Y
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1231 12314055	Surgical and medical procedures	Hysterectomy	01JAN1983	31DEC1983	N
	C4591001 1231 12314057	Vascular disorders	Hypertension	30DEC2001		Y
	C4591001 1231 12314060	Surgical and medical procedures	Coronary arterial stent insertion	01JUN2014	03JUN2014	N
		Vascular disorders	Hypertension	01JUN2003		Y
	C4591001 1231 12314063	Gastrointestinal disorders	Gastritis	01AUG2017		Y
		Vascular disorders	Hypertension	01MAR2008		Y
	C4591001 1231 12314065	Eye disorders	Glaucoma	01FEB1990		Y
	C4591001 1231 12314069	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
	C4591001 1231 12314081	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01FEB2018		Y
		Vascular disorders	Hypertension	01FEB2016		Y
			Intermittent claudication	01JAN2018		Y
	C4591001 1231 12314082	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2000		Y
	C4591001 1231 12314083	Cardiac disorders	Arrhythmia supraventricular	01JUN1980		Y
	C4591001 1231 12314089	Cardiac disorders	Arrhythmia	01JAN2010		Y
			Arteriosclerosis coronary artery	15JUN2014		Y
		Gastrointestinal disorders	Gastritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JUN2012		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15SEP2005		Y
		Surgical and medical procedures	Coronary artery bypass	01JUN2015	15JUN2015	N
	C4591001 1231 12314091	Respiratory, thoracic and mediastinal disorders	Asthma	23JAN2018		Y
		Vascular disorders	Hypertension	05OCT2015		Y
	C4591001 1231 12314092	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01SEP2016	01OCT2016	N
		Surgical and medical procedures	Cancer surgery	01OCT2016	15OCT2016	N
			Peripheral artery bypass	01FEB2017	15FEB2017	N
		Vascular disorders	Arterial thrombosis	01FEB2017	15FEB2017	N
			Hypertension	01JAN1995		Y
	C4591001 1231 12314094	Endocrine disorders	Hypothyroidism	01AUG2017		Y
	C4591001 1231 12314101	Metabolism and nutrition disorders	Dyslipidaemia	01MAY2000		Y
		Psychiatric disorders	Sleep disorder	01JUN2012		Y
	C4591001 1231 12314103	Eye disorders	Keratoconus	01AUG2000	02AUG2000	N
		Surgical and medical procedures	Corneal transplant	01AUG2000	02AUG2000	N
		Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 1231 12314110	Gastrointestinal disorders	Diverticulum intestinal	01JAN2015		Y
			Hiatus hernia	30OCT2000		Y
		Infections and infestations	Diverticulitis	01JAN2015	31DEC2015	N
				01JAN2019	31DEC2019	N
			Onychomycosis	30OCT2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Metabolic syndrome	21AUG2019		Y
		Vascular disorders	Hypertension	30JUL2008		Y
	C4591001 1231 12314118	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN1995		Y
	C4591001 1231 12314120	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma	03FEB2011	24MAR2011	N
			Colon cancer	03FEB2011	24MAR2011	N
		Surgical and medical procedures	Colectomy	03FEB2011	24MAR2011	N
		Vascular disorders	Hypertension	03MAR1997		Y
	C4591001 1231 12314125	Endocrine disorders	Hypothyroidism	01AUG1998		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	11JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	11MAR2019		Y
	C4591001 1231 12314131	Endocrine disorders	Hypothyroidism	01DEC2019		Y
	C4591001 1231 12314139	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1231 12314146	Endocrine disorders	Hypothyroidism	01JUN2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2010		Y
		Vascular disorders	Aortic aneurysm	01SEP2017		Y
			Hypertension	01JUN2010		Y
	C4591001 1231 12314147	Blood and lymphatic system disorders	Hypercoagulation	01JAN2005		Y
		Psychiatric disorders	Sleep disorder	01JAN2005		Y
		Vascular disorders	Hypertension	27APR2000		Y
	C4591001 1231 12314148	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JUN2004	10JUN2004	N
				01MAY2004	01JUN2004	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	01APR2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB1995		Y
	C4591001 1231 12314149	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2019		Y
		Vascular disorders	Hypertension	01AUG2008		Y
	C4591001 1231 12314153	Cardiac disorders	Acute myocardial infarction	01MAY2008	02MAY2008	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2008		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAY2008	02MAY2008	N
		Vascular disorders	Hypertension	01MAY2008		Y
	C4591001 1231 12314158	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2018		Y
		Nervous system disorders	Ischaemic stroke	01AUG2018	01SEP2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2015		Y
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 1231 12314163	Psychiatric disorders	Anxiety	01AUG2008		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	30AUG1991		Y
	C4591001 1231 12314165	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1231 12314168	Metabolism and nutrition disorders	Gout	01JUN2016		Y
	C4591001 1231 12314176	Metabolism and nutrition disorders	Dyslipidaemia	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314177	Respiratory, thoracic and mediastinal disorders	Bronchiectasis	02APR1975		Y
	C4591001 1231 12314180	Vascular disorders	Hypertension	10APR2017		Y
	C4591001 1231 12314182	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
	C4591001 1231 12314187	Respiratory, thoracic and mediastinal disorders	Emphysema	25AUG2010		Y
	C4591001 1231 12314190	Vascular disorders	Hypertension	03AUG2010		Y
	C4591001 1231 12314197	Reproductive system and breast disorders	Benign prostatic hyperplasia	31AUG2018		Y
		Vascular disorders	Hypertension	25AUG2018		Y
	C4591001 1231 12314199	Cardiac disorders	Arrhythmia	26APR2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	10JUN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1990		Y
	C4591001 1231 12314201	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1231 12314206	Cardiac disorders	Angina unstable	01MAY2017	15JUN2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01MAY2017		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Surgical and medical procedures	Coronary artery bypass	01MAY2017	15JUN2017	N
		Vascular disorders	Hypertension	01MAY2017		Y
	C4591001 1231 12314207	Vascular disorders	Hypertension	01MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314209	Nervous system disorders	Migraine	25MAY2010		Y
	C4591001 1231 12314211	Cardiac disorders	Ventricular extrasystoles	08AUG2017		Y
		Vascular disorders	Hypertension	08AUG2017		Y
	C4591001 1231 12314213	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostatic adenoma	01AUG2017		Y
	C4591001 1231 12314214	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Infections and infestations	Diverticulitis	01MAY2004	01OCT2014	N
		Metabolism and nutrition disorders	Dyslipidaemia	01FEB2015		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	01JUN2012	01APR2018	N
		Surgical and medical procedures	Diverticulectomy	01OCT2014	01OCT2014	N
			Internal fixation of fracture	01APR2018	01APR2018	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12314220	Metabolism and nutrition disorders	Dyslipidaemia	02JUN2012		Y
		Psychiatric disorders	Generalised anxiety disorder	01FEB2016		Y
	C4591001 1231 12314222	Skin and subcutaneous tissue disorders	Telangiectasia	01FEB1984		Y
	C4591001 1231 12314231	Gastrointestinal disorders	Gastroesophageal reflux disease	12DEC2018		Y
		Infections and infestations	Laryngitis	01FEB2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12JUN2010		Y
		Vascular disorders	Hypertension	11FEB2013		Y
	C4591001 1231 12314233	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	19MAR2013	30NOV2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314234	Musculoskeletal and connective tissue disorders	Neck pain	19NOV2010		Y
	C4591001 1231 12314240	Metabolism and nutrition disorders	Type 2 diabetes mellitus	03MAY2017		Y
	C4591001 1231 12314241	Vascular disorders	Hypertension	03AUG2005		Y
	C4591001 1231 12314250	Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	07JUL1990		Y
		Vascular disorders	Hypertension	02FEB2020		Y
	C4591001 1231 12314254	Psychiatric disorders	Anxiety disorder	14APR2015		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	11JUN2015		Y
	C4591001 1231 12314255	Endocrine disorders	Hypothyroidism	01OCT2004		Y
	C4591001 1231 12314257	Nervous system disorders	Polyneuropathy	01JAN2016	01SEP2016	N
		Psychiatric disorders	Delirium tremens	01JAN2016	01SEP2016	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12314275	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to bone	10OCT2017	09FEB2018	N
			Seminoma	10OCT2017	09FEB2018	N
	C4591001 1231 12314281	Endocrine disorders	Hypothyroidism	15AUG2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2005		Y
			Type 2 diabetes mellitus	26OCT2005		Y
		Vascular disorders	Hypertension	18DEC2010		Y
	C4591001 1231 12314282	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01NOV2003	01JAN2009	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1231 12314286	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Psychiatric disorders	Depression	01JAN2020		Y
	C4591001 1231 12314293	Endocrine disorders	Hypothyroidism	19JUL2006		Y
		Metabolism and nutrition disorders	Dyslipidaemia	19JUN2019		Y
		Vascular disorders	Hypertension	24AUG2006		Y
	C4591001 1231 12314299	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10AUG2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	10MAR2020		Y
			Rhinitis allergic	20DEC2017		Y
		Vascular disorders	Thrombosis	10AUG2011	10NOV2011	N
	C4591001 1231 12314301	Metabolism and nutrition disorders	Type 2 diabetes mellitus	06AUG2015		Y
		Vascular disorders	Hypertension	07AUG2013		Y
	C4591001 1231 12314307	Eye disorders	Ocular pemphigoid	07JAN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG1985		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01OCT2019		Y
	C4591001 1231 12314312	Gastrointestinal disorders	Irritable bowel syndrome	19AUG2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	15JUN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUL2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Nephrectomy	05SEP1994	05SEP1994	N
	C4591001 1231 12314315	Psychiatric disorders	Insomnia	01JAN2009		Y
		Vascular disorders	Hypertension	01MAR2009		Y
	C4591001 1231 12314316	Cardiac disorders	Acute myocardial infarction	28JUN2019	25JUL2019	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	29JUN2019		Y
		Surgical and medical procedures	Coronary angioplasty	28JUN2019	28JUN2019	N
			Coronary arterial stent insertion	28JUN2019	28JUN2019	N
			Coronary revascularisation	14JUL2019	15JUL2019	N
	C4591001 1231 12314321	Cardiac disorders	Myocardial infarction	01JUL2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2000		Y
	C4591001 1231 12314323	Gastrointestinal disorders	Gastrooesophageal reflux disease	01AUG2020		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12314331	Metabolism and nutrition disorders	Dyslipidaemia	08AUG2015		Y
	C4591001 1231 12314335	Cardiac disorders	Supraventricular extrasystoles	20APR2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	13JUN2018		Y
	C4591001 1231 12314344	Musculoskeletal and connective tissue disorders	Osteoarthritis	01DEC2015		Y
	C4591001 1231 12314345	Cardiac disorders	Silent myocardial infarction	01JUL2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01DEC1952		Y
	C4591001 1231 12314347	Cardiac disorders	Myocardial ischaemia	10AUG2018		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	10AUG2018		Y
	C4591001 1231 12314349	Gastrointestinal disorders	Inguinal hernia	01APR2020		Y
		Vascular disorders	Hypertension	06APR2020	11DEC2020	N
	C4591001 1231 12314350	Musculoskeletal and connective tissue disorders	Fibromyalgia	01AUG2012		Y
	C4591001 1231 12314364	Renal and urinary disorders	Focal segmental glomerulosclerosis	10MAY2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN1998		Y
	C4591001 1231 12314365	Endocrine disorders	Hypothyroidism	01JUN2015		Y
		Gastrointestinal disorders	Diverticulum	01FEB2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2015	10OCT2011	N
		Surgical and medical procedures	Mastectomy	01SEP2011	10OCT2011	N
	C4591001 1231 12314367	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	10OCT2011	10OCT2011	N
		Vascular disorders	Hypertension	16NOV2016	31AUG2017	N
	C4591001 1231 12314369	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2013		Y
		Vascular disorders	Hypertension	04MAY2005		Y
	C4591001 1231 12314377	Nervous system disorders	Carpal tunnel syndrome	04MAY2005		Y
		Surgical and medical procedures	Thyroidectomy	10AUG2014		Y
	C4591001 1231 12314378	Endocrine disorders	Autoimmune thyroiditis	10JUN2005		Y
			Hypothyroidism	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
			Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314383	Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1231 12314384	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12314398	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1231 12314399	Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1231 12314401	Skin and subcutaneous tissue disorders	Psoriasis	05APR2016		Y
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1231 12314403	Psychiatric disorders	Anxiety disorder	01JAN2015		Y
	C4591001 1231 12314409	Metabolism and nutrition disorders	Dyslipidaemia	06JUN2016		Y
			Type 2 diabetes mellitus	03JUL2017		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JUN1981		Y
		Vascular disorders	Hypertension	04JUL2005		Y
	C4591001 1231 12314410	Vascular disorders	Hypertension	01JUN2000		Y
	C4591001 1231 12314411	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1231 12314412	Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1231 12314413	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	19JUN2020	19JUN2020	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	01JAN1997	N
			Nasal operation	19JUN2020	19JUN2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Palatal operation	19JUN2020	19JUN2020	N
	C4591001 1231 12314414	Metabolism and nutrition disorders	Type 2 diabetes mellitus	31AUG2015		Y
		Vascular disorders	Hypertension	19AUG1992		Y
	C4591001 1231 12314415	Surgical and medical procedures	Radical hysterectomy	01AUG2007	01AUG2007	N
	C4591001 1231 12314426	Cardiac disorders	Acute myocardial infarction	01MAR2001	07MAR2001	N
			Arrhythmia	01JAN2002	15OCT2020	N
			Cardiac failure	01JAN2001		Y
		Endocrine disorders	Hypothyroidism	01JAN2012		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2002		Y
			Hyperuricaemia	01JAN2002		Y
	C4591001 1231 12314428	Cardiac disorders	Acute myocardial infarction	01JAN1996	02JAN1996	N
			Atrial fibrillation	01JAN2011		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN1996	02JAN1996	N
		Vascular disorders	Hypertension	01JAN1983		Y
	C4591001 1231 12314431	Cardiac disorders	Acute myocardial infarction	04MAY1998	20MAY1998	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	04MAY2005		Y
		Surgical and medical procedures	Large intestinal polypectomy	14AUG2020	14AUG2020	N
	C4591001 1231 12314432	Reproductive system and breast disorders	Benign prostatic hyperplasia	02AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	06JUL2010		Y
		Vascular disorders	Hypertension	06SEP2015		Y
	C4591001 1231 12314438	Cardiac disorders	Arrhythmia	15JUN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN2020		Y
	C4591001 1231 12314441	Surgical and medical procedures	Meningioma surgery	03FEB2020	03FEB2020	N
		Vascular disorders	Hypertension	01AUG1990		Y
	C4591001 1231 12314443	Metabolism and nutrition disorders	Hypercholesterolaemia	10AUG2005		Y
		Vascular disorders	Hypertension	10AUG2000		Y
	C4591001 1231 12314446	Endocrine disorders	Hypothyroidism	01JUN2020		Y
	C4591001 1231 12314448	Cardiac disorders	Acute myocardial infarction	01APR2005	02APR2005	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01APR2005	02APR2005	N
			Stent placement	01JAN2013	01JAN2013	N
		Vascular disorders	Ischaemia	01JAN2013	01JAN2013	N
	C4591001 1231 12314453	Eye disorders	Dry eye	12DEC2017		Y
			Glaucoma	07JUL2007		Y
			Macular oedema	01MAR2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL1996		Y
		Surgical and medical procedures	Eye operation	06JUN2018	06JUN2018	N
			Gastric bypass	07NOV2006	07NOV2006	N
			Strictureplasty	15DEC2006	15DEC2006	N
			Vitrectomy	09JUN2016	09JUN2016	N
		Vascular disorders	Hypertension	06JUN2000		Y
	C4591001 1231 12314455	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1975		Y
	C4591001 1231 12314456	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314458	Endocrine disorders	Hypothyroidism	02APR2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	02APR2018		Y
		Vascular disorders	Hypertension	02MAR2018		Y
	C4591001 1231 12314460	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10JUN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	10JUN2014		Y
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12314465	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01APR2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01OCT2018	01JUN2019	N
		Reproductive system and breast disorders	Erectile dysfunction	01AUG2019		Y
		Surgical and medical procedures	Radical prostatectomy	01DEC2018	15DEC2018	N
	C4591001 1231 12314473	Metabolism and nutrition disorders	Hypercholesterolaemia	10JUN2006		Y
		Vascular disorders	Hypertension	01MAR2006		Y
	C4591001 1231 12314483	Vascular disorders	Hypertension	15JUN2010		Y
	C4591001 1231 12314488	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	26AUG2015		Y
	C4591001 1231 12314493	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Renal and urinary disorders	Glomerulonephritis	01JAN1998	01FEB1998	N
	C4591001 1231 12314495	Infections and infestations	Onychomycosis	01NOV2019		Y
	C4591001 1231 12314498	Metabolism and nutrition disorders	Hypercholesterolaemia	10OCT2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	10OCT2010		Y
	C4591001 1231 12314507	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
	C4591001 1231 12314514	Endocrine disorders	Hypothyroidism	01MAY2017		Y
	C4591001 1231 12314518	Endocrine disorders	Hypothyroidism	03AUG2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	08APR2010		Y
		Vascular disorders	Hypertension	12DEC2019		Y
	C4591001 1231 12314524	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1231 12314527	Psychiatric disorders	Anxiety disorder	01JAN2010		Y
	C4591001 1231 12314533	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2010		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01DEC2017	01DEC2017	N
		Vascular disorders	Hypertension	01JUL2000		Y
	C4591001 1231 12314536	Cardiac disorders	Arrhythmia	01JUN1998		Y
	C4591001 1231 12314540	Metabolism and nutrition disorders	Dyslipidaemia	13AUG2015		Y
	C4591001 1231 12314543	Endocrine disorders	Hypothyroidism	05JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	03JAN2015		Y
		Vascular disorders	Hypertension	03JAN2010		Y
	C4591001 1231 12314544	Vascular disorders	Hypertension	27AUG2015		Y
	C4591001 1231 12314545	Metabolism and nutrition disorders	Hypercholesterolaemia	30JUN2016		Y
		Surgical and medical procedures	Aortic valve replacement	30JUN2016	10JUL2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Aortic arteriosclerosis	30JUN2016	10JUL2016	N
			Hypertension	01JAN1985		Y
	C4591001 1231 12314546	Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12314549	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
	C4591001 1231 12314551	Cardiac disorders	Sinus bradycardia	01NOV2016	14NOV2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	10JAN2015	15JUL2015	N
		Vascular disorders	Hypertension	09AUG1995		Y
	C4591001 1231 12314556	Cardiac disorders	Arrhythmia	01MAY2013		Y
		Endocrine disorders	Hypothyroidism	15FEB2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	01FEB2015	15FEB2015	N
		Surgical and medical procedures	Thyroidectomy	15FEB2015	15FEB2015	N
	C4591001 1231 12314558	Metabolism and nutrition disorders	Hypercholesterolaemia	07JUL2004		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	20JUN2004	10JUN2008	N
	C4591001 1231 12314561	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y
	C4591001 1231 12314563	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN1981		Y
			Polycystic liver disease	01JAN1981		Y
		Endocrine disorders	Hypothyroidism	01JUL2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01FEB2008		Y
		Vascular disorders	Hypertension	01FEB2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314567	Endocrine disorders	Hypothyroidism	01MAY1973		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	05OCT2008		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12314569	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12314578	Nervous system disorders	Ischaemic stroke	14JUL2019	31JUL2019	N
	C4591001 1231 12314579	Nervous system disorders	Essential tremor	01JAN2000		Y
	C4591001 1231 12314581	Psychiatric disorders	Insomnia	01JAN2013		Y
		Vascular disorders	Hypertension	01APR2013		Y
	C4591001 1231 12314584	Renal and urinary disorders	Dysuria	01MAR2020		Y
	C4591001 1231 12314587	Endocrine disorders	Hypothyroidism	18AUG2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	13AUG2010		Y
		Vascular disorders	Hypertension	13AUG2010		Y
	C4591001 1231 12314588	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	21AUG2018		Y
		Surgical and medical procedures	Aortic valve replacement	12FEB2019	21FEB2019	N
			Coronary artery bypass	12FEB2019	21FEB2019	N
			Intra-thoracic aortic aneurysm repair	12FEB2019	21FEB2019	N
		Vascular disorders	Aortic aneurysm	12FEB2019	21FEB2019	N
	C4591001 1231 12314592	Metabolism and nutrition disorders	Type 2 diabetes mellitus	16AUG2017		Y
		Vascular disorders	Hypertension	17MAY2017		Y
	C4591001 1231 12314593	Vascular disorders	Hypertension	01AUG2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314594	Gastrointestinal disorders	Hyperchlorhydria	03AUG2015		Y
		Vascular disorders	Hypertension	03AUG2015		Y
	C4591001 1231 12314598	Psychiatric disorders	Insomnia	01FEB2004		Y
		Vascular disorders	Hypertension	01JUN2004		Y
	C4591001 1231 12314600	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12314605	Infections and infestations	Vulvovaginal mycotic infection	01JAN2019		Y
	C4591001 1231 12314623	Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12314624	Endocrine disorders	Hypothyroidism	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12314626	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperuricaemia	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2000		Y
	C4591001 1231 12314631	Endocrine disorders	Hypothyroidism	20OCT2018		Y
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12314632	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
	C4591001 1231 12314651	Vascular disorders	Hypertension	01AUG2016		Y
	C4591001 1231 12314652	Endocrine disorders	Hypothyroidism	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314653	Nervous system disorders	Anosmia	01AUG1984		Y
	C4591001 1231 12314657	Cardiac disorders	Arrhythmia	01OCT2019		Y
	C4591001 1231 12314658	Respiratory, thoracic and mediastinal disorders	Emphysema	18JUL2017		Y
		Vascular disorders	Hypertension	08AUG2010		Y
	C4591001 1231 12314660	Metabolism and nutrition disorders	Obesity	01JAN1975		Y
		Surgical and medical procedures	Metabolic surgery	24OCT2017	24OCT2017	N
		Vascular disorders	Hypertension	01AUG2003		Y
	C4591001 1231 12314662	Endocrine disorders	Hypothyroidism	02AUG2010		Y
		Metabolism and nutrition disorders	Insulin resistance	02AUG2004		Y
		Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12314663	Endocrine disorders	Hypothyroidism	16OCT1996		Y
	C4591001 1231 12314664	Endocrine disorders	Hypothyroidism	01DEC2014		Y
	C4591001 1231 12314668	Cardiac disorders	Mitral valve prolapse	01JUN2010		Y
		Gastrointestinal disorders	Dental caries	01MAR2020		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL1993		Y
		Vascular disorders	Hypertension	01JUL2000		Y
	C4591001 1231 12314669	Vascular disorders	Hypertension	05SEP2003		Y
	C4591001 1231 12314673	Endocrine disorders	Hypothyroidism	01JAN2008		Y
	C4591001 1231 12314675	Nervous system disorders	Cervical cord compression	01MAR2015		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1231 12314676	Respiratory, thoracic and mediastinal disorders	Asthma	12AUG1957		Y
	C4591001 1231 12314681	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2014		Y
		Psychiatric disorders	Type 2 diabetes mellitus	01JUN2000		Y
		Psychiatric disorders	Anxiety disorder	01JUN2014		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01SEP1994	03SEP1994	N
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12314690	Gastrointestinal disorders	Gastroesophageal reflux disease	15JUL2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
	C4591001 1231 12314692	Psychiatric disorders	Affective disorder	08SEP2011		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12314696	Vascular disorders	Hypertension	09AUG2000		Y
	C4591001 1231 12314702	Vascular disorders	Hypertension	25AUG2009		Y
	C4591001 1231 12314704	Vascular disorders	Hypertension	20DEC2017		Y
	C4591001 1231 12314707	Gastrointestinal disorders	Gastroesophageal reflux disease	04OCT1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	03JUL1990		Y
		Vascular disorders	Hypertension	08AUG1990		Y
	C4591001 1231 12314711	Endocrine disorders	Hypothyroidism	01JUN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT1972		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314732	Vascular disorders	Hypertension	01FEB2000		Y
	C4591001 1231 12314736	Metabolism and nutrition disorders	Dyslipidaemia	12DEC2002		Y
			Type 2 diabetes mellitus	12FEB2017		Y
	C4591001 1231 12314737	Vascular disorders	Hypertension	12DEC2002		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1231 12314741	Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 1231 12314747	Metabolism and nutrition disorders	Hypercholesterolaemia	03MAR2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12314753	Cardiac disorders	Acute myocardial infarction	06AUG2008	06AUG2008	N
			Coronary artery disease	21AUG2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2016	N
		Surgical and medical procedures	Coronary arterial stent insertion	06AUG2008	06AUG2008	N
			Prostatectomy	01JAN2016	31DEC2016	N
	C4591001 1231 12314755	Metabolism and nutrition disorders	Hypercholesterolaemia	23AUG2000		Y
	C4591001 1231 12314759	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01NOV2017		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2020		Y
		Social circumstances	Tobacco user	01JAN1972	30SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314767	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2018		Y
			Type 2 diabetes mellitus	01JUN2018		Y
		Surgical and medical procedures	Aortic valve replacement	01JUN2018	15JUN2018	N
			Mitral valve replacement	01JUN2018	15JUN2018	N
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 1231 12314769	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02MAY2016		Y
		Vascular disorders	Hypertension	05AUG2019		Y
	C4591001 1231 12314770	Psychiatric disorders	Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	04DEC2017		Y
	C4591001 1231 12314775	Endocrine disorders	Hypothyroidism	01JAN2013		Y
	C4591001 1231 12314778	Endocrine disorders	Hypothyroidism	01AUG2018		Y
	C4591001 1231 12314780	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2008		Y
		Surgical and medical procedures	Chemotherapy	01DEC2017	31JAN2018	N
		Vascular disorders	Hypertension	17AUG2010		Y
	C4591001 1231 12314784	Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2017		Y
	C4591001 1231 12314785	Psychiatric disorders	Sleep disorder	01JAN2016		Y
	C4591001 1231 12314786	Injury, poisoning and procedural complications	Ligament rupture	13DEC2019		Y
			Meniscus injury	13DEC2019		Y
		Musculoskeletal and connective tissue disorders	Joint effusion	13DEC2019		Y
			Osteoarthritis	13DEC2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314793	Cardiac disorders	Coronary artery disease	01AUG2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	11AUG2010		Y
		Renal and urinary disorders	Renal failure	17AUG2016		Y
		Surgical and medical procedures	Coronary artery bypass	11SEP2016	20SEP2016	N
		Vascular disorders	Hypertension	11AUG2010		Y
	C4591001 1231 12314799	Eye disorders	Glaucoma	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01SEP2008	01SEP2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12314802	Reproductive system and breast disorders	Endometriosis	28JUL2014	01SEP2014	N
	C4591001 1231 12314805	Gastrointestinal disorders	Hiatus hernia	01FEB2000		Y
		Vascular disorders	Hypertension	01FEB1995		Y
	C4591001 1231 12314807	Cardiac disorders	Ventricular extrasystoles	01AUG2017		Y
		Endocrine disorders	Thyroid mass	01AUG2015		Y
		Gastrointestinal disorders	Hiatus hernia	02AUG2017		Y
		Vascular disorders	Hypertension	08AUG2018		Y
	C4591001 1231 12314811	Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1231 12314820	Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12314821	Metabolism and nutrition disorders	Dyslipidaemia	27APR2003		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	10JUL2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	27APR2003		Y
	C4591001 1231 12314827	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12314829	Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12314830	Infections and infestations	Myiasis	01SEP2019		Y
	C4591001 1231 12314837	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12314841	Endocrine disorders	Hypothyroidism	09JUL2015		Y
		Surgical and medical procedures	Mitral valve replacement	12APR2006		Y
	C4591001 1231 12314850	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01DEC2015		Y
	C4591001 1231 12314856	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12314860	Vascular disorders	Hypertension	01AUG2013		Y
	C4591001 1231 12314865	Cardiac disorders	Acute myocardial infarction	01MAR2019	01APR2019	N
	C4591001 1231 12314867	Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12314871	Cardiac disorders	Supraventricular tachycardia	01JAN2006		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1997		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1231 12314875	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Coronary arterial stent insertion	02MAY2014	07AUG2017	N
	C4591001 1231 12314879	Gastrointestinal disorders	Gastroesophageal reflux disease	07JUL2015		Y
	C4591001 1231 12314881	Musculoskeletal and connective tissue disorders	Osteopenia	03MAR2017		Y
	C4591001 1231 12314888	Vascular disorders	Aneurysm	17AUG2017	11NOV2017	N
	C4591001 1231 12314891	Gastrointestinal disorders	Hypertension Gastritis	11AUG2005 01AUG2020		Y Y
		Immune system disorders	Drug hypersensitivity	01FEB1988 13APR1989 13JAN2000		Y Y Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG1990		Y
		Psychiatric disorders	Anxiety disorder	01AUG2019		Y
		Renal and urinary disorders	Nephrolithiasis	02AUG2019		Y
		Vascular disorders	Hypertension	01AUG1990		Y
	C4591001 1231 12314898	Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1963		Y
	C4591001 1231 12314902	Metabolism and nutrition disorders	Hypercholesterolaemia	10APR2018		Y
	C4591001 1231 12314904	Surgical and medical procedures Psychiatric disorders	Cerebrovascular accident prophylaxis Anxiety disorder	01MAR2018 08JAN2020		Y Y
	C4591001 1231 12314906	Nervous system disorders	Cerebrovascular accident	08DEC2012	28DEC2012	N
	C4591001 1231 12314916	Vascular disorders	Hypertension	16JUN2020		Y
	C4591001 1231 12314927	Cardiac disorders	Angina unstable	08AUG2018	10AUG2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Constipation	02APR2016		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	16AUG2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	08AUG2018	10AUG2018	N
		Vascular disorders	Hypertension	16AUG1990		Y
	C4591001 1231 12314932	Immune system disorders	Drug hypersensitivity	31AUG1978		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	15AUG2019		Y
	C4591001 1231 12314941	Endocrine disorders	Hypothyroidism	01AUG2020		Y
	C4591001 1231 12314942	Metabolism and nutrition disorders	Type 2 diabetes mellitus	08AUG2010		Y
		Vascular disorders	Hypertension	08AUG2000		Y
	C4591001 1231 12314950	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Psychiatric disorders	Insomnia	01DEC2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JUL2019		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1231 12314953	Surgical and medical procedures	Arterial therapeutic procedure	13OCT2009	13OCT2009	N
		Vascular disorders	Hypertension	04MAY2000		Y
	C4591001 1231 12314957	Psychiatric disorders	Schizoaffective disorder	01NOV2009		Y
	C4591001 1231 12314960	Vascular disorders	Hypertension	01MAR2000		Y
	C4591001 1231 12314961	Metabolism and nutrition disorders	Dyslipidaemia	16MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314966	Cardiac disorders	Acute myocardial infarction	08APR2019	08APR2019	N
		Surgical and medical procedures	Coronary arterial stent insertion	08APR2019	08APR2019	N
	C4591001 1231 12314971	Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2018		Y
	C4591001 1231 12314972	Respiratory, thoracic and mediastinal disorders	Bronchospasm	01SEP2018		Y
		Vascular disorders	Hypertension	12AUG2010		Y
	C4591001 1231 12314973	Endocrine disorders	Hypothyroidism	01MAR2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1231 12314976	Cardiac disorders	Arrhythmia	07JUL2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	07JUL2002		Y
			Hyperglycaemia	07JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	07JUL2018		Y
		Vascular disorders	Hypertension	07JUL2010		Y
	C4591001 1231 12314978	Vascular disorders	Hypertension	06JUN1998		Y
	C4591001 1231 12314979	Vascular disorders	Hypertension	01AUG2005		Y
	C4591001 1231 12314982	Endocrine disorders	Hypothyroidism	02FEB2010		Y
		Eye disorders	Glaucoma	05MAY2020		Y
	C4591001 1231 12314988	Psychiatric disorders	Bruxism	01JAN1975		Y
	C4591001 1231 12314989	Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2010		Y
		Vascular disorders	Hypertension	01JUN2014		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12314991	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2019		Y
	C4591001 1231 12314993	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1231 12314997	Endocrine disorders	Hypothyroidism	13AUG1997		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN1992		Y
		Nervous system disorders	Neuropathy peripheral	01JUN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Dermatitis allergic	23AUG2018		Y
	C4591001 1231 12315000	Endocrine disorders	Hypothyroidism	08AUG2018		Y
	C4591001 1231 12315002	Cardiac disorders	Arrhythmia	01MAR2010		Y
	C4591001 1231 12315003	Gastrointestinal disorders	Inguinal hernia	18AUG2010	20AUG2010	N
		Hepatobiliary disorders	Cholecystitis acute	17AUG2020	17AUG2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	03FEB2019		Y
	C4591001 1231 12315004	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	09AUG1990		Y
		Vascular disorders	Hypertension	12AUG2010		Y
	C4591001 1231 12315006	Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12315007	Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315010	Vascular disorders	Hypertension	01FEB2010		Y
	C4591001 1231 12315011	Metabolism and nutrition disorders	Hypercholesterolaemia	21AUG2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	12AUG2015		Y
		Vascular disorders	Hypertension	12AUG2015		Y
	C4591001 1231 12315016	Psychiatric disorders	Anxiety disorder	20JUN2018		Y
	C4591001 1231 12315018	Cardiac disorders	Acute myocardial infarction	15AUG2012	17AUG2012	N
	C4591001 1231 12315020	Vascular disorders	Hypertension	10JUN2013		Y
	C4591001 1231 12315022	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2018		Y
		Vascular disorders	Hypertension	01DEC2016		Y
	C4591001 1231 12315024	Cardiac disorders	Angina unstable	01AUG2016	11AUG2016	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2010		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12315025	Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2000		Y
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12315030	Vascular disorders	Hypertension	29AUG2015		Y
	C4591001 1231 12315033	Cardiac disorders	Arrhythmia	03AUG1998		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	02AUG2010		Y
		Vascular disorders	Hypertension	01AUG2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315035	Psychiatric disorders	Depression	01MAY2018		Y
	C4591001 1231 12315037	Metabolism and nutrition disorders	Dyslipidaemia	01FEB2012		Y
		Vascular disorders	Type 2 diabetes mellitus	01JAN2002		Y
			Hypertension	02FEB2013		Y
			Peripheral vascular disorder	02JAN2011		Y
	C4591001 1231 12315040	Metabolism and nutrition disorders	Dyslipidaemia	15AUG2019		Y
		Vascular disorders	Hypertension	11MAR2020		Y
	C4591001 1231 12315041	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12315042	Vascular disorders	Hypertension	01JUN1990		Y
	C4591001 1231 12315044	Metabolism and nutrition disorders	Vitamin D deficiency	01JUN2020		Y
	C4591001 1231 12315046	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2019		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12315049	Cardiac disorders	Acute myocardial infarction	19MAY2004	19MAY2004	N
		Metabolism and nutrition disorders	Dyslipidaemia	26MAY2004		Y
		Surgical and medical procedures	Stent placement	19MAY2004	19MAY2004	N
		Vascular disorders	Hypertension	21MAY2004		Y
	C4591001 1231 12315050	Endocrine disorders	Hypothyroidism	28AUG1990		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	02FEB2003		Y
	C4591001 1231 12315051	Endocrine disorders	Hypothyroidism	01AUG2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315069	Metabolism and nutrition disorders	Gout	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12315075	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1990		Y
			Type 2 diabetes mellitus	01MAY2016		Y
		Nervous system disorders	Cerebrovascular accident	01MAY2001	01JUN2001	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1231 12315077	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	02FEB2010		Y
	C4591001 1231 12315086	Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2005		Y
	C4591001 1231 12315096	Endocrine disorders	Hypothyroidism	31JUL2016		Y
		Psychiatric disorders	Anxiety disorder	28AUG2017		Y
	C4591001 1231 12315106	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2017		Y
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12315107	Vascular disorders	Hypertension	12AUG2015		Y
	C4591001 1231 12315126	Congenital, familial and genetic disorders	Congenital myopia	(b) (6) 1952		Y
		Gastrointestinal disorders	Irritable bowel syndrome	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2015	01JAN2018	N
		Social circumstances	Tobacco user	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315141	Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2019		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1231 12315148	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
	C4591001 1231 12315159	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2008		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01OCT2018		Y
	C4591001 1231 12315161	Gastrointestinal disorders	Barrett's oesophagus	01FEB2010		Y
	C4591001 1231 12315173	Skin and subcutaneous tissue disorders	Psoriasis	01MAY1968		Y
	C4591001 1231 12315174	Gastrointestinal disorders	Gastritis	01JUN2017		Y
		Psychiatric disorders	Anxiety disorder	01JUN2006		Y
			Insomnia	01JUN2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01SEP2008		Y
			Emphysema	01SEP2008		Y
	C4591001 1231 12315179	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1231 12315193	Psychiatric disorders	Sleep disorder	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN1998	01JAN1998	N
	C4591001 1231 12315207	Gastrointestinal disorders	Chronic gastritis	13MAY2000		Y
	C4591001 1231 12315210	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01NOV2012	28FEB2013	N
		Surgical and medical procedures	Radical hysterectomy	01FEB2013	28FEB2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315232	Gastrointestinal disorders	Dental caries	01FEB2020	13OCT2020	N
	C4591001 1231 12315235	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	29AUG2003		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1231 12315237	Gastrointestinal disorders	Irritable bowel syndrome	01FEB2019		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1984		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12315240	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2016		Y
	C4591001 1231 12315245	Immune system disorders	Seasonal allergy	01MAY2011		Y
		Psychiatric disorders	Anxiety disorder	10MAY2005		Y
	C4591001 1231 12315250	Endocrine disorders	Hypothyroidism	07JUL2014		Y
	C4591001 1231 12315251	Cardiac disorders	Acute myocardial infarction	15SEP2013	18SEP2013	N
				27SEP2008	02OCT2008	N
		Surgical and medical procedures	Renal surgery	17SEP2018	24SEP2018	N
	C4591001 1231 12315254	Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1231 12315256	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2004		Y
		Surgical and medical procedures	Coronary artery bypass	01JUN2004	03JUN2004	N
		Vascular disorders	Hypertension	01JUN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315261	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01NOV2004	01SEP2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1231 12315262	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2013		Y
	C4591001 1231 12315266	Endocrine disorders	Hypothyroidism	03APR2014		Y
		Metabolism and nutrition disorders	Dyslipidaemia	03APR2014		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03APR2018	03APR2019	N
		Surgical and medical procedures	Hysterectomy	03APR2003		Y
	C4591001 1231 12315267	Metabolism and nutrition disorders	Obesity	30DEC2016		Y
		Vascular disorders	Hypertension	01JUL2009		Y
	C4591001 1231 12315273	General disorders and administration site conditions	Hernia	30AUG2010		Y
	C4591001 1231 12315274	Congenital, familial and genetic disorders	Thalassaemia minor	05JAN1981		Y
		Endocrine disorders	Hypothyroidism	05JAN2011		Y
	C4591001 1231 12315290	Vascular disorders	Deep vein thrombosis	01JAN2012	01JUN2012	N
	C4591001 1231 12315293	Vascular disorders	Hypertension	30AUG2018		Y
	C4591001 1231 12315301	Gastrointestinal disorders	Pancreatic cyst	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Psychiatric disorders	Insomnia	01MAR2019		Y
	C4591001 1231 12315305	Nervous system disorders	Epilepsy	01JAN1974		Y
	C4591001 1231 12315314	Gastrointestinal disorders	Gastroesophageal reflux disease	01AUG2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hiatus hernia	01AUG2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2000		Y
	C4591001 1231 12315323	Endocrine disorders	Hypothyroidism	01AUG2018		Y
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12315327	Psychiatric disorders	Panic attack	03APR2012		Y
		Surgical and medical procedures	Thyroidectomy	03APR2017	03APR2017	N
	C4591001 1231 12315328	Surgical and medical procedures	Vascular stent insertion	30SEP2017		Y
		Vascular disorders	Hypertension	28DEC2017		Y
	C4591001 1231 12315332	Endocrine disorders	Hypothyroidism	01JUN2000		Y
	C4591001 1231 12315339	Metabolism and nutrition disorders	Dyslipidaemia	05MAR2017		Y
			Type 2 diabetes mellitus	05MAR2017		Y
		Vascular disorders	Hypertension	05AUG2017		Y
	C4591001 1231 12315341	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01AUG2019		Y
	C4591001 1231 12315344	Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12315350	Endocrine disorders	Hypothyroidism	07JUL2006		Y
		Vascular disorders	Hypertension	05MAY2015		Y
	C4591001 1231 12315354	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	25MAY1978	25MAY1978	N
		Surgical and medical procedures	Thyroidectomy	25MAY1978		Y
	C4591001 1231 12315356	Metabolism and nutrition disorders	Type 1 diabetes mellitus	09AUG2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315366	Social circumstances	Tobacco user	20AUG1975		Y
	C4591001 1231 12315379	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1231 12315383	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10AUG2005		Y
	C4591001 1231 12315384	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Gastrointestinal disorders	Haemorrhoids	13JUN1989		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
	C4591001 1231 12315388	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2015		Y
	C4591001 1231 12315390	Cardiac disorders	Arteriosclerosis coronary artery	04FEB2010	18FEB2010	N
		Surgical and medical procedures	Aortic valve replacement	04FEB2010	18FEB2010	N
			Coronary artery bypass	04FEB2010	18FEB2010	N
	C4591001 1231 12315392	Metabolism and nutrition disorders	Dyslipidaemia	18AUG2019		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	24AUG2013	26AUG2013	N
		Surgical and medical procedures	Spinal operation	24AUG2013	26AUG2013	N
	C4591001 1231 12315399	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2008		Y
	C4591001 1231 12315403	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2017		Y
	C4591001 1231 12315404	Cardiac disorders	Arrhythmia	01DEC2019		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN2002		Y
		Renal and urinary disorders	Haematuria	02JUN2020		Y
		Surgical and medical procedures	Thyroidectomy	01JAN1975	31DEC1975	N
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 1231 12315405	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2010		Y
			Obesity	01JAN2010		Y
		Vascular disorders	Hypertension	01JUN2015		Y
	C4591001 1231 12315411	Endocrine disorders	Autoimmune thyroiditis	05JUN2012		Y
	C4591001 1231 12315425	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01AUG1964		Y
		Vascular disorders	Hypertension	01AUG2014		Y
	C4591001 1231 12315428	Cardiac disorders	Acute myocardial infarction	18OCT2011	25OCT2011	N
		Surgical and medical procedures	Coronary arterial stent insertion	18OCT2011	25OCT2011	N
		Vascular disorders	Hypertension	18OCT2011		Y
	C4591001 1231 12315433	Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 1231 12315439	Metabolism and nutrition disorders	Dyslipidaemia	10SEP2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	10FEB2013		Y
	C4591001 1231 12315442	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	22DEC2010	29DEC2010	N
		Vascular disorders	Hypertension	29DEC2010		Y
	C4591001 1231 12315443	Gastrointestinal disorders	Coeliac disease	13JUL2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315444	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1231 12315447	Gastrointestinal disorders	Gastritis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1231 12315455	Endocrine disorders	Hypothyroidism	12AUG1980		Y
		Psychiatric disorders	Anxiety disorder	01APR2020		Y
		Renal and urinary disorders	Nephrolithiasis	12APR2015		Y
	C4591001 1231 12315468	Vascular disorders	Hypertension	01JUN1998		Y
	C4591001 1231 12315476	Endocrine disorders	Hypothyroidism	30AUG2000		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	10JUN2020		Y
	C4591001 1231 12315483	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
	C4591001 1231 12315486	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2014		Y
	C4591001 1231 12315488	Eye disorders	Myopia	10AUG2010		Y
		Gastrointestinal disorders	Gastritis	06JUL2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	11MAY2016		Y
		Surgical and medical procedures	Cataract operation	10AUG2010	17AUG2010	N
		Vascular disorders	Hypertension	13APR2015		Y
	C4591001 1231 12315490	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02AUG2017		Y
		Vascular disorders	Hypertension	01MAR2018		Y
	C4591001 1231 12315500	Metabolism and nutrition disorders	Hypercholesterolaemia	02APR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Metrorrhagia	01SEP2011	13DEC2011	N
		Surgical and medical procedures	Hysterectomy	13DEC2011	13DEC2011	N
	C4591001 1231 12315501	Metabolism and nutrition disorders	Obesity	01MAR2020		Y
	C4591001 1231 12315507	Vascular disorders	Hypertension	05MAY2000		Y
	C4591001 1231 12315508	Gastrointestinal disorders	Chronic gastritis	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
		Psychiatric disorders	Insomnia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1231 12315509	Metabolism and nutrition disorders	Obesity	01JAN2001		Y
	C4591001 1231 12315510	Metabolism and nutrition disorders	Hypercholesterolaemia	20AUG2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	13AUG2015		Y
		Vascular disorders	Hypertension	14AUG2002		Y
	C4591001 1231 12315515	Metabolism and nutrition disorders	Obesity	01JAN2013		Y
		Vascular disorders	Hypertension	05JUL2007		Y
	C4591001 1231 12315520	Metabolism and nutrition disorders	Obesity	01JAN1998		Y
	C4591001 1231 12315522	Surgical and medical procedures	Stent placement	01JAN2012	08JAN2012	N
	C4591001 1231 12315523	Cardiac disorders	Arrhythmia	01AUG2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05AUG2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2010		Y
			Peyronie's disease	01AUG2009		Y
	C4591001 1231 12315524	Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12315530	Metabolism and nutrition disorders	Hypercholesterolaemia	20JUL2000		Y
		Vascular disorders	Hypertension	22SEP2010		Y
	C4591001 1231 12315531	Metabolism and nutrition disorders	Dyslipidaemia	06JUN2018		Y
			Type 2 diabetes mellitus	20DEC2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	03MAR2019		Y
	C4591001 1231 12315536	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2015		Y
	C4591001 1231 12315539	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12315548	Gastrointestinal disorders	Hiatus hernia	01AUG2000		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1231 12315549	Vascular disorders	Hypertension	20JUN2010		Y
	C4591001 1231 12315555	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Coronary arterial stent insertion	02JUL2018	02JUL2018	N
	C4591001 1231 12315556	Metabolism and nutrition disorders	Hypercholesterolaemia	31AUG2009		Y
		Vascular disorders	Hypertension	23SEP2010		Y
	C4591001 1231 12315557	Vascular disorders	Hypertension	08AUG2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315562	Vascular disorders	Hypertension	15JAN2009		Y
	C4591001 1231 12315564	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2015		Y
		Psychiatric disorders	Depression	01JUN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12315565	Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1231 12315573	Congenital, familial and genetic disorders	Type IIa hyperlipidaemia	12AUG1976		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2015	05JUN2015	N
		Surgical and medical procedures	Hernia repair	15JUN2014	15JUN2014	N
			Prostatic operation	05JUN2015	05JUN2015	N
		Vascular disorders	Hypertension	02AUG1994		Y
	C4591001 1231 12315574	Metabolism and nutrition disorders	Hypercholesterolaemia	18MAR2020		Y
		Vascular disorders	Hypertension	18AUG2014		Y
	C4591001 1231 12315582	Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 1231 12315584	Psychiatric disorders	Anxiety disorder	14APR2020		Y
	C4591001 1231 12315588	Congenital, familial and genetic disorders	Thalassaemia minor	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1231 12315589	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01DEC2002	01DEC2008	N
		Psychiatric disorders	Insomnia	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01FEB2015	01JUN2017	N
		Surgical and medical procedures	Carotid endarterectomy	01JUN2019	01JUN2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12315592	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01FEB2020	01FEB2020	N
			Hysterectomy	01JAN2004	01JAN2004	N
	C4591001 1231 12315593	Cardiac disorders	Atrial fibrillation	07JAN2020	17MAR2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1231 12315594	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1231 12315598	Endocrine disorders	Hypothyroidism	01APR2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2010		Y
	C4591001 1231 12315602	Metabolism and nutrition disorders	Hyperuricaemia	01JAN1990		Y
		Vascular disorders	Hypertension	02APR2010		Y
	C4591001 1231 12315607	Eye disorders	Cataract	01JAN2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1231 12315611	Nervous system disorders	Migraine	20MAR2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315612	Respiratory, thoracic and mediastinal disorders	Asthma	12DEC1970		Y
		Vascular disorders	Hypertension	12DEC2018		Y
	C4591001 1231 12315614	Metabolism and nutrition disorders	Gout	30AUG2005		Y
		Vascular disorders	Hypertension	24AUG2000		Y
	C4591001 1231 12315617	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Nervous system disorders	Lacunar infarction	01JAN2018	01JAN2018	N
	C4591001 1231 12315619	Reproductive system and breast disorders	Benign prostatic hyperplasia	31AUG2019		Y
	C4591001 1231 12315634	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01AUG2010		Y
	C4591001 1231 12315640	Cardiac disorders	Acute myocardial infarction	07NOV2019	07NOV2019	N
	C4591001 1231 12315653	Ear and labyrinth disorders	Deafness unilateral	01JUL1960		Y
		Eye disorders	Glaucoma	01JUL2017		Y
		Gastrointestinal disorders	Haematochezia	15AUG2020		Y
		Metabolism and nutrition disorders	Obesity	01JUL2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1231 12315656	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2019		Y
	C4591001 1231 12315657	Gastrointestinal disorders	Irritable bowel syndrome	03APR2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	03APR2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	03APR2005		Y
		Vascular disorders	Hypertension	01MAY2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1231 12315660	Vascular disorders	Hypertension	01AUG2000		Y
	C4591001 1231 12315661	Metabolism and nutrition disorders	Dyslipidaemia	03MAY2016		Y
	C4591001 1231 12315662	Endocrine disorders	Hypothyroidism	04MAY2015		Y
	C4591001 1231 12315664	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2005		Y
	C4591001 1231 12315664	Vascular disorders	Hypertension	01MAR2017		Y
	C4591001 1231 12315668	Endocrine disorders	Hypothyroidism	14AUG2019		Y
	C4591001 1231 12315669	Nervous system disorders	Haemorrhagic stroke	11AUG2011	11AUG2011	N
	C4591001 1231 12315670	Metabolism and nutrition disorders	Hypercholesterolaemia	12SEP2010		Y
	C4591001 1231 12315671	Nervous system disorders	Essential tremor	01JUL2012		Y
	C4591001 1231 12315671	Cardiac disorders	Acute myocardial infarction	24MAR1994	24MAR1994	N
	C4591001 1231 12315672	Surgical and medical procedures	Bladder polypectomy	01JAN2015	31DEC2015	N
	C4591001 1231 12315672	Surgical and medical procedures	Bladder polypectomy	01JAN2017	31DEC2017	N
	C4591001 1231 12315672	Surgical and medical procedures	Coronary arterial stent insertion	16SEP2013	16SEP2013	N
	C4591001 1231 12315672	Vascular disorders	Arteriosclerosis	01FEB1994		Y
	C4591001 1231 12315672	Nervous system disorders	Temporal lobe epilepsy	11AUG2000		Y
	C4591001 1231 12315683	Reproductive system and breast disorders	Benign prostatic hyperplasia	15JAN2020		Y
	C4591001 1231 12315683	Vascular disorders	Hypertension	30AUG2000		Y
	C4591001 1231 12315683	Endocrine disorders	Hypothyroidism	08AUG2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Thyroidectomy	08AUG2001	08AUG2001	N
		Vascular disorders	Hypertension	01AUG2019		Y
	C4591001 1231 12315685	Psychiatric disorders	Depression	07JUL1987		Y
	C4591001 1232 12321001	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
	C4591001 1232 12321016	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1232 12321017	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1232 12321020	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1232 12321031	Social circumstances	Postmenopause	01JAN2009		Y
	C4591001 1232 12321034	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321035	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
	C4591001 1232 12321039	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
	C4591001 1232 12321050	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1232 12321058	General disorders and administration site conditions	Pain	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Investigations	Heart rate irregular	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1998		Y
		Nervous system disorders	Migraine	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1232 12321062	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321064	Metabolism and nutrition disorders	Gout	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1232 12321065	Surgical and medical procedures	Hysterectomy	01JAN2000		Y
	C4591001 1232 12321067	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1232 12321073	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rash	01APR2020		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1232 12321076	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2018	N
	C4591001 1232 12321077	Nervous system disorders	Cerebrovascular accident	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1232 12321078	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Gout	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2015		Y
			Vitamin D deficiency	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321082	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321083	Endocrine disorders	Hypothyroidism	01JAN1984		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		General disorders and administration site conditions	Pain	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2002		Y
	C4591001 1232 12321085	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2003		Y
	C4591001 1232 12321096	Cardiac disorders	Myocardial infarction	01JUL2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30SEP2019	30NOV2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321097	Endocrine disorders	Hypothyroidism	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1232 12321102	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Lyme disease	01JAN2012		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1232 12321103	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1232 12321106	Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1232 12321107	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1232 12321109	Metabolism and nutrition disorders	Gout	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1998		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
	C4591001 1232 12321110	Endocrine disorders	Thyroid disorder	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
	C4591001 1232 12321113	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	01JAN1987	31DEC1987	N
	C4591001 1232 12321117	Nervous system disorders	Migraine	01JAN1970		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Rosacea	01JAN2010		Y
	C4591001 1232 12321118	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
	C4591001 1232 12321125	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1232 12321127	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Nervous system disorders	Neuralgia	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
	C4591001 1232 12321129	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1232 12321131	Cardiac disorders	Sinus node dysfunction	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1997		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN1992		Y
	C4591001 1232 12321133	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2011		Y
	C4591001 1232 12321134	Metabolism and nutrition disorders	Gout	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1232 12321137	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
	C4591001 1232 12321144	Social circumstances	Postmenopause	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321148					
	C4591001 1232 12321149	Eye disorders	Cataract	01JAN2015		Y
	C4591001 1232 12321153	Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1232 12321156	Metabolism and nutrition disorders	Gluten sensitivity	01JAN2008		Y
	C4591001 1232 12321157	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Depression	01JAN2000		Y
			Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321161	Immune system disorders	Seasonal allergy	01JAN2014		Y
		Infections and infestations	Diverticulitis	01JAN2020		Y
		Social circumstances	Menopause	01JAN2016		Y
	C4591001 1232 12321165	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Renal and urinary disorders	Nephropathy	01JAN2015		Y
	C4591001 1232 12321170	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2010		Y
	C4591001 1232 12321178	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2012		Y
		Immune system disorders	Seasonal allergy	01JAN2000		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
			Sleep apnoea syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1232 12321184	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321187	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN1980		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2018		Y
	C4591001 1232 12321191	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1232 12321192	Cardiac disorders	Myocardial infarction	01JAN2003	31DEC2003	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN1990		Y
		Investigations	Blood cholesterol increased	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Follicular thyroid cancer	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1232 12321200	Metabolism and nutrition disorders	Gout	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1232 12321201	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1232 12321203	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1982		Y
	C4591001 1232 12321215	General disorders and administration site conditions	Pain	01JAN1974		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1232 12321217	Investigations	Blood cholesterol increased	01JAN2008		Y
	C4591001 1232 12321218	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anal cancer	01NOV2010	31DEC2010	N
		Surgical and medical procedures	Tonsillectomy	01JAN1948	31DEC1948	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321222	Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1232 12321228	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986	31DEC1986	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321230	General disorders and administration site conditions	Pain	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1232 12321235	Vascular disorders	Hypertension	01MAR2020		Y
	C4591001 1232 12321239	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1232 12321251	Surgical and medical procedures	Hysterectomy	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321252	Nervous system disorders	Migraine	01MAY2018		Y
		Vascular disorders	Hypertension	01MAY2018		Y
	C4591001 1232 12321256	Eye disorders	Glaucoma	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1999		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1232 12321257	Nervous system disorders	Tremor	01JAN2015		Y
		Psychiatric disorders	Anxiety	01NOV2019		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2012		Y
	C4591001 1232 12321259	Eye disorders	Glaucoma	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
	C4591001 1232 12321269	Cardiac disorders	Myocardial infarction	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321273	Investigations	Blood cholesterol increased	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Acne	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1232 12321275	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2004		Y
			Rheumatoid arthritis	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1232 12321276	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1232 12321286	Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1232 12321300	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1232 12321306	Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1232 12321322	Social circumstances	Menopause	01JAN2002		Y
	C4591001 1232 12321325	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1232 12321326	Cardiac disorders	Myocardial infarction	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2011		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Social circumstances	Menopause	01JAN1991		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1232 12321334	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Thrombosis	01JAN2017		Y
	C4591001 1232 12321340	Renal and urinary disorders	Nephrolithiasis	01JAN2000	31DEC2000	N
	C4591001 1232 12321342	Endocrine disorders	Thyroid disorder	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321345	Immune system disorders	Multiple allergies	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine cancer	01OCT2019	31MAY2020	N
		Psychiatric disorders	Depression	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01OCT2019	31OCT2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321349	Immune system disorders	Allergy to chemicals	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Psychiatric disorders	Bipolar disorder	01JAN2015		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321357	Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1232 12321360	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1954		Y
			Chronic obstructive pulmonary disease	01JAN2020		Y
		Surgical and medical procedures	Female sterilisation	01JAN1979	31DEC1979	N
			Knee operation	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1232 12321365	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Surgical and medical procedures	Hand repair operation	01JAN2005	31DEC2005	N
			Wound closure	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1232 12321367	Endocrine disorders	Hypothyroidism	01JAN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 1232 12321369	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2020		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2020	31JAN2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1994		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1232 12321372	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1232 12321375	Metabolism and nutrition disorders	Diabetes mellitus	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1232 12321379	Nervous system disorders	Cerebrovascular accident	01SEP2018	30SEP2018	N
	C4591001 1232 12321381	Surgical and medical procedures	Facial operation	01JAN2002	31DEC2002	N
	C4591001 1232 12321383	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1232 12321387†	Investigations	Blood cholesterol increased	01JAN1974		Y
			HIV test positive	01JAN1991		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tonsil cancer	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN1974		Y
	C4591001 1232 12321388	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Infections and infestations	Hepatitis C	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Bipolar disorder	01JAN2018		Y
			Depression	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1232 12321389†	Investigations	HIV test positive	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1232 12321390	Endocrine disorders	Hyperthyroidism	01JAN1994		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321398	Surgical and medical procedures	Hysterectomy	01JAN1984		Y
	C4591001 1232 12321399	Blood and lymphatic system disorders	Anaemia	01JAN1997		Y
		Investigations	Blood cholesterol increased	01JAN1997		Y
		Skin and subcutaneous tissue disorders	Lichen planus	01JAN1999		Y
	C4591001 1232 12321403	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1232 12321407	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
	C4591001 1232 12321409	Investigations	Hormone level abnormal	01JAN2019		Y
		Nervous system disorders	Disturbance in attention	01JAN2000		Y
		Social circumstances	Menopause	01JAN2019		Y
	C4591001 1232 12321411	Cardiac disorders	Myocardial infarction	01JAN1997	31DEC1997	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Diabetic neuropathy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1235 12351001	Cardiac disorders	Ventricular extrasystoles	01AUG2019		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1235 12351010	Endocrine disorders	Autoimmune thyroiditis	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2003		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1235 12351012	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1235 12351022	Nervous system disorders	Essential tremor	01JUL2020		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1235 12351031	Endocrine disorders	Hypothyroidism	01JAN2004		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAY2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2000		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2016		Y
			Raynaud's phenomenon	01JAN2004		Y
	C4591001 1235 12351032	Cardiac disorders	Ventricular extrasystoles	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1235 12351043	Respiratory, thoracic and mediastinal disorders	Pulmonary mass	01JAN2015		Y
			Rhinitis allergic	01JAN2010		Y
	C4591001 1235 12351046	Cardiac disorders	Ventricular extrasystoles	01JAN2003		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1235 12351047	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1235 12351056	Musculoskeletal and connective tissue disorders	Pain in extremity	01APR2020		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Renal and urinary disorders	Bladder spasm	01JAN2010		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1987		Y
	C4591001 1235 12351062	Infections and infestations	Diverticulitis	01JAN2012		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JUL2020		Y
			Malignant melanoma	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1235 12351069	Endocrine disorders	Hypothyroidism	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	01SEP2017		Y
		Investigations	Lipids increased	01JAN1995		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01SEP2017		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1235 12351075	Infections and infestations	Vaginal infection	01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2001		Y
	C4591001 1235 12351076	Endocrine disorders	Basedow's disease	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01APR2016	31JUL2017	N
		Psychiatric disorders	Insomnia	01JAN2016		Y
		Reproductive system and breast disorders	Premature menopause	01JAN2017		Y
	C4591001 1235 12351078	Gastrointestinal disorders	Colitis ulcerative	01JAN2016		Y
			Gastroesophageal reflux disease	01JAN2005		Y
		Infections and infestations	Onychomycosis	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Restless legs syndrome	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1235 12351080	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351081	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Vascular disorders	Vitamin D deficiency	01JAN2018		Y
			Hypertension	01JAN2010		Y
	C4591001 1235 12351082	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1998		Y
		Psychiatric disorders	Anxiety disorder	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1235 12351086	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Eye disorders	Dry eye	01JAN2012		Y
		Infections and infestations	Herpes simplex	01JAN2000		Y
			Vaginal infection	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Psychiatric disorders	Depression	01JAN1998		Y
			Insomnia	01JAN1998		Y
		Surgical and medical procedures	Endometrial ablation	01JAN2006		Y
			Female sterilisation	01JAN2002		Y
	C4591001 1235 12351087	Investigations	False positive investigation result	01JAN1989	31DEC1994	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1995		Y
		Social circumstances	Menopause	01JAN2018		Y
	C4591001 1235 12351091	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Social circumstances	Menopause	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Endometrial ablation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351094	Gastrointestinal disorders	Steatorrhoea	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2011		Y
		Renal and urinary disorders	Urinary retention	01JAN2000		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011		Y
	C4591001 1235 12351095	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Contraception	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1997		Y
	C4591001 1235 12351096	Social circumstances	Menopause	01JAN2012		Y
	C4591001 1235 12351099	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
	C4591001 1235 12351102	Social circumstances	Menopause	01JAN2015		Y
	C4591001 1235 12351104	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
	C4591001 1235 12351107	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hypomagnesaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1235 12351111	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1235 12351113	Eye disorders	Conjunctivitis allergic	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Social circumstances	Menopause	01JAN2008		Y
	C4591001 1235 12351114	Psychiatric disorders	Insomnia	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2007		Y
	C4591001 1235 12351117	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Social circumstances	Menopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1235 12351118	Cardiac disorders	Arrhythmia	01JAN2002		Y
		Metabolism and nutrition disorders	Gout	01JAN2016		Y
			Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2010		Y
		Nervous system disorders	Migraine	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Sleep disorder	01JAN2015		Y
	C4591001 1235 12351120	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	01JAN1993		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
			Rhinitis allergic	01JAN2000		Y
	C4591001 1235 12351122	Surgical and medical procedures	Female sterilisation	01JAN1995		Y
		Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1235 12351123	Cardiac disorders	Coronary artery disease	01JAN1998		Y
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Investigations	Lipids increased	01JAN1998		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	01MAR2020	31MAY2020	N
		Social circumstances	Menopause	01JAN1985		Y
	C4591001 1235 12351129	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Social circumstances	Menopause	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351132	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01APR2020		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2005		Y
	C4591001 1235 12351135	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Herpes simplex	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of the oral cavity	01DEC2019		Y
		Psychiatric disorders	Depression	01JAN2020		Y
			Insomnia	01JAN2017		Y
		Social circumstances	Menopause	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351136	Ear and labyrinth disorders	Vertigo	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1980		Y
		Social circumstances	Menopause	01JAN1995		Y
	C4591001 1235 12351139	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2013		Y
		Nervous system disorders	Restless legs syndrome	01JAN2018		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1976		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1235 12351140	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1235 12351147	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351148	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2008		Y
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Cardiac pacemaker insertion	01JAN2018		Y
			Mitral valve repair	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1235 12351150	Cardiac disorders	Atrial fibrillation	01JAN2014		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2017	31DEC2017	N
			Gastric bypass	01JAN2011		Y
			Hip arthroplasty	01JAN2010		Y
				01JAN2017		Y
	C4591001 1235 12351160	Infections and infestations	Sinusitis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Renal and urinary disorders	Urinary retention	01JAN2018		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1235 12351163	Eye disorders	Glaucoma	01JAN2017		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01APR2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351176	Eye disorders	Dry eye	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01MAR2020		Y
		Investigations	Bone density decreased	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1235 12351177	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma late onset	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1235 12351179	Endocrine disorders	Hypothyroidism	01JAN1995		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN1995		Y
	C4591001 1235 12351182	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1235 12351183	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351184	Gastrointestinal disorders	Pelvic floor dysfunction	01MAR2020		Y
		Renal and urinary disorders	Bladder spasm	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Surgical and medical procedures	Hysterectomy	01JAN2017		Y
	C4591001 1235 12351185	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Surgical and medical procedures	Hormone replacement therapy	01JAN2014		Y
			Hysterectomy	01JAN2004		Y
	C4591001 1235 12351194	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Aortic valve replacement	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351199	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2011		Y
			Type 2 diabetes mellitus	01JAN2011		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1235 12351201	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1235 12351202	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1235 12351203	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1235 12351204	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Gout	01JAN2018		Y
	C4591001 1235 12351205	Cardiac disorders	Atrial fibrillation	01JAN2020		Y
		Congenital, familial and genetic disorders	Tourette's disorder	01JAN1973		Y
		Reproductive system and breast disorders	Amenorrhoea	01JAN2019		Y
	C4591001 1235 12351206	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1235 12351210	Infections and infestations	Urinary tract infection	01JAN1980		Y
			Vaginal infection	01JAN1998		Y
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1235 12351211	Metabolism and nutrition disorders	Hypocholesterolaemia	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1975		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1235 12351213	Gastrointestinal disorders	Anal fissure	01JAN2010	01NOV2020	N
			Gastritis	01JAN2019		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Menopause	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1235 12351221	Investigations	Lipids increased	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1235 12351227	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Infections and infestations	Herpes simplex	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN1990		Y
		Psychiatric disorders	Affective disorder	01JAN2000		Y
		Renal and urinary disorders	Pollakiuria	01JAN2000		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Surgical and medical procedures	Oophorectomy bilateral	01JAN2010		Y
	C4591001 1241 12411008	Immune system disorders	Iodine allergy	01JAN1980		Y
		Infections and infestations	Sinusitis	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2019	31DEC2019	N
			Rhinitis allergic	01MAY2020	30JUN2020	N
		Social circumstances	Menopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JUN2019		Y
	C4591001 1241 12411015	Endocrine disorders	Autoimmune hypothyroidism	01JAN1985		Y
		Immune system disorders	Food allergy	01JAN1990	31DEC1990	N
		Skin and subcutaneous tissue disorders	Alopecia	01DEC2019		Y
		Social circumstances	Menopause	01JAN2013		Y
		Surgical and medical procedures	Appendicectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411035	Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411067	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Social circumstances	Menopause	01JAN1995		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1995		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411086	Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Social circumstances	Menopause	01JAN2000		Y
	C4591001 1241 12411092	Cardiac disorders	Atrial fibrillation	01OCT2011		Y
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Infections and infestations	Labyrinthitis	01JAN2012		Y
		Nervous system disorders	Cerebrovascular accident	01JUL2011	31JUL2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411105	General disorders and administration site conditions	Cyst	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12411107	Cardiac disorders	Coronary artery disease	01JAN2008		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2018		Y
		Social circumstances	Tobacco user	01JAN1970	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1241 12411115	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12411117	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01OCT2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1241 12411128	Gastrointestinal disorders	Umbilical hernia	01JAN2010		Y
	C4591001 1241 12411147	Psychiatric disorders	Depression	01APR2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2017	31JAN2017	N
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12411151	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411160	Cardiac disorders	Acute myocardial infarction	10SEP2018	20SEP2018	N
		Gastrointestinal disorders	Diverticulum intestinal	01JAN2005		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01SEP2018		Y
		Social circumstances	Menopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1241 12411172	Endocrine disorders	Autoimmune thyroiditis	01JAN1996	31DEC2000	N
			Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Reproductive system and breast disorders	Artificial menopause	01JAN2004	31DEC2004	N
	C4591001 1241 12411173	Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1973	31DEC2018	N
		Social circumstances	Menopause	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411174	Immune system disorders	Drug hypersensitivity	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990		Y
	C4591001 1241 12411176	Cardiac disorders	Arrhythmia	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Rheumatic disorder	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1241 12411182	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411187	Eye disorders	Cataract	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Social circumstances	Menopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JUL2010		Y
	C4591001 1241 12411191	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1241 12411192	Musculoskeletal and connective tissue disorders	Back pain	14AUG2020	14AUG2020	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
	C4591001 1241 12411193	Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2020		Y
			Vitamin D deficiency	01JAN2018		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1241 12411196	Social circumstances	Menopause	01JAN1988		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411199	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Social circumstances	Menopause	01AUG2017		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12411200	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01SEP2019	25NOV2019	N
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Surgical and medical procedures	Radical prostatectomy	25NOV2019	25NOV2019	N
		Vascular disorders	Hypertension	01MAY2017		Y
	C4591001 1241 12411218	Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1980	31DEC2015	N
		Social circumstances	Menopause	01JAN2012		Y
		Surgical and medical procedures	Breast operation	01JAN2012	31DEC2012	N
			Carpal tunnel decompression	01FEB2010	28FEB2010	N
			Female sterilisation	25JUL2000	25JUL2000	N
	C4591001 1241 12411238	Gastrointestinal disorders	Inguinal hernia	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2018	15MAR2019	N
		Surgical and medical procedures	Prostatectomy	15MAR2019	15MAR2019	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411241	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411246	Social circumstances	Menopause	01JAN2015		Y
	C4591001 1241 12411249	Metabolism and nutrition disorders	Glucose tolerance impaired	01MAR2019		Y
		Nervous system disorders	Migraine	01MAR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
			Joint surgery	01SEP2018		Y
	C4591001 1241 12411252	Social circumstances	Menopause	01JUN2017		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411254	Social circumstances	Menopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411259	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Infections and infestations	Labyrinthitis	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000	31DEC2018	N
		Social circumstances	Menopause	01JAN2011		Y
	C4591001 1241 12411306	Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1241 12411321	Musculoskeletal and connective tissue disorders	Tendon disorder	01JAN2015		Y
	C4591001 1241 12411322	Social circumstances	Menopause	01JAN2015		Y
	C4591001 1241 12411325	Ear and labyrinth disorders	Deafness neurosensory	01JAN1982		Y
		Social circumstances	Menopause	01JAN2015		Y
	C4591001 1241 12411340	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411364	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411371	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411391	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Nervous system disorders	Tension headache	01JAN2018		Y
		Surgical and medical procedures	Rotator cuff repair	01JAN2018	31DEC2018	N
			Vasectomy	01JAN2000	31DEC2000	N
	C4591001 1241 12411392	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Social circumstances	Menopause	01MAY2017		Y
	C4591001 1241 12411394	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
			Osteoporosis	01JAN2018		Y
		Skin and subcutaneous tissue disorders	Leukoplakia	01JAN2015		Y
		Social circumstances	Menopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411397	Cardiac disorders	Cardiac failure congestive	01JAN2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	01JAN2010		Y
			Gouty arthritis	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411404	Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
	C4591001 1241 12411405	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411406	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411425	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 1241 12411428	Immune system disorders	Food allergy	01JAN2005		Y
	C4591001 1241 12411429	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Cholecystectomy	01JUL2007	31JUL2007	N
	C4591001 1241 12411430	Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411448	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
	C4591001 1241 12411479	Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1241 12411485	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Social circumstances	Menopause	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411496	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2000	31DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411498	Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01APR2019		Y
		Social circumstances	Menopause	01JAN2017		Y
	C4591001 1241 12411523	Renal and urinary disorders	Nephrolithiasis	01JAN2005	31DEC2005	N
	C4591001 1241 12411529	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2017		Y
	C4591001 1241 12411534	Surgical and medical procedures	Mitral valve replacement	01JAN2017	31DEC2017	N
	C4591001 1241 12411545	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411550	Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411551	Metabolism and nutrition disorders	Obesity	01JAN1995	31DEC2008	N
		Surgical and medical procedures	Metabolic surgery	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2008		Y
			Varicose vein	01JAN2008		Y
	C4591001 1241 12411554	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411559	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
				01JUN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glucose tolerance impaired	01AUG2019		Y
		Social circumstances	Menopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411560	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411571	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Surgical and medical procedures	Coronary angioplasty	01JUN2011	30JUN2011	N
		Vascular disorders	Hypertension	01JAN1985		Y
	C4591001 1241 12411585	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1974		Y
	C4591001 1241 12411614	Cardiac disorders	Acute myocardial infarction	01MAR2010	31MAR2010	N
			Coronary artery disease	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Glucose tolerance impaired	01JAN2010		Y
		Surgical and medical procedures	Cardiac operation	01JUL2010	31JUL2010	N
	C4591001 1241 12411615	Cardiac disorders	Extrasystoles	01JAN2015		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1241 12411618	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
	C4591001 1241 12411620	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1989		Y
				01JAN2016		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411621	Gastrointestinal disorders	Gastritis	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1996		Y
		Psychiatric disorders	Depression	01JAN2013	31DEC2013	N
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
	C4591001 1241 12411622	Gastrointestinal disorders	Duodenal ulcer	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1241 12411623	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1981	31DEC1981	N
			Hysterectomy	01JAN1994	31DEC1994	N
	C4591001 1241 12411627	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Injury, poisoning and procedural complications	Femur fracture	01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2017		Y
		Social circumstances	Menopause	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411628	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1241 12411642	Cardiac disorders	Mitral valve prolapse	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411643	Nervous system disorders	Carpal tunnel syndrome	01JAN2013		Y
	C4591001 1241 12411644	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2018		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986		Y
	C4591001 1241 12411669	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1241 12411670	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411671	Cardiac disorders	Mitral valve prolapse	01JAN2003		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
	C4591001 1241 12411675	Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	01JAN2013		Y
			Insulin resistance	01JAN2013		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Thyroidectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1241 12411676	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign bone neoplasm	01JAN1964	31DEC1964	N
		Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Cataract operation	01JAN2019	31DEC2019	N
			Osteotomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411682	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Menopause	01JAN1999		Y
		Vascular disorders	Hypertension	01JAN1983		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411691	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12411704	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010	31DEC2010	N
		Social circumstances	Menopause	01JAN2013		Y
	C4591001 1241 12411705	Infections and infestations	Chikungunya virus infection	01JAN2008	31AUG2020	Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01AUG2020	31AUG2020	N
		Nervous system disorders	Polyneuropathy	01JAN2018	31DEC2018	Y
		Psychiatric disorders	Anxiety	01JAN2005		Y
	C4591001 1241 12411711	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411721	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016	31DEC2018	Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Hysterectomy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411722	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
	C4591001 1241 12411728	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2000	31DEC2000	Y
		Surgical and medical procedures	Hysterectomy			N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411732	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010	31JUL2020	N
		Surgical and medical procedures	Knee arthroplasty	01DEC2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411739	Social circumstances	Menopause	01JAN2003		Y
	C4591001 1241 12411748	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Social circumstances	Menopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411751	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Infections and infestations	Labyrinthitis	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12411752	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411753	Surgical and medical procedures	Hysterectomy	01JAN1987	31DEC1987	N
	C4591001 1241 12411755	Reproductive system and breast disorders	Benign prostatic hyperplasia	01DEC2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411759	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1241 12411761	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2000		Y
			Dust allergy	01JAN1995		Y
			Mycotic allergy	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Social circumstances	Menopause	01JAN2003		Y
	C4591001 1241 12411770	Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12411783	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975		Y
	C4591001 1241 12411788	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2019		Y
		Surgical and medical procedures	Meniscus operation	01JAN1975	31DEC1975	N
	C4591001 1241 12411789	Cardiac disorders	Acute myocardial infarction	01JAN2013	31DEC2013	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1241 12411794	Eye disorders	Glaucoma	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Bursitis	01JUN2020		Y
		Surgical and medical procedures	Cataract operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12411795	Eye disorders	Glaucoma	01JAN1990		Y
		Gastrointestinal disorders	Diverticulum	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2011		Y
		Social circumstances	Menopause	01JAN2002		Y
		Surgical and medical procedures	Cataract operation	01JAN2003	31DEC2003	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411796	Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1241 12411811	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1964	16SEP2020	N
	C4591001 1241 12411821	Endocrine disorders	Hypogonadism	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Nervous system disorders	Sciatica	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Hysterectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12411822	Cardiac disorders	Atrial fibrillation	01JAN1980	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017	31DEC2017	N
			Intestinal polyp	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010	31MAR2020	N
		Social circumstances	Tobacco user	01JAN1970		Y
		Surgical and medical procedures	Appendicectomy	01JAN1983	31DEC1983	N
			Hysterectomy	01JAN1996	31DEC1996	N
			Mammoplasty	01JAN1980	31DEC1980	N
			Oophorectomy bilateral	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411825	Vascular disorders	Hypertension	01DEC2018		Y
	C4591001 1241 12411829	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Surgical and medical procedures	Appendicectomy	01JAN2011	31DEC2011	N
			Female sterilisation	01JAN1990	31DEC1990	N
	C4591001 1241 12411831	Immune system disorders	Drug hypersensitivity	01JAN1970		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2015	31DEC2015	N
			Knee arthroplasty	27APR2019	27APR2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411844	Eye disorders	Glaucoma	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1977	07SEP2020	N
		Surgical and medical procedures	Cholecystectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411852	Infections and infestations	Labyrinthitis	01JAN2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2020		Y
			Type 2 diabetes mellitus	01JUL2020		Y
		Social circumstances	Menopause	01JAN1992		Y
		Surgical and medical procedures	Splenectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12411853	Nervous system disorders	Migraine	01JAN1976	31AUG2020	N
		Surgical and medical procedures	Cholecystectomy	01AUG2012	31AUG2012	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Metabolic surgery	01AUG2012	31AUG2012	N
		Vascular disorders	Hypertension	01MAY2019		Y
	C4591001 1241 12411876	Surgical and medical procedures	Appendicectomy	01JAN1980	31DEC1980	N
			Cardiac operation	01MAR2007	31MAR2007	N
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1241 12411883	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2015	31DEC2015	N
	C4591001 1241 12411890	Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Menopause	01JAN1996		Y
	C4591001 1241 12411891	Gastrointestinal disorders	Gastritis	01JAN2017		Y
		Infections and infestations	Sinusitis	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411896	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1975	31DEC2019	N
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1241 12411902	Surgical and medical procedures	Haemorrhoid operation	01JAN2010	31DEC2010	N
	C4591001 1241 12411910	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411916	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2014		Y
		Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411918	Surgical and medical procedures	Cholecystectomy	01JAN1991	31DEC1991	N
			Thyroidectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12411922	Endocrine disorders	Hyperthyroidism	01DEC2018	31JAN2020	N
		Musculoskeletal and connective tissue disorders	Bursitis	01JAN2019		Y
		Social circumstances	Menopause	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12411923	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12411928	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411933	Surgical and medical procedures	Cholecystectomy	01JAN2008	31DEC2008	N
	C4591001 1241 12411934	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Skin and subcutaneous tissue disorders	Neurodermatitis	01JAN2018		Y
	C4591001 1241 12411938	Psychiatric disorders	Anxiety	01JAN2019		Y
		Social circumstances	Menopause	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12411941	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1241 12411946	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1241 12411959	Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1241 12411964	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Menopause	01JAN2001		Y
	C4591001 1241 12411966	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1964	31DEC1964	N
	C4591001 1241 12411976	Cardiac disorders	Cardiac failure	01JAN2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12411979	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Gastrointestinal disorders	Dysphagia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Prostatectomy	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1241 12411989	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Immune system disorders	Seasonal allergy	01JAN1965		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 1241 12412000	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1971	31DEC2005	N
		Social circumstances	Menopause	01JAN2014	31DEC2014	N
		Surgical and medical procedures	Female sterilisation	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412005	Cardiac disorders	Arrhythmia	01JAN2001		Y
		Infections and infestations	Labyrinthitis	01JAN2000		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2007		Y
	C4591001 1241 12412017	Vascular disorders	Hypertension	01NOV1999		Y
	C4591001 1241 12412021	Cardiac disorders	Arrhythmia	01OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2000	N
		Social circumstances	Menopause	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1241 12412030	Gastrointestinal disorders	Duodenal ulcer	01JAN2000	31DEC2000	N
		Injury, poisoning and procedural complications	Deafness traumatic	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412033	Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412040	Metabolism and nutrition disorders	Lactose intolerance	01JAN2017		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1988		Y
	C4591001 1241 12412042	Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1241 12412047	Psychiatric disorders	Depression	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412076	Social circumstances	Menopause	01JAN2007		Y
	C4591001 1241 12412077	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1990		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2016	31DEC2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC2016	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1241 12412079	Immune system disorders	Drug hypersensitivity	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1966		Y
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1241 12412085	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12412115	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01AUG2020		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1241 12412116	Cardiac disorders	Atrial fibrillation	01JAN2005		Y
		Nervous system disorders	Parkinson's disease	01JAN2017		Y
	C4591001 1241 12412125	Social circumstances	Menopause	01JAN1997		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12412129	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
			Glucose tolerance impaired	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1241 12412144†	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2015		Y
		Infections and infestations	HIV infection	01JAN2002		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN1980		Y
			Venous thrombosis	01JAN2002		Y
	C4591001 1241 12412145	Cardiac disorders	Myocardial ischaemia	01JAN1990	31DEC1990	N
		Psychiatric disorders	Depression	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1960		Y
		Social circumstances	Menopause	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN1960		Y
	C4591001 1241 12412146	Gastrointestinal disorders	Lumbar hernia	01JAN1987		Y
		Infections and infestations	Sinusitis	01JAN1980		Y
		Surgical and medical procedures	Vasectomy	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12412147	Gastrointestinal disorders	Lumbar hernia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2000		Y
		Nervous system disorders	Carpal tunnel syndrome	01JUN2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Anxiety disorder	01JAN2019		Y
		Social circumstances	Menopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12412164	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2019		Y
		Social circumstances	Menopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412178	Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412184	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1990	31DEC1990	N
		Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1241 12412185	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1983		Y
		Nervous system disorders	Migraine	01JAN1993		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	01JAN1970		Y
	C4591001 1241 12412189	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1997	31DEC1997	N
		Surgical and medical procedures	Hysterectomy	01JAN1997	31DEC1997	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412191	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
			Haemorrhoids	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Carotid arteriosclerosis	01JAN2015		Y
			Tension headache	01JAN1970		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12412196	Cardiac disorders	Arrhythmia	01JAN2005		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1241 12412205	Psychiatric disorders	Depression	01JAN2003		Y
		Social circumstances	Menopause	01JAN2009		Y
	C4591001 1241 12412219	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Social circumstances	Menopause	01JAN1998		Y
	C4591001 1241 12412220	Cardiac disorders	Acute myocardial infarction	28JAN2020	28JAN2020	N
			Coronary artery disease	01JAN2015		Y
	C4591001 1241 12412224	Gastrointestinal disorders	Gastritis	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1966		Y
		Surgical and medical procedures	Prostatic operation	01JAN2014	31DEC2014	N
	C4591001 1241 12412230	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2014		Y
		Surgical and medical procedures	Aortic aneurysm repair	01APR2014	30APR2014	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12412231	Eye disorders	Glaucoma	01SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1985	31DEC1985	N
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01SEP2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412238	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412241	Cardiac disorders	Acute myocardial infarction	01JUN2014	30JUN2014	N
			Coronary artery disease	01JUN2014		Y
		Eye disorders	Glaucoma	01JAN1996		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
	C4591001 1241 12412242	Cardiac disorders	Arteriosclerosis coronary artery	27NOV2018	27NOV2018	N
		Surgical and medical procedures	Cardiac operation	27NOV2018	27NOV2018	N
			Coronary angioplasty	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1241 12412250	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12412251	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1989	31DEC1989	N
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412263	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
	C4591001 1241 12412266	Psychiatric disorders	Anxiety	01JAN2018		Y
		Social circumstances	Menopause	01JAN2006		Y
	C4591001 1241 12412272	Cardiac disorders	Rheumatic heart disease	01JAN1973	31DEC2005	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2000	31DEC2000	N
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12412273	Infections and infestations	Sinusitis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2009	31DEC2009	N
		Psychiatric disorders	Anxiety	01JUN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2009	31DEC2009	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412286	Vascular disorders	Hypertension	16OCT2000		Y
	C4591001 1241 12412287	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	31DEC2004	N
			Uterine leiomyoma	01JAN1983	31DEC1983	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
			Hysterectomy	01JAN1983	31DEC1983	N
			Metabolic surgery	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412297	Metabolism and nutrition disorders	Dyslipidaemia	01APR2020		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1241 12412298	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	31DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1241 12412300	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1966		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412302	Cardiac disorders	Cardiac disorder	01MAR2008		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JUL2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01APR2020		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01MAR2008	31MAR2008	N
	C4591001 1241 12412305	Gastrointestinal disorders	Gastritis	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2015		Y
		Social circumstances	Menopause	01JAN1985		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1241 12412309	Infections and infestations	Chikungunya virus infection	01JUN2020	30JUN2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2017	31DEC2018	N
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12412310	Immune system disorders	Iodine allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Social circumstances	Menopause	01JAN1990		Y
		Surgical and medical procedures	Coronary artery surgery	01JAN2016	31DEC2016	N
	C4591001 1241 12412316	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2016	31DEC2016	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2016	31DEC2016	N
			Inguinal hernia repair	01JAN2016	31DEC2016	N
	C4591001 1241 12412318	Hepatobiliary disorders	Hepatic steatosis	01JAN2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
		Surgical and medical procedures	Bone prosthesis insertion	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412319	Endocrine disorders	Hypothyroidism	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid neoplasm	01JAN2017	31DEC2017	N
		Social circumstances	Menopause	01JAN2006		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1990	31DEC1990	N
			Thyroidectomy	01JAN2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 1241 12412325	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1991	31DEC1991	N
		Psychiatric disorders	Insomnia	01JAN2013		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1965		Y
		Surgical and medical procedures	Hysterectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1241 12412326	Hepatobiliary disorders	Cholelithiasis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1990		Y
	C4591001 1241 12412340	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01APR2020		Y
		Surgical and medical procedures	Cataract operation	01OCT2019	31OCT2019	N
	C4591001 1241 12412349	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2019		Y
	C4591001 1241 12412356	Hepatobiliary disorders	Cholelithiasis	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Salpingectomy	01JAN2002	31DEC2002	N
	C4591001 1241 12412359	Cardiac disorders	Mitral valve disease	01JAN1992	31DEC1992	N
		Surgical and medical procedures	Mitral valve replacement	01JAN1992	31DEC1992	N
	C4591001 1241 12412372	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Psychiatric disorders	Anxiety disorder	01JAN1979		Y
			Insomnia	01JAN1963		Y
		Surgical and medical procedures	Oophorectomy	01JAN2017	31DEC2017	N
			Salpingectomy	01JAN2017	31DEC2017	N
	C4591001 1241 12412376	Immune system disorders	Food allergy	01JAN2011		Y
			Iodine allergy	01JAN2011		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Psychiatric disorders	Anxiety disorder	01JAN2014		Y
	C4591001 1241 12412384	Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
	C4591001 1241 12412446	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1241 12412469	Eye disorders	Cataract	01JAN2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1957		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412474	Injury, poisoning and procedural complications	Injury	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Splenectomy	01JAN2005	31DEC2005	N
	C4591001 1241 12412487	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
	C4591001 1241 12412488	Infections and infestations	Acute pulmonary histoplasmosis	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1984		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 1241 12412492	Metabolism and nutrition disorders	Gluten sensitivity	01JAN1994		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1990		Y
		Surgical and medical procedures	Tenoplasty	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412496	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1975		Y
	C4591001 1241 12412499	Psychiatric disorders	Depression	01JAN2007		Y
	C4591001 1241 12412503	Metabolism and nutrition disorders	Dyslipidaemia	01JAN1992		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Uterine leiomyoma	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN2013	31DEC2013	N
			Thyroidectomy	01JAN2012	31DEC2012	N
	C4591001 1241 12412511	Social circumstances	Menopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1241 12412514	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2010		Y
		Surgical and medical procedures	Uterine leiomyoma	01JAN2010	31DEC2010	N
			Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1241 12412520	Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1241 12412521	Psychiatric disorders	Insomnia	01SEP2020		Y
		Social circumstances	Menopause	01JAN1991		Y
			Tobacco user	01JAN1980		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2019		Y
	C4591001 1241 12412522	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1241 12412524	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2010		Y
		Surgical and medical procedures	Abdominoplasty	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Mammoplasty	01JAN2010	31DEC2010	N
	C4591001 1241 12412526	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1241 12412533	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2018		Y
		Psychiatric disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Reproductive system and breast disorders	Depression	01AUG2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01APR2020		Y
		Vascular disorders	Hypertension	01OCT2019		Y
	C4591001 1241 12412536	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colorectal cancer	01JAN2007	31DEC2007	N
		Surgical and medical procedures	Colectomy	01JAN2007	31DEC2007	N
	C4591001 1241 12412538	Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
	C4591001 1241 12412541	Immune system disorders	Drug hypersensitivity	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y
		Surgical and medical procedures	Phlebectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Varicose vein	01AUG2005	31AUG2005	N
	C4591001 1241 12412542	Immune system disorders	Drug hypersensitivity	01JAN1965		Y
		Social circumstances	Menopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1241 12412545	Injury, poisoning and procedural complications	Eye injury	01JAN1968	31DEC1968	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN2000	31DEC2000	N
		Psychiatric disorders	Depression	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1970		Y
		Surgical and medical procedures	Eye operation	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1241 12412567†	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Infections and infestations	HIV infection	01JAN2015		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
			Gout	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1241 12412568	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Infections and infestations	Hepatitis C	01JAN1989	31DEC1993	N
		Social circumstances	Menopause	01JAN2012		Y
	C4591001 1246 12461001	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2013	31DEC2013	N
			Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1246 12461013	Social circumstances	Postmenopause	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1246 12461027	Metabolism and nutrition disorders	Hypercholesterolaemia	06SEP2000		Y
			Type 2 diabetes mellitus	28AUG2017		Y
		Surgical and medical procedures	Coronary artery bypass	06SEP2000	06SEP2000	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1246 12461035	Eye disorders	Visual impairment	01MAY2017		Y
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01DEC2018		Y
		Nervous system disorders	Headache	01MAY2016		Y
		Psychiatric disorders	Depression	01AUG2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1246 12461040	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Obesity	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2019	31DEC2019	N
			Coronary artery bypass	01JAN2007	31DEC2007	N
				01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1246 12461048	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1246 12461051	Cardiac disorders	Prinzmetal angina	01JAN2011		Y
		Metabolism and nutrition disorders	Gout	01JAN1996		Y
			Hypercholesterolaemia	01JAN2019		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Renal and urinary disorders	Urethral stenosis	01JAN1993		Y
		Vascular disorders	Deep vein thrombosis	01JAN2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	01JAN1994		Y
	C4591001 1246 12461056	Cardiac disorders	Angina pectoris	01JAN2005		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2004		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2005	31DEC2005	N
			Hysterectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1246 12461063	Surgical and medical procedures	Cholecystectomy	01JAN2018	31DEC2018	N
			Hysterectomy	01JAN1991	31DEC1991	N
	C4591001 1246 12461077	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1246 12461124	Gastrointestinal disorders	Peptic ulcer	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1982		Y
			Type 2 diabetes mellitus	01JAN1982		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1246 12461132	Surgical and medical procedures	Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1247 12471001	Metabolism and nutrition disorders	Dyslipidaemia	01DEC2000		Y
			Iron deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01APR2019		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
		Vascular disorders	Hypertension	01DEC2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471005	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
	C4591001 1247 12471007	Investigations	Mammogram	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2007		Y
	C4591001 1247 12471039	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2009		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1247 12471041	Psychiatric disorders	Stress	01JUL2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1247 12471042	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Infections and infestations	Otitis media chronic	01JAN2011		Y
		Nervous system disorders	Headache	01JAN2011		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2011		Y
	C4591001 1247 12471047	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471049	Gastrointestinal disorders	Constipation	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1247 12471056	Gastrointestinal disorders	Barrett's oesophagus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1247 12471063	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1968		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1247 12471066	Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1247 12471067	Reproductive system and breast disorders	Cervical dysplasia	01JAN2020	08JAN2020	N
	C4591001 1247 12471068	Investigations	Blood cholesterol increased	01JAN2016		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1247 12471070	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1247 12471083	Cardiac disorders	Coronary artery disease	01JAN2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1990		Y
	C4591001 1247 12471093	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Nervous system disorders	Tension headache	01JAN2000		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1247 12471094	Endocrine disorders	Hypothyroidism	01JAN1998		Y
		Gastrointestinal disorders	Peptic ulcer	01APR2019		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1247 12471095	Infections and infestations	Acute hepatitis B	01JAN2000	31DEC2000	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2020	N
	C4591001 1247 12471098	Psychiatric disorders	Depression	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2016		Y
	C4591001 1247 12471104	Nervous system disorders	Restless legs syndrome	01JAN2010		Y
	C4591001 1247 12471105	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN1988	31DEC1988	N
	C4591001 1247 12471110	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1247 12471116	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1247 12471117	Social circumstances	Postmenopause	01JAN2003		Y
	C4591001 1247 12471135	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1991		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1247 12471138	Social circumstances	Postmenopause	01JAN2011		Y
	C4591001 1247 12471157	Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1247 12471160	Surgical and medical procedures	Salpingectomy	01JAN1989	31DEC1989	N
	C4591001 1247 12471163	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1247 12471166	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1981		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1247 12471170	Social circumstances	Postmenopause	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1247 12471187	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1247 12471188	Social circumstances	Postmenopause	01JAN2004		Y
	C4591001 1247 12471194	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1247 12471210	Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1247 12471216	Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1247 12471219	Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1247 12471227	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1247 12471228	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2011		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1247 12471229	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2001		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1247 12471235	Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1986		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Female sterilisation	01JAN2002	31DEC2002	N
	C4591001 1247 12471238	Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1247 12471243	Metabolism and nutrition disorders	Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1247 12471249	Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1248 12481002	Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Surgical and medical procedures	Cancer surgery	01MAR2009	31MAR2009	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1248 12481003	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Renal and urinary disorders	Nephrotic syndrome	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1248 12481006	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2020		Y
		Surgical and medical procedures	Hysterectomy	01JAN2011	31DEC2011	N
	C4591001 1248 12481008	Gastrointestinal disorders	Pancreatitis	01JAN2018	31DEC2018	N
		Hepatobiliary disorders	Cholelithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Aortic valve replacement	01AUG2017	31AUG2017	N
			Cholecystectomy	01JAN2018	31DEC2018	N
		Vascular disorders	Aortic stenosis	01AUG2017	31AUG2017	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481015	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1248 12481020	Endocrine disorders	Thyroid mass	01JAN2019		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2015		Y
	C4591001 1248 12481021	Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1248 12481027	Immune system disorders	Seasonal allergy	01JAN2008		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
		Surgical and medical procedures	Medical device removal	01NOV2018	30NOV2018	N
			Orthopaedic procedure	01NOV2017	30NOV2017	N
	C4591001 1248 12481029	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
	C4591001 1248 12481030	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
	C4591001 1248 12481039	Investigations	Blood cholesterol increased	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2020		Y
		Surgical and medical procedures	Artificial urinary sphincter implant	01APR2017	30APR2017	N
				01NOV2018	30NOV2018	N
			Coronary artery bypass	02MAY2018	02MAY2018	N
			Heart valve replacement	02MAY2018	02MAY2018	N
			Urinary tract operation	01OCT2017	31OCT2017	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1248 12481040	Cardiac disorders	Atrial fibrillation	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Investigations	Blood cholesterol increased	01JAN2000		Y
		Vascular disorders	Thrombosis	01JAN2018		Y
	C4591001 1248 12481041	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Investigations	Blood cholesterol increased	01JAN2013		Y
	C4591001 1248 12481042	Cardiac disorders	Cardiac disorder	01JAN2017		Y
			Tachycardia	01JAN2017		Y
		Infections and infestations	Pulmonary sepsis	01NOV2017	30NOV2017	N
		Investigations	Blood cholesterol increased	01JAN2012		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Surgical and medical procedures	Leg amputation	01DEC2017	31DEC2017	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1248 12481043	Surgical and medical procedures	Knee arthroplasty	01OCT2018	31OCT2018	N
	C4591001 1248 12481044	Eye disorders	Glaucoma	01JAN2012		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1248 12481045	Investigations	Cardiac murmur	01JAN1957		Y
	C4591001 1248 12481047	Investigations	Blood cholesterol increased	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUN2019		Y
	C4591001 1248 12481049	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1248 12481050	Nervous system disorders	Cerebrovascular accident	20MAR2020	20MAR2020	N
	C4591001 1248 12481052	Ear and labyrinth disorders	Deafness bilateral	01JAN2017		Y
		Investigations	Blood cholesterol increased	01JAN1990		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN1995		Y
		Social circumstances	Hearing aid user	01JAN2017		Y
	C4591001 1248 12481053	Investigations	Blood cholesterol increased	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1248 12481057	Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
	C4591001 1248 12481058	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Investigations	Blood cholesterol increased	01JAN2010		Y
		Surgical and medical procedures	Exeresis	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1248 12481059	Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1248 12481064	Investigations	Blood cholesterol increased	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1248 12481074	Skin and subcutaneous tissue disorders	Drug eruption	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1248 12481078	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
			Osteoporosis	01JAN2016		Y
	C4591001 1248 12481080	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
	C4591001 1248 12481083	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Investigations	Blood cholesterol increased	15AUG2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
			Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Vulvectomy	01DEC2019	31DEC2019	N
	C4591001 1248 12481084	Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1248 12481096	Investigations	Blood cholesterol increased	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1248 12481100	Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1248 12481101	Investigations	Colonoscopy	01JAN2019	31DEC2019	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2014		Y
	C4591001 1248 12481112	Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481113	Psychiatric disorders	Anxiety	01JAN2003		Y
		Surgical and medical procedures	Meniscus removal	01JAN2019	31DEC2019	N
	C4591001 1248 12481116	Immune system disorders	Seasonal allergy	01JAN1990		Y
	C4591001 1248 12481117	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2010		Y
	C4591001 1248 12481119	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2000		Y
	C4591001 1248 12481120	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2014		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1248 12481124	Endocrine disorders	Hypothyroidism	01JAN1997		Y
		Immune system disorders	Drug hypersensitivity	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
	C4591001 1248 12481127	Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1248 12481128	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481132	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
		Immune system disorders	Drug hypersensitivity	01JAN1987		Y
				01JAN1988		Y
				01JAN1990		Y
		Infections and infestations	Rhinitis	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Erythema	01JAN1985		Y
	C4591001 1248 12481136	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Investigations	Heart rate irregular	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN1994		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2004		Y
	C4591001 1248 12481137	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2008		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2006		Y
		Surgical and medical procedures	Knee arthroplasty	01AUG2018	31AUG2018	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1248 12481139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2017	31DEC2017	N
	C4591001 1248 12481140	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1248 12481141	Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1248 12481142	Gastrointestinal disorders	Colitis ulcerative	01JAN2003		Y
		Psychiatric disorders	Depression	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Knee arthroplasty	31JUL2018	31JUL2018	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1248 12481143	Investigations	Blood cholesterol increased	01JAN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1248 12481148	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2007		Y
		Surgical and medical procedures	Cataract operation	01MAR2020	31MAR2020	N
			Shoulder operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1248 12481149	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Surgical and medical procedures	Mammoplasty	29OCT2019	29OCT2019	N
	C4591001 1248 12481155	Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1248 12481160	Investigations	Blood cholesterol increased	01JAN2010		Y
	C4591001 1248 12481163	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Blood cholesterol increased	01JAN2015		Y
	C4591001 1248 12481167	Investigations	Blood cholesterol increased	01JAN2020		Y
		Nervous system disorders	Tarsal tunnel syndrome	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN2007		Y
	C4591001 1248 12481168	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood cholesterol increased	01JAN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Menopause	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1248 12481174	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUN2000		Y
		Skin and subcutaneous tissue disorders	Dyshidrotic eczema	01JAN1995		Y
	C4591001 1248 12481180	Skin and subcutaneous tissue disorders	Eczema	01JAN2018		Y
		Social circumstances	Menopause	01JAN2014		Y
	C4591001 1248 12481181	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1248 12481182	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Investigations	Blood cholesterol increased	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage II	01JAN2003	31DEC2003	N
		Surgical and medical procedures	Foot operation	01JAN2020	31JAN2020	N
			Skin neoplasm excision	01JUL2020	31JUL2020	N
			Vascular stent insertion	01JAN2018	31DEC2018	N
				01JUL2020	31JUL2020	N
	C4591001 1248 12481183	Immune system disorders	Anaphylactic reaction	01JAN1964		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2005		Y
	C4591001 1248 12481184	Eye disorders	Blindness unilateral	(b) (6) 1964		Y
	C4591001 1248 12481196	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1248 12481197	Immune system disorders	Seasonal allergy	01JAN2018		Y
		Investigations	Blood cholesterol	01JAN2009		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN1999		Y
	C4591001 1248 12481203	Cardiac disorders	Coronary artery disease	01JAN2007		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2020	31JAN2020	N
	C4591001 1248 12481207	Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
	C4591001 1248 12481209	Social circumstances	Postmenopause	01MAY2012		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1248 12481214	Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 1248 12481225	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Limb operation	01JUN2019		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1248 12481238	Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
	C4591001 1248 12481241	Eye disorders	Macular degeneration	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
		Nervous system disorders	Essential tremor	01JAN2019		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
			Attention deficit hyperactivity disorder	01JAN2000		Y
		Renal and urinary disorders	Incontinence	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1248 12481248	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Investigations	Biopsy lymph gland	01JAN2014	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2014	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1248 12481249	Endocrine disorders	Hypothyroidism	01JAN2010		Y
	C4591001 1248 12481250	Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1251 12511001	Immune system disorders	Drug hypersensitivity	01JAN2020		Y
		Metabolism and nutrition disorders	Gout	01JAN2006		Y
			Hypercholesterolaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Nervous system disorders	Diabetic neuropathy	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1251 12511002	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2004		Y
		Social circumstances	Postmenopause	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1251 12511004	Infections and infestations	Ophthalmic herpes zoster	01JAN2018		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
	C4591001 1251 12511006	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Migraine	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1251 12511008	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	22JUL2019		Y
	C4591001 1251 12511009	Immune system disorders	Drug hypersensitivity	01JAN1963		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Vascular disorders	Hypertension	22DEC2017		Y
	C4591001 1251 12511010	Cardiac disorders	Coronary artery disease	01JAN2010		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2010	31DEC2010	N
	C4591001 1251 12511011	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1251 12511014	Nervous system disorders	Migraine	01JAN1960		Y
		Psychiatric disorders	Depression	01JAN1960		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511018	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1961		Y
				01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511019	Immune system disorders	Drug hypersensitivity	01JAN1942		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511020	Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1251 12511023	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2009		Y
			Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Female sterilisation	01JAN2006	31DEC2006	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1251 12511024	Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	01JAN2005		Y
	C4591001 1251 12511026	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1995		Y
			Spinal osteoarthritis	01JAN1995		Y
		Social circumstances	Postmenopause	01JAN1985		Y
		Surgical and medical procedures	Hysterectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1251 12511028	Cardiac disorders	Mitral valve prolapse	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01MAR1986		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Bipolar I disorder	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2007		Y
		Social circumstances	Postmenopause	01JAN1992		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511029	Metabolism and nutrition disorders	Gout	01JAN1992		Y
			Hypercholesterolaemia	01JAN2010		Y
			Type 1 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511034	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2004	31DEC2004	N
	C4591001 1251 12511036	Nervous system disorders	Migraine	01JAN1982		Y
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
	C4591001 1251 12511042	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1955		Y
		Social circumstances	Tobacco user	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511043	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1969		Y
			Osteoarthritis	01JAN1969		Y
	C4591001 1251 12511047	Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1251 12511048	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Prostatomegaly	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511050	Infections and infestations	Chronic hepatitis C	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAR2020		Y
			Back pain	01JAN1997		Y
			Intervertebral disc protrusion	01JAN1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2018		Y
		Psychiatric disorders	Anxiety disorder	01JAN2017		Y
			Bipolar II disorder	01JAN2011		Y
			Depression	01JAN2018		Y
			Drug abuse	01JAN2002		Y
			Insomnia	01JAN2009		Y
			Major depression	01JAN2011		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JAN1999		Y
		Social circumstances	Postmenopause	17OCT2018		Y
			Tobacco user	01JAN1989		Y
		Surgical and medical procedures	Female sterilisation	27FEB1992	27FEB1992	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511052	Gastrointestinal disorders	Gastrooesophageal reflux disease	09JUN2014		Y
			Irritable bowel syndrome	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Appendicitis	01JAN2008	31DEC2008	N
		Investigations	Colonoscopy	01JAN2007	31DEC2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
			Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2006		Y
			Back pain	09JUN2008		Y
			Intervertebral disc degeneration	01JAN2004		Y
			Osteoarthritis	01JAN2006		Y
			Osteoporosis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm benign	01JAN1964	31DEC1964	N
		Nervous system disorders	Migraine	09JUN1964		Y
		Psychiatric disorders	Depression	09JUN2011		Y
		Social circumstances	Postmenopause	01JAN1988		Y
		Surgical and medical procedures	Appendicectomy	01JAN2008	31DEC2008	N
			Cholecystectomy	13MAY2019	13MAY2019	N
			Hip arthroplasty	13MAY2019	13MAY2019	N
			Hysterectomy	01JAN1988	31DEC1988	N
			Limb operation	01JAN2015	31DEC2015	N
			Spinal operation	28NOV2016	28NOV2016	N
		Vascular disorders	Hot flush	01JAN2000		Y
			Hypertension	01JAN2014		Y
	C4591001 1251 12511053	Cardiac disorders	Cardiac failure congestive	01JAN2019		Y
			Tachycardia	01JAN2014		Y
		Ear and labyrinth disorders	Hypoacusis	01JAN2000		Y
		Gastrointestinal disorders	Dyspepsia	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	01APR2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2015		Y
			Osteoarthritis	01JAN2014		Y
			Spinal osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1998		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2003		Y
		Surgical and medical procedures	Cardiac ablation	01AUG2016	01AUG2016	N
			Carpal tunnel decompression	01JAN2016	31DEC2017	N
			Knee arthroplasty	01MAR2018	01MAR2018	N
			Shoulder operation	16SEP2015	16SEP2015	N
			Spinal operation	18JUL2014	18JUL2014	N
		Vascular disorders	Hypertension	01JAN1993		Y
	C4591001 1251 12511054	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	01JAN2007	31DEC2012	N
			Uterine leiomyoma	01JAN1998	31DEC1998	N
		Surgical and medical procedures	Hysterectomy	01JAN1998	31DEC1998	N
		Vascular disorders	Hypertension	01JAN2014		Y
			Thrombosis	01JAN2016	31DEC2016	N
	C4591001 1251 12511055	Psychiatric disorders	Bipolar disorder	01JAN2015		Y
			Depression	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1980		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tobacco user	01JAN1982		Y
		Surgical and medical procedures	Appendicectomy	01JAN1990	31DEC1990	N
			Elbow operation	01JAN1995	31DEC1995	N
			Hysterectomy	01JAN1978	31DEC1978	N
	C4591001 1251 12511056	Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
		Reproductive system and breast disorders	Ovarian cyst	01JAN1989	31DEC1989	N
		Social circumstances	Postmenopause	01JAN1989		Y
	C4591001 1251 12511057	Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01AUG2019		Y
				01JAN2019		Y
			Seasonal allergy	01JAN1974		Y
		Psychiatric disorders	Anxiety	01JAN1987		Y
			Depression	01JAN1987		Y
			Insomnia	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2002		Y
	C4591001 1251 12511063	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN2007		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1251 12511067	Infections and infestations	Tuberculosis	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01NOV2016		Y
		Surgical and medical procedures	Coronary artery bypass	01NOV2016	01NOV2016	N
			Vasectomy	01JAN1973	31DEC1973	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01NOV2016		Y
	C4591001 1251 12511069	Infections and infestations	Poliomyelitis	01JAN1953	31DEC1953	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1996	31DEC1996	N
		Nervous system disorders	Post polio syndrome	01JAN1953		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1251 12511071	Cardiac disorders	Atrial fibrillation	30JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN1997		Y
	C4591001 1251 12511072	Gastrointestinal disorders	Constipation	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1251 12511073	Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1251 12511076	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Surgical and medical procedures	Vasectomy	01JAN1992	31DEC1992	N
	C4591001 1251 12511078	Immune system disorders	Drug hypersensitivity	01JAN1992		Y
		Psychiatric disorders	Depression	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1251 12511085	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Psychiatric disorders	Anxiety	01JAN1999		Y
			Depression	01JAN1999		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1994	31DEC1994	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511086	Immune system disorders	Allergy to arthropod sting	01JAN1997		Y
			Sarcoidosis	01JAN1979		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1959		Y
		Social circumstances	Postmenopause	01JAN2002		Y
		Surgical and medical procedures	Female sterilisation	01JAN1989	31DEC1989	N
			Hysterectomy	01MAR2002	31MAR2002	N
			Urinary bladder suspension	01JAN2008	31DEC2008	N
	C4591001 1251 12511087	Hepatobiliary disorders	Cholecystitis	01JAN2010	31DEC2010	N
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Iron deficiency	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JUN2020		Y
			Osteopenia	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Hypertonic bladder	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1994		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
	C4591001 1251 12511088	Gastrointestinal disorders	Large intestine polyp	01JAN2016	31DEC2016	N
		General disorders and administration site conditions	Pain	01JAN2009		Y
		Infections and infestations	Fungal skin infection	01JAN2006		Y
		Investigations	Arthroscopy	01JAN2017	31DEC2017	N
			Colonoscopy	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1996		Y
				01JAN2000		Y
				01JAN2012		Y
				01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Hip arthroplasty	10OCT2015	31JAN2020	N
			Shoulder operation	15OCT2015	15OCT2015	N
		Vascular disorders	Hot flush	01JAN2007		Y
	C4591001 1251 12511092	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1994		Y
		Surgical and medical procedures	Vasectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN1994		Y
	C4591001 1251 12511100	Immune system disorders	Drug hypersensitivity	01JAN1975		Y
			Seasonal allergy	01JAN2002		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Muscle spasms	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2002		Y
			Emphysema	01JAN2002		Y
		Social circumstances	Postmenopause	01JAN1989		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1251 12511102	Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1997		Y
			Osteoporosis	01JAN2018		Y
		Nervous system disorders	Essential tremor	01JAN2018		Y
			Migraine	01JAN1975		Y
		Psychiatric disorders	Anxiety	01JAN1993		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1994	31DEC1994	N
	C4591001 1251 12511105	Immune system disorders	Seasonal allergy	01JAN1970		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Surgical and medical procedures	Genitourinary operation	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1251 12511106	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2007	29FEB2008	N
		Nervous system disorders	Cervical radiculopathy	01JAN2015		Y
		Social circumstances	Postmenopause	01FEB2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 1251 12511107	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2019		Y
		Investigations	Colonoscopy	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511110	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2008		Y
			Osteopenia	01JAN2008		Y
			Spinal osteoarthritis	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2001		Y
			Depression	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	01JAN1995		Y
			Sleep apnoea syndrome	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Female sterilisation	01JAN2001	31DEC2001	N
		Vascular disorders	Hot flush	01JAN2008		Y
	C4591001 1251 12511111	Ear and labyrinth disorders	Vertigo	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN1967		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2017		Y
			Hypercholesterolaemia	01JAN2010		Y
			Hypertriglyceridaemia	01JAN2010		Y
			Vitamin D deficiency	01JAN2019	31MAY2020	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Nervous system disorders	Nerve compression	01JAN2015		Y
			Sciatica	01JAN2014	31DEC2014	N
		Psychiatric disorders	Anxiety	01JAN2002		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	01JAN1990		Y
			Insomnia	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1251 12511116	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Nervous system disorders	Carotid artery disease	01JAN2005		Y
		Renal and urinary disorders	Nephropathy	01JAN2005		Y
		Surgical and medical procedures	Carotid endarterectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1251 12511118	Cardiac disorders	Atrial fibrillation	01JAN2012		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				01JAN2010		Y
		Investigations	Colonoscopy	01JAN2008	31DEC2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2000	31DEC2000	N
		Social circumstances	Postmenopause	01JAN1996		Y
	C4591001 1251 12511120	Congenital, familial and genetic disorders	Congenital cystic kidney disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Renal and urinary disorders	Nocturia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1251 12511125	Immune system disorders	Seasonal allergy	01JAN2018		Y
	C4591001 1251 12511126	Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Rubber sensitivity	01JAN2010		Y
			Seasonal allergy	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Investigations	Colonoscopy	01JAN2015	31DEC2015	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2018		Y
		Nervous system disorders	Sinus headache	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Insomnia	01JAN2010		Y
		Skin and subcutaneous tissue disorders	Rash	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2019		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2018	31DEC2018	N
			Female sterilisation	01JAN1988		Y
	C4591001 1251 12511132	Immune system disorders	Seasonal allergy	01JAN1963		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2004		Y
			Osteoporosis	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511133	Endocrine disorders	Hypothyroidism	01JAN2012		Y
		General disorders and administration site conditions	Pain	01JAN2013		Y
		Immune system disorders	Drug hypersensitivity	(b) (6) 1958		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
			Hyperlipidaemia	01MAY2020		Y
		Psychiatric disorders	Anxiety	01JAN2019		Y
			Depression	01JAN2019		Y
		Surgical and medical procedures	Knee operation	01FEB2020		Y
			Neck surgery	01JAN2018	31DEC2018	N



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal operation	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1251 12511134	Endocrine disorders	Hypothyroidism	01JAN1980		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2016		Y
			Osteoporosis	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN1990		Y
	C4591001 1251 12511136	Gastrointestinal disorders	Gastroesophageal reflux disease	02FEB2020		Y
		Infections and infestations	Urinary tract infection	01JAN2017		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1251 12511145	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Neck pain	01JAN2017		Y
			Pain in extremity	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2002		Y
		Psychiatric disorders	Depression	01JAN2007		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2001		Y
			Emphysema	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN1982		Y
	C4591001 1251 12511151	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511152	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1993		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2020		Y
		Social circumstances	Postmenopause	01JAN2000		Y
	C4591001 1251 12511158	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN2010		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2017		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511160	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Obesity	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1990		Y
			Osteoarthritis	01JAN1990		Y
		Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN1997	31DEC1997	N
	C4591001 1251 12511164	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1251 12511167	Gastrointestinal disorders	Constipation	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN2019		Y
		Psychiatric disorders	Anxiety	02FEB2020		Y
			Insomnia	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Hysterectomy	01JUN1972		Y
	C4591001 1251 12511169	Endocrine disorders	Thyroid cyst	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN1970		Y
		Reproductive system and breast disorders	Uterine prolapse	01JAN1986	31DEC1986	N
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1986		Y
			Thyroidectomy	01JAN2010	31DEC2010	N
	C4591001 1251 12511170	Investigations	Colonoscopy	01JAN1999	31DEC1999	N
				01JAN2020	31DEC2020	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Cardiac operation	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1251 12511177	Vascular disorders	Hypertension	01JAN2002		Y
	C4591001 1251 12511181	Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1251 12511182	Blood and lymphatic system disorders	Anaemia	01JAN2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Metabolism and nutrition disorders	Gout	01JAN2010		Y
			Hypercholesterolaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1979		Y
			Osteoarthritis	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01FEB2019	31DEC2019	N
		Psychiatric disorders	Nicotine dependence	01JAN1970		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1960		Y
			Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Colectomy	01FEB2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1251 12511186	Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2008	31DEC2008	N
	C4591001 1251 12511189	Immune system disorders	Drug hypersensitivity	01JAN1976		Y
		Surgical and medical procedures	Vasectomy	01JAN1988	01JAN1988	N
	C4591001 1251 12511190	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1251 12511192	Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Psychiatric disorders	Depression	01JAN1975		Y
			Insomnia	01JAN2018		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN1980	31DEC1980	N
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Hysterectomy	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511193	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2018		Y
		Nervous system disorders	Migraine	01JAN1969		Y
	C4591001 1251 12511199	Immune system disorders	Rubber sensitivity	01JAN2010		Y
		Investigations	Colonoscopy	13MAR2020	13MAR2020	N
		Musculoskeletal and connective tissue disorders	Myalgia	01JAN2018		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Caesarean section	01JAN1978	31DEC1978	N
				01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511200	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1251 12511203	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1984		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	22AUG2019		Y
		Social circumstances	Postmenopause	01JAN1980		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	01JAN1976	N
	C4591001 1251 12511206	Endocrine disorders	Hypothyroidism	01JAN2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Social circumstances	Postmenopause	01JAN1995		Y
		Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
			Nasal septal operation	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1251 12511209	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Psychiatric disorders	Anxiety	01FEB2020		Y
	C4591001 1251 12511210	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2016		Y
		Injury, poisoning and procedural complications	Road traffic accident	01JAN2012	31DEC2012	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2012		Y
		Psychiatric disorders	Insomnia	01JUL2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JUL2020		Y
		Social circumstances	Tobacco user	01JAN1983		Y
		Surgical and medical procedures	Sinus operation	01JAN1969		Y
	C4591001 1251 12511211	Gastrointestinal disorders	Gastroesophageal reflux disease	03JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	02JAN2019		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1984	31DEC1984	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511213	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign uterine neoplasm	01JAN2007	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
	C4591001 1251 12511222	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1251 12511225	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1995		Y
		Immune system disorders	Drug hypersensitivity	01JAN2012		Y
			Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2012		Y
			Transient ischaemic attack	01JAN2014	31DEC2014	N
		Psychiatric disorders	Bipolar disorder	01JAN1993		Y
			Insomnia	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2006		Y
			Emphysema	01JAN2006		Y
		Social circumstances	Postmenopause	01JAN2003		Y
		Surgical and medical procedures	Hysterectomy	01JAN1982	31DEC1982	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1251 12511227	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985		Y
			Seasonal allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Vitamin D deficiency	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	13JUN2014		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2016	31DEC2016	N
			Dizziness	01JAN2014		Y
			Seizure	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN1980		Y
		Reproductive system and breast disorders	Prostatic disorder	01JAN1980		Y
		Surgical and medical procedures	Knee operation	01JAN1992	31DEC1992	N
			Neck surgery	01JAN2014	31DEC2014	N
			Spinal fusion surgery	10JAN2009	10JAN2009	N
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 1251 12511230	Immune system disorders	Drug hypersensitivity	01JAN1964		Y
	C4591001 1251 12511235	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
			Hiatus hernia	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Cerebrovascular accident	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Vasectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1251 12511237	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1251 12511243	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1970		Y
			Irritable bowel syndrome	01JAN1957		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1984		Y
				01JAN1999		Y
				01JAN2000		Y
			Seasonal allergy	01JAN1960		Y
		Investigations	Blood oestrogen increased	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acoustic neuroma	01JAN2016		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Hysterectomy	01JAN1996	31DEC1996	N
	C4591001 1251 12511244	Eye disorders	Cataract	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1990		Y
			Fibromyalgia	01JAN1985		Y
			Foot deformity	01JAN2009	31DEC2010	N
			Osteoarthritis	01JAN1998		Y
				01JAN2000		Y
			Scoliosis	01JAN1977		Y
			Spinal osteoarthritis	01JAN2000		Y
			Spinal stenosis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	01JAN1979	31DEC1979	N
		Psychiatric disorders	Depression	01JAN1985		Y
		Respiratory, thoracic and mediastinal disorders	Epistaxis	15AUG2020		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Surgical and medical procedures	Bunion operation	01JAN2010	31DEC2010	N
			Oophorectomy	01JAN1979	31DEC1979	N
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511248	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2005		Y
			Haemorrhoids	01JAN2010		Y
			Impaired gastric emptying	01JAN2005		Y
			Irritable bowel syndrome	01JAN2011		Y
		Hepatobiliary disorders	Cholecystitis	01OCT1979	31DEC1980	N
			Nonalcoholic fatty liver disease	01JAN2010		Y
		Infections and infestations	Chronic sinusitis	01JAN1990		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN1987		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2010		Y
			Osteoarthritis	01JAN2008		Y
			Spinal osteoarthritis	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1987	31DEC1987	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2005	31DEC2006	N
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2006	31DEC2006	N
			Cholecystectomy	01JAN1980	31JAN1980	N
			Female sterilisation	23SEP1979	23SEP1979	N
			Hysterectomy	01JAN1987	31DEC1987	N
			Oesophagogastric fundoplasty	08AUG2019	08AUG2019	N
			Tonsillectomy	01JAN2004	31DEC2004	N
		Vascular disorders	Hot flush	01JAN1990		Y
			Hypertension	01JAN1990		Y
	C4591001 1251 12511249	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1251 12511250	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Investigations	Arthroscopy	01JAN2005	31DEC2005	N
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Psychiatric disorders	Nicotine dependence	01JAN1968		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2009	31DEC2009	N
	C4591001 1251 12511251	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1251 12511257	Musculoskeletal and connective tissue disorders	Back pain	01JAN2014		Y
		Nervous system disorders	Nerve compression	01DEC2019		Y
	C4591001 1251 12511258	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1980		Y
		Psychiatric disorders	Nicotine dependence	01JAN1977		Y
	C4591001 1251 12511260	Cardiac disorders	Cardiac disorder	01JAN2002		Y
			Myocardial infarction	06JUN2002	06JUN2002	N
		Immune system disorders	Allergy to plants	01JAN1960		Y
			Drug hypersensitivity	01JAN1954		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2006		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2005		Y
			Sleep apnoea syndrome	01JAN2007		Y
		Social circumstances	Tobacco user	01JAN1980		Y
		Surgical and medical procedures	Cardiac operation	01JUN2002	01JUN2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hysterectomy	01JAN1990	31DEC1990	N
	C4591001 1251 12511261	Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemia	01JAN1993	31DEC2005	N
			Prostate cancer	01JAN2012	31DEC2012	N
		Psychiatric disorders	Depression	01JAN1993		Y
		Surgical and medical procedures	Prostatectomy	01JAN2012	31DEC2012	N
			Vasectomy	01JAN1981	31DEC1981	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1251 12511263	Immune system disorders	Drug hypersensitivity	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2015		Y
			Tobacco user	01JAN2012		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hot flush	01JAN2016		Y
			Hypertension	01JAN2018		Y
	C4591001 1251 12511264	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1999		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
		Psychiatric disorders	Anxiety	01JAN2008		Y
			Depression	01JAN2008		Y
			Post-traumatic stress disorder	01JAN1971		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2014		Y
		Surgical and medical procedures	Hip arthroplasty	29JUL2019	29JUL2019	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1251 12511265	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Psychiatric disorders	Insomnia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2001		Y
			Tobacco user	01JAN1985		Y
	C4591001 1251 12511267	Nervous system disorders	Neuralgia	01JAN2012		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
		Surgical and medical procedures	Ankle operation	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1252 12521003	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
			Rotator cuff syndrome	01JAN2002	31DEC2002	N
		Psychiatric disorders	Anxiety	01JAN2011		Y
		Renal and urinary disorders	Nephrolithiasis	12APR2019	30APR2019	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2008		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	03OCT2014		Y
		Surgical and medical procedures	Ankle operation	01JAN1986	31DEC1986	N
			Carpal tunnel decompression	01JAN2000	31DEC2000	N
			Renal stone removal	12APR2019	12APR2019	N
			Rotator cuff repair	01JAN2002	31DEC2002	N
		Vascular disorders	Deep vein thrombosis	06APR2018		Y
			Hypertension	01JAN2000		Y
	C4591001 1252 12521005	Cardiac disorders	Arteriosclerosis coronary artery	01JAN2000		Y
			Atrial fibrillation	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	30MAY2018		Y
		Investigations	Carotid bruit	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2002		Y
			Type 2 diabetes mellitus	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01JAN2015		Y
			Osteoarthritis	01JAN2005		Y
		Nervous system disorders	Restless legs syndrome	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	30MAY2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1998		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1252 12521006	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y
			Osteoarthritis	01JAN2010		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1252 12521007	Investigations	Cardiac murmur	04DEC2019		Y
		Metabolism and nutrition disorders	Gout	09MAY2018		Y
			Hyperlipidaemia	09MAY2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	09MAY2012		Y
		Vascular disorders	Hypertension	09MAY2010		Y
	C4591001 1252 12521008	Blood and lymphatic system disorders	Anaemia	24MAY2019		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JUL2018		Y
		Metabolism and nutrition disorders	Gout	03AUG2020		Y
			Hyperlipidaemia	14SEP2017		Y
			Obesity	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	20MAR2020		Y
		Nervous system disorders	Neuropathy peripheral	02JUL2018		Y
		Renal and urinary disorders	Hypertonic bladder	26JUN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	27FEB2018		Y
		Vascular disorders	Hypertension	02JUL2018		Y
	C4591001 1252 12521010	Ear and labyrinth disorders	Vertigo	02OCT2019		Y
		Immune system disorders	Seasonal allergy	18APR2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1252 12521011	Cardiac disorders	Coronary artery disease	01APR2018		Y
		Endocrine disorders	Hypogonadism	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01JAN2009		Y
		Psychiatric disorders	Anxiety	04MAR2019		Y
			Depression	09APR2018		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
		Surgical and medical procedures	Angioplasty	09APR2018	09APR2018	N
	C4591001 1252 12521012	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	25JUL2020		Y
		Vascular disorders	Arteriosclerosis	08JUL2020		Y
			Hypertension	25MAR2020		Y
	C4591001 1252 12521014	Injury, poisoning and procedural complications	Ankle fracture	10MAY1996	30JUN1996	N
			Foot fracture	10MAY1996	30JUN1996	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2019		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2019	31DEC2019	N
			Vasectomy	01JAN1991	31DEC1991	N
	C4591001 1252 12521017	Endocrine disorders	Hypothyroidism	01JAN2017		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12DEC2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2009		Y
			Intervertebral disc degeneration	01JAN2008		Y
		Nervous system disorders	Migraine	01JAN2017		Y
			Sciatica	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Attention deficit hyperactivity disorder	01JAN2015		Y
			Depression	01JAN2012		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Hysterectomy	01APR2014	30APR2014	N
			Spinal fusion surgery	01JAN2010	31DEC2010	N
		Vascular disorders	Deep vein thrombosis	01MAR2015		Y
	C4591001 1252 12521018	Ear and labyrinth disorders	Vertigo	02OCT2019		Y
		Immune system disorders	Seasonal allergy	18APR2018		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1252 12521022	Gastrointestinal disorders	Gastroesophageal reflux disease	19AUG2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	25JUL2018		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN1983	31DEC1983	N
				01JAN1993	31DEC1993	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2010		Y
			Chronic obstructive pulmonary disease	25JUL2018		Y
			Rhinitis allergic	16OCT2019		Y
		Surgical and medical procedures	Finger amputation	01JAN1977	31DEC1977	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1252 12521025	Vascular disorders	Hypertension	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1252 12521026	Cardiac disorders	Cardiac failure congestive	09JAN2020		Y
			Coronary artery disease	31DEC2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2002		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	17JUN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN1989	31DEC1989	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1252 12521027	Gastrointestinal disorders	Gastric ulcer	01JAN2012	31DEC2017	N
		Surgical and medical procedures	Female sterilisation	01JAN1982	31DEC1982	N
			Gastrectomy	01AUG2017	31DEC2017	N
			Hernia repair	01JUL2008	31JUL2008	N
	C4591001 1252 12521028	Surgical and medical procedures	Hysterectomy	01JAN1995	31DEC1995	N
	C4591001 1252 12521030	Surgical and medical procedures	Hernia repair	01JAN2010	31DEC2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1252 12521031	Endocrine disorders	Hypogonadism	01JAN2017		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2017	28FEB2018	N
			Osteoarthritis	01JAN1995		Y
		Nervous system disorders	Sciatica	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Knee arthroplasty	01FEB2018	28FEB2018	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01NOV2018	30NOV2018	N
	C4591001 1252	Vascular disorders	Hypertension	01JAN1988		Y
	12521032	Endocrine disorders	Hypogonadism	25JUL2018		Y
		Injury, poisoning and procedural complications	Joint injury	16APR2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22AUG2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	11DEC2019		Y
			Osteoarthritis	22AUG2019		Y
		Psychiatric disorders	Insomnia	16APR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	16APR2018		Y
	C4591001 1252	Vascular disorders	Hypertension	16APR2018		Y
	12521033	Cardiac disorders	Coronary artery disease	01JAN2015		Y
			Myocardial infarction	13FEB2015	13FEB2015	N
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Injury, poisoning and procedural complications	Foot fracture	01JAN2015	31DEC2015	N
		Psychiatric disorders	Depression	01JAN2018		Y
			Insomnia	01JAN2018		Y
		Surgical and medical procedures	Caesarean section	01JAN1987	31DEC1987	N
				01JAN1989	31DEC1989	N
			Limb operation	01JAN2015	31DEC2015	N
			Stent placement	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1252	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01JAN2015	31DEC2019	N
	12521037					
		Nervous system disorders	Hypoaesthesia	01JAN2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2015		Y
	C4591001 1252 12521038	Surgical and medical procedures	Hernia repair	01JAN2017	31DEC2017	N
			Prostatic operation	01JAN2015	31DEC2015	N
				01JAN2016	31DEC2016	N
	C4591001 1252 12521040	Cardiac disorders	Atrial fibrillation	27AUG2019		Y
		Endocrine disorders	Hypothyroidism	27AUG2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05JUL2018		Y
		Vascular disorders	Hypertension	05JUL2018		Y
	C4591001 1254 12541001	Musculoskeletal and connective tissue disorders	Osteoarthritis	01OCT2010		Y
	C4591001 1254 12541002	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
	C4591001 1254 12541004	Eye disorders	Glaucoma	01JAN2010		Y
			Presbyopia	01APR2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1995		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2002		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
					31OCT2018	N
		Psychiatric disorders	Anxiety	01JAN2010	28FEB2011	N
			Insomnia	01AUG2010	31DEC2011	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
		Surgical and medical procedures	Glaucoma surgery	01APR2019	30APR2019	N
			Hip arthroplasty	01OCT2018	31OCT2018	N
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541006	Eye disorders	Cataract	01JAN2017	21JUL2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01JAN2005	31DEC2005	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Cataract operation	21JUL2020	21JUL2020	N
			Mole excision	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1254 12541009	Cardiac disorders	Myocardial infarction	01JAN2008	31DEC2008	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	01JAN2001		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1990		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2008	31DEC2008	N
		Vascular disorders	Aortic dilatation	01JAN2018		Y
			Hypertension	01JAN2008		Y
	C4591001 1254 12541010	Ear and labyrinth disorders	Tinnitus	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Psychiatric disorders	Depression	01JAN2015		Y
			Insomnia	01JAN2010		Y
		Surgical and medical procedures	Aortic aneurysm repair	01NOV2018	30NOV2018	N
			Vascular stent insertion	01JAN2003	31DEC2003	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1254 12541011	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002	31DEC2010	N
			Osteoporosis	01JAN2014		Y
	C4591001 1254 12541012	Surgical and medical procedures	Knee arthroplasty	01JAN2010	31DEC2010	N
		Endocrine disorders	Autoimmune thyroiditis	01JAN2015		Y
		Injury, poisoning and procedural complications	Lumbar vertebral fracture	01JAN2017	31JAN2017	N
		Nervous system disorders	Trigeminal neuralgia	01JAN2018		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2018		Y
	C4591001 1254 12541013	Cardiac disorders	Sinus tachycardia	01JAN2018		Y
		Eye disorders	Myopia	01JAN1995		Y
			Presbyopia	01JAN1990		Y
		Infections and infestations	Appendicitis	01JAN1971	31DEC1971	N
			Herpes virus infection	01JAN1980		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2003		Y
			Obesity	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1965		Y
			Intervertebral disc degeneration	01JAN1965		Y
			Neck pain	01JAN1965		Y
			Spinal osteoarthritis	01JAN1965		Y
		Psychiatric disorders	Bipolar disorder	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Appendicectomy	01JAN1971	31DEC1971	N
			Gastrectomy	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1254 12541014	Ear and labyrinth disorders	Tinnitus	01JAN2000		Y
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Constipation	01JAN2012		Y
		Infections and infestations	Ear infection	01JAN2000		Y
			Urinary tract infection	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN2018		Y
		Renal and urinary disorders	Calculus bladder	01JAN2014		Y
			Hypertonic bladder	01JAN2015		Y
			Nephrolithiasis	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Ureteral stent insertion	01FEB2020	29FEB2020	N
				01MAR2020	31MAR2020	N
	C4591001 1254 12541015	Eye disorders	Glaucoma	01JAN2018		Y
			Myopia	01JAN2018		Y
			Presbyopia	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
			Rotator cuff syndrome	01JAN2015	31DEC2015	N
		Surgical and medical procedures	Caesarean section	01JAN1985	31DEC1985	N
			Rotator cuff repair	01JAN2015	31DEC2015	N
		Vascular disorders	Hot flush	01JAN2015		Y
			Hypertension	01JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541016	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN2016		Y
			Depression	01JAN2016		Y
	C4591001 1254 12541017	Immune system disorders	Seasonal allergy	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Prostatectomy	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541018	Eye disorders	Presbyopia	01JAN2002		Y
		Gastrointestinal disorders	Oesophagitis	01JAN2012		Y
	C4591001 1254 12541019	Cardiac disorders	Atrial tachycardia	01JAN2005	31DEC2005	N
		Eye disorders	Cataract	01JAN2013	31DEC2013	N
			Myopia	01JAN1990		Y
			Presbyopia	01JAN1980		Y
		Infections and infestations	Urinary tract infection	01JAN2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2019		Y
			Hyperlipidaemia	01JAN2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN1997		Y
			Spinal osteoarthritis	01JAN1997		Y
		Nervous system disorders	Migraine	01JAN2017	31DEC2017	N
			Transient ischaemic attack	01JAN2017	31DEC2017	N
		Surgical and medical procedures	Cardiac ablation	01JAN2005	31DEC2005	N
			Cataract operation	01JAN2013	31DEC2013	N
			Spinal fusion surgery	01JAN1999	31DEC1999	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541021	Eye disorders	Myopia	01JAN2010		Y
			Presbyopia	01JAN2013		Y
		Gastrointestinal disorders	Inflammatory bowel disease	01JAN2000		Y
			Tongue coated	01JAN2000	31DEC2017	N
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1972		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2015	31DEC2015	N
		Psychiatric disorders	Insomnia	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Rash pruritic	01JAN2015	31DEC2019	N
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1254 12541022	Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
			Inguinal hernia	01JAN1956	31DEC1960	N
		Injury, poisoning and procedural complications	Cartilage injury	01JAN2007	31DEC2009	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2010	31DEC2010	N
				01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
		Surgical and medical procedures	Chondroplasty	01JAN2006	31DEC2006	N
			Inguinal hernia repair	01JAN1960	31DEC1960	N
			Skin neoplasm excision	01JAN2010	31DEC2010	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2011	31DEC2011	N
				01JAN2012	31DEC2012	N
	C4591001 1254 12541024	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Eye disorders	Cataract	01JAN2010		Y
			Visual impairment	01JAN2016		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2008	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2007		Y
			Seasonal allergy	01JAN2010		Y
		Injury, poisoning and procedural complications	Head injury	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1254 12541025	Eye disorders	Presbyopia	01JAN2005		Y
		Infections and infestations	Urinary tract infection	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Depression	01JAN2010		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2016		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541026	Blood and lymphatic system disorders	Anaemia	01JAN2011		Y
		Ear and labyrinth disorders	Deafness	01JAN1990		Y
			Meniere's disease	01JAN1990		Y
		Gastrointestinal disorders	Gastric ulcer	01JAN2010	31DEC2011	N
			Gastrooesophageal reflux disease	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Bursitis	01SEP2019	31MAR2020	N
			Osteoarthritis	01JAN2005	31DEC2011	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2009		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN2011	31DEC2011	N
	C4591001 1254 12541028	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2002		Y
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1254 12541037	Blood and lymphatic system disorders	Anaemia	01JAN2015		Y
		Endocrine disorders	Hyperparathyroidism	01JAN2018		Y
		Eye disorders	Myopia	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Vitamin D deficiency	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2010	31DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN1985	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Neuropathy peripheral	01JAN2010		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN2015		Y
			Urinary tract obstruction	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
		Surgical and medical procedures	Dental implantation	01JAN2018	31DEC2018	N
			Hip arthroplasty	01JAN2015	31DEC2015	N
			Tonsillectomy	01JAN1950	31DEC1950	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1254 12541043	Cardiac disorders	Cardiac failure congestive	01JAN2007	31DEC2008	N
			Mitral valve stenosis	01JAN2007	31DEC2008	N
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Barrett's oesophagus	01JAN2007		Y
			Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1950		Y
			Seasonal allergy	01JAN1988		Y
		Infections and infestations	Herpes simplex	01JAN1985		Y
			Pneumonia	01JAN2015	31DEC2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01JAN2017	31DEC2017	N
		Nervous system disorders	Hypoaesthesia	01JAN2013		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2002	31DEC2002	N
			Hernia repair	01JAN2010	31DEC2010	N
			Mitral valve repair	01JAN2008	31DEC2008	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541045	Eye disorders	Presbyopia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2019		Y
			Spinal osteoarthritis	01JAN2019		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
	C4591001 1254 12541047	Eye disorders	Myopia	01JAN1960		Y
			Presbyopia	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN1971		Y
		Infections and infestations	Pneumonia	01JAN2019	31DEC2019	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2005		Y
			Psoriatic arthropathy	01JAN1993		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2017	31DEC2017	N
		Renal and urinary disorders	Nephrolithiasis	01MAY2020	31MAY2020	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1997		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2017	31JAN2017	N
	C4591001 1254 12541048	Cardiac disorders	Cardiomegaly	01JAN2014		Y
		Eye disorders	Myopia	01JAN1970		Y
			Presbyopia	01JAN2005		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Large intestine polyp	01JAN1990		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Infections and infestations	Chronic sinusitis	01JAN1980		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Herpes zoster	01JAN1980	31DEC1980	N
			Pneumonia	01JAN1970	31DEC1970	N
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	01JAN2013	31DEC2014	N
		Nervous system disorders	Neuropathy peripheral	01JAN2005		Y
		Psychiatric disorders	Insomnia	01JAN1990		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1971		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1980		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1980		Y
		Surgical and medical procedures	Abdominal hernia repair	01JAN2010	31DEC2010	N
			Inguinal hernia repair	01JAN1990	31DEC1990	N
			Meniscus operation	01JAN1995	31DEC1995	N
	C4591001 1254 12541059	Eye disorders	Presbyopia	01JAN2008		Y
		Gastrointestinal disorders	Abdominal distension	01JAN1995		Y
			Gastroesophageal reflux disease	01JAN1990	31DEC2005	N
		General disorders and administration site conditions	Fatigue	01JAN2001		Y
		Infections and infestations	Pneumonia	01JAN2016	31DEC2016	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2001		Y
			Osteoarthritis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2000		Y
		Reproductive system and breast disorders	Ovarian cyst ruptured	01JAN1976	31DEC1976	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1965		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Nasal polyps	01JAN1980	31DEC1998	N
		Surgical and medical procedures	Meniscus operation	01JAN2010	31DEC2010	N
			Nasal polypectomy	01JAN1998	31DEC1998	N
			Oesophagogastric fundoplasty	01JAN2005	31DEC2005	N
			Oophorectomy	01JAN1976	31DEC1976	N
	C4591001 1254 12541060	Eye disorders	Hypermetropia	01JAN1970		Y
			Myopia	01JAN1970		Y
		Injury, poisoning and procedural complications	Compression fracture	01JAN1991	31DEC1992	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2013	31DEC2013	N
		Nervous system disorders	Neuropathy peripheral	01JAN2015		Y
			Subarachnoid haemorrhage	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Surgical and medical procedures	Fracture treatment	01JAN1960	31DEC1960	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1254 12541065	Eye disorders	Cataract	01JAN2010		Y
			Myopia	01JAN1970		Y
			Presbyopia	01JAN2010		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2018		Y
		Metabolism and nutrition disorders	Obesity	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	01JAN1995	31DEC1995	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2019		Y
		Renal and urinary disorders	Mixed incontinence	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2017		Y
		Surgical and medical procedures	Appendicectomy	01JAN1970	31DEC1970	N
			Breast conserving surgery	01JAN1995	31DEC1995	N
			Cataract operation	01JAN2010	31DEC2010	N
			Spinal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1254 12541070	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
			Type 2 diabetes mellitus	01JAN2013		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN2013		Y
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1254 12541074	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN1990		Y
		Reproductive system and breast disorders	Uterine cyst	01JAN2017	31DEC2018	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Surgical and medical procedures	Uterine cystectomy	01JAN2018	31DEC2018	N
	C4591001 1254 12541076	Infections and infestations	Hepatitis A	01JAN1975	31DEC1975	N
		Injury, poisoning and procedural complications	Ligament rupture	01JAN2007	31DEC2008	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Nervous system disorders	Trigeminal nerve disorder	01JAN2016		Y
		Social circumstances	Menopause	01JAN2015		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
			Ligament operation	01JAN2008	31DEC2008	N
		Vascular disorders	Hypertension	01JAN2019		Y
		Eye disorders	Myopia	01JAN1962		Y
			Presbyopia	01JAN2017		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2015	31DEC2019	N
		Psychiatric disorders	Insomnia	01JAN2019		Y
		Surgical and medical procedures	Lithotripsy	01JAN1993	31DEC1993	N
		Immune system disorders	Drug hypersensitivity	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	01JAN2016		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1988	31DEC1988	N
		Immune system disorders	Allergy to plants	01JAN2000		Y
			Drug hypersensitivity	01JAN1966	31DEC1966	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acinic cell carcinoma of salivary gland	01JAN2014	31DEC2014	N
			Uterine leiomyoma	01JAN2005	31DEC2006	N
		Nervous system disorders	Migraine	01JAN1975		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN2004	31DEC2004	N
			Cholecystectomy	01JAN1988	31DEC1988	N
			Gastrectomy	01JAN2000	31DEC2000	N
			Hysterectomy	01JAN2006	31DEC2006	N
			Parotidectomy	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tonsillectomy	01JAN1984	31DEC1984	N
	C4591001 1254 12541092	Cardiac disorders	Arrhythmia	01FEB2016		Y
			Coronary artery disease	01FEB2016		Y
			Myocardial infarction	01FEB2016	29FEB2016	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2016		Y
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 1254 12541093	Eye disorders	Myopia	01JAN1980		Y
		Psychiatric disorders	Bipolar disorder	01JAN2017		Y
			Depression	01JAN2017		Y
			Insomnia	01JAN2010		Y
		Renal and urinary disorders	Nocturia	01MAR2020		Y
			Urinary hesitation	01MAR2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN1999	31DEC2000	N
	C4591001 1254 12541095	Eye disorders	Cataract	01JAN2014	31DEC2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2002		Y
		Immune system disorders	Seasonal allergy	01JAN2005		Y
		Metabolism and nutrition disorders	Obesity	01JAN1965		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2005		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2000		Y
		Surgical and medical procedures	Cataract operation	01JAN2018	31DEC2018	N
			Vasectomy	01JAN1990	31DEC1990	N
		Vascular disorders	Hypertension	01JAN2002		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541096	Endocrine disorders	Hypothyroidism	01JAN2016		Y
		Eye disorders	Myopia	01JAN1980		Y
			Presbyopia	01JAN2015		Y
		Gastrointestinal disorders	Abdominal distension	01JAN2015		Y
			Constipation	01JAN2015		Y
		Investigations	Hepatic enzyme increased	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2010		Y
			Generalised anxiety disorder	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Menometrorrhagia	01JAN2018	31DEC2018	N
		Social circumstances	Menopause	01JAN2004		Y
		Surgical and medical procedures	Uterine dilation and curettage	01JAN2018	31DEC2018	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1254 12541097	Eye disorders	Vitreous detachment	01JAN2017	31DEC2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Joint range of motion decreased	01JAN2018	30SEP2019	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1996		Y
		Surgical and medical procedures	Elbow operation	01SEP2019	30SEP2019	N
			Eye operation	01JAN2017	31DEC2017	N
			Tonsillectomy	01JAN1967	31DEC1967	N
	C4591001 1254 12541098	Immune system disorders	Drug hypersensitivity	01JAN1962		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Epicondylitis	01JAN2003	31DEC2008	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
			Spinal osteoarthritis	01JAN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN1999	31DEC2009	N
		Reproductive system and breast disorders	Atrophic vulvovaginitis	01JAN2015		Y
		Surgical and medical procedures	Carpal tunnel decompression	01JAN2009	31DEC2009	N
			Elbow operation	01JAN2008	31DEC2008	N
	C4591001 1254 12541103	Ear and labyrinth disorders	Vertigo	01JAN2005		Y
		Eye disorders	Presbyopia	01JAN2016		Y
		Immune system disorders	Allergy to animal	(b) (6) 1964		Y
		Infections and infestations	Oral herpes	01JAN2000		Y
		Injury, poisoning and procedural complications	Wrist fracture	01JAN2018	31DEC2018	N
		Musculoskeletal and connective tissue disorders	Trigger finger	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	(b) (6) 1964		Y
		Skin and subcutaneous tissue disorders	Eczema	01JAN1969		Y
		Surgical and medical procedures	Lipoma excision	01JAN2013	31DEC2013	N
	C4591001 1254 12541106	Blood and lymphatic system disorders	Anaemia	01JAN1980		Y
		Cardiac disorders	Supraventricular tachycardia	01JAN1998	31DEC2000	N
		Congenital, familial and genetic disorders	Thalassaemia minor	01JAN1980		Y
		Eye disorders	Presbyopia	01JAN1980		Y
		Immune system disorders	Drug hypersensitivity	01JAN1983		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN1985		Y
		Infections and infestations	Urinary tract infection	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Cardiac ablation	01JAN2000	31DEC2000	N
			Female sterilisation	01JAN1984	31DEC1984	N
	C4591001 1254 12541108	Eye disorders	Glaucoma	01JAN2018		Y
			Presbyopia	01JAN2001		Y
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2000	31DEC2000	N
		Investigations	Blood testosterone decreased	01JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
			Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1254 12541122	Eye disorders	Presbyopia	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1979		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2008	31DEC2008	N
		Psychiatric disorders	Depression	01JAN2012		Y
		Social circumstances	Menopause	01JAN2008		Y
		Surgical and medical procedures	Caesarean section	23JUN1987	23JUN1987	N
			Hysterectomy	01JAN2008	31DEC2008	N
			Knee operation	01JAN1997	31DEC1997	N
			Limb operation	01NOV2019	30NOV2019	N
			Mammoplasty	01JAN2002	31DEC2002	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Rhinoplasty	01JAN1996	31DEC1996	N
	C4591001 1254 12541125	Immune system disorders	Drug hypersensitivity	01JAN2017	31DEC2017	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 1254 12541127	Endocrine disorders	Hypothyroidism	01JAN1999		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000	31DEC2000	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2012		Y
		Nervous system disorders	Migraine	01JUN2020		Y
		Social circumstances	Bereavement	01JUL2020		Y
		Surgical and medical procedures	Caesarean section	01JAN1989	31DEC1989	N
			Keratomileusis	01JAN1995	31DEC1995	N
	C4591001 1254 12541128	Immune system disorders	Seasonal allergy	01JAN2005		Y
		Infections and infestations	Sinusitis	05JUN2020	20JUN2020	N
		Social circumstances	Postmenopause	01JAN2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1254 12541129	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2018	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2018	31DEC2018	N
	C4591001 1254 12541130	Immune system disorders	Drug hypersensitivity	01JAN1976	31DEC1976	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1254 12541132	Endocrine disorders	Hypothyroidism	01JAN1985		Y
		Infections and infestations	Herpes simplex	01JAN1998		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	01JAN2015		Y
			Osteoporosis	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN2001	31DEC2004	N
		Psychiatric disorders	Depression	01JAN1990		Y
			Insomnia	01JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
	C4591001 1254 12541136	Immune system disorders	Seasonal allergy	01JAN2010		Y
	C4591001 1254 12541137	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1985	31DEC1985	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2009	31DEC2009	N
	C4591001 1254 12541138	Endocrine disorders	Adrenal mass	01JUN2020	31JUL2020	N
		Gastrointestinal disorders	Dyspepsia	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Surgical and medical procedures	Adrenalectomy	01JUL2020	31JUL2020	N
	C4591001 1254 12541141	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1987	31DEC1987	N
				01JAN2010	31DEC2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1993		Y
			Intervertebral disc protrusion	01JAN1993		Y
		Psychiatric disorders	Depression	01JAN2005	31DEC2008	N
		Renal and urinary disorders	Urinary retention	01JAN2019		Y
		Surgical and medical procedures	Knee operation	01JAN1987	31DEC1987	N
				01JAN2010	31DEC2010	N
			Spinal fusion surgery	01JAN2004	31DEC2004	N
			Spinal laminectomy	01JAN2003	31DEC2003	N
			Spinal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1254 12541143	Injury, poisoning and procedural complications	Meniscus injury	01JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2016	31DEC2016	N
			Osteoarthritis	01JAN2017		Y
		Nervous system disorders	Sciatica	01JAN2017		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2018		Y
			Nephrolithiasis	01MAR2015	31MAR2015	N
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01DEC2016	31DEC2016	N
			Tonsillectomy	01JAN1970	31DEC1970	N
	C4591001 1254 12541146	Cardiac disorders	Myocardial infarction	01JAN2001	31DEC2001	N
		Eye disorders	Eyelid ptosis	01JAN2017	31DEC2017	N
		Gastrointestinal disorders	Abdominal hernia	01JAN2014	31JAN2015	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Intestinal cyst	01JAN2005	31DEC2005	N
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
				01JAN2010		Y
		Infections and infestations	Epiglottitis	01JAN2001	31DEC2001	N
		Injury, poisoning and procedural complications	Meniscus injury	01JAN2011	31DEC2013	N
		Investigations	Arthroscopy	01SEP2013	30SEP2013	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005	31DEC2010	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2005	31DEC2012	N
		Psychiatric disorders	Depression	01JAN1964		Y
			Post-traumatic stress disorder	01JAN1964		Y
		Renal and urinary disorders	Urinary incontinence	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01SEP2015	30SEP2015	N
			Sleep apnoea syndrome	01AUG2008	31DEC2016	N
		Surgical and medical procedures	Appendectomy	01JAN1964	31DEC1964	N
			Coronary arterial stent insertion	01JAN2001	31DEC2001	N
			Eyelid operation	01JAN2017	31DEC2017	N
			Hernia repair	01JAN2015	31JAN2015	N
			Knee arthroplasty	01JAN2010	31DEC2010	N
			Prostatectomy	01JAN2012	31DEC2012	N
			Spinal operation	01JAN2005	31DEC2005	N
		Vascular disorders	Deep vein thrombosis	01JAN2010	31DEC2010	N
				01SEP2013	30SEP2013	N
	C4591001 1254 12541149	Eye disorders	Presbyopia	01JAN2006	31DEC2010	N
		Infections and infestations	Sinusitis	01JAN2000	31DEC2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2008		Y
		Surgical and medical procedures	Keratomileusis	01JAN2010	31DEC2010	N
			Sinus operation	01JAN2005	31DEC2005	N
				01JAN2018	31DEC2018	N
	C4591001 1254 12541160	Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Eye disorders	Cataract	01JAN2012		Y
			Myopia	01JAN1970		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2019		Y
		Investigations	Angiogram peripheral	01JAN2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
			Obesity	01JAN1989		Y
			Type 2 diabetes mellitus	01JAN1999		Y
		Nervous system disorders	Cerebrovascular accident	01JUL2004		Y
			Hemiparesis	01JUL2004		Y
		Respiratory, thoracic and mediastinal disorders	Pneumonitis	01JAN1981	31DEC1981	N
					01JAN1984	31DEC1984
		Social circumstances	Menopause	01JAN2007		Y
		Surgical and medical procedures	Female sterilisation	01JAN1990	31DEC1990	N
			Vascular stent insertion	01JAN2019	31DEC2019	N
		Vascular disorders	Peripheral vascular disorder	01APR2019		Y
	C4591001 1254 12541191†	Cardiac disorders	Supraventricular tachycardia	01JAN2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Immune system disorders	Drug hypersensitivity	01JAN1975		Y
					01JAN1976	

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	HIV infection	14JUL1986		Y
		Nervous system disorders	Neuropathy peripheral	01MAR2000		Y
		Psychiatric disorders	Bipolar disorder	01JAN1973		Y
			Depression	01JAN1973		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2005		Y
		Surgical and medical procedures	Lithotripsy	01JAN2005	31DEC2005	N
				01JAN2017	31DEC2017	N
	C4591001 1254 12541192	Blood and lymphatic system disorders	Thrombocytopenia	24JUN2019		Y
		Ear and labyrinth disorders	Deafness	01JAN2018		Y
		Eye disorders	Diabetic retinopathy	01JAN2012		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y
		General disorders and administration site conditions	Fatigue	01JAN2017		Y
		Hepatobiliary disorders	Cirrhosis alcoholic	01JAN2017		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatic cancer	01JAN2015		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2017		Y
		Psychiatric disorders	Major depression	30SEP2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2020		Y
		Surgical and medical procedures	Cancer surgery	01JAN2015	31DEC2015	N
				01MAR2020	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 1254 12541195	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2008		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Surgical and medical procedures	Female sterilisation	01SEP1986	30SEP1986	N
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1254 12541196	Gastrointestinal disorders	Constipation	01SEP2020		Y
		Immune system disorders	Seasonal allergy	01SEP2020		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	01AUG2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1970		Y
	C4591001 1254 12541197	Immune system disorders	Drug hypersensitivity	01JAN1980	31DEC1980	N
				01JAN1995	31DEC1995	N
				01JAN2000	31DEC2000	N
			Seasonal allergy	01JAN1964		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1985		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1254 12541198	Injury, poisoning and procedural complications	Joint injury	01JAN1970	31DEC1970	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Psychiatric disorders	Depression	01JAN2015		Y
		Surgical and medical procedures	Knee arthroplasty	01JAN1970	31DEC1970	N
	C4591001 1254 12541200	Blood and lymphatic system disorders	Anaemia	01JAN2003		Y
		Gastrointestinal disorders	Constipation	01JAN2015		Y
			Gastroesophageal reflux disease	01JAN2017		Y
		Hepatobiliary disorders	Cholelithiasis	01JAN1995	31DEC1995	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hepatic steatosis	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2012		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1995	31DEC1995	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1254 12541203	Eye disorders	Presbyopia	01JAN2018		Y
		Injury, poisoning and procedural complications	Head injury	01JAN1972	31DEC1972	N
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2000	31DEC2000	N
		Nervous system disorders	Migraine	01JAN1972		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN1980	31DEC1990	N
	C4591001 1254 12541207	Surgical and medical procedures	Wrist surgery	01JAN2000	31DEC2000	N
		Eye disorders	Myopia	01JAN1967		Y
			Presbyopia	01JAN2015		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Injury, poisoning and procedural complications	Limb injury	01JAN2016	31DEC2016	N
		Nervous system disorders	Headache	01JAN2020		Y
		Surgical and medical procedures	Tenoplasty	01JAN2016	31DEC2016	N
	C4591001 1254 12541209	Eye disorders	Myopia	01JAN1958		Y
		Gastrointestinal disorders	Umbilical hernia	01JAN2010	31DEC2015	N
		Immune system disorders	Drug hypersensitivity	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014	31DEC2015	N
		Surgical and medical procedures	Prostatectomy	01JAN2015	31DEC2015	N
			Umbilical hernia repair	01JAN2015	31DEC2015	N
	C4591001 1258 12581005	Gastrointestinal disorders	Gastroesophageal reflux disease	07NOV2014		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Infections and infestations	Chronic sinusitis	10DEC2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15OCT2018		Y
			Hypertriglyceridaemia	04FEB2016		Y
			Obesity	31MAR2016		Y
			Type 2 diabetes mellitus	13MAY2014		Y
		Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	10DEC2015		Y
		Nervous system disorders	Migraine	06MAR2015		Y
			Restless legs syndrome	01JAN2007		Y
		Psychiatric disorders	Anxiety	16MAR2015		Y
			Insomnia	07NOV2014		Y
			Major depression	07NOV2014		Y
		Renal and urinary disorders	Chronic kidney disease	27MAR2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20APR2015		Y
			Sleep apnoea syndrome	13MAR2015		Y
		Surgical and medical procedures	Cholecystectomy	20OCT2008	20OCT2008	N
			Hysterectomy	01JAN1987	31DEC1987	N
		Vascular disorders	Hypertension	07NOV2014		Y
	C4591001 1258 12581006	Gastrointestinal disorders	Dyspepsia	01JAN1990		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Haemorrhoids	14JUL2015		Y
		Musculoskeletal and connective tissue disorders	Spinal pain	01JAN1997		Y
		Nervous system disorders	Paraesthesia	15APR2015		Y
		Psychiatric disorders	Alcohol abuse	01JAN1998		Y
			Drug abuse	01JAN1975	31DEC1999	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01AUG2007		Y
		Vascular disorders	Hypertension	06APR2007		Y
	C4591001 1258 12581010	Musculoskeletal and connective tissue disorders	Neck pain	16APR2014		Y
	C4591001 1258 12581011	Congenital, familial and genetic disorders	Type V hyperlipidaemia	24OCT2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	13FEB2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10MAR2014		Y
				12APR2014		Y
			Back pain	20JUL2013		Y
			Osteoarthritis	16MAY2018		Y
				16OCT2014		Y
		Nervous system disorders	Diabetic neuropathy	13FEB2013		Y
		Renal and urinary disorders	Urge incontinence	19JUN2013		Y
		Vascular disorders	Hypertension	16APR2013		Y
	C4591001 1258 12581012	Cardiac disorders	Palpitations	30SEP2013		Y
			Supraventricular extrasystoles	06FEB2020		Y
			Ventricular extrasystoles	06FEB2020		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	07JUL2014		Y
		Metabolism and nutrition disorders	Obesity	23MAR2010		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	27JUL2018		Y
			Back pain	10AUG2017		Y
			Intervertebral disc disorder	03JUN2011		Y
			Intervertebral disc protrusion	17FEB2015		Y
		Nervous system disorders	Migraine	20JAN2015		Y
			Myelopathy	03JUN2011		Y
		Psychiatric disorders	Anxiety	09JUN2014		Y
		Renal and urinary disorders	Chronic kidney disease	25SEP2017		Y
			Urinary incontinence	01SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	08OCT2015		Y
			Rhinitis allergic	01JAN1962		Y
		Vascular disorders	Hypertension	10MAR2013		Y
	C4591001 1258 12581015	Blood and lymphatic system disorders	Anaemia	26MAR2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07MAR2013		Y
			Type 2 diabetes mellitus	07MAR2013		Y
		Musculoskeletal and connective tissue disorders	Back pain	12JUL2006		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	27JUN2009	29JUN2010	N
		Nervous system disorders	Seizure	10MAR2017	10MAR2017	N
		Respiratory, thoracic and mediastinal disorders	Asthma	26JUN2013		Y
		Surgical and medical procedures	Hysterectomy	01JAN2000	31DEC2000	N
		Vascular disorders	Hypertension	14NOV2007		Y
	C4591001 1258 12581017	Cardiac disorders	Tricuspid valve incompetence	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2013		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Seasonal allergy	01JAN1980		Y
		Metabolism and nutrition disorders	Gout	29NOV2016		Y
			Obesity	12AUG2013		Y
			Type 2 diabetes mellitus	10FEB2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30MAR2011		Y
			Rotator cuff syndrome	20MAR2012		Y
		Nervous system disorders	Cerebral ischaemia	10DEC2013		Y
			Myelopathy	14JAN2013		Y
			Sciatica	21MAR2013		Y
		Psychiatric disorders	Anxiety	10FEB2013		Y
			Depression	11FEB2013		Y
		Renal and urinary disorders	Chronic kidney disease	01SEP2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	27DEC1996		Y
			Sleep apnoea syndrome	10SEP2013		Y
		Vascular disorders	Intermittent claudication	29MAR2016		Y
			Peripheral arterial occlusive disease	01DEC2015		Y
	C4591001 1258 12581019	Gastrointestinal disorders	Gastrooesophageal reflux disease	26FEB2018		Y
		General disorders and administration site conditions	Gait disturbance	05AUG2020		Y
		Infections and infestations	Sinusitis	02SEP2020	04SEP2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	24JUN2020		Y
		Psychiatric disorders	Anxiety	20MAY2020		Y
		Reproductive system and breast disorders	Erectile dysfunction	28MAR2019		Y
		Vascular disorders	Deep vein thrombosis	27APR2017		Y
			Hypertension	29JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1258 12581020	Gastrointestinal disorders	Gastroesophageal reflux disease	07MAR1996		Y
		Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19JUL1999		Y
			Hypertriglyceridaemia	08DEC2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	06FEB2002		Y
			Enthesopathy	09JUN2013		Y
			Osteoarthritis	03JUN2013		Y
				17DEC2018		Y
		Nervous system disorders	Neuropathy peripheral	16NOV2017		Y
		Psychiatric disorders	Depression	28FEB2019		Y
		Renal and urinary disorders	Hypertonic bladder	21OCT2014		Y
			Renal failure	28AUG2017		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01MAR2018		Y
			Pulmonary hypertension	28AUG2017		Y
		Vascular disorders	Hypertension	08DEC2015		Y
	C4591001 1258 12581021	Cardiac disorders	Arteriosclerosis coronary artery	22AUG2016		Y
			Coronary artery disease	12MAR2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	05MAR2013		Y
			Obesity	01JAN1975		Y
			Type 2 diabetes mellitus	05JUN2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	04MAR2014		Y
			Back pain	04MAR2014		Y
			Pain in extremity	04MAR2014		Y
		Renal and urinary disorders	Chronic kidney disease	07MAR2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	05JUN2013		Y
	C4591001 1258 12581024	Cardiac disorders	Cardiovascular disorder	28JUL2014	26AUG2014	N
			Diastolic dysfunction	02APR2015		Y
			Hypertensive heart disease	06AUG2012		Y
			Left ventricular hypertrophy	26AUG2014		Y
		Eye disorders	Glaucoma	26JUN2014		Y
		Metabolism and nutrition disorders	Hyperkalaemia	15MAR2016		Y
			Obesity	23JUL2013		Y
			Type 2 diabetes mellitus	27OCT2014		Y
		Psychiatric disorders	Anxiety	05FEB2013		Y
			Depression	05FEB2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20JUN2013		Y
		Social circumstances	Postmenopause	01JUN2016		Y
		Vascular disorders	Hypertension	06APR2012		Y
	C4591001 1258 12581025	Metabolism and nutrition disorders	Hyperlipidaemia	04FEB2013		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	16DEC2002		Y
			Osteoarthritis	10NOV2010		Y
			Osteoporosis	16DEC2002		Y
		Nervous system disorders	Multiple sclerosis	23AUG2008		Y
		Renal and urinary disorders	Hypertonic bladder	14APR2014		Y
		Vascular disorders	Hypertension	04FEB2013		Y
	C4591001 1258 12581028	Metabolism and nutrition disorders	Hyperlipidaemia	13DEC2013		Y
			Obesity	08FEB2018		Y
			Type 2 diabetes mellitus	30DEC2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	13MAR2017		Y
		Nervous system disorders	Diabetic neuropathy	13JUN2018		Y
			Restless legs syndrome	06JUL2017		Y
		Psychiatric disorders	Depression	01AUG2020		Y
		Respiratory, thoracic and mediastinal disorders	Nasal congestion	10SEP2019		Y
		Vascular disorders	Hypertension	30DEC2013		Y
	C4591001 1258 12581029	Immune system disorders	Seasonal allergy	01JAN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	30SEP2002		Y
		Musculoskeletal and connective tissue disorders	Back pain	27AUG1995		Y
			Spinal osteoarthritis	23MAR2015		Y
			Spinal pain	23SEP2013		Y
		Psychiatric disorders	Anxiety	31OCT2014		Y
			Psychotic disorder	24MAY2004		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Hypertension	24SEP2014		Y
	C4591001 1258 12581030	Metabolism and nutrition disorders	Diabetic ketoacidosis	10SEP2000	10SEP2000	N
			Hyperlipidaemia	13SEP2018		Y
			Hypoglycaemia	03AUG2001	03AUG2001	N
			Type 2 diabetes mellitus	03SEP2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2013		Y
				15APR1994		Y
		Nervous system disorders	Headache	10MAR2011		Y
		Psychiatric disorders	Substance abuse	01JAN2012	31DEC2015	N
		Vascular disorders	Hypertension	31JAN2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1258 12581031	Ear and labyrinth disorders	Peripheral arterial occlusive disease	27OCT2017		Y
			Deafness bilateral	10JAN2017		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30JUN1997		Y
			Odynophagia	28NOV2017		Y
			Pancreatitis chronic	09MAR2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08SEP2014		Y
			Hypokalaemia	01SEP2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	26OCT2015		Y
			Osteoarthritis	04SEP2018		Y
				08SEP2014		Y
		Nervous system disorders	Dizziness	10JUL2020		Y
			Migraine without aura	10JUL2016		Y
			Neuropathy peripheral	20APR2017		Y
			Restless legs syndrome	26OCT2015		Y
		Psychiatric disorders	Alcohol abuse	08SEP2014	30JUN2018	N
			Anxiety	26OCT2015		Y
			Depression	26OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07JAN2015		Y
		Social circumstances	Postmenopause	01JAN2012		Y
		Vascular disorders	Aortic arteriosclerosis	08SEP2014		Y
	Hypertension		17JAN2019		Y	
	Intermittent claudication		26OCT2015		Y	
	Peripheral arterial occlusive disease		27JUN2016		Y	
	Varicose vein		28FEB2018		Y	
	C4591001 1258 12581032	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1973		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JAN2017		Y
		Psychiatric disorders	Anxiety	14FEB2013		Y
		Renal and urinary disorders	Cystitis interstitial	20OCT2015		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01JAN1968		Y
		Vascular disorders	Hypertension	25FEB2013		Y
	C4591001 1258 12581041	Gastrointestinal disorders	Constipation	08APR2014		Y
			Gastrooesophageal reflux disease	05NOV2014		Y
		Metabolism and nutrition disorders	Obesity	26JUN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	10AUG2016		Y
			Osteoarthritis	30NOV2015		Y
			Osteopenia	29MAR2016		Y
		Social circumstances	Postmenopause	01JAN2005		Y
	C4591001 1258 12581042	Infections and infestations	Otitis media	20SEP2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04FEB2013		Y
			Type 2 diabetes mellitus	02JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	09APR2013		Y
		Nervous system disorders	Headache	09MAY2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	10APR2019		Y
			Erectile dysfunction	20JUL2013		Y
			Prostatism	08NOV2013		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	07MAY2020		Y
		Vascular disorders	Hypertension	04FEB2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1258 12581056	Congenital, familial and genetic disorders	Venous angioma of brain	03SEP2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	13JUN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29JUL2020		Y
		Musculoskeletal and connective tissue disorders	Back pain	13JUN2017		Y
		Nervous system disorders	Headache	09SEP2020		Y
		Psychiatric disorders	Anxiety	17APR2017		Y
			Depression	31DEC2014		Y
		Renal and urinary disorders	Urinary retention	31MAR2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	31MAR2017		Y
		Vascular disorders	Hypertension	29DEC2016		Y
	C4591001 1258 12581068	Gastrointestinal disorders	Gastroesophageal reflux disease	01NOV2017		Y
		Vascular disorders	Hypertension	01JAN2019		Y
	C4591001 1258 12581076	Injury, poisoning and procedural complications	Muscle strain	16MAR2017		Y
		Vascular disorders	Hypertension	01AUG2017		Y
	C4591001 1260 12601003	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1260 12601015	Psychiatric disorders	Depression	01JAN2005		Y
		Surgical and medical procedures	Vasectomy	06NOV2013	06NOV2013	N
	C4591001 1260 12601019	Gastrointestinal disorders	Irritable bowel syndrome	01JAN2008		Y
		Nervous system disorders	Amnesia	01JAN2008		Y
	C4591001 1260 12601020	Injury, poisoning and procedural complications	Craniocerebral injury	01JAN1999	31DEC1999	N
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2003		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1260 12601021	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Surgical and medical procedures	Coronary artery bypass	01JAN2015	31DEC2015	N
	C4591001 1260 12601025	Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y
			Gastrooesophageal reflux disease	01JAN2016		Y
		Psychiatric disorders	Anxiety	01JAN1974		Y
			Depression	01JAN1974		Y
	C4591001 1260 12601026	Immune system disorders	Seasonal allergy	01FEB2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y
	C4591001 1260 12601027	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1260 12601030	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1260 12601031	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1260 12601033	Immune system disorders	Drug hypersensitivity	01JAN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1260 12601035	Social circumstances	Menopause	01JAN2005		Y
	C4591001 1260 12601037	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Colostomy	01JAN2010	31DEC2010	N
	C4591001 1260 12601039	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2005		Y
			Spinal osteoarthritis	01JAN2005		Y
	C4591001 1260 12601040	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1260 12601041	Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
	C4591001 1260 12601043	Psychiatric disorders	Agitated depression	01JAN2014		Y
	C4591001 1260 12601046	Musculoskeletal and connective tissue disorders	Osteoarthritis	10FEB2020	10FEB2020	N
		Surgical and medical procedures	Knee arthroplasty	10FEB2020	10FEB2020	N
	C4591001 1260 12601052	Gastrointestinal disorders	Duodenogastric reflux	01JAN1997		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016	31OCT2016	N
		Surgical and medical procedures	Prostatic operation	01OCT2016	31OCT2016	N
		Vascular disorders	Hypertension	01JAN1996		Y
	C4591001 1260 12601053	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1260 12601054	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2010		Y
	C4591001 1260 12601056	Immune system disorders	Drug hypersensitivity	01JAN2008		Y
		Nervous system disorders	Amnesia	01JAN2009		Y
			Cognitive disorder	01JAN2016		Y
	C4591001 1260 12601059	Immune system disorders	Contrast media allergy	01JAN2000		Y
	C4591001 1260 12601060	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2005		Y
	C4591001 1260 12601062	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Social circumstances	Postmenopause	01JAN2019		Y
	C4591001 1260 12601064	Immune system disorders	Allergy to metals	01JAN1985		Y
			Drug hypersensitivity	01JAN1976		Y
				01JAN1985		Y
		Nervous system disorders	Migraine	01JAN2016		Y
	C4591001 1260 12601066	Cardiac disorders	Atrial flutter	07SEP2016		Y
			Coronary artery disease	01JAN2009		Y
		Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JAN2018		Y
			Depression	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2009		Y
	C4591001 1260 12601069	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Social circumstances	Ex-tobacco user	01JAN1965	31DEC1999	N
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1260 12601071	Immune system disorders	Food allergy	01JAN1959		Y
		Investigations	Cardiac murmur	01JAN1955		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroma	01JAN1991	31DEC1991	N
		Skin and subcutaneous tissue disorders	Alopecia	01JAN1993		Y
	C4591001 1260 12601072	Ear and labyrinth disorders	Vertigo	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2010		Y
		Infections and infestations	Diverticulitis	01JAN2019	31DEC2019	N
		Reproductive system and breast disorders	Vaginal haemorrhage	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Sigmoidectomy	01JAN2019	31DEC2019	N
			Uterine dilation and curettage	01JAN2019	31DEC2019	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1260 12601073	Cardiac disorders	Myocardial infarction	01JAN2006	31DEC2006	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1995		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1260 12601079	Immune system disorders	Drug hypersensitivity	01JAN2019		Y
			Rubber sensitivity	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1260 12601081	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1980		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1260 12601083	Immune system disorders	Seasonal allergy	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	13APR2015		Y
		Nervous system disorders	Migraine with aura	13APR2012		Y
		Psychiatric disorders	Generalised anxiety disorder	23NOV2009		Y
		Surgical and medical procedures	Vasectomy	01JAN2010	31DEC2010	N
	C4591001 1260 12601087	Endocrine disorders	Hypothyroidism	01OCT2018		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Salpingectomy	01JAN2002	31DEC2002	N
	C4591001 1260 12601089	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Schwannoma	01JAN2016		Y
	C4591001 1260 12601090	Metabolism and nutrition disorders	Hyperlipidaemia	29SEP2008		Y
		Nervous system disorders	Cognitive disorder	29NOV2018		Y
	C4591001 1260 12601093	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
				01JAN2011		Y
				01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2010	31DEC2010	N
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 1260 12601095	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
	C4591001 1260 12601101	Immune system disorders	Allergy to arthropod sting	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Tibia fracture	01JAN2011	31DEC2011	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Surgical and medical procedures	Skin neoplasm excision	01JAN1990	31DEC1990	N
	C4591001 1260 12601102	Injury, poisoning and procedural complications	Joint injury	01JAN2001	31DEC2001	N
		Investigations	Biopsy breast	01JAN1990	31DEC1990	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2019	31DEC2019	N
		Surgical and medical procedures	Breast conserving surgery	01JAN2019	31DEC2019	N
			Cholecystectomy	01JAN1979	31DEC1979	N
	C4591001 1260 12601103	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Infections and infestations	Diverticulitis	01JAN2012		Y
			Pneumonia	01JAN2016	31DEC2016	N
				01JAN2018	31DEC2018	N
		Injury, poisoning and procedural complications	Femur fracture	01JAN2004	31DEC2004	N
		Musculoskeletal and connective tissue disorders	Polyarthritis	01JAN2000		Y
		Nervous system disorders	Migraine	01JAN1975		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1999	31DEC1999	N
			Hysterectomy	01JAN1990	31DEC1990	N
			Skin neoplasm excision	01JAN2011	31DEC2011	N
	C4591001 1260 12601105	Immune system disorders	Seasonal allergy	01JAN1990		Y
				01JAN2010		Y
	C4591001 1260 12601109	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1260 12601113	Immune system disorders	Drug hypersensitivity	01JAN1982		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2010	31DEC2010	N
	C4591001 1260 12601121	Renal and urinary disorders	Renal failure	15DEC2005		Y
	C4591001 1260 12601122	Nervous system disorders	Cerebrovascular accident	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1260 12601131	Metabolism and nutrition disorders	Obesity	16MAY2019		Y
		Musculoskeletal and connective tissue disorders	Tendonitis	01MAY2020		Y
		Vascular disorders	Hypertension	16MAY2019		Y
	C4591001 1261 12611003	Surgical and medical procedures	Bone lesion excision	01JAN2003	31DEC2003	N
			Toe operation	01JAN2005	31DEC2005	N
	C4591001 1261 12611012	Cardiac disorders	Atrial fibrillation	15OCT2002		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	15MAR2019		Y
		Vascular disorders	Hypertension	15OCT2002		Y
	C4591001 1261 12611014	Infections and infestations	Urinary tract infection	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN1996		Y
		Surgical and medical procedures	Urinary bladder suspension	01JAN2004	31DEC2004	N
	C4591001 1261 12611015	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2012		Y
		Vascular disorders	Deep vein thrombosis	01NOV2019	31MAR2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1261 12611018	Endocrine disorders	Hypothyroidism	01JAN2001		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2001	31DEC2001	N
	C4591001 1261 12611019	Cardiac disorders	Coronary artery disease	17MAY2017		Y
	C4591001 1261 12611021	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Gastrointestinal disorders	Oesophageal spasm	01JAN2008		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
	C4591001 1261 12611040	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1993		Y
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1261 12611044	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JAN1964		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	01JAN2019		Y
		Vascular disorders	Hypertension	01JAN1978		Y
	C4591001 1261 12611048	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
			Obesity	01JAN2020		Y
		Musculoskeletal and connective tissue disorders	Facet joint syndrome	01JAN2020		Y
			Spondyloarthropathy	01JAN2020		Y
	C4591001 1261 12611055	Gastrointestinal disorders	Colitis ischaemic	01JAN2010	31DEC2010	N
		Nervous system disorders	Migraine	01JAN2010		Y
		Surgical and medical procedures	Appendicectomy	01JAN1961	31DEC1961	N
	C4591001 1261 12611061	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1997		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Cervical spinal stenosis	01MAY2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01MAR2020		Y
	C4591001 1261 12611066	Congenital, familial and genetic disorders	Cerebral palsy	01JAN1954		Y
		Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Psychiatric disorders	Anxiety	01JAN1995		Y
			Depression	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Urticaria	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Vascular disorders	Hypertension	01JAN2016		Y
	C4591001 1261 12611068	Social circumstances	Postmenopause	01JAN2014		Y
	C4591001 1261 12611069	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Nervous system disorders	Sacral radiculopathy	01JAN2016		Y
	C4591001 1261 12611072	Musculoskeletal and connective tissue disorders	Osteoporosis	01AUG2020		Y
		Nervous system disorders	Migraine	01JAN1985		Y
	C4591001 1261 12611073	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1261 12611075	Cardiac disorders	Cardiovascular disorder	01MAY2018		Y
		Psychiatric disorders	Anxiety	01JAN2014		Y
	C4591001 1261 12611079	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2007	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2009		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1261 12611080	Immune system disorders	Seasonal allergy	01JAN1974		Y
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1261 12611081	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1264 12641007	Ear and labyrinth disorders	Deafness	01JAN1969		Y
		Immune system disorders	Drug hypersensitivity	01JAN1946		Y
		Surgical and medical procedures	Ligament operation	01JAN2000	31DEC2000	N
			Vasectomy	01JAN1971	31DEC1971	N
	C4591001 1264 12641010	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
	C4591001 1264 12641016	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1980		Y
		Metabolism and nutrition disorders	Gout	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 1264 12641019	Immune system disorders	Seasonal allergy	01JAN1985		Y
		Investigations	Blood cholesterol increased	01JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2011	31DEC2012	N
		Social circumstances	Postmenopause	01JAN2011		Y
		Surgical and medical procedures	Appendectomy	01JAN2008	31DEC2008	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Breast conserving surgery	01JAN2011	31DEC2011	N
	C4591001 1264 12641027	Metabolism and nutrition disorders	Gout	01MAY2007		Y
	C4591001 1264 12641030	Cardiac disorders	Myocardial infarction	01MAR1999	31MAR1999	N
		Endocrine disorders	Hypogonadism	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1971		Y
		Infections and infestations	Genital herpes	01JAN1975		Y
		Investigations	Blood cholesterol increased	01JAN1999	31DEC2020	N
			Prostatic specific antigen increased	01JAN2014		Y
		Surgical and medical procedures	Stent placement	01MAR1999	31MAR1999	N
		Vascular disorders	Deep vein thrombosis	01JAN2014		Y
	C4591001 1264 12641031	Immune system disorders	Seasonal allergy	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2005		Y
		Social circumstances	Menopause	01JAN2010		Y
		Surgical and medical procedures	Caesarean section	01JAN1991	31DEC1991	N
				01JAN1994	31DEC1994	N
	C4591001 1264 12641038	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Hypersensitivity	01JAN1980		Y
		Infections and infestations	Herpes simplex	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Mixed connective tissue disease	01JAN1983		Y
		Surgical and medical procedures	Caesarean section	28AUG1980	28AUG1980	N
			Mammoplasty	01JAN2014	31DEC2014	N
		Vascular disorders	Raynaud's phenomenon	01JAN1983		Y
	C4591001 1264 12641039	Immune system disorders	Seasonal allergy	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01JAN1970		Y
		Surgical and medical procedures	Female sterilisation	01JAN1983	31DEC1983	N
			Removal of foreign body from throat	01JAN2007	31DEC2007	N
	C4591001 1264 12641040	Blood and lymphatic system disorders	Iron deficiency anaemia	01JAN2013		Y
		Cardiac disorders	Coronary artery disease	01JAN2006		Y
		Endocrine disorders	Hypothyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	06JAN2006	06JAN2006	N
				16SEP2019	16SEP2019	N
			Spinal fusion surgery	01JAN2000	31JAN2000	N
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 1264 12641044	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2013		Y
		Psychiatric disorders	Cardiovascular somatic symptom disorder	01JAN2016	30APR2020	N
		Surgical and medical procedures	Tenoplasty	01JAN2019	31DEC2019	N
			Vasectomy	01JAN2005	31DEC2005	N
	C4591001 1264 12641045	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JAN2000	31DEC2000	N
	C4591001 1264 12641054	Immune system disorders	Seasonal allergy	01JAN1960		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Large granular lymphocytosis	01NOV2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1980		Y
			Rosacea	01JAN1985		Y
		Surgical and medical procedures	Appendicectomy	01JAN1963	31DEC1963	N
			Limb operation	01JAN1979	31DEC1979	N
			Tonsillectomy	01JAN1960	31DEC1960	N
		Vascular disorders	Aneurysm	01JAN2014	31DEC2014	N
	C4591001 1264 12641057	Surgical and medical procedures	Female sterilisation	01JAN2000	31DEC2000	N
			Limb operation	01JAN2003	31DEC2003	N
	C4591001 1264 12641059	Immune system disorders	Drug hypersensitivity	01JAN1990		Y
			Seasonal allergy	01JAN2002		Y
		Nervous system disorders	Migraine	01JAN1980		Y
		Psychiatric disorders	Anxiety	01JAN2015		Y
			Insomnia	01JAN2015		Y
		Reproductive system and breast disorders	Cystocele	01FEB2020	29FEB2020	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1980		Y
		Surgical and medical procedures	Rectocele repair	01FEB2020	29FEB2020	N
		Vascular disorders	Hypertension	01JUN2020		Y
	C4591001 1264 12641061	Injury, poisoning and procedural complications	Concussion	01JAN2016	30JUN2017	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JUN2018		Y
		Nervous system disorders	Cervicogenic vertigo	01JAN2016		Y
		Surgical and medical procedures	Hernia repair	01JUN2019	30JUN2019	N
	C4591001 1264 12641063	Immune system disorders	Seasonal allergy	01JAN2006		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Nasal polyps	01JAN2017		Y
	C4591001 1264 12641067	Investigations	Blood cholesterol increased	01JAN2012		Y
		Nervous system disorders	Guillain-Barre syndrome	01JAN2015	31DEC2015	N
			Tremor	01JAN2015		Y
		Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2015		Y
		Surgical and medical procedures	Vasectomy	01JAN1970	31DEC1970	N
	C4591001 1264 12641074	Infections and infestations	Herpes zoster	01MAR2020	30APR2020	N
	C4591001 1264 12641076	Cardiac disorders	Atrial fibrillation	01MAR2015	31DEC2015	N
		Immune system disorders	Allergy to arthropod sting	01JAN2010		Y
			Seasonal allergy	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Chondromalacia	01JAN1988	31DEC1988	N
			Intervertebral disc degeneration	01JAN1995		Y
			Rotator cuff syndrome	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Cardiac ablation	01JAN2015	31DEC2015	N
			Knee operation	01JAN1988	31DEC1988	N
			Shoulder operation	01JAN1996	31DEC1996	N
			Vasectomy	01JAN1978	31DEC1978	N
	C4591001 1264 12641077	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN1990		Y
		Vascular disorders	Hypertension	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641079	Blood and lymphatic system disorders	Normocytic anaemia	01APR2008		Y
		Cardiac disorders	Myocardial infarction	01JAN2006	31DEC2006	N
		Eye disorders	Macular hole	01APR2013		Y
		Gastrointestinal disorders	Haemorrhoids	01JAN2006		Y
		Immune system disorders	Contrast media allergy	12SEP2005		Y
			Drug hypersensitivity	01JAN1982		Y
				11JAN2008		Y
				12SEP2005		Y
				17AUG2018		Y
				19DEC2007		Y
			Seasonal allergy	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN1985		Y
			Type 2 diabetes mellitus	01JAN2003		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2004		Y
			Myofascial pain syndrome	01JAN1995		Y
		Nervous system disorders	Carotid artery stenosis	03DEC2018		Y
			Cerebrovascular accident	01JAN1995	31DEC1995	N
			Hemiparesis	01JAN1995	31DEC1995	N
			Neuropathy peripheral	01JAN1995	31DEC1995	N
		Psychiatric disorders	Conversion disorder	01JUN2004		Y
			Depression	01JAN1995		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01MAR2019		Y
		Social circumstances	Postmenopause	01JAN2000		Y
		Surgical and medical procedures	Cholecystectomy	01JAN1968	31DEC1968	N
		Vascular disorders	Hypertension	01JAN1980		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641080	Immune system disorders	Drug hypersensitivity	01JAN1951		Y
			Seasonal allergy	01JAN1970		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
			Echocardiogram	01AUG2020	31AUG2020	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2011	31DEC2011	N
		Surgical and medical procedures	Meniscus operation	01JAN2010	31DEC2010	N
			Polypectomy	01JAN2016	31DEC2016	N
			Prostatectomy	01JAN2011	31DEC2011	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1264 12641085	Blood and lymphatic system disorders	Anaemia	01JAN1990		Y
		General disorders and administration site conditions	Fibrosis	01JAN1960		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Infections and infestations	Chronic pulmonary histoplasmosis	01JAN1960		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN1987		Y
		Psychiatric disorders	Depression	01JAN2000		Y
	C4591001 1264 12641097	Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Encephalitis	01JAN1995	31DEC1995	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Scoliosis	01JAN1953		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2000	N
		Social circumstances	Menopause	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2000	31DEC2000	N
	C4591001 1264 12641098	Immune system disorders	Seasonal allergy	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN1972		Y
		Social circumstances	Menopause	01JAN2009		Y
		Surgical and medical procedures	Female sterilisation	01JAN1988	31DEC1988	N
	C4591001 1264 12641099	Blood and lymphatic system disorders	Iron deficiency anaemia	01DEC2004		Y
		Cardiac disorders	Coronary artery disease	01SEP2010		Y
		Gastrointestinal disorders	Haemorrhoids	01AUG2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2004		Y
			Obesity	01NOV2004		Y
			Type 2 diabetes mellitus	01NOV2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2009		Y
		Skin and subcutaneous tissue disorders	Hand dermatitis	01NOV2015		Y
		Surgical and medical procedures	Coronary artery bypass	01OCT2010	31OCT2010	N
			Skin neoplasm excision	01JAN2015	31DEC2015	N
	C4591001 1264 12641102	Cardiac disorders	Coronary artery disease	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Appendectomy	01JAN1973	31DEC1973	N
			Hysterectomy	01JAN1973	31DEC1973	N
			Intestinal resection	01JAN2007	31DEC2007	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Knee arthroplasty	01JAN2015	31DEC2015	N
			Mammoplasty	01JAN1978	31DEC1978	N
			Vascular stent insertion	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1264 12641107	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JUN2018		Y
		Investigations	Blood cholesterol increased	01JAN1995		Y
			Blood potassium decreased	01JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1995		Y
			Intervertebral disc protrusion	01FEB2020		Y
		Psychiatric disorders	Anxiety disorder	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Cough	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1991		Y
	C4591001 1264 12641111	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2013		Y
			Hyperlipidaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2010		Y
		Renal and urinary disorders	Proteinuria	01JAN2018		Y
		Surgical and medical procedures	Cyst removal	01JAN1983	31DEC1983	N
			Vasectomy	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1264 12641112	Endocrine disorders	Hypothyroidism	01JAN1990		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1264 12641114	Immune system disorders	Seasonal allergy	01JAN2015		Y
		Investigations	Colonoscopy	01JAN2016	31DEC2016	N
		Metabolism and nutrition disorders	Lactose intolerance	01JAN1980		Y
		Surgical and medical procedures	Transplant	23JUN1983	23JUN1983	N
	C4591001 1264 12641117	Congenital, familial and genetic disorders	Dopa-responsive dystonia	01JAN2008		Y
		Immune system disorders	Drug hypersensitivity	01JAN1973		Y
			Seasonal allergy	01JAN1969		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUL2020		Y
		Nervous system disorders	Restless legs syndrome	01JAN2008		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1995		Y
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	01JAN2005		Y
	C4591001 1264 12641121	Immune system disorders	Seasonal allergy	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2015		Y
		Surgical and medical procedures	Metabolic surgery	01APR2016	30APR2016	N
	C4591001 1264 12641128	Congenital, familial and genetic disorders	Factor V Leiden carrier	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	01JAN1995		Y
		Nervous system disorders	Migraine	01JAN2015		Y
	C4591001 1264 12641130	Immune system disorders	Allergy to animal	01JAN1968	31DEC1970	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2019		Y
		Renal and urinary disorders	Micturition urgency	01JUN2020		Y
		Surgical and medical procedures	Blepharoplasty	08MAR2021	08MAR2021	N
	C4591001 1264 12641133	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN1991		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Drug hypersensitivity	01JAN1956		Y
			Food allergy	01JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1990		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1982		Y
	C4591001 1264 12641134	Cardiac disorders	Atrial fibrillation	01JAN2012	31DEC2012	N
		Surgical and medical procedures	Cardiac ablation	01JAN2012	31DEC2012	N
	C4591001 1264 12641136	Blood and lymphatic system disorders	Anaemia	01SEP2018		Y
		Gastrointestinal disorders	Dyspepsia	01SEP2018		Y
		Immune system disorders	Allergy to arthropod sting	01JAN1970		Y
			Contrast media allergy	01JAN1959		Y
			Drug hypersensitivity	01JAN1978		Y
				01JAN1990		Y
			Food allergy	01JAN1959		Y
			Iodine allergy	01JAN1959		Y
		Infections and infestations	Oral herpes	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2001		Y
			Muscular weakness	01JAN2001		Y
		Psychiatric disorders	Insomnia	01OCT2018		Y
		Surgical and medical procedures	Cholecystectomy	01SEP2018	30SEP2018	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1264 12641137	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2000		Y
		Renal and urinary disorders	Polyuria	01JAN2019		Y
		Reproductive system and breast disorders	Prostatomegaly	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1264 12641138	Psychiatric disorders	Anxiety	01JAN2010		Y
			Insomnia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Surgical and medical procedures	Hernia repair	01JAN2014	31DEC2018	N
			Hip arthroplasty	01JAN2018	31DEC2018	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
	C4591001 1264 12641139	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Surgical and medical procedures	Skin neoplasm excision	01AUG2019	31AUG2019	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1264 12641149	Surgical and medical procedures	Hip arthroplasty	01JAN2016	31DEC2016	N
	C4591001 1264 12641155	Immune system disorders	Seasonal allergy	01JAN1989		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAY2017		Y
		Surgical and medical procedures	Limb operation	01JAN1983	31DEC1983	N
			Tenoplasty	01JAN1976	31DEC1976	N
		Vascular disorders	Hypertension	01MAR2016		Y
	C4591001 1264 12641163	Social circumstances	Postmenopause	01JAN2010		Y
		Surgical and medical procedures	Female sterilisation	01JAN2003	31DEC2003	N
	C4591001 1264 12641164	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN1956		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Chronic lymphocytic leukaemia	01JAN2009		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2009	31DEC2009	N
			Tonsillectomy	01JAN1956	31DEC1956	N
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1264 12641169	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Investigations	Arthroscopy	01JAN2014	31DEC2014	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1990		Y
		Surgical and medical procedures	Limb operation	01JAN2013	31DEC2013	N
			Muscle operation	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1264 12641170	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Immune system disorders	Seasonal allergy	01JAN1982		Y
		Infections and infestations	Herpes simplex	01JAN1997		Y
		Nervous system disorders	Migraine	01JAN1989		Y
		Surgical and medical procedures	Intra-uterine contraceptive device insertion	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN1999	31DEC2009	N
	C4591001 1264 12641174	Ear and labyrinth disorders	Motion sickness	01JAN2000		Y
		Immune system disorders	Seasonal allergy	01JAN1990		Y
		Investigations	Prostatic specific antigen increased	23MAR2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	09SEP2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01DEC2008		Y
		Reproductive system and breast disorders	Erectile dysfunction	24FEB2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Prostatectomy	23FEB2009	23FEB2009	N
			Vasectomy	01JAN1996	31DEC1996	N
	C4591001 1264 12641178	Endocrine disorders	Hypothyroidism	01JUN2008		Y
		Immune system disorders	Seasonal allergy	01FEB2020		Y
		Infections and infestations	Scarlet fever	01JAN1958	31DEC1958	N
			Varicella	01JAN1957	31DEC1957	N
				01JAN1967	31DEC1967	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	01OCT2019	06MAR2020	N
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Social circumstances	Postmenopause	01OCT2000		Y
		Surgical and medical procedures	Female sterilisation	01JAN1987	31DEC1987	N
			Rotator cuff repair	06MAR2020	06MAR2020	N
	C4591001 1264 12641180	Vascular disorders	Hypertension	01JAN2005	31DEC2010	N
		Immune system disorders	Drug hypersensitivity	01JAN1964		Y
			Seasonal allergy	01JAN1994		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2010		Y
			Mammoplasty	01JAN2001	31DEC2001	N
		Vascular disorders	Hypertension	01JAN2017		Y
	C4591001 1264 12641182	Immune system disorders	Mycotic allergy	01JAN1980		Y
		Investigations	Arthroscopy	01JAN2006	31DEC2006	N
			Tuberculin test positive	01JAN1990	31DEC1990	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN1971		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Back pain	01JAN2000		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2014		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN1995	31DEC1995	N
			Tonsillectomy	01JAN1959	31DEC1959	N
	C4591001 1264 12641194	Cardiac disorders	Coronary artery disease	01JAN1990		Y
		Endocrine disorders	Hyperthyroidism	01JAN2015		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1264 12641195	Ear and labyrinth disorders	Ear pain	01NOV2015	31DEC2015	N
			Tinnitus	01NOV2015	31DEC2015	N
			Vertigo	01NOV2015	31DEC2015	N
		Immune system disorders	Rubber sensitivity	01JAN2010		Y
			Seasonal allergy	01JAN1950		Y
		Investigations	Biopsy breast normal	01JAN2018	31DEC2018	N
			Biopsy skin normal	01JAN1985	31DEC1985	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1950		Y
		Skin and subcutaneous tissue disorders	Eczema	01MAR2018		Y
			Urticaria	01JAN1980		Y
				01JAN2000		Y
			Vitiligo	01JAN2016		Y
		Surgical and medical procedures	Acupuncture	01NOV2015	31DEC2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Female sterilisation	01JAN1974	31DEC1974	N
	C4591001 1264 12641196	Immune system disorders	Seasonal allergy	01JAN2016		Y
		Injury, poisoning and procedural complications	Joint injury	01JAN1994	31DEC1994	N
			Sports injury	01JAN1996	31DEC1996	N
		Nervous system disorders	Radiculopathy	01JAN1996	31DEC1996	N
		Surgical and medical procedures	Bone operation	01JAN2003		Y
			Peripheral nerve transposition	01JAN1996	31DEC1996	N
	C4591001 1264 12641198	Cardiac disorders	Aortic valve incompetence	01JAN1994	31DEC1994	N
				01JAN1988		Y
		Infections and infestations	Sinusitis	01JAN1975	31DEC1983	N
			Subacute endocarditis	01JUN1988	31JUL1988	N
		Injury, poisoning and procedural complications	Snake bite	01JAN2005	31DEC2005	N
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2004		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2004		Y
		Surgical and medical procedures	Ethmoid sinus surgery	01JAN1977	31DEC1977	N
	C4591001 1264 12641205	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01JUN2017		Y
		Surgical and medical procedures	Cataract operation	01FEB2016	29FEB2016	N
				01MAR2016	31MAR2016	N
	C4591001 1264 12641214	Cardiac disorders	Coronary artery disease	01JAN2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1996		Y
		Hepatobiliary disorders	Hepatic steatosis	01JAN2018		Y
		Immune system disorders	Drug hypersensitivity	01JAN1997		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01JAN2000		Y
				01JAN2019		Y
			Seasonal allergy	01JAN1993		Y
		Infections and infestations	Diverticulitis	01JAN2017	31DEC2017	N
		Nervous system disorders	Carpal tunnel syndrome	01JAN2007		Y
		Surgical and medical procedures	Breast conserving surgery	01JAN1992	31DEC1992	N
			Cholecystectomy	01JAN2019	31DEC2019	N
			Colectomy	01JAN2017	31DEC2017	N
			Hysterectomy	01JAN1997	31DEC1997	N
			Mastectomy	01JAN1992	31DEC1992	N
			Meniscus operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 1264 12641217	Congenital, familial and genetic disorders	Hydrocele	01JAN2020		Y
		Immune system disorders	Anaphylactic reaction	01JAN2000		Y
			Seasonal allergy	01JAN2005		Y
		Psychiatric disorders	Anxiety	01JAN2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Surgical and medical procedures	Cystoprostatectomy	01JUN2007	30JUN2007	N
			Hydrocele operation	01AUG2020	31AUG2020	N
			Vasectomy	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 1264 12641219	Psychiatric disorders	Libido decreased	01JAN2014		Y
		Respiratory, thoracic and mediastinal disorders	Allergic sinusitis	01JAN2000		Y
		Surgical and medical procedures	Hernia repair	01JAN1962	31DEC1962	N
			Nasal septal operation	23SEP2020	23SEP2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Transurethral prostatectomy	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1264 12641220	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
			Irritable bowel syndrome	01JAN2000		Y
		General disorders and administration site conditions	Drug intolerance	01JAN2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
			Lactose intolerance	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	24SEP2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2015		Y
		Skin and subcutaneous tissue disorders	Alopecia	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2001		Y
		Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 1264 12641222	Musculoskeletal and connective tissue disorders	Myalgia	01JAN2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1963		Y
	C4591001 1264 12641223	Cardiac disorders	Supraventricular tachycardia	01JAN1975		Y
		Eye disorders	Dry eye	01JAN2010		Y
		Immune system disorders	Drug hypersensitivity	01JAN1989		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2016		Y
		Nervous system disorders	Neuralgia	01JAN2016		Y
		Psychiatric disorders	Depression	01JAN2000	31DEC2018	N
			Insomnia	01JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Foot operation	01JAN1989	31DEC1989	N
	C4591001 1264 12641224	General disorders and administration site conditions	Drug intolerance	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
			Seasonal allergy	01JAN2000		Y
		Investigations	Blood triglycerides increased	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Spondylitis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2010		Y
		Surgical and medical procedures	Ankle operation	01JAN2005	31DEC2005	N
			Vasectomy	01JAN2015		Y
	C4591001 1264 12641229	Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	01JAN2010		Y
		Surgical and medical procedures	Ligament operation	01JAN1990	31DEC1990	N
			Meniscus operation	01JAN1990	31DEC1990	N
				01JAN2016	31DEC2016	N
			Vasectomy	01JAN1991	31DEC1991	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1264 12641230	Nervous system disorders	Neuropathy peripheral	01JAN2006		Y
		Psychiatric disorders	Depression	01JAN2012		Y
		Reproductive system and breast disorders	Erectile dysfunction	01JAN2013		Y
		Surgical and medical procedures	Vasectomy	01JAN1989	31DEC1989	N
	C4591001 1265 12651001	Eye disorders	Cataract	16APR2019	29MAY2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	04DEC2009		Y
		Immune system disorders	Drug hypersensitivity	08DEC2007		Y
				17APR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				29SEP2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	27FEB2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	03APR2017		Y
			Prostate cancer	03JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2017		Y
		Skin and subcutaneous tissue disorders	Urticaria	04DEC2009		Y
		Surgical and medical procedures	Cataract operation	29MAY2019	29MAY2019	N
		Vascular disorders	Hypertension	04DEC2009		Y
	C4591001 1265 12651002	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	26FEB2016	26FEB2016	N
			Melanocytic naevus	06DEC2018		Y
		Nervous system disorders	Morton's neuralgia	26OCT2016		Y
		Vascular disorders	Hypertension	06DEC2018		Y
	C4591001 1265 12651005	Infections and infestations	Rhinitis	06JAN2003		Y
		Injury, poisoning and procedural complications	Femoral neck fracture	02JUN2018	11FEB2020	N
			Post procedural hypothyroidism	10FEB2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	04APR2013		Y
		Musculoskeletal and connective tissue disorders	Muscular weakness	18NOV2017		Y
			Osteoporosis	10DEC2006		Y
			Synovial cyst	25SEP2015	03DEC2015	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	25FEB2013		Y
		Nervous system disorders	Dizziness	10APR2018		Y
			Hemiplegic migraine	04MAR2003		Y
			Ischaemic stroke	18NOV2017	18NOV2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lacunar stroke	01APR2013	01APR2013	N
		Psychiatric disorders	Major depression	20JAN2006		Y
		Surgical and medical procedures	Chondroplasty	03DEC2015	03DEC2015	N
			Hip arthroplasty	02JUN2018	02JUN2018	N
				11FEB2020	11FEB2020	N
			Thyroidectomy	27DEC2016	27DEC2016	N
		Vascular disorders	Hypertension	17SEP2015		Y
			Varicose vein	30MAR2018		Y
	C4591001 1265 12651008	Blood and lymphatic system disorders	Iron deficiency anaemia	31AUG2007		Y
		Hepatobiliary disorders	Cholecystitis	16FEB2002	10FEB2003	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	29JUN2017	29JUN2017	N
			Malignant melanoma in situ	01JAN1996	31DEC1996	N
			Ovarian germ cell teratoma benign	01JAN1994	31DEC1994	N
		Nervous system disorders	Migraine	01JAN1999		Y
		Psychiatric disorders	Generalised anxiety disorder	12AUG2014		Y
		Reproductive system and breast disorders	Menorrhagia	01JAN2006	05MAY2006	N
		Surgical and medical procedures	Abdominoplasty	01MAY2003	31MAY2003	N
			Appendectomy	01JAN1995	31DEC1995	N
			Cholecystectomy	10FEB2003	10FEB2003	N
			Endometrial ablation	01APR2006	30APR2006	N
				05MAY2006	05MAY2006	N
			Female sterilisation	01JAN1999	31DEC1999	N
			Mammoplasty	01MAY2003	31MAY2003	N
			Metabolic surgery	03DEC2001	03DEC2001	N
			Oophorectomy	01JAN1994	31DEC1994	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651011	Endocrine disorders	Hypothyroidism	18DEC2007		Y
		Immune system disorders	Drug hypersensitivity	06JUL2005		Y
		Investigations	Hysteroscopy	14JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	01AUG2005	31AUG2005	N
		Respiratory, thoracic and mediastinal disorders	Asthma	11NOV2010		Y
		Vascular disorders	Hypertension	18DEC2007		Y
	C4591001 1265 12651012	Gastrointestinal disorders	Diverticulum intestinal	10SEP2004		Y
			Gastroesophageal reflux disease	25MAY2017		Y
			Haemorrhoids	01FEB2010		Y
		Immune system disorders	Drug hypersensitivity	10JUL2008		Y
				10OCT2001		Y
				17DEC2009		Y
		Investigations	Biopsy colon	15JAN2019	15JAN2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	30JUL2020		Y
			Hyperlipidaemia	09MAY2007		Y
			Obesity	03SEP2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15OCT2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	16JAN2019		Y
		Renal and urinary disorders	Chronic kidney disease	14DEC2017		Y
		Surgical and medical procedures	Knee arthroplasty	13AUG2018	13AUG2018	N
				19FEB2018	19FEB2018	N
			Shoulder operation	26NOV2019	26NOV2019	N
			Skin neoplasm excision	01JAN2015	31JAN2015	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Aortic aneurysm	15JAN2018		Y
			Aortic arteriosclerosis	11SEP2017		Y
			Essential hypertension	14JUN2006		Y
			Peripheral artery aneurysm	13JAN2018		Y
	C4591001 1265 12651014	Endocrine disorders	Hypothyroidism	28NOV2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	01JAN2017	14JUL2017	N
		Reproductive system and breast disorders	Ovarian cyst	03APR2009		Y
		Social circumstances	Postmenopause	01AUG2011		Y
		Surgical and medical procedures	Caesarean section	01JAN1993	31DEC1993	N
				01JAN2000	31DEC2000	N
			Polypectomy	14JUL2017	14JUL2017	N
	C4591001 1265 12651015	Immune system disorders	Drug hypersensitivity	06NOV2014		Y
			Rubber sensitivity	06NOV2014		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	17DEC2015		Y
		Nervous system disorders	Carotid arteriosclerosis	10JUL2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	06NOV2014		Y
			Sleep apnoea syndrome	10JUL2015		Y
		Surgical and medical procedures	Urinary incontinence surgery	01JAN2012	31DEC2012	N
	C4591001 1265 12651018	Blood and lymphatic system disorders	Iron deficiency anaemia	08SEP2006		Y
		Ear and labyrinth disorders	Deafness neurosensory	12SEP2012		Y
		Eye disorders	Vitreous detachment	25NOV2015		Y
		Immune system disorders	Drug hypersensitivity	09DEC2005		Y
		Infections and infestations	Rhinitis	17AUG2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	19NOV2008		Y
		Reproductive system and breast disorders	Fibrocystic breast disease	17DEC2014		Y
		Surgical and medical procedures	Abdominal panniculectomy	21JUN2006	21JUN2006	N
			Appendicectomy	01JAN1982	31DEC1982	N
			Gastric bypass	01JAN2002	31DEC2002	N
				18APR2010	18APR2010	N
				19MAR2010	19MAR2010	N
				19MAR2010	19MAR2010	N
				25NOV2015	25NOV2015	N
				19APR2016		Y
	C4591001 1265 12651019	Blood and lymphatic system disorders	Anaemia macrocytic	19APR2016		Y
		Ear and labyrinth disorders	Deafness neurosensory	10OCT2014		Y
		Eye disorders	Cataract	29MAY2019		Y
			Myopia	29MAY2019		Y
		Infections and infestations	Poliomyelitis	01JAN1947	31DEC1947	N
		Metabolism and nutrition disorders	Hyperlipidaemia	15NOV2004		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	10OCT2014		Y
			Osteoporosis	07AUG2019		Y
			Spondyloarthropathy	27JAN2014		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	10JUN2003		Y
		Psychiatric disorders	Major depression	10MAR2005		Y
		Surgical and medical procedures	Spinal laminectomy	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1945	31DEC1945	N
			Tracheostomy	01JAN1947	31DEC1947	N
		Vascular disorders	Aortic arteriosclerosis	27JAN2014		Y
			Essential hypertension	15NOV2004		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651023	Endocrine disorders	Thyroiditis	28JAN2004	31DEC2004	N
		Eye disorders	Cataract nuclear	20NOV2017		Y
			Glaucoma	20NOV2017		Y
		Gastrointestinal disorders	Large intestine polyp	17SEP2018		Y
		Infections and infestations	Varicella	11SEP1992	30SEP1992	N
		Metabolism and nutrition disorders	Hyperlipidaemia	02OCT2017		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	26JAN2005		Y
	C4591001 1265 12651026	Gastrointestinal disorders	Constipation	01MAY2019		Y
		Immune system disorders	Drug hypersensitivity	21DEC2016		Y
				31OCT2003		Y
			Food allergy	28MAR2007		Y
		Investigations	Biopsy	01OCT2003	31OCT2003	N
			Cystoscopy	20MAY2019	20MAY2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	22NOV2004		Y
			Overweight	02DEC2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fallopian tube cancer	01OCT2002	31DEC2003	N
			Ovarian cancer	01OCT2002	31OCT2003	N
		Nervous system disorders	Carpal tunnel syndrome	24JAN2020		Y
		Renal and urinary disorders	Stress urinary incontinence	04SEP2013		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	22JAN2013		Y
		Surgical and medical procedures	Benign breast lump removal	01JAN1978	31DEC1978	N
			Carpal tunnel decompression	20FEB2020	20FEB2020	N
			Colporrhaphy	20MAY2019	20MAY2019	N
			Hysterosalpingo-oophorectomy	01OCT2002	31OCT2002	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Lipoma excision	25MAR2013	25MAR2013	N
			Urinary bladder suspension	20MAY2019	20MAY2019	N
		Vascular disorders	Hypertension	04FEB2011		Y
	C4591001 1265 12651033	Eye disorders	Cataract	01FEB2012		Y
			Macular fibrosis	23JUN2014		Y
			Retinal tear	17FEB2016	17FEB2016	N
		Immune system disorders	Drug hypersensitivity	09JUL2008		Y
		Nervous system disorders	Essential tremor	15NOV2012		Y
		Psychiatric disorders	Insomnia	13OCT2010		Y
		Surgical and medical procedures	Cataract operation	03JUL2014	03JUL2014	N
			Retinopexy	17FEB2016	17FEB2016	N
	C4591001 1265 12651034	Congenital, familial and genetic disorders	Type V hyperlipidaemia	30NOV2016		Y
		Eye disorders	Blepharitis	07NOV2012		Y
		Infections and infestations	Conjunctivitis	22FEB2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	30NOV2016		Y
		Psychiatric disorders	Anxiety disorder	06OCT2004		Y
		Skin and subcutaneous tissue disorders	Rosacea	22FEB2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	25AUG2019		Y
	C4591001 1265 12651038	Infections and infestations	Papilloma viral infection	20JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	17APR2000		Y
			Obesity	19JAN2018		Y
		Reproductive system and breast disorders	Atrophic vulvovaginitis	20JAN2017		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2012	31DEC2012	N
			Lipoma excision	01JAN2014	31DEC2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	20JAN2017		Y
	C4591001 1265 12651039	Gastrointestinal disorders	Large intestine polyp	12JAN2011		Y
		Hepatobiliary disorders	Hepatic steatosis	01OCT2019		Y
		Investigations	Arthroscopy	08SEP2004	08SEP2004	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	30MAY2017		Y
			Hyperlipidaemia	29DEC2015		Y
		Musculoskeletal and connective tissue disorders	Bursitis	05DEC2015		Y
				17MAY2018		Y
			Osteoarthritis	19AUG2004		Y
				23MAY2018		Y
			Trigger finger	17MAY2018		Y
		Nervous system disorders	Ischaemic stroke	03DEC2015	03DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	29DEC2015		Y
		Surgical and medical procedures	Appendectomy	01APR2014	01APR2014	N
			Umbilical hernia repair	01APR2014	01APR2014	N
		Vascular disorders	Hypertension	03DEC2015		Y
	C4591001 1265 12651045	Musculoskeletal and connective tissue disorders	Osteoarthritis	14MAR2017		Y
		Surgical and medical procedures	Hip arthroplasty	01JAN2008	31DEC2008	N
			Large intestinal polypectomy	11FEB2020	11FEB2020	N
	C4591001 1265 12651046	Immune system disorders	Drug hypersensitivity	18MAY2005		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01OCT2015		Y
	C4591001 1265 12651048	Endocrine disorders	Hypothyroidism	11MAR2015		Y
		Gastrointestinal disorders	Diverticulum intestinal	11MAR2015		Y
		Infections and infestations	Helicobacter infection	01JAN1990	31DEC1990	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	12MAR2015		Y
			Hyperlipidaemia	12MAR2015		Y
			Hypertriglyceridaemia	29JAN2019		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	11MAR2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	11MAR2015		Y
		Renal and urinary disorders	Hydronephrosis	05JUL2015	20OCT2017	N
			Nephrolithiasis	01JAN1980	31DEC1980	N
		Reproductive system and breast disorders	Breast cyst	07APR2015		Y
			Uterine polyp	01JAN2013	31DEC2013	N
		Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	17FEB2016		Y
		Surgical and medical procedures	Bunion operation	01JAN2012	31DEC2012	N
			Caesarean section	01JAN1989	31DEC1989	N
			Cholecystectomy	30SEP2015	30SEP2015	N
			Endometrial ablation	01JAN2013	31DEC2013	N
	C4591001 1265 12651050	Ear and labyrinth disorders	Deafness neurosensory	26JAN2020		Y
			Mixed deafness	26JAN2020		Y
		Immune system disorders	Drug hypersensitivity	06JUN2007		Y
		Infections and infestations	Varicella	21JUL2000	31DEC2000	N
		Metabolism and nutrition disorders	Dyslipidaemia	26JAN2020		Y
			Vitamin D deficiency	26JAN2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06APR2016		Y
		Respiratory, thoracic and mediastinal disorders	Vocal cord leukoplakia	26JAN2020		Y
		Surgical and medical procedures	Cataract operation	30AUG2016	30AUG2016	N
			Intraocular lens implant	01SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Large intestinal polypectomy	12OCT2015	12OCT2015	N
				13MAY2010	13MAY2010	N
	C4591001 1265 12651051	Gastrointestinal disorders	Diverticulum intestinal	23APR2016		Y
			Gastroesophageal reflux disease	20AUG2020		Y
		Immune system disorders	Drug hypersensitivity	15OCT2016		Y
				20AUG2014		Y
		Metabolism and nutrition disorders	Obesity	15OCT2016		Y
			Vitamin D deficiency	15OCT2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	20AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	12JUL2016	31DEC2016	N
		Nervous system disorders	Migraine	20AUG2020		Y
		Surgical and medical procedures	Gastric bypass	01JAN2009	31DEC2009	N
	C4591001 1265 12651052	Metabolism and nutrition disorders	Glucose tolerance impaired	18DEC2013	16FEB2017	N
			Hyperlipidaemia	18DEC2013		Y
			Obesity	23APR2012		Y
			Type 2 diabetes mellitus	16FEB2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	10MAR2016	10MAR2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	15SEP2019		Y
		Surgical and medical procedures	Polypectomy	10MAR2016	10MAR2016	N
		Vascular disorders	Essential hypertension	23APR2012		Y
	C4591001 1265 12651054	Endocrine disorders	Hyperparathyroidism	18JUL2003	31MAY2018	N
			Hypothyroidism	15OCT2004		Y
		Eye disorders	Vitreous detachment	07AUG2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Chronic sinusitis	09APR2003	31DEC2003	N
			Rhinitis	27JUN2008		Y
			Varicella	13JAN1993	31DEC1993	N
		Musculoskeletal and connective tissue disorders	Arthropathy	15SEP2017		Y
			Osteoarthritis	07OCT2005		Y
			Osteoporosis	25AUG2006		Y
		Reproductive system and breast disorders	Cervical polyp	06JAN2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	10JAN2020		Y
		Surgical and medical procedures	Parathyroidectomy	31MAY2018	31MAY2018	N
	C4591001 1265 12651056	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAY2018	29JUN2018	N
		Skin and subcutaneous tissue disorders	Eczema	24APR2018		Y
		Surgical and medical procedures	Skin neoplasm excision	29JUN2018	29JUN2018	N
	C4591001 1265 12651057	Cardiac disorders	Acute myocardial infarction	06MAY2012	06MAY2012	N
			Coronary artery disease	06MAY2012		Y
		Gastrointestinal disorders	Diverticulum intestinal	02FEB2012		Y
		Immune system disorders	Drug hypersensitivity	20AUG2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	18MAY2016		Y
			Hyperlipidaemia	05MAY2012		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	04MAY2012		Y
		Surgical and medical procedures	Coronary arterial stent insertion	06MAY2012	06MAY2012	N
			Tonsillectomy	01JAN1970	31DEC1970	N
		Vascular disorders	Hypertension	05MAY2012		Y
	C4591001 1265 12651068	Cardiac disorders	Aortic valve incompetence	19JUL2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Ear and labyrinth disorders	Tinnitus	01JAN1993		Y
		Endocrine disorders	Hypothyroidism	30JAN2006		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	20JAN2014		Y
			Hyperlipidaemia	16NOV2007		Y
			Obesity	09FEB2007		Y
		Musculoskeletal and connective tissue disorders	Bursitis	09JAN2003		Y
		Psychiatric disorders	Anxiety disorder	26JUN2006		Y
			Breathing-related sleep disorder	08JUL2011		Y
			Major depression	17OCT2018		Y
			Panic disorder	26JUN2006		Y
		Surgical and medical procedures	Large intestinal polypectomy	24JAN2018	24JAN2018	N
			Nervous system neoplasm surgery	29APR1990	29APR1990	N
	C4591001 1265 12651069	Immune system disorders	Drug hypersensitivity	13JUL2009		Y
		Metabolism and nutrition disorders	Overweight	16JAN2013		Y
		Surgical and medical procedures	Large intestinal polypectomy	27APR2018	27APR2018	N
	C4591001 1265 12651070	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	16JUL2020		Y
	C4591001 1265 12651071	Endocrine disorders	Hypothyroidism	31JAN2017		Y
		General disorders and administration site conditions	Fatigue	31JAN2017		Y
		Psychiatric disorders	Depression	11JAN2017		Y
		Social circumstances	Postmenopause	28SEP2016		Y
	C4591001 1265 12651074	Metabolism and nutrition disorders	Hyperlipidaemia	07DEC2015		Y
			Obesity	07DEC2015	31DEC2020	N
		Social circumstances	Postmenopause	01JAN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651080	Gastrointestinal disorders	Gastroesophageal reflux disease	06JUN2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02APR2013		Y
		Nervous system disorders	Cervical radiculopathy	06JUN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	05AUG2015		Y
		Surgical and medical procedures	Bunion operation	11JUL2017	11JUL2017	N
			Foot operation	19DEC2017	19DEC2017	N
	C4591001 1265 12651085	Congenital, familial and genetic disorders	Factor V Leiden mutation	17JUN2009		Y
		Infections and infestations	Varicella	04AUG2000	31DEC2000	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	18FEB2015		Y
			Hyperlipidaemia	18FEB2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01APR2005		Y
			Pulmonary embolism	04MAR2009	31DEC2009	N
	C4591001 1265 12651087	Cardiac disorders	Atrial fibrillation	15OCT2018		Y
		Endocrine disorders	Hypothyroidism	14NOV2008		Y
		Eye disorders	Cataract nuclear	29NOV2018		Y
			Conjunctivitis allergic	02JUN2015		Y
			Dry eye	02JUN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	30JUN2017		Y
			Hyperlipidaemia	26NOV2008		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	14JUN2017		Y
		Nervous system disorders	Essential tremor	15OCT2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	15OCT2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	02FEB2016		Y
			Chronic obstructive pulmonary disease	02FEB2016		Y
		Surgical and medical procedures	Large intestinal polypectomy	13NOV2019	13NOV2019	N
				28AUG2017	28AUG2017	N
	C4591001 1265 12651088	Ear and labyrinth disorders	Hypoacusis	20AUG2018		Y
			Mixed deafness	20AUG2018		Y
		Gastrointestinal disorders	Diverticulum	11DEC2017		Y
			Gastroesophageal reflux disease	29SEP2008		Y
			Hiatus hernia	19JAN2017		Y
			Small intestinal obstruction	17OCT2014	31DEC2014	N
		Immune system disorders	Drug hypersensitivity	08DEC2011		Y
				24NOV2009		Y
		Investigations	Biopsy lymph gland	01OCT2018	01OCT2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	19JAN2012		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	27OCT2005		Y
				29APR2009		Y
			Osteopenia	02NOV2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	28SEP2018	01OCT2018	N
		Nervous system disorders	Carpal tunnel syndrome	05SEP2006		Y
		Psychiatric disorders	Anxiety disorder	19OCT2018		Y
			Major depression	15NOV2018		Y
		Renal and urinary disorders	Stress urinary incontinence	01JUN2002	30JUN2002	N
		Respiratory, thoracic and mediastinal disorders	Asthma exercise induced	24APR2019		Y
			Rhinitis allergic	08AUG2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Sleep apnoea syndrome	29NOV2011		Y
		Surgical and medical procedures	Abdominal hernia repair	17OCT2014	17OCT2014	N
			Arthrodesis	04JAN2018	04JAN2018	N
			Bunion operation	15DEC2014	15DEC2014	N
			Large intestinal polypectomy	11DEC2017	11DEC2017	N
			Mastectomy	01OCT2018	01OCT2018	N
			Mastoidectomy	01JAN1973	31DEC1973	N
			Osteotomy	15DEC2014	15DEC2014	N
			Toe operation	15DEC2014	15DEC2014	N
			Urethral bulking agent injection	01JUN2006	30JUN2006	N
			Urinary bladder suspension	01JUN2002	30JUN2002	N
		Vascular disorders	Essential hypertension	07DEC2011		Y
	C4591001 1265 12651091	Immune system disorders	Drug hypersensitivity	28MAY2013		Y
				30OCT2017		Y
		Infections and infestations	Genital herpes simplex	03MAR2010	02NOV2017	N
			Oral herpes	02NOV2017		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	16DEC2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	07SEP2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm skin	07SEP2020		Y
		Psychiatric disorders	Anxiety disorder	20SEP2011		Y
			Insomnia	16DEC2009		Y
			Major depression	25JAN2018		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	05MAR2013		Y
				07DEC2011		Y
		Surgical and medical procedures	Bunion operation	01MAR2009	31MAR2009	N
			Carpal tunnel decompression	07DEC2011	07DEC2011	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				15JUN2012	15JUN2012	N
			Cataract operation	19SEP2018	19SEP2018	N
				22OCT2018	22OCT2018	N
			Hip arthroplasty	01JAN2001	31DEC2001	N
			Inguinal hernia repair	23APR2010	23APR2010	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
				01JAN2017	31DEC2017	N
			Mammoplasty	01JAN1990	31DEC1990	N
			Nasal septal operation	01JAN1990	31DEC1990	N
			Tonsillectomy	01JAN1980	31DEC1980	N
		Vascular disorders	Hypertension	02NOV2017		Y
	C4591001 1265 12651095	Endocrine disorders	Hypothyroidism	13MAY2010		Y
		Gastrointestinal disorders	Diarrhoea	16NOV2010		Y
		Immune system disorders	Drug hypersensitivity	14MAY2010		Y
		Injury, poisoning and procedural complications	Iliotibial band syndrome	16MAY2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	24SEP2018		Y
			Overweight	24SEP2018		Y
		Musculoskeletal and connective tissue disorders	Bursitis	16MAY2017		Y
			Tendonitis	11JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	22FEB2012	06JUN2012	N
		Psychiatric disorders	Anxiety	10OCT2016		Y
			Major depression	01NOV2019		Y
		Surgical and medical procedures	Adhesiolysis	01JAN1984	31DEC1984	N
			Anorectal operation	01JAN1984	31DEC1984	N
			Colectomy	01JAN1971	31DEC1971	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Colectomy total	01JAN1985	31DEC1985	N
			Explorative laparotomy	06JUN2012	06JUN2012	N
			Gastroenterostomy	07OCT2010	07OCT2010	N
			Hysterosalpingo-oophorectomy	06JUN2012	06JUN2012	N
			Mammoplasty	01JAN1980	31DEC1980	N
			Proctectomy	01JAN1984	31DEC1984	N
		Vascular disorders	Essential hypertension	30MAY2010		Y
	C4591001 1265 12651100	Musculoskeletal and connective tissue disorders	Arthralgia	13SEP2017		Y
		Psychiatric disorders	Anxiety disorder	20SEP2006		Y
		Renal and urinary disorders	Calculus urinary	20NOV2008	31DEC2008	N
		Vascular disorders	Essential hypertension	26APR2013		Y
	C4591001 1265 12651102	Cardiac disorders	Aortic valve stenosis	03MAY2016		Y
			Coronary artery disease	08JAN2018		Y
			Left ventricular hypertrophy	03MAY2016		Y
			Palpitations	12FEB2019		Y
		Congenital, familial and genetic disorders	Thalassaemia beta	22NOV2010		Y
			Type IIa hyperlipidaemia	03MAY2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	30OCT2012		Y
		Immune system disorders	Allergy to animal	01NOV2016		Y
		Investigations	Biopsy	16APR2013	16APR2013	N
		Nervous system disorders	Migraine	22NOV2010		Y
			Syncope	01SEP1994	30SEP1994	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07MAR2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	18NOV2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Purpura	03MAY2016		Y
		Surgical and medical procedures	Aortic valve replacement	15NOV2016	15NOV2016	N
			Appendicectomy	01JAN1968	31DEC1968	N
			Cancer surgery	01JAN2015	31DEC2015	N
			Coronary arterial stent insertion	16OCT2019	16OCT2019	N
			Inguinal hernia repair	06JAN2011	06JAN2011	N
		Vascular disorders	Aortic arteriosclerosis	15DEC2016		Y
			Essential hypertension	03MAY2016		Y
	C4591001 1265 12651103	Gastrointestinal disorders	Abdominal pain upper	01SEP2016		Y
		Vascular disorders	Hypertension	01SEP2016		Y
	C4591001 1265 12651105	Gastrointestinal disorders	Constipation	25OCT2015		Y
			Impaired gastric emptying	25OCT2015		Y
		General disorders and administration site conditions	Oedema peripheral	02SEP2014		Y
		Immune system disorders	Drug hypersensitivity	13JUN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26DEC2019		Y
			Vitamin D deficiency	16JUN2009		Y
		Musculoskeletal and connective tissue disorders	Fibromyalgia	04JAN2006		Y
			Osteoporosis	09SEP2014		Y
			Rheumatoid arthritis	16JAN2017		Y
	C4591001 1265 12651107	Metabolism and nutrition disorders	Hypercholesterolaemia	31AUG1999		Y
		Musculoskeletal and connective tissue disorders	Synovial cyst	15FEB2008		Y
			Trigger finger	26MAR2020	06AUG2020	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Salivary gland cancer	01JAN1980	31DEC1980	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Carpal tunnel syndrome	26MAR2020	06AUG2020	N
			Epilepsy	04AUG2020		Y
			Seizure	01JAN1970	31DEC1970	N
		Surgical and medical procedures	Carpal tunnel decompression	06AUG2020	06AUG2020	N
			Intervertebral disc operation	01JAN1984	31DEC1984	N
			Salivary gland resection	01JAN1980	31DEC1980	N
			Tendon sheath incision	06AUG2020	06AUG2020	N
	C4591001 1265 12651109	Musculoskeletal and connective tissue disorders	Scoliosis	10MAR2011		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	10MAR2011		Y
	C4591001 1265 12651112	Eye disorders	Refraction disorder	22JUN2006		Y
		Infections and infestations	Varicella	28AUG1991	31DEC1991	N
		Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	18JUL2020		Y
		Surgical and medical procedures	Cataract operation	01FEB2016	01FEB2016	N
				01JAN2015	31DEC2015	N
				21DEC2015	21DEC2015	N
		Vascular disorders	Hypertension	18JAN2016		Y
	C4591001 1265 12651113	Gastrointestinal disorders	Diverticulum intestinal	20APR2017		Y
			Haemorrhoids	20APR2017		Y
		Investigations	Arthroscopy	30OCT2019	30OCT2019	N
			Urogram	21APR2015	21APR2015	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	03OCT2019	30OCT2019	N
		Renal and urinary disorders	Nephrolithiasis	02JUL2015	31DEC2015	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	09AUG2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Inguinal hernia repair	01JAN2000	31DEC2000	N
			Rotator cuff repair	30OCT2019	30OCT2019	N
			Ureteral stent insertion	02JUL2015	02JUL2015	N
				21APR2015	21APR2015	N
			Ureteric calculus removal	02JUL2015	02JUL2015	N
	C4591001 1265 12651115	Endocrine disorders	Hypothyroidism	27JUN2003		Y
		Immune system disorders	Drug hypersensitivity	05APR2013		Y
				20JUN2001		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	17SEP2014		Y
			Hyperlipidaemia	25FEB2005		Y
			Obesity	25FEB2005		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	07SEP2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	04FEB2015	06DEC2018	N
	C4591001 1265 12651116	Metabolism and nutrition disorders	Hyperlipidaemia	11APR2014		Y
			Type 2 diabetes mellitus	16JAN2016		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	04APR2016		Y
			Trigger finger	29JUL2019		Y
	C4591001 1265 12651117	Endocrine disorders	Hypogonadism male	03FEB2009		Y
			Hypothyroidism	27JUN2019		Y
		Investigations	Apnoea test	06DEC2018		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	12OCT2012		Y
			Hyperlipidaemia	03FEB2009		Y
		Nervous system disorders	Lumbar radiculopathy	21MAY2014		Y
			Restless legs syndrome	03FEB2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	03FEB2009		Y
			Bronchitis chronic	02FEB2011		Y
		Surgical and medical procedures	Spinal laminectomy	21SEP2016	21SEP2016	N
		Vascular disorders	Essential hypertension	04OCT2012		Y
	C4591001 1265 12651118	Ear and labyrinth disorders	Deafness bilateral	15JAN2019		Y
		Eye disorders	Cataract	27OCT2016		Y
			Dermatochalasis	31AUG2018		Y
			Maculopathy	27OCT2016		Y
		General disorders and administration site conditions	Gait disturbance	05JAN2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	14JAN2019		Y
		Nervous system disorders	Seizure	07DEC2017	07DEC2017	N
		Surgical and medical procedures	Blepharoplasty	14DEC2018	14DEC2018	N
	C4591001 1265 12651119	Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2010	31JAN2020	N
			Type 2 diabetes mellitus	01JAN2020		Y
			Vitamin D deficiency	16DEC2009		Y
		Psychiatric disorders	Anxiety	12JAN2009		Y
			Major depression	26JUL2014		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	28MAR2007		Y
			Prostatic dysplasia	19JUN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20NOV2019		Y
			Rhinitis allergic	19DEC2009		Y
			Sleep apnoea syndrome	30JUN2010		Y
		Vascular disorders	Essential hypertension	02MAR2006		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651120	Gastrointestinal disorders	Haemorrhoids	07APR2016		Y
		Investigations	Colonoscopy	06NOV2012	06NOV2012	N
		Musculoskeletal and connective tissue disorders	Osteopenia	18MAY2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	17JUN2013		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	10JAN2011		Y
			Lichen sclerosus	02MAR2016		Y
		Surgical and medical procedures	Blepharoplasty	07MAY2012	07MAY2012	N
	C4591001 1265 12651121	Eye disorders	Myopia	28JAN2011		Y
			Strabismus	27DEC2010		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	12JAN2009		Y
		Immune system disorders	Allergy to vaccine	07JUN2007		Y
			Drug hypersensitivity	20SEP2007		Y
		Injury, poisoning and procedural complications		29JAN2004		Y
			Ankle fracture	11SEP2019	31DEC2019	N
			Fibula fracture	25SEP2018	31DEC2018	N
			Superficial injury of eye	23AUG2020	30SEP2020	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	29DEC2016		Y
			Hyperlipidaemia	30DEC2016		Y
			Vitamin D deficiency	26NOV2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	17SEP2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	08APR2010		Y
			Rhinitis allergic	21AUG2007		Y
		Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JAN1997	31DEC1997	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Large intestinal polypectomy	15JAN2020	15JAN2020	N
			Myringotomy	21FEB2008	21FEB2008	N
				29JUN2018	29JUN2018	N
			Nasal septal operation	01JAN1977	31DEC1977	N
			Open reduction of fracture	16SEP2019	16SEP2019	N
	C4591001 1265 12651122	Cardiac disorders	Atrial fibrillation	27FEB2019		Y
			Chronic left ventricular failure	01JUL2015		Y
		Eye disorders	Cataract	22SEP2015		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	27FEB2019		Y
		Immune system disorders	Drug hypersensitivity	06SEP2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	13JUN2016		Y
			Hyperlipidaemia	27FEB2019		Y
			Obesity	21JUL2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of skin	21JUL2015	31DEC2015	N
		Nervous system disorders	Restless legs syndrome	27FEB2019		Y
		Psychiatric disorders	Alcoholism	21SEP2015	31DEC2017	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	23SEP2019		Y
		Surgical and medical procedures	Large intestinal polypectomy	11APR2017	11APR2017	N
		Vascular disorders	Hypertension	27FEB2019		Y
	C4591001 1265 12651123	General disorders and administration site conditions	Oedema peripheral	12JUL2018		Y
		Metabolism and nutrition disorders	Obesity	30JAN2020		Y
			Type 2 diabetes mellitus	26MAR2013		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	20JAN2006		Y
		Nervous system disorders	Amnesia	02JUN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Intraocular lens implant	15AUG2017	15AUG2017	N
				26SEP2017	26SEP2017	N
		Vascular disorders	Essential hypertension	08SEP2006		Y
	C4591001 1265 12651125	Cardiac disorders	Mitral valve incompetence	03MAR2015		Y
			Mitral valve prolapse	03MAR2015		Y
		Eye disorders	Cataract	09JAN2018		Y
			Eyelid cyst	09JAN2018	17JAN2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	10JUN2003		Y
		Immune system disorders	Drug hypersensitivity	08OCT2009		Y
		Infections and infestations	Urinary tract infection	12JUN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	12MAR2008		Y
			Osteopenia	31MAY2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	05JUL2005		Y
		Nervous system disorders	Migraine	02JUN2003		Y
		Renal and urinary disorders	Nephrolithiasis	08NOV2012	31DEC2012	N
			Renal disorder	16SEP2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	07DEC2009		Y
		Respiratory, thoracic and mediastinal disorders	Dyspnoea	01JAN2019	31DEC2019	N
			Rhinitis allergic	08SEP2010		Y
		Skin and subcutaneous tissue disorders	Dermal cyst	01JUL2019		Y
			Drug eruption	21JAN2004		Y
		Surgical and medical procedures	Lithotripsy	17JAN2012	17JAN2012	N
			Ureteral stent insertion	05JAN2012	05JAN2012	N
		Vascular disorders	Aortic arteriosclerosis	02APR2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spider vein	27MAR2020		Y
	C4591001 1265 12651127	Metabolism and nutrition disorders	Obesity	26APR2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	21FEB2019		Y
			Rotator cuff syndrome	28JAN2020		Y
				29JAN2020		Y
		Skin and subcutaneous tissue disorders	Drug eruption	28FEB2018		Y
			Eczema	26APR2019		Y
		Surgical and medical procedures	Rotator cuff repair	05MAR2020	05MAR2020	N
			Tenodesis	05MAR2020	05MAR2020	N
		Vascular disorders	Hypertension	28JAN2019		Y
	C4591001 1265 12651129	Blood and lymphatic system disorders	Anaemia	18OCT2016		Y
		Eye disorders	Glaucoma	16MAY2017		Y
			Vitreous floaters	16MAY2017		Y
		Gastrointestinal disorders	Diverticulum intestinal	03MAR2015		Y
			Gastroesophageal reflux disease	14DEC2005		Y
			Rectal haemorrhage	21DEC2015		Y
		Investigations	Biopsy lymph gland	13MAY2019	13MAY2019	N
			Colonoscopy	16FEB2015	16FEB2015	N
		Metabolism and nutrition disorders	Hyperlipidaemia	21MAR2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	26NOV2011		Y
			Enthesopathy	01SEP2004		Y
			Osteoporosis	01DEC2011		Y
			Scoliosis	04JAN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	05APR2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Nervous system disorders	Cerebrovascular accident	28MAY2004		Y
			Seizure	22JAN2004		Y
		Psychiatric disorders	Bipolar II disorder	24AUG2006		Y
		Surgical and medical procedures	Bunion operation	03AUG2015	03AUG2015	N
				06JUN2016	06JUN2016	N
			Gastric bypass	01JAN2009	31DEC2009	N
				26NOV2011		Y
			Postoperative care	05JUL2013		Y
			Rhinoplasty	01JAN1980	31DEC1980	N
			Simple mastectomy	13MAY2019	13MAY2019	N
			Foot fracture	19APR2017		Y
	C4591001 1265 12651130	Injury, poisoning and procedural complications				
		Metabolism and nutrition disorders	Obesity	06FEB2015		Y
		Renal and urinary disorders	Chronic kidney disease	27JUL2014		Y
		Social circumstances	Postmenopause	01JAN2015		Y
	C4591001 1265 12651131	Gastrointestinal disorders	Gastroesophageal reflux disease	23JAN2006		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	25AUG2015		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	01MAR2018		Y
				13JUL2018		Y
			Metatarsalgia	01MAR2018		Y
			Pain in extremity	01MAR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	22NOV2016	22NOV2016	N
		Nervous system disorders	Migraine	01OCT2004		Y
		Surgical and medical procedures	Arthrodesis	13JUL2018	13JUL2018	N
			Bunion operation	13JUL2018	13JUL2018	N
			Osteotomy	13JUL2018	13JUL2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Varicose vein	13JUN2011		Y
	C4591001 1265 12651132	Gastrointestinal disorders	Gastroesophageal reflux disease	21JUL2016		Y
			Pharyngo-oesophageal diverticulum	21JUL2016		Y
			Small intestinal obstruction	15DEC2017		Y
				29MAR2019		Y
		Investigations	Colonoscopy	21FEB2014		Y
					21FEB2014	N
		Psychiatric disorders	Generalised anxiety disorder	05APR2019		Y
			Insomnia	05APR2019		Y
			Major depression	21OCT2005		Y
			Social anxiety disorder	05APR2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	20NOV2018		Y
		Social circumstances	Personal relationship issue	05APR2019		Y
		Surgical and medical procedures	Cholecystectomy	12DEC2014	12DEC2014	N
			Ligament operation	01JAN1991	31DEC1991	N
			Pharyngeal operation	11OCT2016	11OCT2016	N
		Vascular disorders	Hypertension	20NOV2018		Y
	C4591001 1265 12651133	Blood and lymphatic system disorders	Leukopenia	03DEC2019		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	29NOV2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	19NOV2013		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	19NOV2013		Y
		Surgical and medical procedures	Inguinal hernia repair	01JAN2013	31DEC2013	N
			Meniscus removal	01JAN2013	31DEC2013	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651135	Cardiac disorders	Palpitations	16APR2008		Y
		Immune system disorders	Drug hypersensitivity	02NOV2012		Y
		Infections and infestations	Herpes simplex	27SEP2016		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	17APR2007		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	22JAN2016		Y
		Surgical and medical procedures	Open reduction of fracture	02NOV2012	02NOV2012	N
			Scrotal operation	22JUL2004	22JUL2004	N
	C4591001 1265 12651137	Psychiatric disorders	Major depression	20AUG2018	31DEC2018	N
	C4591001 1265 12651140	Cardiac disorders	Tachycardia paroxysmal	30MAR2020		Y
		Gastrointestinal disorders	Inguinal hernia	27SEP2012		Y
		Immune system disorders	Drug hypersensitivity	12MAR2018		Y
		Injury, poisoning and procedural complications	Cervical vertebral fracture	06MAR2018	31DEC2018	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01APR2014		Y
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	20JUN2006	29APR2008	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	05FEB2018	19FEB2020	N
		Nervous system disorders	Spondylitic myelopathy	19FEB2020		Y
		Renal and urinary disorders	Renal cyst	23NOV2015		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1968	31DEC1968	N
			Transurethral prostatectomy	07AUG2009	07AUG2009	N
		Vascular disorders	Essential hypertension	20JUN2006		Y
	C4591001 1265 12651141	Eye disorders	Dry eye	31OCT2012		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Glaucoma	17NOV2011		Y
		Hepatobiliary disorders	Hepatic steatosis	29MAY2014		Y
		Investigations	Blood bilirubin increased	15APR2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	20JUL2014		Y
			Hyperlipidaemia	01FEB2008		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01FEB2008		Y
		Nervous system disorders	Carpal tunnel syndrome	02JUL2004		Y
		Psychiatric disorders	Depression	10JAN2007		Y
			Insomnia	20MAY2009		Y
		Surgical and medical procedures	Intraocular lens implant	31OCT2012		Y
		Vascular disorders	Aortic arteriosclerosis	29MAY2014		Y
			Hypertension	16SEP2014		Y
	C4591001 1265 12651150†	Cardiac disorders	Aortic valve stenosis	24JAN2019		Y
		Endocrine disorders	Basedow's disease	01JAN2001	31DEC2001	N
		Eye disorders	Endocrine ophthalmopathy	24MAY2012		Y
			Optic atrophy	29NOV2017		Y
			Uveitis	29NOV2017		Y
		Gastrointestinal disorders	Anogenital dysplasia	03SEP2014		Y
		Immune system disorders	Drug hypersensitivity	15MAY2012		Y
				24MAY2012		Y
		Infections and infestations	Cytomegalovirus infection	01JAN1990	31DEC1990	N
			Pneumocystis jirovecii pneumonia	01JAN1990	31DEC1990	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	15MAY2012		Y
		Investigations	HIV test positive	01JAN1989		Y
			Proctoscopy	20AUG2014	20AUG2014	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	03FEB2020		Y
			Osteopenia	21MAY2013	07FEB2020	N
			Osteoporosis	07FEB2020		Y
		Nervous system disorders	Myasthenia gravis	29AUG2012		Y
		Surgical and medical procedures	Orbital decompression	01JAN1996	31DEC1996	N
		Vascular disorders	Hypertension	22MAY2012		Y
	C4591001 1265 12651152	General disorders and administration site conditions	Complication associated with device	06FEB2019		Y
		Immune system disorders	Drug hypersensitivity	09MAR2017		Y
		Injury, poisoning and procedural complications	Joint dislocation	25OCT2018		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	25OCT2018		Y
			Osteopenia	09MAR2017		Y
			Osteoporosis	01JUL2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	25FEB2015		Y
		Psychiatric disorders	Major depression	21FEB2017		Y
		Surgical and medical procedures	Bunion operation	15JAN2019	15JAN2019	N
			Cholecystectomy	01JAN1995	31DEC1995	N
			Joint arthroplasty	15JAN2019	15JAN2019	N
			Laparotomy	01JAN1983	31DEC1983	N
			Open reduction of fracture	11FEB2019	11FEB2019	N
			Toe operation	11FEB2019	11FEB2019	N
	C4591001 1265 12651154	Congenital, familial and genetic disorders	Type V hyperlipidaemia	12FEB2008		Y
		Eye disorders	Cataract nuclear	20OCT2019		Y
			Refraction disorder	22OCT2019		Y
		Metabolism and nutrition disorders	Hyperglycaemia	23DEC2012		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	23DEC2012		Y
			Type 2 diabetes mellitus	26DEC2012		Y
		Vascular disorders	Essential hypertension	19NOV2004		Y
	C4591001 1265 12651156	Congenital, familial and genetic disorders	Ectrodactyly	30JUN2017		Y
		Infections and infestations	Syphilis	16AUG2019	31DEC2019	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	04JUN2017		Y
		Musculoskeletal and connective tissue disorders	Myalgia	08NOV2018		Y
		Nervous system disorders	Cervical radiculopathy	19MAY2017		Y
			Nerve compression	30JUN2017	12OCT2017	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01AUG2019		Y
			Pulmonary mass	19MAY2017		Y
		Skin and subcutaneous tissue disorders	Dandruff	29DEC2017		Y
		Surgical and medical procedures	Peripheral nerve decompression	04NOV2015	04NOV2015	N
			Tendon transfer	12OCT2017	12OCT2017	N
		Vascular disorders	Aortic arteriosclerosis	08SEP2020		Y
	C4591001 1265 12651157	General disorders and administration site conditions	Treatment noncompliance	26NOV2018		Y
		Metabolism and nutrition disorders	Hyperglycaemia	23OCT2017		Y
			Hyperlipidaemia	07JUN2016		Y
			Obesity	20MAY2016		Y
			Type 2 diabetes mellitus	23OCT2017		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
		Vascular disorders	Hypertension	20MAY2016		Y
	C4591001 1265 12651158	Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	09AUG2016		Y
		Infections and infestations	Herpes zoster	26AUG2013	31DEC2013	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	13DEC2017		Y
			Hyperlipidaemia	02JUN2006		Y
		Renal and urinary disorders	Nephrolithiasis	05SEP2013		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	05NOV2003		Y
		Surgical and medical procedures	Lithotripsy	31MAR2017	31MAR2017	N
			Umbilical hernia repair	09OCT2015	09OCT2015	N
			Ureteral stent insertion	31MAR2017	31MAR2017	N
	C4591001 1265 12651160	Investigations	Biopsy colon	14NOV2017	14NOV2017	N
			Colonoscopy	14NOV2017	14NOV2017	N
			Sigmoidoscopy	01NOV2001	30NOV2001	N
			Tuberculin test positive	10APR2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12JUL2007		Y
			Hyperuricaemia	23JUN2020		Y
			Obesity	29OCT2005		Y
			Type 2 diabetes mellitus	13NOV2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	23JUN2020		Y
		Reproductive system and breast disorders	Gynaecomastia	01MAR2007		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	07MAY2012		Y
			Sleep apnoea syndrome	06AUG2012		Y
		Vascular disorders	Aortic dilatation	18APR2016		Y
			Essential hypertension	23JAN2006		Y
	C4591001 1265 12651163	Gastrointestinal disorders	Large intestine polyp	28NOV2018		Y
		Investigations	Colonoscopy	05DEC2018	05DEC2018	N
			Ureteroscopy	13JUL2012	13JUL2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Gout	17APR2006		Y
			Hyperlipidaemia	17APR2006		Y
			Type 2 diabetes mellitus	28NOV2018		Y
		Reproductive system and breast disorders	Organic erectile dysfunction	28DEC2010		Y
		Surgical and medical procedures	Lithotripsy	13JUL2012	13JUL2012	N
			Nephrectomy	06AUG2012	06AUG2012	N
				09AUG2016		Y
			Ureteral stent insertion	06AUG2012	06AUG2012	N
				13JUL2012	13JUL2012	N
		Vascular disorders	Aortic arteriosclerosis	28NOV2018		Y
			Essential hypertension	17APR2006		Y
	C4591001 1265 12651169	Endocrine disorders	Hypothyroidism	07FEB2019		Y
		Immune system disorders	Drug hypersensitivity	04FEB2019		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	09MAR2019		Y
			Hyperlipidaemia	09MAR2019		Y
			Obesity	08FEB2019		Y
		Psychiatric disorders	Anxiety	08FEB2019		Y
		Social circumstances	Postmenopause	01JAN2017		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2009	31DEC2009	N
	C4591001 1265 12651171	Blood and lymphatic system disorders	Pancytopenia	05NOV2012		Y
			Thrombocytopenia	09APR2016		Y
		Immune system disorders	Drug hypersensitivity	02APR2010		Y
				26JAN2010		Y
		Investigations	Cardiac stress test	31JUL2009	31JUL2009	N
			Colonoscopy	18MAR2010	18MAR2010	N
				21APR2003	21APR2003	N

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Echocardiogram	20JUN2008	20JUN2008	N
				30MAR2010	30MAR2010	N
			Magnetic resonance imaging joint	31OCT2007	31OCT2007	N
			Scan myocardial perfusion	18OCT2000	18OCT2000	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	25MAY2017		Y
			Hyperlipidaemia	28APR2009		Y
		Social circumstances	Disease risk factor	16JUN2016		Y
		Surgical and medical procedures	Cardiac ablation	01SEP2009	01SEP2009	N
				14OCT2012		Y
			Inguinal hernia repair	01JAN1997	31DEC1997	N
			Tonsillectomy	03MAR2009	03MAR2009	N
	C4591001 1265 12651172	Immune system disorders	Drug hypersensitivity	15APR2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	13JAN2017		Y
			Obesity	22MAR2011		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	22SEP2014		Y
		Social circumstances	Postmenopause	01JAN2017		Y
	C4591001 1265 12651176	Gastrointestinal disorders	Large intestine polyp	04MAY2013		Y
		Investigations	Biopsy soft tissue	13SEP2016	13SEP2016	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	05OCT2017		Y
		Social circumstances	Postmenopause	01JAN2005		Y
		Surgical and medical procedures	Cheilectomy	13SEP2016	13SEP2016	N
			Myomectomy	12MAR2004	12MAR2004	N
	C4591001 1265 12651178	Gastrointestinal disorders	Gastroesophageal reflux disease	04FEB2007		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	20FEB2016		Y
			Hyperlipidaemia	16DEC2003		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Pseudofolliculitis	12SEP2013		Y
		Vascular disorders	Hypertension	09SEP2019		Y
	C4591001 1265 12651179	Congenital, familial and genetic disorders	Type V hyperlipidaemia	27OCT2008		Y
		Gastrointestinal disorders	Large intestine polyp	23OCT2018		Y
		Immune system disorders	Seasonal allergy	14OCT2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	20SEP2018		Y
		Nervous system disorders	Carpal tunnel syndrome	06NOV2018		Y
		Psychiatric disorders	Major depression	15OCT2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	06OCT2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	14OCT2008		Y
		Surgical and medical procedures	Carpal tunnel decompression	07MAR2019	07MAR2019	N
			Tonsillectomy	01JAN1969	31DEC1969	N
	C4591001 1265 12651181	Metabolism and nutrition disorders	Hyperlipidaemia	31MAR2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	06JAN2012		Y
		Renal and urinary disorders	Haematuria	05JUL2013		Y
		Vascular disorders	Hypertension	06JAN2012		Y
	C4591001 1265 12651183	Cardiac disorders	Sinus tachycardia	02DEC2013		Y
		Congenital, familial and genetic disorders	Thalassaemia	17MAR2006		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	24OCT2005		Y
		Immune system disorders	Drug hypersensitivity	09MAR2005		Y
		Infections and infestations	Rhinitis	26AUG2003		Y
		Investigations	Biopsy colon	13MAR2017	13MAR2017	N
			Gastrointestinal tract biopsy	17DEC2010	17DEC2010	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	24APR2009		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	01MAR2006		Y
			Lumbar spinal stenosis	26OCT2011		Y
			Osteoarthritis	21JUN2016		Y
		Nervous system disorders	Carpal tunnel syndrome	28DEC2007		Y
			Headache	04OCT2010		Y
		Renal and urinary disorders	Urinary incontinence	15APR2013		Y
		Reproductive system and breast disorders	Cervical dysplasia	05DEC2006	22FEB2010	N
		Respiratory, thoracic and mediastinal disorders	Asthma	12FEB2007		Y
		Skin and subcutaneous tissue disorders	Dermatitis contact	13JUN2016		Y
			Drug eruption	05JUL2001		Y
		Surgical and medical procedures	Female sterilisation	01JAN1986	31DEC1986	N
			Hysterectomy	22FEB2010	22FEB2010	N
			Knee arthroplasty	21JUN2016	21JUN2016	N
			Shoulder operation	24MAY2017	24MAY2017	N
		Vascular disorders	Hypertension	01JAN2008	31DEC2008	N
		Gastrointestinal disorders	Diverticulum intestinal	11DEC2008		Y
	C4591001 1265 12651184	Investigations	Blood pressure increased	09NOV2011		Y
		Metabolism and nutrition disorders	Obesity	03APR2005		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01AUG2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	03DEC2007	03DEC2007	N
		Respiratory, thoracic and mediastinal disorders	Asthma	15NOV2012		Y
			Asthma	17DEC2009		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1265 12651185	Gastrointestinal disorders	Crohn's disease	28AUG2006		Y
		Immune system disorders	Drug hypersensitivity	28AUG2006		Y
		Metabolism and nutrition disorders	Malnutrition	10JUN2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	07JUN2012		Y
		Surgical and medical procedures	Colectomy	01JAN1983	31DEC1983	N
				28AUG2006		Y
			Explorative laparotomy	08JUN2016	08JUN2016	N
			Ileostomy	01JAN1983	31DEC1983	N
				28AUG2006		Y
	C4591001 1269 12691003	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2005		Y
		Psychiatric disorders	Depression	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2008		Y
	C4591001 1269 12691005	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
	C4591001 1269 12691008	Gastrointestinal disorders	Diarrhoea	01SEP2008		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01MAY2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
	C4591001 1269 12691009	Musculoskeletal and connective tissue disorders	Back pain	01JAN1991		Y
			Osteoarthritis	01JAN2007		Y
	C4591001 1269 12691015	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1269 12691017	Blood and lymphatic system disorders	Anaemia	01JAN2018		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2018		Y
		Endocrine disorders	Hypothyroidism	01JAN2014		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2018		Y
			Gastroesophageal reflux disease	01JAN2018		Y
		Immune system disorders	Seasonal allergy	01JAN1975		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2011		Y
			Back pain	01JAN2019		Y
		Social circumstances	Postmenopause	01JAN2013		Y
	C4591001 1269 12691019	Gastrointestinal disorders	Constipation	01JUN2020		Y
		Immune system disorders	Drug hypersensitivity	01JAN1955		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2014		Y
		Psychiatric disorders	Anxiety	01JAN2020		Y
		Social circumstances	Postmenopause	01JAN2006		Y
	C4591001 1269 12691021	Cardiac disorders	Wolff-Parkinson-White syndrome	01JAN2017		Y
		Eye disorders	Glaucoma	01JAN2019		Y
		Immune system disorders	Seasonal allergy	01JAN1974		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2017		Y
		Surgical and medical procedures	Vasectomy	01JAN1995	31DEC1995	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691023	Eye disorders	Cataract	01JAN2016		Y
		Immune system disorders	Drug hypersensitivity	01JAN2016		Y
		Renal and urinary disorders	Nephrolithiasis	01JAN2019	26JUL2020	N
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1966		Y
		Social circumstances	Postmenopause	07DEC2014		Y
		Surgical and medical procedures	Cataract operation	01DEC2017	31DEC2017	N
			Cholecystectomy	01JAN1989	31DEC1989	N
			Gastric bypass	01JAN2002	31DEC2002	N
		Vascular disorders	Hypertension	01JAN2015	31DEC2016	N
	C4591001 1269 12691024	Nervous system disorders	Headache	01JAN1990		Y
		Surgical and medical procedures	Hysterectomy	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 1269 12691028	Immune system disorders	Drug hypersensitivity	01JAN1995		Y
				01JAN2010		Y
			Seasonal allergy	01JAN2000		Y
		Social circumstances	Postmenopause	01JAN2010		Y
	C4591001 1269 12691035	Endocrine disorders	Hypothyroidism	01JAN2008		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1988		Y
	C4591001 1269 12691036	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2018		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1987	31DEC1987	N
				01JAN1997	31DEC1997	N
				01JAN2007	31DEC2007	N
		Vascular disorders	Hypertension	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691038	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2019		Y
		Psychiatric disorders	Insomnia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2018		Y
		Surgical and medical procedures	Hysterectomy	01JAN1981	31DEC1981	N
			Tonsillectomy	01JAN1942	31DEC1942	N
		Vascular disorders	Hypertension	01JAN1987		Y
	C4591001 1269 12691040	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Irritable bowel syndrome	01JAN1990		Y
		Infections and infestations	Otitis media	01AUG2020	07AUG2020	N
		Renal and urinary disorders	Nephrolithiasis	01JAN2018	31DEC2018	N
		Surgical and medical procedures	Hernia repair	01JAN2005	31DEC2005	N
	C4591001 1269 12691043	Eye disorders	Cataract	01JAN2018		Y
		Gastrointestinal disorders	Diarrhoea	01JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2016		Y
		Surgical and medical procedures	Caesarean section	01JAN1981	31DEC1981	N
				01JAN1984	31DEC1984	N
			Knee arthroplasty	01JAN2018	31DEC2018	N
			Tonsillectomy	01JAN1949	31DEC1949	N
	C4591001 1269 12691044	Nervous system disorders	Parkinson's disease	01JAN2017		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1968	31DEC1968	N
			Hernia repair	01JAN2007	31DEC2007	N
			Intestinal resection	01JAN1968	31DEC1968	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691046	Immune system disorders	Drug hypersensitivity	01JAN2013		Y
		Infections and infestations	Tinea infection	01JAN2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2016		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN1984		Y
			Muscle spasms	01JAN2015		Y
			Osteoarthritis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	01FEB2020		Y
		Nervous system disorders	Neuropathy peripheral	01JAN2014		Y
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1269 12691049	Eye disorders	Glaucoma	01JAN2015		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
	C4591001 1269 12691052	Immune system disorders	Drug hypersensitivity	01JAN1981		Y
		Social circumstances	Postmenopause	01JAN2018		Y
		Surgical and medical procedures	Cholecystectomy	01JAN2001	31DEC2001	N
	C4591001 1269 12691053	Infections and infestations	Pneumonia	01DEC2019	31DEC2019	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2009		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2018		Y
		Nervous system disorders	Sciatica	01JAN1986		Y
		Psychiatric disorders	Depression	01JAN2019		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN1972		Y
		Social circumstances	Postmenopause	01JAN2006		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691054	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2011		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Psychiatric disorders	Anxiety	01JAN1981		Y
		Vascular disorders	Hypertension	01JAN2011		Y
	C4591001 1269 12691061	Cardiac disorders	Myocardial infarction	01JAN2005	31DEC2005	N
		Surgical and medical procedures	Angioplasty	01JAN2005	31DEC2005	N
			Appendectomy	01JAN1974	31DEC1974	N
			Stent placement	01JAN2005	31DEC2005	N
		Vascular disorders	Hypertension	01JAN2004		Y
	C4591001 1269 12691066	Eye disorders	Cataract	01JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2006		Y
			Osteoporosis	01JAN2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2003	31DEC2003	N
			Endometrial cancer	01JAN2001	31DEC2001	N
		Nervous system disorders	Cerebrovascular accident	01JAN2019	31DEC2019	N
		Psychiatric disorders	Anxiety	01MAR2020		Y
		Social circumstances	Postmenopause	01JAN2001		Y
	C4591001 1269 12691067	Cardiac disorders	Myocardial infarction	01JAN2001	31DEC2001	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2010		Y
			Pancreatic failure	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
			Type 2 diabetes mellitus	01JAN2010		Y
		Nervous system disorders	Neuropathy peripheral	01JAN1995		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	01JAN1980		Y
		Surgical and medical procedures	Angioplasty	01JAN2001		Y
			Prostatectomy	01JAN2005	31DEC2005	N
			Stent placement	01JAN2001	31DEC2001	N
	C4591001 1269 12691068	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2000		Y
			Osteoporosis	01JAN2018		Y
		Nervous system disorders	Tension headache	01JAN1990		Y
		Psychiatric disorders	Depression	01JAN2000		Y
		Renal and urinary disorders	Hypertonic bladder	01JAN2015		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	01JAN1968	31DEC1968	N
		Surgical and medical procedures	Cataract operation	01JAN2018	30NOV2018	N
				01JAN2019	31DEC2019	N
			Hysterectomy	01JAN2000	31DEC2000	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1269 12691069	Immune system disorders	Seasonal allergy	01JAN1956		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1996		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2000	31DEC2000	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN2016		Y
		Skin and subcutaneous tissue disorders	Psoriasis	01JAN2001		Y
		Surgical and medical procedures	Hysterectomy	01JAN1985	31DEC1985	N
	C4591001 1269 12691071	Injury, poisoning and procedural complications	Ankle fracture	01JAN1981	31DEC1981	N
			Wound	01JAN2019	31DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691079	Nervous system disorders	Headache	01JAN2000		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1973		Y
		Immune system disorders	Drug hypersensitivity	01JAN1968		Y
		Investigations	Arthroscopy	01JAN2012	31DEC2012	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2017		Y
		Nervous system disorders	Peripheral sensory neuropathy	01JAN2018		Y
		Surgical and medical procedures	Intervertebral disc operation	01JAN1982	31DEC1982	N
			Shoulder operation	01JAN2010	31DEC2010	N
				01JAN2014	31DEC2014	N
		C4591001 1269 12691080	Metabolism and nutrition disorders	Hyperlipidaemia	01NOV2019	
	C4591001 1269 12691082	Social circumstances	Postmenopause	01NOV2000		Y
		Ear and labyrinth disorders	Tinnitus	01JAN2002		Y
		Endocrine disorders	Hypothyroidism	01JAN1963		Y
		Eye disorders	Presbyopia	01JAN1992		Y
		Immune system disorders	Seasonal allergy	01JAN1950		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2000		Y
			Osteoarthritis	01JAN2000		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1993	31DEC1993	N
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
		Vascular disorders	Hypertension	01JAN1990		Y
	C4591001 1269 12691083	Eye disorders	Cataract	01JAN2018	31DEC2019	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1990		Y
			Haemorrhoids	01JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 1269 12691085	Surgical and medical procedures	Cholecystectomy	01JAN2010	31DEC2010	N
		Endocrine disorders	Hypothyroidism	01JAN1996		Y
		Immune system disorders	Seasonal allergy	01JAN1980		Y
	C4591001 1269 12691086	Social circumstances	Postmenopause	01DEC2000		Y
		Immune system disorders	Allergy to animal	01JAN1980		Y
			Seasonal allergy	01JAN1980		Y
	C4591001 1269 12691092	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2005		Y
		Social circumstances	Postmenopause	01JAN1993		Y
	C4591001 1269 12691098	Surgical and medical procedures	Gastrectomy	01JAN2008	31DEC2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1987		Y
		Social circumstances	Postmenopause	01JAN2004		Y
		Surgical and medical procedures	Appendicectomy	01JAN1996	31DEC1996	N
			Arthrodesis	01JAN2004	31DEC2004	N
	C4591001 1269 12691100		Cholecystectomy	01JAN2010	31DEC2010	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN1991		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2001		Y
		Nervous system disorders	Migraine	01JAN2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
		Surgical and medical procedures	Vasectomy	01JAN2002	31DEC2002	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691101	Nervous system disorders	Neuropathy peripheral	01JAN2018		Y
	C4591001 1269 12691102	Blood and lymphatic system disorders	Haemolytic anaemia	01JAN1963	31DEC1963	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01FEB2020		Y
		Nervous system disorders	Headache	01JAN2010		Y
			Neuropathy peripheral	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JAN2018		Y
		Surgical and medical procedures	Vasectomy	01JAN1996		Y
	C4591001 1269 12691109	Endocrine disorders	Hypothyroidism	01JAN2009		Y
		Infections and infestations	Bronchitis	01DEC2019	31DEC2019	N
			Diverticulitis	01JAN1960		Y
		Injury, poisoning and procedural complications	Concussion	01JAN1965	31DEC1965	N
		Musculoskeletal and connective tissue disorders	Fibromyalgia	01JAN2007		Y
		Nervous system disorders	Headache	01JAN2005		Y
		Surgical and medical procedures	Appendicectomy	01JAN1956	31DEC1956	N
			Cataract operation	01MAR2020	31MAR2020	N
				01MAY2020	31MAY2020	N
			Colon operation	01JAN2008	31DEC2008	N
			Retinal operation	01OCT2019	31OCT2019	N
	C4591001 1269 12691111	Immune system disorders	Hypersensitivity	01JAN2015		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JAN2016		Y
			Hyperlipidaemia	01JAN2005		Y
		Musculoskeletal and connective tissue disorders	Arthritis	01JAN2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1967		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Hernia hiatus repair	01JAN2016	31DEC2016	N
			Knee arthroplasty	01JAN2016	31DEC2016	N
		Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 1269 12691112	Endocrine disorders	Hypothyroidism	01JAN2015		Y
		General disorders and administration site conditions	Peripheral swelling	01JAN2010		Y
		Immune system disorders	Seasonal allergy	01JAN2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN1990		Y
		Surgical and medical procedures	Tonsillectomy	01JAN1964	31DEC1964	N
	C4591001 1269 12691114	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN1997	31MAR2020	N
		Vascular disorders	Hypertension	01JAN2013		Y
	C4591001 1269 12691118	Cardiac disorders	Atrial fibrillation	01NOV2017		Y
		Immune system disorders	Seasonal allergy	01JAN1963		Y
		Infections and infestations	Onychomycosis	01JAN1990		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2010	31DEC2010	N
		Surgical and medical procedures	Cardioversion	01JAN2018	31DEC2018	N
			Radical prostatectomy	01JAN2010	31DEC2010	N
	C4591001 1269 12691120	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2018		Y
			Osteoarthritis	01JAN1997		Y
			Scoliosis	01JAN2014		Y
		Social circumstances	Postmenopause	01JAN1996		Y
		Surgical and medical procedures	Female sterilisation	01JAN1971	31DEC1971	N
			Tonsillectomy	01JAN1954	31DEC1954	N
	C4591001 1269 12691124	Ear and labyrinth disorders	Tinnitus	01JAN1980		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2000		Y
		Metabolism and nutrition disorders	Gout	01JUL2020		Y
			Hyperlipidaemia	01JAN1985		Y
		Psychiatric disorders	Anxiety	01JAN1980		Y
			Obsessive-compulsive disorder	01JAN1980		Y
		Renal and urinary disorders	Chronic kidney disease	01JAN1985		Y
			Single functional kidney	01JAN1980		Y
	C4591001 1269 12691128	Gastrointestinal disorders	Haemorrhoids	01JAN1976		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	01JAN2009	31DEC2009	N
		Surgical and medical procedures	Inguinal hernia repair	01JAN2017	31DEC2017	N
	C4591001 1269 12691131	Cardiac disorders	Atrial fibrillation	01JAN2013	31DEC2013	N
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2010		Y
		Surgical and medical procedures	Cardioversion	01JAN2013	31DEC2013	N
			Tonsillectomy	01JAN1961	31DEC1961	N
		Vascular disorders	Hypertension	01JAN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1269 12691132	Immune system disorders	Drug hypersensitivity	01JAN1980		Y
			Seasonal allergy	01JAN2000		Y
		Psychiatric disorders	Mental disorder	01JAN1979	31DEC1979	N
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2015		Y
		Social circumstances	Postmenopause	01JAN2014		Y
		Surgical and medical procedures	Appendicectomy	01JAN1985	31DEC1985	N
			Tonsillectomy	01JAN1974	31DEC1974	N
	C4591001 1269 12691134	Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Appendicectomy	01APR2020	30APR2020	N
	C4591001 1269 12691135	Congenital, familial and genetic disorders	Von Willebrand's disease	01JAN2000		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
	C4591001 1269 12691137	Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1269 12691138	Gastrointestinal disorders	Constipation	01JAN2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN2008		Y
			Type 2 diabetes mellitus	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	01JAN2015		Y
			Osteoarthritis	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JAN2010		Y
		Social circumstances	Postmenopause	01JAN2006		Y
		Surgical and medical procedures	Ankle operation	01JAN1997	31DEC1997	N
			Surgery	01JAN1983	31DEC1983	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 1269 12691139	Gastrointestinal disorders	Gastroesophageal reflux disease	01JAN2014		Y
		Psychiatric disorders	Depression	01JAN1981		Y
			Insomnia	01JAN2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01JAN1961		Y
		Surgical and medical procedures	Bunion operation	01JAN2014	31DEC2014	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 1269 12691141	Cardiac disorders	Palpitations	01JAN2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2005	31DEC2007	N
		Social circumstances	Postmenopause	01JAN2008		Y
		Surgical and medical procedures	Hysterectomy	01JAN2015	31DEC2015	N
			Mastectomy	01JAN2006	31DEC2006	N
			Tonsillectomy	01JAN1965	31DEC1965	N
	C4591001 1269 12691142	Immune system disorders	Drug hypersensitivity	01JAN2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2003		Y
		Psychiatric disorders	Anxiety	01JAN1998		Y
		Surgical and medical procedures	Haemorrhoid operation	01JAN2006	31DEC2006	N
			Hysterectomy	01JAN1999	31DEC1999	N
	C4591001 1270 12701001	Eye disorders	Astigmatism	11MAR2020		Y
			Cataract	11MAR2020		Y
			Dermatochalasis	11MAR2020		Y
			Meibomian gland dysfunction	11MAR2020	30MAR2020	N
			Presbyopia	11MAR2020		Y
			Retinal degeneration	11MAR2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	18JAN2019	28FEB2020	N
		Immune system disorders	Allergy to vaccine	01JUN1970		Y
			Drug hypersensitivity	05JUN2001		Y
				06JUN2016		Y
		Investigations	Tuberculin test positive	23JUL2007		Y
		Metabolism and nutrition disorders	Diabetic dyslipidaemia	29SEP2014		Y
			Hyperlipidaemia	08NOV1995		Y
			Obesity	28OCT2014		Y
			Type 2 diabetes mellitus	28JUL2007		Y
		Musculoskeletal and connective tissue disorders	Arthritis	30MAR2006		Y
			Osteoarthritis	02DEC2016	01JUN2017	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	16JAN2014	18MAR2014	N
			Malignant melanoma	29AUG2009	29AUG2009	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	27AUG2007		Y
		Surgical and medical procedures	Skin lesion removal	29AUG2009	29AUG2009	N
	C4591001 1270 12701002	Immune system disorders	Drug hypersensitivity	16JAN2009		Y
		Infections and infestations	Rhinitis	13FEB2006		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	04DEC2006		Y
			Temporomandibular joint syndrome	16NOV2009		Y
		Nervous system disorders	Tension headache	03JUL2012		Y
		Reproductive system and breast disorders	Pelvic pain	18SEP2008	30JUN2012	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	29MAR2007		Y
			Nasal septum deviation	21NOV2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Alopecia	28DEC2007		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	01JAN2012	N
	C4591001 1270 12701005	Ear and labyrinth disorders	Deafness neurosensory	27AUG2008		Y
		Immune system disorders	Drug hypersensitivity	24JAN2019		Y
		Infections and infestations	Chronic sinusitis	18DEC2007		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	18DEC2007		Y
			Osteoarthritis	02JAN2007		Y
				09JUN2006		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	28OCT2016		Y
			Pulmonary mass	28DEC2016		Y
		Vascular disorders	Varicose vein	18DEC2007		Y
	C4591001 1270 12701006	Eye disorders	Blindness unilateral	25MAY2007		Y
			Retinal detachment	16SEP2016		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	13MAR2008		Y
		Investigations	Alanine aminotransferase increased	25JUL2008		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	24MAR2008		Y
			Hyperlipidaemia	13MAR2008		Y
		Nervous system disorders	Migraine	12MAY2011		Y
		Psychiatric disorders	Insomnia	09JAN2019		Y
		Renal and urinary disorders	Lower urinary tract symptoms	10JAN2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	09JAN2019		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	03JAN2018		Y
	C4591001 1270 12701009	Ear and labyrinth disorders	Deafness neurosensory	26JUN2020		Y
		Eye disorders	Cataract	23MAR2018		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dry age-related macular degeneration	23MAR2018		Y
			Maculopathy	23MAR2018		Y
			Myopia	23MAR2018		Y
		Gastrointestinal disorders	Aphthous ulcer	11MAR2008		Y
			Diverticulum intestinal	31OCT2008		Y
			Haemorrhoids	07FEB2011		Y
		Immune system disorders	Drug hypersensitivity	23MAR2001		Y
				24FEB2019		Y
		Musculoskeletal and connective tissue disorders	Joint contracture	10JUN2015		Y
			Osteopenia	31AUG2012		Y
			Spinal osteoarthritis	08FEB2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	08NOV2016	08NOV2016	N
		Nervous system disorders	Cervical radiculopathy	07FEB2011		Y
		Psychiatric disorders	Insomnia	02SEP2009		Y
	C4591001 1270 12701012	Immune system disorders	Drug hypersensitivity	10OCT2015		Y
				12OCT2015		Y
		Infections and infestations	Herpes simplex	14OCT2015		Y
			Herpes zoster	14OCT2015		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	21MAR2016		Y
			Osteoarthritis	30MAY2019		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14OCT2015		Y
			Nasal polyps	14OCT2015		Y
			Rhinitis allergic	14OCT2015		Y
		Skin and subcutaneous tissue disorders	Cold urticaria	19OCT2019		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Purpura senile	31AUG2016		Y
		Vascular disorders	Hypertension	21MAR2016		Y
	C4591001 1270 12701016	Cardiac disorders	Atrial fibrillation	17DEC2019		Y
			Left ventricular failure	17DEC2019		Y
			Palpitations	28DEC2018		Y
		Gastrointestinal disorders	Diverticulum intestinal	14DEC2010		Y
			Haemorrhoids	14DEC2010		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	15DEC2016		Y
		Musculoskeletal and connective tissue disorders	Plantar fasciitis	21OCT2013		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	10AUG2018	06SEP2018	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	19APR2005		Y
		Surgical and medical procedures	Skin neoplasm excision	04SEP2018	06SEP2018	N
		Vascular disorders	Aortic arteriosclerosis	30OCT2017		Y
	C4591001 1270 12701017	Ear and labyrinth disorders	Deafness neurosensory	19OCT2017		Y
		Endocrine disorders	Hypothyroidism	21JUL2008		Y
		Gastrointestinal disorders	Diverticulum intestinal	06OCT2006		Y
		Immune system disorders	Drug hypersensitivity	03JUN2010		Y
				13DEC2002		Y
			Food allergy	02JUN2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	04MAR2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Invasive ductal breast carcinoma	03NOV2015	17FEB2016	N
		Surgical and medical procedures	Breast conserving surgery	19NOV2015	19NOV2015	N
	C4591001 1270 12701019	Eye disorders	Myopia	17DEC2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Presbyopia	17DEC2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26FEB2009		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	06MAR2018		Y
			Plantar fasciitis	10JUN2009		Y
		Nervous system disorders	Facial neuralgia	14JAN2019		Y
			Lumbar radiculopathy	25APR2012		Y
		Psychiatric disorders	Major depression	16MAY2001		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	13APR2011		Y
			Erectile dysfunction	08NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	26FEB2009		Y
	C4591001 1270 12701024	Ear and labyrinth disorders	Deafness neurosensory	11JUN2019		Y
		Endocrine disorders	Hypothyroidism	12APR2011		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	21SEP2017		Y
			Hypertriglyceridaemia	07JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	05JAN2018	05JAN2018	N
				15AUG2011	15AUG2011	N
				16MAY2012	16MAY2012	N
				18MAR2015	18MAR2015	N
				20MAY2011	20MAY2011	N
				25SEP2019	25SEP2019	N
				29APR2011	29APR2011	N
			Squamous cell carcinoma of skin	19SEP2017	19SEP2017	N
	C4591001 1270 12701026	Respiratory, thoracic and mediastinal disorders	Asthma	03MAR2006		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1270 12701027	Ear and labyrinth disorders	Deafness bilateral	19AUG2009		Y
		General disorders and administration site conditions	Oedema peripheral	08NOV2018		Y
		Infections and infestations	Onychomycosis	08AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	24JAN2000		Y
			Type 1 diabetes mellitus	01JUL2000		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	08NOV2018		Y
			Osteopenia	22JAN2012		Y
		Nervous system disorders	Neuropathy peripheral	29SEP2006		Y
			Post polio syndrome	29SEP2006		Y
		Renal and urinary disorders	Nephrolithiasis	10DEC2013	10DEC2013	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	29SEP2006		Y
		Social circumstances	Menopause	01JAN1990		Y
		Vascular disorders	Aortic arteriosclerosis	03DEC2013		Y
			Hypertension	22JUN2001		Y
	C4591001 1270 12701028	Congenital, familial and genetic disorders	Stargardt's disease	11APR2019		Y
		Endocrine disorders	Hypothyroidism	19JAN2006		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05DEC2011		Y
		Musculoskeletal and connective tissue disorders	Muscle spasms	05JUL2017		Y
		Psychiatric disorders	Insomnia	11OCT2016		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	07OCT2016		Y
	C4591001 1270 12701029	Congenital, familial and genetic disorders	Corneal dystrophy	06JAN2015		Y
		Eye disorders	Blepharitis	15DEC2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Dry eye	16DEC2014		Y
			Normal tension glaucoma	22SEP2019		Y
				23MAY2018		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	10SEP2009		Y
		Immune system disorders	Drug hypersensitivity	22OCT2004		Y
		Infections and infestations	Rhinitis	09DEC2014		Y
		Metabolism and nutrition disorders	Hypertriglyceridaemia	07NOV2014		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	17NOV2010		Y
			Osteopenia	14SEP2017		Y
		Nervous system disorders	Cervical radiculopathy	16MAR2020		Y
			Lumbar radiculopathy	17NOV2010		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	17JAN2014		Y
			Upper-airway cough syndrome	09DEC2014		Y
		Surgical and medical procedures	Intraocular lens implant	11APR2015		Y
		Vascular disorders	Hypertension	26JAN2006		Y
	C4591001 1270 12701031	Ear and labyrinth disorders	Deafness neurosensory	01DEC2008		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	22JUN2018		Y
		Vascular disorders	Hypertension	29OCT2019		Y
	C4591001 1270 12701032	Eye disorders	Presbyopia	13FEB2019		Y
		Gastrointestinal disorders	Hiatus hernia	24JUN2013		Y
		Immune system disorders	Drug hypersensitivity	04APR2019		Y
				04JUL2013		Y
				15NOV2018		Y
		Injury, poisoning and procedural complications	Incisional hernia	27FEB2018	20DEC2019	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Glucose tolerance impaired	05JAN2009		Y
			Hyperlipidaemia	21NOV2017		Y
			Hypertriglyceridaemia	04JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	13FEB2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	14DEC2018	14DEC2018	N
			Breast cancer	26FEB2020	09MAR2020	N
		Psychiatric disorders	Attention deficit hyperactivity disorder	01JAN2006		Y
		Renal and urinary disorders	Urge incontinence	31DEC2008		Y
		Reproductive system and breast disorders	Genitourinary syndrome of menopause	06JUL2009		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	03DEC2019		Y
		Skin and subcutaneous tissue disorders	Myxoid cyst	01JAN1999		Y
		Social circumstances	Menopause	30NOV2018		Y
		Vascular disorders	Aortic arteriosclerosis	01JAN2000		Y
	C4591001 1270 12701036	Immune system disorders	Drug hypersensitivity	26MAR2018		Y
		Infections and infestations	Diverticulitis	22NOV2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	21NOV2018		Y
	C4591001 1270 12701038	Ear and labyrinth disorders	Deafness bilateral	19MAY2003		Y
		General disorders and administration site conditions	Oedema peripheral	06JAN2017		Y
		Immune system disorders	Drug hypersensitivity	05SEP2019		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2009		Y
			Obesity	01JAN2001		Y
				01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Type 2 diabetes mellitus	01JAN2001		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	05SEP2019		Y
			Back pain	10APR2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dysplastic naevus	13FEB2020		Y
			Prostate cancer	01JAN2009	31DEC2009	N
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	06JAN2017		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	13FEB2020		Y
			Purpura senile	13FEB2020		Y
		Vascular disorders	Hypertension	06JAN2017		Y
	C4591001 1270 12701039	Skin and subcutaneous tissue disorders	Urticaria	01JAN2010		Y
		Social circumstances	Menopause	01JAN2010		Y
	C4591001 1270 12701040	Eye disorders	Cataract	13MAR2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	23FEB2017		Y
		Immune system disorders	Drug hypersensitivity	07MAY2009		Y
				30AUG2018		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	06AUG2017		Y
		Musculoskeletal and connective tissue disorders	Back pain	26MAR2020		Y
			Foot deformity	04JAN2018		Y
				16JAN2018		Y
			Neck pain	07JAN2020		Y
		Psychiatric disorders	Depression	23MAY2019		Y
			Generalised anxiety disorder	07JUL2015		Y
			Insomnia	19MAR2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23MAY2019		Y
		Skin and subcutaneous tissue disorders	Rosacea	23MAY2019		Y
		Social circumstances	Menopause	01JAN1995		Y
	C4591001 1270 12701042	Gastrointestinal disorders	Haemorrhoids	15OCT2008		Y
		Immune system disorders	Drug hypersensitivity	06AUG2002		Y
				11APR2011		Y
				29AUG2002		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	26OCT2013		Y
			Iron deficiency	20JUN2014		Y
			Type 2 diabetes mellitus	16JAN2007		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	25OCT2011		Y
		Nervous system disorders	Lumbar radiculopathy	20AUG2012		Y
		Psychiatric disorders	Anxiety	29JUL2008		Y
		Renal and urinary disorders	Haematuria	17MAY2016		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	05DEC2012		Y
		Surgical and medical procedures	Hysterectomy	15DEC2005	15DEC2005	N
	C4591001 1270 12701043	Gastrointestinal disorders	Large intestine polyp	13JUN2018	18OCT2018	N
		Immune system disorders	Drug hypersensitivity	02MAY2020		Y
				06DEC1999		Y
				15DEC2017		Y
				26DEC2013		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	29SEP2000		Y
		Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	12JUL2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	29DEC2017	12JUN2018	N
		Nervous system disorders	Migraine	21JAN2010		Y
		Psychiatric disorders	Insomnia	29JUL2019		Y
		Social circumstances	Menopause	16JUN2017		Y
		Surgical and medical procedures	Large intestinal polypectomy	18OCT2018	18OCT2018	N
			Micrographic skin surgery	12JUN2018	12JUN2018	N
	C4591001 1270 12701044	Ear and labyrinth disorders	Tinnitus	01OCT2015		Y
		Eye disorders	Pterygium	11JUL2018		Y
		General disorders and administration site conditions	Pain	04APR2017		Y
		Hepatobiliary disorders	Hepatic steatosis	17AUG2010		Y
		Immune system disorders	Drug hypersensitivity	03APR2010		Y
				20OCT2015		Y
				30JUN2010		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	27JUN2017		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	30AUG2019		Y
		Nervous system disorders	Cluster headache	04APR2017		Y
			Lumbar radiculopathy	07JUL2020		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	02NOV2012		Y
		Vascular disorders	Hypertension	04FEB2020		Y
	C4591001 1270 12701047	Endocrine disorders	Hypothyroidism	29APR2015		Y
		Immune system disorders	Drug hypersensitivity	01JAN2000		Y
				03JUL2006		Y
				12AUG2016		Y
				24MAY2011		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Hyperlipidaemia	24MAY2011		Y
			Type 1 diabetes mellitus	01JAN1985		Y
		Nervous system disorders	Neuropathy peripheral	29APR2015		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	31AUG2006		Y
		Vascular disorders	Aortic arteriosclerosis	01SEP2018		Y
			Hypertension	13NOV2019		Y
	C4591001 1270 12701049	Endocrine disorders	Hypothyroidism	06NOV2017		Y
		Gastrointestinal disorders	Haemorrhoids	13FEB2008		Y
		Metabolism and nutrition disorders	Gout	13FEB2020		Y
			Hypertriglyceridaemia	01MAR2012		Y
		Musculoskeletal and connective tissue disorders	Dupuytren's contracture	20JAN2006		Y
		Respiratory, thoracic and mediastinal disorders	Pulmonary mass	09SEP2009		Y
			Sleep apnoea syndrome	07JUN2017		Y
	C4591001 1270 12701050	Immune system disorders	Drug hypersensitivity	20JAN2004		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	31JAN2019		Y
		Musculoskeletal and connective tissue disorders	Arthritis	20JUL2018	04FEB2019	N
			Osteopenia	21NOV2008		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	22JAN2006		Y
		Surgical and medical procedures	Hip arthroplasty	04FEB2019	04FEB2019	N
	C4591001 1270 12701052	Ear and labyrinth disorders	Tinnitus	21DEC2007		Y
		Endocrine disorders	Hypothyroidism	04JUN2003		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	21DEC2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Hepatobiliary disorders	Hepatic steatosis	21MAY2007		Y
		Investigations	Liver function test increased	21MAY2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	17NOV2003		Y
			Type 2 diabetes mellitus	17DEC2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Seborrhoeic keratosis	20OCT2005		Y
		Nervous system disorders	VIth nerve paralysis	04FEB2010		Y
		Psychiatric disorders	Insomnia	28JAN2008		Y
			Major depression	18OCT2011		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	25JAN2008		Y
		Vascular disorders	Aortic arteriosclerosis	27DEC2019		Y
	C4591001 1270 12701053	Blood and lymphatic system disorders	Anaemia	12FEB2018		Y
		Endocrine disorders	Hyperparathyroidism primary	12APR2018		Y
		Gastrointestinal disorders	Diverticulum intestinal	04OCT2006		Y
			Large intestine polyp	16MAR2017	16MAR2017	N
		Immune system disorders	Drug hypersensitivity	22JAN2015		Y
		Infections and infestations	Appendiceal abscess	13MAY2020	13MAY2020	N
			Appendicitis perforated	13MAY2020	13MAY2020	N
		Injury, poisoning and procedural complications	Post procedural hypothyroidism	25MAR2019		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	20FEB2009		Y
			Osteopenia	03NOV2017		Y
		Psychiatric disorders	Drug use disorder	27MAR2019		Y
		Renal and urinary disorders	Chronic kidney disease	01MAR2018		Y
		Reproductive system and breast disorders	Breast mass	23JAN2015		Y
		Surgical and medical procedures	Appendicectomy	13MAY2020	13MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Large intestinal polypectomy	16MAR2017	16MAR2017	N
			Thyroidectomy	12APR2018	12APR2018	N
		Vascular disorders	Aortic arteriosclerosis	27NOV2017		Y
			Hypertension	23SEP2019		Y
	C4591001 1270 12701054	Immune system disorders	Drug hypersensitivity	21DEC2001		Y
				24AUG2010		Y
		Investigations	Biopsy breast	18DEC2009	18DEC2009	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	18SEP2018		Y
			Obesity	10SEP2018		Y
		Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	24AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Intraductal proliferative breast lesion	08MAR2011	08MAR2011	N
		Nervous system disorders	Cerebrovascular disorder	06JAN2019		Y
		Psychiatric disorders	Major depression	02DEC2015		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	23SEP2014		Y
			Sleep apnoea syndrome	25FEB2020		Y
	C4591001 1270 12701055	Metabolism and nutrition disorders	Hyperlipidaemia	29SEP2019		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	14APR2011	08MAY2019	N
		Nervous system disorders	Sciatica	01MAR2020		Y
		Psychiatric disorders	Major depression	28OCT2014		Y
		Surgical and medical procedures	Hysterectomy	08MAY2019	08MAY2019	N
		Vascular disorders	Hypertension	20MAR2007		Y
	C4591001 1270 12701057	Congenital, familial and genetic disorders	Factor V Leiden mutation	06JUL2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	05JUN2011		Y
		General disorders and administration site conditions	Pain	07MAR2019		Y
		Immune system disorders	Drug hypersensitivity	30MAY2019		Y
		Infections and infestations	Genital herpes simplex	03APR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	06JUL2011		Y
			Type 2 diabetes mellitus	06JUL2011		Y
		Musculoskeletal and connective tissue disorders	Arthritis	27FEB2019		Y
			Lumbar spinal stenosis	28JUL2011		Y
			Osteoarthritis	27FEB2019		Y
		Nervous system disorders	Lumbar radiculopathy	11MAY2018		Y
			Neuropathy peripheral	21NOV2016		Y
		Psychiatric disorders	Anxiety	18DEC2017		Y
			Insomnia	20SEP2017		Y
		Reproductive system and breast disorders	Erectile dysfunction	21NOV2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	05JAN2011		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	20SEP2017		Y
		Vascular disorders	Deep vein thrombosis	06JUL2011		Y
	C4591001 1270 12701058	Immune system disorders	Drug hypersensitivity	02DEC2004		Y
				08APR2003		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	28FEB2020		Y
		Skin and subcutaneous tissue disorders	Eczema	06MAY2019		Y
		Social circumstances	Menopause	06MAY2018		Y
	C4591001 1270 12701059	Cardiac disorders	Coronary artery disease	22JAN2020		Y
		Metabolism and nutrition disorders	Gout	16NOV2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hyperlipidaemia	20JUL2006		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	09SEP2005		Y
		Skin and subcutaneous tissue disorders	Rosacea	01NOV2002		Y
		Vascular disorders	Hypertension	26AUG1998		Y
	C4591001 1270 12701060	Eye disorders	Cataract	16JUL2019		Y
		Gastrointestinal disorders	Diverticulum intestinal	18NOV2009		Y
		Psychiatric disorders	Anxiety	29DEC2006		Y
		Social circumstances	Menopause	01JAN1993		Y
	C4591001 1270 12701061	Eye disorders	Myopia	24MAR2014		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	08AUG2016		Y
			Vertebral foraminal stenosis	08AUG2016		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2012		Y
		Nervous system disorders	Cervical radiculopathy	08AUG2016		Y
			Myelopathy	08AUG2016		Y
	C4591001 1270 12701062	Immune system disorders	Drug hypersensitivity	12DEC2008		Y
		Injury, poisoning and procedural complications	Humerus fracture	12APR2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12DEC2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	04JUN2007		Y
		Social circumstances	Menopause	01JAN2012		Y
		Vascular disorders	Hypertension	11MAR2017		Y
	C4591001 1270 12701063	Immune system disorders	Drug hypersensitivity	14JAN2013		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Injury, poisoning and procedural complications	Pelvic fracture	10AUG2013	25SEP2013	N
		Investigations	Colonoscopy	16MAY2016	16MAY2016	N
		Metabolism and nutrition disorders	Vitamin D deficiency	16JUN2011	10JAN2017	N
		Musculoskeletal and connective tissue disorders	Arthralgia	03JAN2013		Y
			Rotator cuff syndrome	18NOV2009	03MAR2010	N
		Skin and subcutaneous tissue disorders	Actinic keratosis	04DEC2019		Y
		Surgical and medical procedures	Skin neoplasm excision	22DEC2016	22DEC2016	N
	C4591001 1270 12701066	Eye disorders	Retinal vascular disorder	12MAR2012		Y
		Gastrointestinal disorders	Diverticulum intestinal	24JAN2005		Y
		Metabolism and nutrition disorders	Diabetes mellitus	12DEC2009		Y
			Dyslipidaemia	22DEC2009		Y
			Hyperlipidaemia	22DEC2009		Y
		Nervous system disorders	Cerebrovascular accident	27AUG2016		Y
		Psychiatric disorders	Major depression	01DEC2009		Y
		Renal and urinary disorders	Chronic kidney disease	22DEC2009		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	27JAN2017		Y
		Vascular disorders	Hypertension	22DEC2009		Y
	C4591001 1270 12701067	Infections and infestations	Perirectal abscess	13MAY2019	30SEP2019	N
		Injury, poisoning and procedural complications	Ulna fracture	11SEP2017	31DEC2017	N
		Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	23AUG2016		Y
		Psychiatric disorders	Insomnia	20NOV2010		Y
		Surgical and medical procedures	Synovial cyst removal	17JUL2017	17JUL2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701070	Cardiac disorders	Tachycardia paroxysmal	21MAR2006		Y
		Ear and labyrinth disorders	Deafness neurosensory	30NOV2018		Y
		Eye disorders	Dermatochalasis	30NOV2017		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	16FEB2011		Y
			Plantar fasciitis	27DEC2017		Y
		Nervous system disorders	Post polio syndrome	20DEC2007		Y
		Skin and subcutaneous tissue disorders	Brow ptosis	30NOV2017		Y
	C4591001 1270 12701072	Ear and labyrinth disorders	Tinnitus	04JAN2006		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	09OCT2019		Y
		Investigations	High density lipoprotein decreased	09NOV2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	13JAN2016		Y
				26DEC2002		Y
			Type 2 diabetes mellitus	13JAN2016		Y
		Musculoskeletal and connective tissue disorders	Back pain	27FEB2012		Y
			Intervertebral disc protrusion	25OCT2013		Y
			Osteoarthritis	01MAR2012		Y
				28JUL2013		Y
			Tendonitis	28JAN2013		Y
		Nervous system disorders	Lumbar radiculopathy	24SEP2013		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	16JUL2020	16JUL2020	N
				28SEP2011		Y
			Purpura senile	16JUL2020		Y
			Rosacea	06JUL2020		Y
		Surgical and medical procedures	Skin neoplasm excision	18MAR2020	18MAR2020	N
		Vascular disorders	Aortic dilatation	14MAY2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Hypertension	11JUN2006		Y
	C4591001 1270 12701073	Blood and lymphatic system disorders	Iron deficiency anaemia	09JAN2020		Y
		Gastrointestinal disorders	Diverticulum intestinal	10MAY2010		Y
			Gastroesophageal reflux disease	04DEC2011		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07OCT2010		Y
			Obesity	05OCT2006		Y
		Nervous system disorders	Headache	04JUL2007		Y
		Vascular disorders	Hypertension	05OCT2006		Y
	C4591001 1270 12701075	Metabolism and nutrition disorders	Hyperlipidaemia	05JUL2019		Y
			Type 2 diabetes mellitus	04MAR2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	21DEC2009	03FEB2010	N
		Renal and urinary disorders	Urinary incontinence	08SEP2014		Y
		Vascular disorders	Aortic arteriosclerosis	21SEP2016		Y
			Embolism venous	03MAR2016	03MAR2016	N
			Peripheral venous disease	24JUN2009		Y
	C4591001 1270 12701077	Cardiac disorders	Coronary artery disease	06NOV2019		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	11DEC2019		Y
		Immune system disorders	Drug hypersensitivity	06NOV2019		Y
				13FEB2019		Y
				18DEC2011		Y
				26JUN2012		Y
				29JUL2014		Y
		Infections and infestations	Rhinitis	06NOV2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11NOV2019		Y
			Type 2 diabetes mellitus	11NOV2019		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Arthralgia	21MAR2020		Y
				27JUL2020		Y
			Pain in extremity	27MAY2020		Y
			Trigger finger	24JUL2020		Y
		Nervous system disorders	Carotid artery stenosis	15DEC2015		Y
			Thoracic radiculopathy	26FEB2020		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	26JUN2012		Y
		Vascular disorders	Aortic aneurysm	19MAY2015		Y
			Hypertension	26JUN2012		Y
	C4591001 1270 12701078	Gastrointestinal disorders	Gastroesophageal reflux disease	23JUN2006		Y
		Investigations	Prostatic specific antigen increased	06OCT2015		Y
		Skin and subcutaneous tissue disorders	Psoriasis	24JAN2006		Y
		Surgical and medical procedures	Spinal operation	06MAR2017	06MAR2017	N
		Vascular disorders	Hypertension	21NOV2013		Y
	C4591001 1270 12701079	Eye disorders	Cataract	15MAR2015	10SEP2018	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	07DEC2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07SEP2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	25JUL2019		Y
		Renal and urinary disorders	Incontinence	12JUN2008		Y
		Skin and subcutaneous tissue disorders	Rosacea	26FEB2020		Y
		Surgical and medical procedures	Cataract operation	10SEP2018	10SEP2018	N
			Hysterectomy	01JAN1986	01JAN1986	N
			Intraocular lens implant	04OCT2018		Y
	C4591001 1270 12701080	General disorders and administration site conditions	Oedema peripheral	17JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Immune system disorders	Food allergy	17JAN2014		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	02MAY2007		Y
			Obesity	20NOV2006		Y
		Musculoskeletal and connective tissue disorders	Back pain	08APR2009		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	03MAY2015		Y
		Vascular disorders	Aortic arteriosclerosis	08FEB2020		Y
			Hypertension	12MAY2005		Y
	C4591001 1270 12701081	Hepatobiliary disorders	Cholecystitis acute	21FEB2020	21FEB2020	N
		Immune system disorders	Drug hypersensitivity	30NOV2004		Y
		Musculoskeletal and connective tissue disorders	Foot deformity	19DEC2019		Y
			Osteoarthritis	17FEB2006		Y
		Psychiatric disorders	Depression	18JAN2005		Y
		Renal and urinary disorders	Hypertonic bladder	04MAY2020		Y
		Reproductive system and breast disorders	Uterine cervix stenosis	17SEP2018		Y
		Surgical and medical procedures	Cholecystectomy	21FEB2020	21FEB2020	N
	C4591001 1270 12701083	Eye disorders	Hypermetropia	14JAN2015		Y
			Presbyopia	14JAN2015		Y
		Immune system disorders	Drug hypersensitivity	16JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19NOV2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	28AUG2018		Y
			Bursitis	01OCT2019		Y
			Osteopenia	23OCT2015		Y
			Spinal osteoarthritis	16OCT2015		Y

## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Spinal pain	28AUG2018		Y
		Nervous system disorders	Sciatica	28AUG2018		Y
		Vascular disorders	Hypertension	16OCT2015		Y
	C4591001 1270 12701092	Gastrointestinal disorders	Gastroesophageal reflux disease	12SEP2014		Y
		Hepatobiliary disorders	Hepatic steatosis	04MAY2010		Y
		Immune system disorders	Drug hypersensitivity	23JAN2013		Y
		Metabolism and nutrition disorders	Obesity	29MAY2008	24JUL2020	N
			Type 2 diabetes mellitus	07OCT2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	06APR2020	24JUL2020	N
		Nervous system disorders	Neuropathy peripheral	12AUG2019		Y
		Renal and urinary disorders	Chronic kidney disease	12AUG2019		Y
		Surgical and medical procedures	Polypectomy	24JUL2020	24JUL2020	N
		Vascular disorders	Hypertension	29MAY2008		Y
	C4591001 1270 12701093	Gastrointestinal disorders	Diverticulum intestinal	13FEB2015		Y
			Gastroesophageal reflux disease	10AUG2012		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	12SEP2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	10SEP2013		Y
				12SEP2014		Y
			Back pain	10SEP2013		Y
			Intervertebral disc degeneration	10SEP2013		Y
			Lumbar spinal stenosis	25JUN2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	15APR2013	15APR2013	N
		Nervous system disorders	Sciatica	25JUN2019		Y
		Psychiatric disorders	Insomnia	03SEP2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Renal and urinary disorders	Nephrolithiasis	13AUG2019		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	03SEP2020		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	02JUN2014		Y
		Vascular disorders	Aortic arteriosclerosis	29JUL2019		Y
			Hypertension	25SEP2014		Y
	C4591001 1270 12701094	Gastrointestinal disorders	Gastrooesophageal reflux disease	01JUL2020		Y
		Immune system disorders	Allergy to arthropod sting	17FEB2017		Y
			Drug hypersensitivity	04SEP2018		Y
				17FEB2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	01JUL2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUL2020		Y
			Sjogren's syndrome	07JUN2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN1989	31DEC1989	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	04MAR2010		Y
		Surgical and medical procedures	Mastectomy	01JAN1989	31DEC1989	N
	C4591001 1270 12701095	Endocrine disorders	Hypothyroidism	19MAY1998		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	24JAN2018		Y
		Immune system disorders	Drug hypersensitivity	17JUN2003		Y
			Food allergy	01FEB2018		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	21OCT2005		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	09AUG2016		Y
		Vascular disorders	Aortic arteriosclerosis	25JUL2016		Y
			Hypertension	29JAN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701096	Gastrointestinal disorders	Gastroesophageal reflux disease	12DEC2008		Y
		Immune system disorders	Drug hypersensitivity	16APR2004		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	07JUN2004		Y
			Obesity	26FEB2017		Y
			Type 2 diabetes mellitus	24JAN2008		Y
			Vitamin D deficiency	12NOV2010		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	28MAR2017		Y
			Sleep apnoea syndrome	19DEC2018		Y
	C4591001 1270 12701101	Gastrointestinal disorders	Gastroesophageal reflux disease	16OCT2012		Y
		Investigations	High density lipoprotein decreased	14MAR2014		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	18OCT2012		Y
			Hypercholesterolaemia	16OCT2012		Y
		Musculoskeletal and connective tissue disorders	Back pain	16OCT2012		Y
			Scoliosis	16OCT2012		Y
			Spinal stenosis	15JUL2016		Y
		Reproductive system and breast disorders	Erectile dysfunction	16OCT2012		Y
		Vascular disorders	Aortic aneurysm	12AUG2019		Y
			Hypertension	16OCT2012		Y
			Peripheral artery aneurysm	12AUG2019		Y
	C4591001 1270 12701102	Ear and labyrinth disorders	Deafness bilateral	29MAY2020		Y
		Gastrointestinal disorders	Diverticulum intestinal	25SEP2003		Y
			Gastroesophageal reflux disease	12JUN2003		Y
		Immune system disorders	Drug hypersensitivity	01JUL2003		Y
				17JUN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				25SEP2003		Y
			Seasonal allergy	05FEB2019		Y
		Nervous system disorders	Migraine	05FEB2019		Y
		Psychiatric disorders	Anxiety	02AUG2004		Y
		Renal and urinary disorders	Kidney small	09JUN2009		Y
		Reproductive system and breast disorders	Haemospermia	29JUL2016		Y
		Vascular disorders	Hypertension	09JUN2009		Y
			Peripheral artery aneurysm	03MAY2019		Y
	C4591001 1270 12701103	Cardiac disorders	Left ventricular hypertrophy	18AUG2015		Y
		Eye disorders	Open angle glaucoma	07APR2015		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	30JAN2009		Y
			Oesophageal spasm	02DEC2008		Y
		Immune system disorders	Drug hypersensitivity			Y
				05FEB2008		Y
				15JUN2012		Y
				30JAN2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01DEC2015		Y
			Obesity	24FEB2006		Y
			Type 2 diabetes mellitus	30SEP2019		Y
		Musculoskeletal and connective tissue disorders	Exostosis	13AUG2014		Y
			Joint instability	25JUN2019		Y
			Osteoarthritis	01DEC2015		Y
				22JUN2007		Y
			Spinal osteoarthritis	26NOV2007		Y
		Nervous system disorders	Neuropathy peripheral	15SEP2019		Y
		Psychiatric disorders	Anxiety	27OCT2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Depression	30JAN2018		Y
		Renal and urinary disorders	Urge incontinence	30MAR2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	12AUG2010		Y
			Sleep apnoea syndrome	06FEB2016		Y
		Surgical and medical procedures	Gastric banding	20FEB2008	20FEB2008	N
			Knee arthroplasty	01JUN2007	01JUN2007	N
		Vascular disorders	Hypertension	06JUL2006		Y
	C4591001 1270 12701104	Eye disorders	Corneal epithelium defect	27FEB2017		Y
			Maculopathy	17MAR2011		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	17MAR2020		Y
		Metabolism and nutrition disorders	Vitamin D deficiency	23APR2016		Y
		Vascular disorders	Arteriosclerosis	03OCT2016		Y
	C4591001 1270 12701105	Gastrointestinal disorders	Gastroesophageal reflux disease	15DEC2018		Y
		Immune system disorders	Drug hypersensitivity	17MAR2016		Y
				27FEB2009		Y
		Musculoskeletal and connective tissue disorders	Kyphosis	17MAR2016		Y
		Psychiatric disorders	Insomnia	24MAR2009		Y
		Surgical and medical procedures	Skin neoplasm excision	11NOV2018	11NOV2018	N
	C4591001 1270 12701106	Congenital, familial and genetic disorders	Primary familial brain calcification	10MAY2020		Y
		Ear and labyrinth disorders	Vertigo positional	03AUG2007		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	03AUG2007		Y
		Immune system disorders	Drug hypersensitivity	06JAN2017		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	26JUL2016		Y
			Hyperlipidaemia	08FEB2001		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Erectile dysfunction	23APR2014		Y
	C4591001 1270 12701108	Vascular disorders	Hypertension	15NOV2019		Y
		Cardiac disorders	Coronary artery disease	19SEP2018		Y
			Left ventricular failure	04JAN2019		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	05APR1999		Y
		Hepatobiliary disorders	Hepatic steatosis	10MAY2013		Y
		Immune system disorders	Drug hypersensitivity	03MAY2016		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	06OCT2005		Y
			Obesity	02DEC2005		Y
			Type 2 diabetes mellitus	22JUN2009		Y
		Musculoskeletal and connective tissue disorders	Back pain	25JUL2012		Y
			Bursitis	28JAN2016		Y
			Intervertebral disc degeneration	27JUL2012		Y
			Spondylolisthesis	27JUL2012		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	02DEC2005		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	08SEP2005		Y
		Vascular disorders	Aortic arteriosclerosis	02AUG2012		Y
			Hypertension	21NOV2008		Y
			Peripheral artery aneurysm	11OCT2016		Y
			Varicose vein	25JUL2012		Y
	C4591001 1270 12701109	Ear and labyrinth disorders	Deafness bilateral	14FEB2020		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	15NOV2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	20NOV2019	18FEB2020	N



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Skin and subcutaneous tissue disorders	Purpura senile	07FEB2020		Y
		Surgical and medical procedures	Skin neoplasm excision	18FEB2020	18FEB2020	N
		Vascular disorders	Aortic arteriosclerosis	01NOV2019		Y
			Hypertension	24APR2003		Y
	C4591001 1270 12701110	Gastrointestinal disorders	Gastroesophageal reflux disease	18AUG2018		Y
		Hepatobiliary disorders	Gallbladder polyp	25APR2007		Y
		Immune system disorders	Drug hypersensitivity	09DEC1996		Y
				12JUL2013		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	17MAR2007		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	22JUL2015		Y
		Vascular disorders	Hypertension	25APR2007		Y
	C4591001 1270 12701111	Endocrine disorders	Hypothyroidism	30MAR2001		Y
		Eye disorders	Cataract	20JUN2006	14NOV2019	N
			Glaucoma	14NOV2006		Y
			Retinopathy proliferative	21AUG2020		Y
			Vitreous haemorrhage	17JUN2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	08DEC2008		Y
			Type 1 diabetes mellitus	25JUL2012		Y
		Musculoskeletal and connective tissue disorders	Bursa disorder	26NOV2014		Y
			Intervertebral disc degeneration	27APR2007		Y
		Nervous system disorders	Myelopathy	29APR2009		Y
		Renal and urinary disorders	Chronic kidney disease	30APR2019		Y
		Reproductive system and breast disorders	Erectile dysfunction	25JUL2012		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	23APR2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Cataract operation	14NOV2019	14NOV2019	N
		Vascular disorders	Hypertension	08DEC2008		Y
	C4591001 1270 12701112	Musculoskeletal and connective tissue disorders	Osteoarthritis	13FEB2017		Y
			Osteopenia	15FEB2011		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01JAN2002	31DEC2002	N
			Squamous cell carcinoma	01JAN2015	31DEC2015	N
		Reproductive system and breast disorders	Breast calcifications	26MAR2009		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	25AUG2015		Y
			Sleep apnoea syndrome	04APR2011		Y
		Skin and subcutaneous tissue disorders	Psoriasis	16DEC2008		Y
		Social circumstances	Menopause	01JAN1997		Y
		Vascular disorders	Hypertension	26FEB2010		Y
	C4591001 1270 12701113	Blood and lymphatic system disorders	Anaemia vitamin B12 deficiency	27JAN2020		Y
			Iron deficiency anaemia	15JAN2020		Y
		Gastrointestinal disorders	Gastroesophageal reflux disease	08DEC2019		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	11MAR2020		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	05FEB2019	29JAN2020	N
			Pain in extremity	03AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	14OCT2010	20NOV2010	N
		Skin and subcutaneous tissue disorders	Urticaria	25JUN2009		Y
		Surgical and medical procedures	Breast conserving surgery	20NOV2010	20NOV2010	N
			Hip arthroplasty	29JAN2020	29JAN2020	N
		Vascular disorders	Hypertension	05FEB2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 1270 12701114	Musculoskeletal and connective tissue disorders	Osteoarthritis	16FEB2006		Y
				22JAN2019		Y
			Osteopenia	21JUL2006		Y
		Renal and urinary disorders	Urge incontinence	03JUN2019		Y
		Surgical and medical procedures	Intraocular lens implant	17JUL2019		Y
				31JUL2019		Y
	C4591001 1270 12701115	Eye disorders	Normal tension glaucoma	19JUL2017		Y
	C4591001 1270 12701116	Cardiac disorders	Stress cardiomyopathy	07JUL2011		Y
		Endocrine disorders	Hypothyroidism	09MAY2007		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	03FEB2003		Y
			Vitamin B12 deficiency	28FEB2011		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	11MAY2018		Y
		Nervous system disorders	Migraine	04MAR2008		Y
		Skin and subcutaneous tissue disorders	Purpura senile	04JUN2019		Y
		Surgical and medical procedures	Intraocular lens implant	24MAY2017		Y
		Vascular disorders	Aortic arteriosclerosis	06JUL2020		Y
			Hypertension	18JUN2014		Y
	C4591001 1270 12701117	Endocrine disorders	Hypothyroidism	03NOV2009		Y
		Immune system disorders	Drug hypersensitivity	06JUN2007		Y
		Metabolism and nutrition disorders	Gout	30APR2014		Y
			Hyperlipidaemia	15FEB2001		Y
			Obesity	16MAR2014		Y
		Musculoskeletal and connective tissue disorders	Spondylolisthesis	16MAR2014		Y
		Renal and urinary disorders	Renal mass	10JAN2017	06FEB2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
					09MAY2017	N
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	31JAN2006		Y
		Skin and subcutaneous tissue disorders	Actinic keratosis	31JAN2006		Y
		Surgical and medical procedures	Nephrectomy	06FEB2017	06FEB2017	N
				09MAY2017	09MAY2019	N
		Vascular disorders	Aortic arteriosclerosis	02NOV2017		Y
			Hypertension	10MAR2005		Y
	C4591001 1270 12701120	Cardiac disorders	Atrial fibrillation	20OCT2014		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	07FEB2011		Y
			Back pain	11FEB2019		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	25OCT2010		Y
		Surgical and medical procedures	Skin neoplasm excision	24DEC2013	24DEC2013	N
				28DEC2015	28DEC2015	N
	C4591001 1270 12701126	Eye disorders	Astigmatism	12AUG2020		Y
			Cataract	12AUG2020		Y
			Myopia	12AUG2020		Y
			Presbyopia	12AUG2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	01JAN1995		Y
			Type 2 diabetes mellitus	01JAN1988		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon adenoma	09MAR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	17APR2014		Y
	C4591001 1270 12701127	Endocrine disorders	Hypothyroidism	18JAN2007		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Gastroesophageal reflux disease	02SEP2014		Y
		Immune system disorders	Drug hypersensitivity	01JAN2005		Y
				05JUN2015		Y
				10FEB1999		Y
				19SEP2005		Y
				22JUL2009		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	21FEB2001		Y
			Impaired fasting glucose	02SEP2014		Y
		Musculoskeletal and connective tissue disorders	Back pain	14APR2012		Y
			Osteopenia	20SEP2006		Y
			Pain in extremity	01MAY2020		Y
			Spinal osteoarthritis	05NOV2007		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Papillary thyroid cancer	01JAN2006	31DEC2006	N
		Nervous system disorders	Migraine	24DEC2015		Y
			Morton's neuralgia	13DEC2018		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	08MAY2013		Y
		Surgical and medical procedures	Hysterectomy	01SEP2005	30SEP2005	N
		Vascular disorders	Varicose vein	08DEC2016		Y
	C4591001 1270 12701130	Blood and lymphatic system disorders	Polycythaemia	23JUL2020		Y
		Gastrointestinal disorders	Lower gastrointestinal haemorrhage	01NOV2019	07NOV2019	N
			Pancreatic cyst	26MAR2020		Y
		Metabolism and nutrition disorders	Hyperlipidaemia	19OCT2011		Y
			Type 2 diabetes mellitus	06OCT2017		Y
		Surgical and medical procedures	Skin neoplasm excision	01DEC2011		Y
		Vascular disorders	Hypertension	02SEP2004		Y
			Peripheral artery aneurysm	01NOV2019		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 1270 12701138	Endocrine disorders	Hypogonadism male	25MAY2011		Y
		Eye disorders	Astigmatism	01APR2019		Y
			Cataract	17JAN2019	10APR2019	N
			Hypermetropia	03MAY2019		Y
			Presbyopia	03MAY2019		Y
		Injury, poisoning and procedural complications	Muscle strain	07JUL2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	15AUG2019		Y
			Patellofemoral pain syndrome	12JUN2019		Y
			Tendonitis	20NOV2018		Y
		Surgical and medical procedures	Intraocular lens implant	03MAY2019		Y
	C4591001 1270 12701139	Gastrointestinal disorders	Irritable bowel syndrome	08NOV1996		Y
			Large intestine polyp	14JAN2019	08APR2019	N
		Immune system disorders	Drug hypersensitivity	22JAN2004		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc degeneration	08FEB2018		Y
		Nervous system disorders	Lumbar radiculopathy	06JAN2014		Y
		Skin and subcutaneous tissue disorders	Psoriasis	28JAN2019		Y
		Surgical and medical procedures	Hysterectomy	01JAN2004	31DEC2004	N
			Large intestinal polypectomy	08APR2019	08APR2019	N
	C4591001 1270 12701140	Eye disorders	Glaucoma	19FEB2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	01JAN2015	31DEC2015	N
	C4591001 1270 12701143	Gastrointestinal disorders	Diverticulum intestinal	09NOV2005		Y
			Gastroesophageal reflux disease	10MAY2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	15JUN1998		Y
		Immune system disorders	Drug hypersensitivity	13JUN2003		Y
		Metabolism and nutrition disorders	Glucose tolerance impaired	08DEC2009		Y
			Hyperlipidaemia	24MAR2000		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	06JUL2012		Y
			Osteopenia	03NOV2014		Y
		Nervous system disorders	Lumbar radiculopathy	18DEC2012		Y
		Social circumstances	Menopause	01JAN1996		Y
		Vascular disorders	Aortic arteriosclerosis	03MAY2016		Y
			Hypertension	29JAN1998		Y
	C4591001 1270 12701144	Gastrointestinal disorders	Inguinal hernia	11FEB2008	23JUN2020	N
		Metabolism and nutrition disorders	Glucose tolerance impaired	24JAN2017		Y
			Hyperlipidaemia	15OCT2019		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	06JUN2008		Y
		Surgical and medical procedures	Inguinal hernia repair	23JUN2020	23JUN2020	N
		Vascular disorders	Aortic arteriosclerosis	26JUN2015		Y
	C4591001 1270 12701145	Endocrine disorders	Hyperthyroidism	26SEP2016		Y
				29AUG2016		Y
		Immune system disorders	Drug hypersensitivity	07AUG2013		Y
			Food allergy	07AUG2013		Y
		Injury, poisoning and procedural complications	Iliotibial band syndrome	08APR2016		Y
			Ligament sprain	08JUN2020		Y
			Meniscus injury	14JUL2020		Y
			Tibia fracture	17DEC2019	25MAY2020	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Bursitis	08APR2016		Y
			Osteoarthritis	01JUL2015		Y
			Osteopenia	11DEC2017		Y
			Sacroiliitis	10APR2018		Y
			Spinal osteoarthritis	08APR2016		Y
		Nervous system disorders	Lumbar radiculopathy	08APR2016		Y
			Piriformis syndrome	27JUL2018		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	20NOV2014		Y
			Rhinitis allergic	24APR2009		Y
	C4591001 4444 44441005	Eye disorders	Glaucoma	01JAN2000		Y
	C4591001 4444 44441006	Metabolism and nutrition disorders	Hypercholesterolaemia	02MAY2015		Y
	C4591001 4444 44441011	Vascular disorders	Hypertension	08SEP2012		Y
	C4591001 4444 44441013	Vascular disorders	Hypertension	23SEP2013		Y
	C4591001 4444 44441018	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN1990	01JAN2008	N
		Respiratory, thoracic and mediastinal disorders	Asthma	01MAR1970		Y
	C4591001 4444 44441029	Gastrointestinal disorders	Barrett's oesophagus	01JAN2016		Y
	C4591001 4444 44441030	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Metabolism and nutrition disorders	Vitamin B12 deficiency	01JAN2014		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2017		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Metabolic surgery	01JAN2014	31DEC2014	N
	C4591001 4444 44441036	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	01FEB2013	01MAR2013	N
	C4591001 4444 44441039	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 4444 44441041	Reproductive system and breast disorders	Benign prostatic hyperplasia	16SEP2017		Y
		Vascular disorders	Hypertension	16SEP2017		Y
	C4591001 4444 44441042	Musculoskeletal and connective tissue disorders	Osteitis	01JAN2000		Y
		Surgical and medical procedures	Hysterectomy	01JAN1992	31DEC1992	N
	C4591001 4444 44441046	Endocrine disorders	Hypothyroidism	01JUN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUN2018		Y
		Surgical and medical procedures	Phlebectomy	01JUN2018	01JUN2018	N
	C4591001 4444 44441049	Ear and labyrinth disorders	Meniere's disease	15JUN2015		Y
		Surgical and medical procedures	Cochlea implant	02JAN2019	02JAN2019	N
		Vascular disorders	Hypertension	14SEP1989		Y
	C4591001 4444 44441050	Infections and infestations	Urinary tract infection	01JAN2018		Y
		Vascular disorders	Hypertension	01SEP1999		Y
			Varicose vein	01JAN2006		Y
	C4591001 4444 44441051	Vascular disorders	Hypertension	20SEP1990		Y
	C4591001 4444 44441052	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02SEP2010		Y
		Renal and urinary disorders	Hypertonic bladder	05SEP2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441053	Gastrointestinal disorders	Gastritis	14SEP2016		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2002		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	15JUN2000	14JUN2001	N
		Surgical and medical procedures	Knee arthroplasty	01JAN2017	31JAN2017	N
				01JAN2019	31JAN2019	N
		Vascular disorders	Hypertension	11SEP2013		Y
	C4591001 4444 44441054	Reproductive system and breast disorders	Benign prostatic hyperplasia	10OCT2013		Y
		Vascular disorders	Hypertension	20NOV2018		Y
	C4591001 4444 44441057	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2000		Y
			Hyperuricaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 4444 44441058	Endocrine disorders	Autoimmune thyroiditis	01JAN2019		Y
		Metabolism and nutrition disorders	Metabolic syndrome	01JAN2000		Y
		Psychiatric disorders	Insomnia	01JAN2000		Y
	C4591001 4444 44441059	Injury, poisoning and procedural complications	Dental restoration failure	01APR2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01SEP2000		Y
		Nervous system disorders	Neuropathy peripheral	01APR2020		Y
		Surgical and medical procedures	Dental implantation	13DEC2019	30APR2020	N
		Vascular disorders	Hypertension	15SEP2011		Y
	C4591001 4444 44441061	Metabolism and nutrition disorders	Hypercholesterolaemia	03NOV2010		Y
			Hypertriglyceridaemia	03NOV2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01APR2008		Y
		Social circumstances	Tobacco user	05MAR1972		Y
		Vascular disorders	Hypertension	03NOV2010		Y
	C4591001 4444 44441067	Vascular disorders	Hypertension	05JAN2004		Y
	C4591001 4444 44441070	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01JAN1998	03OCT1998	N
		Psychiatric disorders	Insomnia	01MAR2020		Y
		Surgical and medical procedures	Gastric bypass	06JUN2013	09JUN2013	N
			Hysterectomy	03OCT1998	03OCT1998	N
	C4591001 4444 44441074	Endocrine disorders	Hypothyroidism	02MAY1997		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	02SEP2007	03OCT2007	N
		Psychiatric disorders	Panic attack	02MAY2001	04OCT2001	N
		Surgical and medical procedures	Breast conserving surgery	02SEP2007	02SEP2007	N
	C4591001 4444 44441080	Endocrine disorders	Hyperthyroidism	21SEP2017		Y
		Vascular disorders	Hypertension	21SEP2013		Y
	C4591001 4444 44441082	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2012		Y
	C4591001 4444 44441083	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2019		Y
	C4591001 4444 44441085	Cardiac disorders	Coronary artery disease	01JAN2008	01SEP2020	N
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2008		Y
		Nervous system disorders	Carotid arteriosclerosis	01SEP2008		Y
		Surgical and medical procedures	Coronary revascularisation	09SEP2008	14SEP2009	N
		Vascular disorders	Hypertension	01JAN2003		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 4444 44441088	Metabolism and nutrition disorders	Hypercholesterolaemia	09SEP2010		Y
	C4591001 4444 44441089	Metabolism and nutrition disorders	Dyslipidaemia	12SEP2018		Y
		Psychiatric disorders	Anxiety	08AUG2010		Y
	C4591001 4444 44441090	Vascular disorders	Hypertension	12SEP2010		Y
	C4591001 4444 44441091	Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2019		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2016		Y
			Vitamin D deficiency	01JUN2018		Y
	C4591001 4444 44441092	Psychiatric disorders	Depression	01SEP2010		Y
	C4591001 4444 44441093	Vascular disorders	Hypertension	01JAN1995		Y
	C4591001 4444 44441096	Vascular disorders	Hypertension	20JUL2017		Y
	C4591001 4444 44441097	Immune system disorders	Seasonal allergy	01JUN2010		Y
		Respiratory, thoracic and mediastinal disorders	Bronchospasm	01JUN2010		Y
		Vascular disorders	Hypertension	03MAR2019		Y
	C4591001 4444 44441098	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2012		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP1960		Y
		Vascular disorders	Hypertension	01JAN2012		Y
	C4591001 4444 44441104	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2010		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	10SEP2015		Y

<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
		Vascular disorders	Hypertension	08SEP2017		Y
	C4591001 4444 44441107	Endocrine disorders	Hypothyroidism	02SEP2010		Y
		Immune system disorders	Seasonal allergy	01JAN1987		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	05SEP2016		Y
		Psychiatric disorders	Anxiety disorder	10JUN2020		Y
	C4591001 4444 44441109	Vascular disorders	Hypertension	02SEP2015		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	29MAR2010		Y
			Type 2 diabetes mellitus	15SEP2015		Y
	C4591001 4444 44441111	Vascular disorders	Hypertension	02MAR2015		Y
		Cardiac disorders	Sinus tachycardia	01SEP2019		Y
		Endocrine disorders	Hypothyroidism	01MAR2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2015		Y
		Vascular disorders	Peripheral venous disease	01MAR2000		Y
	C4591001 4444 44441112	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Nervous system disorders	Migraine	01JAN2010		Y
	C4591001 4444 44441114	Gastrointestinal disorders	Hiatus hernia	25JUN2010		Y
			Large intestine polyp	25JUN2010	25JUN2010	N
		Infections and infestations	Pneumonia	01SEP2018	30SEP2018	N
		Respiratory, thoracic and mediastinal disorders	Bronchiectasis	01SEP2018		Y
	C4591001 4444 44441116	Ear and labyrinth disorders	Deafness bilateral	01FEB2018		Y
		Gastrointestinal disorders	Poor dental condition	01AUG1995		Y
		Metabolism and nutrition disorders	Obesity	15JAN2000		Y
		Vascular disorders	Hypertension	01JAN2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441122	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 4444 44441127	Metabolism and nutrition disorders	Dyslipidaemia	15AUG1996		Y
	C4591001 4444 44441129	Gastrointestinal disorders	Diverticulum intestinal	01JAN2016		Y
	C4591001 4444 44441130	Vascular disorders	Hypertension	10JUN2015		Y
		Endocrine disorders	Hypothyroidism	01SEP2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2010		Y
	C4591001 4444 44441131	Psychiatric disorders	Anxiety disorder	01MAY2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	08AUG2015		Y
	C4591001 4444 44441133	Musculoskeletal and connective tissue disorders	Osteoporosis	09SEP2015		Y
		Vascular disorders	Hypertension	10OCT2018		Y
		Endocrine disorders	Hypothyroidism	01JUN1974		Y
	C4591001 4444 44441136	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2006		Y
			Type 2 diabetes mellitus	01JAN2009		Y
		Psychiatric disorders	Anxiety	01JUN1995		Y
		Vascular disorders	Hypertension	01JAN2007		Y
		Psychiatric disorders	Insomnia	01SEP2001		Y
	C4591001 4444 44441137	Metabolism and nutrition disorders	Hypercholesterolaemia	10MAR2017		Y
	C4591001 4444 44441140	Respiratory, thoracic and mediastinal disorders	Bronchospasm	01SEP2000	01SEP2001	N
		Vascular disorders	Hypertension	01SEP2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441141	Musculoskeletal and connective tissue disorders	Intervertebral disc disorder	30OCT2019		Y
	C4591001 4444 44441145	Metabolism and nutrition disorders	Dyslipidaemia	04MAR2010		Y
		Psychiatric disorders	Anxiety disorder	07APR2015		Y
	C4591001 4444 44441148	Endocrine disorders	Hypothyroidism	21SEP2010		Y
		Gastrointestinal disorders	Gastritis	01FEB2010		Y
		Musculoskeletal and connective tissue disorders	Pain in extremity	01JUL2018		Y
		Psychiatric disorders	Anxiety	30SEP2010		Y
	C4591001 4444 44441151	Metabolism and nutrition disorders	Dyslipidaemia	10JUN2018		Y
			Obesity	01APR2020		Y
	C4591001 4444 44441152	Metabolism and nutrition disorders	Type 2 diabetes mellitus	04MAY2005		Y
	C4591001 4444 44441153	Cardiac disorders	Coronary artery disease	01JAN2013		Y
		Metabolism and nutrition disorders	Dyslipidaemia	06JUN2018		Y
		Surgical and medical procedures	Coronary angioplasty	01JAN2013	04JAN2013	N
	C4591001 4444 44441158	Eye disorders	Myopia	01JAN1990		Y
		Nervous system disorders	Cerebral infarction	01JAN1998	31DEC1998	N
		Respiratory, thoracic and mediastinal disorders	Vocal cord thickening	01JAN2008	31DEC2008	N
		Surgical and medical procedures	Thyroglossal cyst excision	01JAN2015	31DEC2015	N
	C4591001 4444 44441161	Gastrointestinal disorders	Varices oesophageal	10MAY2014		Y
		Hepatobiliary disorders	Cirrhosis alcoholic	01JAN2013		Y
			Portal hypertension	10MAY2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Psychiatric disorders	Insomnia	01NOV2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	20MAY2013		Y
		Social circumstances	Tobacco user	01JAN1996		Y
		Vascular disorders	Hypertension	08SEP2010		Y
	C4591001 4444 44441164	Social circumstances	Tobacco user	01JAN1970		Y
	C4591001 4444 44441165	Endocrine disorders	Hypothyroidism	08AUG2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1980		Y
		Vascular disorders	Hypertension	10OCT2004		Y
	C4591001 4444 44441167	Gastrointestinal disorders	Coeliac disease	02SEP2018		Y
	C4591001 4444 44441183	Metabolism and nutrition disorders	Type 2 diabetes mellitus	02FEB2010		Y
	C4591001 4444 44441185	Cardiac disorders	Arrhythmia	01APR2016		Y
		Endocrine disorders	Hypothyroidism	01JAN2018		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN2000		Y
		Surgical and medical procedures	Coronary revascularisation	01APR2016	01APR2016	N
	C4591001 4444 44441186	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2010		Y
			Type 2 diabetes mellitus	01SEP2010		Y
	C4591001 4444 44441188	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Vascular disorders	Hypertension	01JAN2013		Y



<b>16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age</b>						
<b>Age Group (Years)</b>	<b>Subject</b>	<b>System Organ Class</b>	<b>Preferred Term</b>	<b>Start Date</b>	<b>End Date</b>	<b>Ongoing (Yes/No)</b>
	C4591001 4444 44441189	Endocrine disorders	Hypothyroidism	01SEP1985		Y
	C4591001 4444 44441193	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	06SEP2000		Y
	C4591001 4444 44441196	Infections and infestations	Diverticulitis	01JAN2016		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	14SEP1960		Y
	C4591001 4444 44441202	Metabolism and nutrition disorders	Hyperuricaemia	12SEP2017		Y
		Vascular disorders	Hypertension	02SEP2015		Y
	C4591001 4444 44441204	Vascular disorders	Hypertension	04APR1989		Y
	C4591001 4444 44441208	Metabolism and nutrition disorders	Obesity	01MAR2015		Y
		Social circumstances	Tobacco user	01FEB1980		Y
		Vascular disorders	Hypertension	01FEB2014		Y
	C4591001 4444 44441210	Endocrine disorders	Hypothyroidism	05JUL2000		Y
		Metabolism and nutrition disorders	Insulin resistance	05AUG2020		Y
			Obesity	16APR2004		Y
		Skin and subcutaneous tissue disorders	Dermatitis atopic	30JUL2020	03OCT2020	N
		Vascular disorders	Hypertension	06JUN1997		Y
	C4591001 4444 44441214	Nervous system disorders	Ischaemic stroke	01APR2013	01APR2013	N
		Social circumstances	Menopause	01JAN2013		Y
		Vascular disorders	Hypertension	01SEP1986		Y
	C4591001 4444 44441215	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2015		Y
		Vascular disorders	Hypertension	08MAY2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441216	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2000		Y
		Vascular disorders	Hypertension	01JUN1997		Y
	C4591001 4444 44441217	Vascular disorders	Hypertension	02SEP2016	01JUL2020	N
	C4591001 4444 44441221	Vascular disorders	Deep vein thrombosis	01JUL2020		Y
			Hypertension	01SEP2018		Y
	C4591001 4444 44441227	Metabolism and nutrition disorders	Hypercholesterolaemia	14MAY2020		Y
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	14JUL2020		Y
	C4591001 4444 44441228	Gastrointestinal disorders	Gastroesophageal reflux disease	01JUL2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2000		Y
		Vascular disorders	Hypertension	01JUL2005		Y
			Venous thrombosis limb	18SEP2020		Y
	C4591001 4444 44441229	Metabolism and nutrition disorders	Metabolic syndrome	01JAN2018		Y
		Vascular disorders	Hypertension	01JAN1980		Y
	C4591001 4444 44441230	Musculoskeletal and connective tissue disorders	Back pain	01SEP2015		Y
			Osteoarthritis	01SEP2015		Y
		Surgical and medical procedures	Hip arthroplasty	19MAR2019	19APR2019	N
		Vascular disorders	Hypertension	01SEP2009		Y
	C4591001 4444 44441231	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01SEP2010	01NOV2013	N
	C4591001 4444 44441233	Eye disorders	Glaucoma	01MAY2014		Y
			Retinal detachment	01MAR2014	02MAR2014	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Infections and infestations	Eye infection toxoplasmal	01JAN2013	30NOV2019	N
		Surgical and medical procedures	Glaucoma surgery	06SEP2020	23SEP2020	N
		Vascular disorders	Hypertension	01JAN2001		Y
	C4591001 4444 44441235	Reproductive system and breast disorders	Benign prostatic hyperplasia	13AUG2019		Y
		Vascular disorders	Hypertension	01MAR2015		Y
	C4591001 4444 44441239	Metabolism and nutrition disorders	Dyslipidaemia	21SEP2007		Y
	C4591001 4444 44441240	Metabolism and nutrition disorders	Hypercholesterolaemia	01OCT2019		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01FEB2015		Y
	C4591001 4444 44441241	Vascular disorders	Hypertension	05JUL2012		Y
	C4591001 4444 44441244	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	01SEP2002	01NOV2002	N
	C4591001 4444 44441251	Metabolism and nutrition disorders	Obesity	13MAR2013		Y
			Type 2 diabetes mellitus	01MAR2013		Y
		Vascular disorders	Hypertension	01MAR2013		Y
	C4591001 4444 44441254	Endocrine disorders	Hypothyroidism	10NOV2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	08SEP2010		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cancer	01SEP2017	03MAY2020	N
		Surgical and medical procedures	Laparoscopic surgery	05NOV2017	05NOV2017	N
	C4591001 4444 44441256	Psychiatric disorders	Insomnia	17AUG2016		Y
	C4591001 4444 44441258	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10JUN2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	10JAN2010		Y
	C4591001 4444 44441259	Vascular disorders	Hypertension	01SEP2015		Y
	C4591001 4444 44441264	Endocrine disorders	Autoimmune thyroiditis	01MAY1978		Y
	C4591001 4444 44441266	Vascular disorders Psychiatric disorders	Hypertension Anxiety	01JAN2013 01SEP2017		Y Y
	C4591001 4444 44441270	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2010		Y
	C4591001 4444 44441274	Vascular disorders Vascular disorders	Hypertension Hypertension	01SEP2010 01JUN2012		Y Y
	C4591001 4444 44441276	Vascular disorders	Hypertension	02APR2010		Y
	C4591001 4444 44441281	Cardiac disorders	Ventricular extrasystoles	15MAY2019		Y
	C4591001 4444 44441283	Vascular disorders Eye disorders	Hypertension Glaucoma	12MAY2012 17FEB2013		Y Y
	C4591001 4444 44441287	Metabolism and nutrition disorders Injury, poisoning and procedural complications	Obesity Ankle fracture	01SEP2013 01JAN2011	31DEC2011	Y N
			Lumbar vertebral fracture	01JAN2018	31DEC2018	N
			Upper limb fracture	01JAN2014	31DEC2014	N
		Musculoskeletal and connective tissue disorders	Osteoporosis	01JAN2018		Y
			Rheumatoid arthritis	01JAN2008		Y
		Vascular disorders	Hypertension	12MAY2014		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441291	Cardiac disorders	Acute myocardial infarction	15SEP2016	17SEP2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	01DEC2015		Y
		Vascular disorders	Hypertension	19OCT2016		Y
	C4591001 4444 44441292	Surgical and medical procedures	Intervertebral disc operation	01NOV2010	01NOV2010	N
	C4591001 4444 44441295	Vascular disorders	Hypertension	02JAN2010		Y
	C4591001 4444 44441299	Metabolism and nutrition disorders	Obesity	05OCT2006		Y
		Psychiatric disorders	Anxiety	19MAR2020		Y
		Vascular disorders	Hypertension	06SEP2017		Y
	C4591001 4444 44441303	Metabolism and nutrition disorders	Dyslipidaemia	01SEP1999		Y
	C4591001 4444 44441305	Hepatobiliary disorders	Hepatic steatosis	01JUN2000		Y
		Metabolism and nutrition disorders	Obesity	01JAN1998		Y
		Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	01JUN2000		Y
		Vascular disorders	Peripheral venous disease	07JAN2015		Y
	C4591001 4444 44441306	Gastrointestinal disorders	Gastritis	01JAN2018		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Psychiatric disorders	Insomnia	01JAN2015		Y
	C4591001 4444 44441308	Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2010		Y
	C4591001 4444 44441312	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Type 2 diabetes mellitus	01JAN2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Angioplasty	01JAN2011	01JAN2011	N
			Carotid endarterectomy	01JAN2013		Y
			Coronary arterial stent insertion	01JAN2011	01JAN2011	N
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 4444 44441313	Reproductive system and breast disorders	Benign prostatic hyperplasia	05JUN2019		Y
		Vascular disorders	Hypertension	01JUN1993		Y
	C4591001 4444 44441314	Surgical and medical procedures	Inguinal hernia repair	01SEP2010	15SEP2010	N
				02FEB2019	15FEB2019	N
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 4444 44441316	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2019		Y
		Surgical and medical procedures	Spinal fusion surgery	01APR2019	01MAY2019	N
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 4444 44441320	Endocrine disorders	Hypothyroidism	01JAN1981		Y
		Injury, poisoning and procedural complications	Arterial injury	03DEC2019		Y
			Neck injury	03DEC2019	03DEC2019	N
	C4591001 4444 44441322	Endocrine disorders	Hypothyroidism	01JAN2000		Y
		Vascular disorders	Hypertension	01JUN2014		Y
	C4591001 4444 44441328			01JUN2014		Y
	C4591001 4444 44441331	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2015		Y
	C4591001 4444 44441338	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01DEC2016		Y
		Respiratory, thoracic and mediastinal disorders	Emphysema	01JUN2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2014		Y
	C4591001 4444 44441340	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2019		Y
	C4591001 4444 44441343	Endocrine disorders	Hypothyroidism	01JAN2007		Y
	C4591001 4444 44441344	Gastrointestinal disorders	Gastritis	15JUN2008		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	15JUN1986		Y
		Vascular disorders	Hypertension	15JUN2008		Y
	C4591001 4444 44441349	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal adenoma	01NOV2012	24DEC2012	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01AUG2019		Y
		Surgical and medical procedures	Nephrectomy	18DEC2012	24DEC2012	N
	C4591001 4444 44441350	Gastrointestinal disorders	Gastritis	08SEP2017		Y
	C4591001 4444 44441354	Gastrointestinal disorders	Gastritis	01JAN1995		Y
	C4591001 4444 44441355	Cardiac disorders	Acute myocardial infarction	01APR2004	02APR2004	N
				01OCT2012	02OCT2012	N
				01SEP2007	02SEP2007	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2004		Y
			Type 2 diabetes mellitus	01APR2007		Y
		Surgical and medical procedures	Angioplasty	01APR2004	02APR2004	N
				01JUN2012	02JUN2012	N
				01SEP2007	02SEP2007	N
			Coronary artery bypass	01APR2017	02APR2017	N
			Stent placement	01APR2004	02APR2004	N
				01JUN2012	02JUN2012	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
				01SEP2007	02SEP2007	N
		Vascular disorders	Hypertension	01APR2004		Y
	C4591001 4444 44441356	Endocrine disorders	Hypothyroidism	03MAY2000		Y
		Gastrointestinal disorders	Hiatus hernia	01FEB1990		Y
		Vascular disorders	Hypertension	03FEB2005		Y
	C4591001 4444 44441362	Injury, poisoning and procedural complications	Subdural haematoma	18DEC2019	01JAN2020	N
	C4591001 4444 44441364	Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y
		Renal and urinary disorders	Nephrolithiasis	02SEP2010		Y
		Vascular disorders	Hypertension	01AUG2015		Y
	C4591001 4444 44441367	Endocrine disorders	Hypothyroidism	01JAN2011		Y
	C4591001 4444 44441370	Immune system disorders	Atopy	01SEP1961		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	01SEP1961		Y
	C4591001 4444 44441371	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2014		Y
		Nervous system disorders	Carotid artery occlusion	01NOV2014		Y
			Cerebrovascular accident	01NOV2014	01NOV2014	N
		Vascular disorders	Hypertension	01NOV2014		Y
	C4591001 4444 44441372	Metabolism and nutrition disorders	Dyslipidaemia	18AUG2018		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	18AUG2018		Y
	C4591001 4444 44441374	Musculoskeletal and connective tissue disorders	Osteoarthritis	07SEP2015		Y
		Vascular disorders	Hypertension	01JAN2012		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441375	Musculoskeletal and connective tissue disorders	Back pain	01SEP2018		Y
			Intervertebral disc protrusion	01SEP2018		Y
	C4591001 4444 44441381	Musculoskeletal and connective tissue disorders	Fibromyalgia	01SEP2000		Y
	C4591001 4444 44441382	Metabolism and nutrition disorders	Hypercholesterolaemia	15SEP2016		Y
	C4591001 4444 44441383	Cardiac disorders	Supraventricular tachycardia	15SEP1962		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	10JUN1990		Y
	C4591001 4444 44441385	Metabolism and nutrition disorders	Hypercholesterolaemia	22SEP2019		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01MAR2012	01DEC2012	N
		Nervous system disorders	Cluster headache	01FEB1980		Y
	C4591001 4444 44441389	Metabolism and nutrition disorders	Hypercholesterolaemia	20JAN2017		Y
	C4591001 4444 44441391	Immune system disorders	Hypersensitivity	02JUN2016		Y
		Psychiatric disorders	Anxiety	01FEB2018		Y
	C4591001 4444 44441392	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10SEP1995		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 4444 44441409	Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colon cancer	01OCT2017	10OCT2017	N
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 4444 44441410	Endocrine disorders	Hypothyroidism	16AUG2016		Y
		Vascular disorders	Hypertension	15JUN2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441411	Gastrointestinal disorders	Hiatus hernia	10SEP2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	15AUG2006	17OCT2006	N
		Psychiatric disorders	Insomnia	11SEP2014		Y
	C4591001 4444 44441414	Immune system disorders	Drug hypersensitivity	01JAN1960		Y
		Metabolism and nutrition disorders	Obesity	01JAN2005		Y
		Vascular disorders	Hypertension	01SEP2000		Y
	C4591001 4444 44441415	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2015		Y
	C4591001 4444 44441416	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2010		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2015		Y
		Psychiatric disorders	Anxiety disorder	01JUN2012		Y
		Vascular disorders	Hypertension	01JUN2010		Y
	C4591001 4444 44441418	Endocrine disorders	Hypothyroidism	01JAN2007		Y
		Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01JAN2007		Y
	C4591001 4444 44441420	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2015		Y
	C4591001 4444 44441421	Gastrointestinal disorders	Chronic gastritis	01JAN2000		Y
		Psychiatric disorders	Post-traumatic stress disorder	01JAN2010		Y
	C4591001 4444 44441422	Metabolism and nutrition disorders	Hypercholesterolaemia	02JUN2003		Y
		Vascular disorders	Hypertension	02JUN2003		Y
	C4591001 4444 44441423	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2017		Y
	C4591001 4444 44441427	Cardiac disorders	Myocardial ischaemia	12JAN2011	12JAN2011	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	01DEC2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	10OCT2015		Y
			Type 2 diabetes mellitus	01DEC2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01DEC2011		Y
		Vascular disorders	Hypertension	01DEC2010		Y
	C4591001 4444 44441429	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2010		Y
	C4591001 4444 44441430	Metabolism and nutrition disorders	Type 2 diabetes mellitus	06JUN2018		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	07JUL2012		Y
	C4591001 4444 44441431	Endocrine disorders	Thyroid mass	09MAR2015		Y
		Musculoskeletal and connective tissue disorders	Back pain	01MAR2018		Y
			Neck pain	01FEB1990		Y
		Nervous system disorders	Paraesthesia	01MAR2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01APR2017		Y
	C4591001 4444 44441434	Cardiac disorders	Acute myocardial infarction	10MAY2017	12MAY2017	N
		Eye disorders	Glaucoma	01JAN2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2017		Y
	C4591001 4444 44441439	Gastrointestinal disorders	Hiatus hernia	01SEP2010		Y
			Intestinal polyp	11NOV2008	01SEP2016	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Irritable bowel syndrome	10JUL2011		Y
	C4591001 4444	Surgical and medical procedures	Large intestinal polypectomy	01SEP2016	01SEP2016	N
	44441441	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2010		Y
		Vascular disorders	Hypertension	01MAR2015		Y
	C4591001 4444	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2019		Y
	44441447		Type 2 diabetes mellitus	01MAR2019		Y
	C4591001 4444	Social circumstances	Tobacco user	01SEP1975		Y
	44441448		Dyslipidaemia	01SEP2005		Y
	C4591001 4444	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2005		Y
	44441449	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2013		Y
		Vascular disorders	Hypertension	01SEP2005		Y
	C4591001 4444	Metabolism and nutrition disorders	Dyslipidaemia	03APR2017		Y
	44441451		Hypertension	03APR2017		Y
	C4591001 4444	Endocrine disorders	Hypothyroidism	01SEP2019		Y
	44441454		Hypothyroidism	01SEP1990		Y
	C4591001 4444	Endocrine disorders	Hypothyroidism	01SEP1990		Y
	44441455	Metabolism and nutrition disorders	Insulin-requiring type 2 diabetes mellitus	01SEP2000		Y
		Vascular disorders	Hypertension	01SEP1990		Y
	C4591001 4444	Vascular disorders	Hypertension	10JAN1990		Y
	44441456		Benign prostatic hyperplasia	22SEP2017		Y
	C4591001 4444	Reproductive system and breast disorders	Benign prostatic hyperplasia	22SEP2017		Y
	44441462		Hypothyroidism	15JUN2000		Y
	C4591001 4444	Endocrine disorders	Hypothyroidism	15JUN2000		Y
	44441463					

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Gastrointestinal disorders	Coeliac disease	30JUN2016		Y
		Nervous system disorders	Neuropathy peripheral	01APR2018		Y
	C4591001 4444 44441465	Psychiatric disorders	Anxiety	02FEB2017		Y
	C4591001 4444 44441466	Surgical and medical procedures	Aortic stent insertion	20NOV2019	20NOV2019	N
		Vascular disorders	Aortic arteriosclerosis	01NOV2018	20NOV2019	N
	C4591001 4444 44441467	Gastrointestinal disorders	Gastritis	01JAN2015		Y
	C4591001 4444 44441468	Infections and infestations	Osteomyelitis	01MAR2012	01JUL2014	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	15AUG1995	01DEC1995	N
		Surgical and medical procedures	Intervertebral disc operation	01MAR2012	01JUL2014	N
		Vascular disorders	Hypertension	01JUL2015		Y
	C4591001 4444 44441471	Cardiac disorders	Myocardial ischaemia	10JAN2017		Y
	C4591001 4444 44441473	Cardiac disorders	Coronary artery occlusion	07FEB1999	07FEB1999	N
			Coronary artery stenosis	14MAR2020	14MAR2020	N
		Hepatobiliary disorders	Cholelithiasis	16MAY1993		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	03MAR2005		Y
		Musculoskeletal and connective tissue disorders	Back pain	01FEB2005	01FEB2021	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01MAR2018	01MAR2018	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2010		Y
		Social circumstances	Tobacco user	01OCT1959	07FEB1999	N
		Surgical and medical procedures	Skin neoplasm excision	01MAR2018	01MAR2018	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	03MAR2005		Y
	C4591001 4444 44441475	Metabolism and nutrition disorders	Obesity	01MAR2018		Y
	C4591001 4444 44441479	Gastrointestinal disorders	Colitis ulcerative	01DEC2001		Y
	C4591001 4444 44441480	Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2018		Y
			Hypertriglyceridaemia	01SEP2018		Y
			Insulin resistance	01SEP2019		Y
	C4591001 4444 44441481	Gastrointestinal disorders	Hiatus hernia	01JAN2000		Y
		Surgical and medical procedures	Coronary revascularisation	01JUN2008	08JUN2008	N
	C4591001 4444 44441484	Cardiac disorders	Coronary artery disease	01JUL2013		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01AUG2013		Y
		Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	05NOV2013	01DEC2013	N
			Chronic obstructive pulmonary disease	01DEC2013		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01AUG2000		Y
	C4591001 4444 44441489	Vascular disorders	Hypertension	10SEP2019		Y
	C4591001 4444 44441493	Psychiatric disorders	Insomnia	01JAN2002		Y
			Sleep disorder	07OCT2018		Y
	C4591001 4444 44441495	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	01SEP2015		Y
		Psychiatric disorders	Stress	01SEP2020		Y
	C4591001 4444 44441496	Metabolism and nutrition disorders	Obesity	10APR2017		Y
		Vascular disorders	Hypertension	01AUG2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441497	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	13AUG2008	01AUG2013	N
	C4591001 4444 44441507	Metabolism and nutrition disorders	Hyperuricaemia	01JUN2020		Y
		Vascular disorders	Hypertension	01JUN2005		Y
	C4591001 4444 44441508	Psychiatric disorders	Depression	08SEP2018		Y
	C4591001 4444 44441509	Metabolism and nutrition disorders	Obesity	01JAN2020		Y
		Vascular disorders	Hypertension	03MAR2010		Y
	C4591001 4444 44441513	Reproductive system and breast disorders	Fibrocystic breast disease	01JAN2000		Y
	C4591001 4444 44441517	Cardiac disorders	Sinus arrhythmia	09SEP2009		Y
		Infections and infestations	Hepatitis A	07JUL1974	07AUG1977	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	08AUG2016	08AUG2019	N
		Respiratory, thoracic and mediastinal disorders	Bronchial hyperreactivity	09SEP2017		Y
		Surgical and medical procedures	Intervertebral disc operation	08AUG2019	08AUG2019	N
	C4591001 4444 44441519	Endocrine disorders	Hypothyroidism	01JUN2014		Y
	C4591001 4444 44441535	Psychiatric disorders	Insomnia	01JAN2016		Y
		Renal and urinary disorders	Renal colic	01NOV2016	03NOV2016	N
	C4591001 4444 44441540	Endocrine disorders	Hypothyroidism	01SEP2010		Y
	C4591001 4444 44441551	Cardiac disorders	Myocardial infarction	12MAR2017	16MAR2017	N
		Surgical and medical procedures	Stent placement	12MAR2017	16MAR2017	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441552	Metabolism and nutrition disorders	Hypercholesterolaemia	03APR2005		Y
		Vascular disorders	Hypertension	10MAR2014		Y
	C4591001 4444 44441568	Respiratory, thoracic and mediastinal disorders	Asthma	10MAY1973		Y
	C4591001 4444 44441571	Metabolism and nutrition disorders	Obesity	01MAR2010		Y
		Vascular disorders	Hypertension	02JUN2017		Y
	C4591001 4444 44441579	Endocrine disorders	Hypothyroidism	02MAY1975		Y
		Vascular disorders	Hypertension	03MAY2018		Y
	C4591001 4444 44441580	Gastrointestinal disorders	Large intestine polyp	23MAY2013		Y
		Surgical and medical procedures	Polypectomy	12SEP2019	12SEP2019	N
				23MAY2013	23MAY2013	N
		Vascular disorders	Hypertension	12JAN2017		Y
	C4591001 4444 44441588	Endocrine disorders	Hypothyroidism	10SEP1999		Y
	C4591001 4444 44441595	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR1995		Y
	C4591001 4444 44441598	Blood and lymphatic system disorders	Antiphospholipid syndrome	01JUL2013		Y
		Eye disorders	Glaucoma	01AUG2018		Y
		Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 4444 44441600	Metabolism and nutrition disorders	Dyslipidaemia	12JUL2017		Y
		Social circumstances	Tobacco user	01JAN1983	01JAN2013	N
		Vascular disorders	Hypertension	12JUL2017		Y
	C4591001 4444 44441602	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441607	Endocrine disorders	Hypothyroidism	03MAR2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01AUG2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	01JAN2002	01MAY2002	N
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JAN1990		Y
			Pulmonary embolism	01JAN2013	01JAN2016	N
		Skin and subcutaneous tissue disorders	Dermatitis atopic	01JAN2010		Y
	C4591001 4444 44441613	Ear and labyrinth disorders	Sudden hearing loss	01SEP2014		Y
			Vertigo	01SEP2014		Y
		Infections and infestations	Rhinitis	01JAN1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
			Hyperuricaemia	01JAN2017		Y
			Obesity	01JAN1977		Y
			Type 2 diabetes mellitus	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2006		Y
	C4591001 4444 44441620	Vascular disorders	Hypertension	01JUN2018		Y
	C4591001 4444 44441621	Metabolism and nutrition disorders	Obesity	01JAN2012		Y
	C4591001 4444 44441625	Psychiatric disorders	Insomnia	01JUL2019		Y
		Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 4444 44441626	Psychiatric disorders	Panic attack	23SEP2014		Y
		Vascular disorders	Hypertension	24SEP2012		Y
	C4591001 4444 44441627	Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2012		Y
		Nervous system disorders	Essential tremor	01JAN2020		Y
		Vascular disorders	Hypertension	03SEP1997		Y
	C4591001 4444 44441630	Musculoskeletal and connective tissue disorders	Osteopenia	01MAR2008		Y
	C4591001 4444 44441631	Cardiac disorders	Aortic valve disease	20MAY2015	11APR2018	N
		Surgical and medical procedures	Aortic valve replacement	11APR2018	11APR2018	N
	C4591001 4444 44441635	Cardiac disorders	Coronary artery disease	19SEP2009		Y
		Metabolism and nutrition disorders	Gout	01FEB1989		Y
			Hypercholesterolaemia	01SEP2009		Y
			Obesity	08JUL2009		Y
		Psychiatric disorders	Anxiety disorder	16AUG2010		Y
		Surgical and medical procedures	Coronary revascularisation	19SEP2009	20SEP2009	N
	C4591001 4444 44441641	Endocrine disorders	Hypothyroidism	09SEP2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	02AUG2000		Y
		Psychiatric disorders	Sleep disorder	04OCT2016		Y
	C4591001 4444 44441642	Metabolism and nutrition disorders	Dyslipidaemia	02SEP2015		Y
			Type 2 diabetes mellitus	01SEP2014		Y
		Vascular disorders	Hypertension	09SEP2015		Y
	C4591001 4444 44441645	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2009		Y
	C4591001 4444 44441647	Metabolism and nutrition disorders	Obesity	01JAN2011		Y
		Vascular disorders	Hypertension	01FEB2014		Y
	C4591001 4444 44441648	Vascular disorders	Hypertension	10JAN2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441651	Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2020		Y
		Vascular disorders	Hypertension	01JAN2015		Y
	C4591001 4444 44441653	Endocrine disorders	Hypothyroidism	01SEP2019		Y
		Surgical and medical procedures	Internal fixation of fracture	07OCT2007	08OCT2007	N
		Vascular disorders	Hypertension	01AUG2018		Y
	C4591001 4444 44441655	Gastrointestinal disorders	Coeliac disease	08SEP2010		Y
	C4591001 4444 44441656	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2020		Y
	C4591001 4444 44441657	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2018		Y
		Vascular disorders	Hypertension	01SEP2018		Y
	C4591001 4444 44441661	Infections and infestations	Uterine infection	01JAN1995	31DEC1995	N
		Surgical and medical procedures	Hysterectomy	02SEP1995	02SEP1995	N
			Oophorectomy	02SEP1995	02SEP1995	N
	C4591001 4444 44441665	Gastrointestinal disorders	Gastritis	09SEP2010		Y
		Hepatobiliary disorders	Cholelithiasis	01MAY1990	01JUL1990	N
		Metabolism and nutrition disorders	Obesity	01JAN2015		Y
		Surgical and medical procedures	Cholecystectomy	01JUL1990	01JUL1990	N
			Hysterectomy	05SEP1996	05SEP1996	N
		Vascular disorders	Hypertension	09SEP2005		Y
	C4591001 4444 44441666	Eye disorders	Myopia	20SEP1976	16JUL2018	N
		Infections and infestations	Appendicitis	23SEP2019	23SEP2019	N
		Psychiatric disorders	Depression	01MAY2016		Y
			Panic attack	01MAY2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Reproductive system and breast disorders	Endometriosis	15JUL2014	30JUL2014	N
	C4591001 4444 44441667	Surgical and medical procedures	Hysterosalpingo-oophorectomy	30JUL2014	31JUL2014	N
		Endocrine disorders	Hypothyroidism	04AUG1984		Y
		Immune system disorders	Drug hypersensitivity	31OCT2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	12JUL2020		Y
			Gluten sensitivity	15DEC2018		Y
	C4591001 4444 44441671	Psychiatric disorders	Depression	15MAY2015		Y
		Congenital, familial and genetic disorders	Stargardt's disease	01JAN1981		Y
		Gastrointestinal disorders	Hiatus hernia	01JAN2000		Y
		Immune system disorders	Drug hypersensitivity	01JAN1990		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2000		Y
		Psychiatric disorders	Depression	01JAN2014		Y
	C4591001 4444 44441674	Metabolism and nutrition disorders	Obesity	01JUN2020		Y
		Vascular disorders	Hypertension	10JUN2014		Y
	C4591001 4444 44441684	Cardiac disorders	Arrhythmia	01FEB1995		Y
		Endocrine disorders	Hypothyroidism	06SEP1989		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2015		Y
		Psychiatric disorders	Depression	01JAN2005		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01FEB1995		Y
	C4591001 4444 44441690	Cardiac disorders	Prinzmetal angina	01JAN2000	01JAN2000	N
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 4444 44441692	Cardiac disorders	Sinus tachycardia	01MAY2017		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441693	Metabolism and nutrition disorders	Dyslipidaemia	03MAR2003		Y
			Type 2 diabetes mellitus	03MAR2003		Y
		Vascular disorders	Hypertension	03MAR2003		Y
	C4591001 4444 44441697	Congenital, familial and genetic disorders	Familial hypertriglyceridaemia	02MAY2000		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	02MAY2000		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	06SEP2018		Y
		Vascular disorders	Hypertension	08SEP2000		Y
	C4591001 4444 44441701	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2000		Y
	C4591001 4444 44441704	Metabolism and nutrition disorders	Hypercholesterolaemia	01APR2010		Y
			Type 2 diabetes mellitus	01JUL2015		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUL2010		Y
		Vascular disorders	Hypertension	01AUG1995		Y
	C4591001 4444 44441706	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2012		Y
		Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 4444 44441708	Gastrointestinal disorders	Chronic gastritis	05JUL2010		Y
	C4591001 4444 44441709	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2000		Y
	C4591001 4444 44441713	Cardiac disorders	Tachycardia	01SEP2016		Y
		Endocrine disorders	Hypothyroidism	01SEP2019		Y
		Vascular disorders	Hypertension	01SEP2016		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441714	Metabolism and nutrition disorders	Hypercholesterolaemia	15MAY2017		Y
			Type 2 diabetes mellitus	15MAY2017		Y
		Surgical and medical procedures	Coronary artery bypass	15MAY2017	15MAY2017	N
	C4591001 4444 44441720	Gastrointestinal disorders	Gastritis	01JAN2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN1998	01JAN1998	N
	C4591001 4444 44441723	Cardiac disorders	Ventricular extrasystoles	02FEB2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	02FEB2017		Y
	C4591001 4444 44441727	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Clear cell renal cell carcinoma	11SEP2017	11OCT2017	N
		Psychiatric disorders	Depression	01JAN2010		Y
		Surgical and medical procedures	Nephrectomy	11OCT2017	11OCT2017	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 4444 44441730	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2016		Y
			Type 2 diabetes mellitus	01SEP2016		Y
		Vascular disorders	Hypertension	01AUG2020		Y
	C4591001 4444 44441732	Psychiatric disorders	Obsessive-compulsive disorder	10AUG2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2015		Y
	C4591001 4444 44441734	Metabolism and nutrition disorders	Dyslipidaemia	01OCT2016		Y
		Vascular disorders	Hypertension	01JUL2016		Y
	C4591001 4444 44441736	Endocrine disorders	Hypothyroidism	01SEP2003		Y
	C4591001 4444 44441737	Metabolism and nutrition disorders	Dyslipidaemia	04FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441740	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUL2013		Y
		Vascular disorders	Hypertension	01JUN2013		Y
	C4591001 4444 44441743	Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	10OCT1958		Y
	C4591001 4444 44441749	Metabolism and nutrition disorders	Gout	15SEP2013		Y
		Vascular disorders	Hypertension	01SEP2009		Y
	C4591001 4444 44441774	Endocrine disorders	Hypothyroidism	01SEP1992		Y
		Vascular disorders	Hypertension	01OCT2018		Y
	C4591001 4444 44441775	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2005		Y
		Vascular disorders	Peripheral venous disease	01JAN2016		Y
	C4591001 4444 44441790	Vascular disorders	Hypertension	01JAN2018		Y
	C4591001 4444 44441792	Endocrine disorders	Hypothyroidism	20FEB1997		Y
		Eye disorders	Glaucoma	01MAY2020		Y
		Metabolism and nutrition disorders	Dyslipidaemia	20FEB2005		Y
		Surgical and medical procedures	Hysterectomy	01JAN2012	31DEC2012	N
		Vascular disorders	Hypertension	20FEB2017		Y
	C4591001 4444 44441802	Eye disorders	Glaucoma	10SEP2015		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	10SEP2018		Y
		Vascular disorders	Hypertension	15SEP1999		Y
	C4591001 4444 44441803	Infections and infestations	Ophthalmic herpes zoster	15JAN1981		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441811	Gastrointestinal disorders	Constipation	04APR1963		Y
		Injury, poisoning and procedural complications	Craniocerebral injury	07MAR2019	19JUL2019	N
		Nervous system disorders	Anosmia	07MAR2019		Y
		Reproductive system and breast disorders	Metrorrhagia	20DEC1989	25SEP2011	N
		Surgical and medical procedures	Hysterectomy	25APR2011	25APR2011	N
	C4591001 4444 44441812	Vascular disorders	Hypertension	01JAN2000		Y
	C4591001 4444 44441813	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	01NOV2019	01DEC2019	N
	C4591001 4444 44441816	Endocrine disorders	Hypothyroidism	07JUL2010		Y
		Gastrointestinal disorders	Constipation	20FEB2010		Y
			Haemorrhoids	15MAY1980		Y
		Infections and infestations	Diverticulitis	01MAR2000		Y
		Metabolism and nutrition disorders	Lactose intolerance	10FEB2010		Y
		Nervous system disorders	Migraine	04SEP1990		Y
		Psychiatric disorders	Anxiety disorder	04SEP2019		Y
		Surgical and medical procedures	Polypectomy	05JUN2010	05JUN2010	N
				10OCT2015	10OCT2015	N
	C4591001 4444 44441820	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01MAR2001	01MAY2011	N
		Reproductive system and breast disorders	Metrorrhagia	01FEB2005	01MAR2005	N
		Surgical and medical procedures	Hysterectomy	01MAR2005	01MAR2005	N
			Mastectomy	01MAY2001	01MAY2001	N
	C4591001 4444 44441821	Vascular disorders	Hypertension	10OCT2013		Y



## 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441822	Endocrine disorders	Hypothyroidism	01JUN2017		Y
		Metabolism and nutrition disorders	Gout	01MAR2015		Y
			Hypercholesterolaemia	01MAR2010		Y
	C4591001 4444 44441829	Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 4444 44441831	Cardiac disorders	Sinus tachycardia	01AUG2000		Y
		Eye disorders	Myopia	01SEP1979	11AUG2020	N
		Gastrointestinal disorders	Gastroesophageal reflux disease	(b) (6) 1946		Y
			Oral mucosal blistering	18SEP2020	20SEP2020	N
		Investigations	Hysteroscopy	19AUG2019	19AUG2019	N
		Metabolism and nutrition disorders	Metabolic syndrome	01SEP2010		Y
		Reproductive system and breast disorders	Uterine polyp	01APR2019	29AUG2019	N
		Surgical and medical procedures	Eye operation	11SEP2020	11SEP2020	N
			Uterine polypectomy	19AUG2019	19AUG2019	N
	C4591001 4444 44441836	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	01OCT2012	01OCT2012	N
	C4591001 4444 44441838	Gastrointestinal disorders	Gastroesophageal reflux disease	02SEP2017		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN1983		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2010		Y
		Vascular disorders	Hypertension	01SEP2019		Y
	C4591001 4444 44441844	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2017		Y
	C4591001 4444 44441845	Metabolism and nutrition disorders	Dyslipidaemia	13SEP2005		Y
		Vascular disorders	Hypertension	14SEP2005		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441846	Eye disorders	Glaucoma	03APR2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	10JUL2015		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01AUG2020		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign ovarian tumour	04FEB2014	02APR2014	N
			Leiomyoma	07JUN2005	01SEP2007	N
		Surgical and medical procedures	Hysterectomy	01SEP2007	01SEP2007	N
			Salpingo-oophorectomy bilateral	01APR2014	01APR2014	N
	C4591001 4444 44441847	Musculoskeletal and connective tissue disorders	Osteopenia	01SEP2020		Y
		Vascular disorders	Hypertension	01AUG2010		Y
	C4591001 4444 44441848	Vascular disorders	Hypertension	01JAN1998		Y
	C4591001 4444 44441853	Endocrine disorders	Hypothyroidism	05SEP2017		Y
		Gastrointestinal disorders	Irritable bowel syndrome	05SEP2019		Y
		Vascular disorders	Hypertension	04SEP2015		Y
	C4591001 4444 44441856	Vascular disorders	Hypertension	01SEP2013		Y
	C4591001 4444 44441858	Gastrointestinal disorders	Coeliac disease	01JUN1965		Y
	C4591001 4444 44441865	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
			Obesity	01JAN2000		Y
			Type 2 diabetes mellitus	15JAN2019		Y
		Vascular disorders	Hypertension	15SEP2005		Y
	C4591001 4444 44441867	Cardiac disorders	Coronary artery disease	09SEP2010		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	09SEP2005		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	08SEP1995	29NOV2011	N
		Surgical and medical procedures	Coronary arterial stent insertion	09SEP2010	09SEP2010	N
			Intervertebral disc operation	29NOV2016	29NOV2016	N
	C4591001 4444 44441873	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Clear cell renal cell carcinoma	01OCT1999	30OCT1999	N
			Prostate cancer	03DEC2015	03FEB2016	N
		Respiratory, thoracic and mediastinal disorders	Asthma	03JAN2000		Y
		Surgical and medical procedures	Nephrectomy	18OCT1999	18OCT1999	N
		Vascular disorders	Hypertension	01MAR2000		Y
	C4591001 4444 44441876	Congenital, familial and genetic disorders	Hereditary haemochromatosis	11MAR2019		Y
		Gastrointestinal disorders	Irritable bowel syndrome	05JAN2019		Y
			Pancreatic cyst	01DEC2009	01DEC2009	N
		Injury, poisoning and procedural complications	Meniscus injury	15AUG2020		Y
		Nervous system disorders	Ischaemic stroke	01JUN2000	01JUN2000	N
			Migraine	01SEP1965		Y
		Surgical and medical procedures	Intestinal polypectomy	06JAN2020	06JAN2020	N
			Pancreatic operation	01DEC2009	01DEC2009	N
	C4591001 4444 44441880	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
		Social circumstances	Menopause	02FEB2015		Y
	C4591001 4444 44441884	Endocrine disorders	Goitre	03JUN2011		Y
	C4591001 4444 44441890	Reproductive system and breast disorders	Benign prostatic hyperplasia	01SEP2011		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44441894	Ear and labyrinth disorders	Vertigo	03AUG2015	07AUG2015	N
		Gastrointestinal disorders	Diverticulum intestinal	06OCT2009		Y
			Hiatus hernia	01JAN2015		Y
			Intestinal polyp	06OCT2009		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2015		Y
		Surgical and medical procedures	Canalith repositioning procedure	06AUG2015	06AUG2015	N
			Polypectomy	06OCT2009	06OCT2009	N
				14OCT2011	14OCT2011	N
	C4591001 4444 44441897	Gastrointestinal disorders	Large intestine polyp	01SEP2016	01SEP2016	N
		Musculoskeletal and connective tissue disorders	Osteopenia	01JUL2010		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	01JUL2016		Y
		Surgical and medical procedures	Appendicectomy	01JUL1963	01JUL1963	N
			Large intestinal polypectomy	01SEP2016	01SEP2016	N
		Vascular disorders	Hypertension	01JUN2017		Y
	C4591001 4444 44441899	Metabolism and nutrition disorders	Dyslipidaemia	06SEP2010		Y
			Obesity	01JUN2005		Y
		Vascular disorders	Arteriosclerosis	06SEP2010		Y
			Hypertension	01FEB2010		Y
	C4591001 4444 44441901	Metabolism and nutrition disorders	Obesity	15MAR2020		Y
		Psychiatric disorders	Panic attack	07SEP2000	12SEP2002	N
		Vascular disorders	Hypertension	15SEP2017		Y
	C4591001 4444 44441905	Infections and infestations	Tuberculosis	11SEP1980	09SEP1981	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Depression	16SEP2000		Y
		Vascular disorders	Hypertension	01SEP2014		Y
	C4591001 4444 44441908	Endocrine disorders	Hypothyroidism	01FEB2008		Y
		Psychiatric disorders	Depression	01OCT2011		Y
		Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	05MAR2020		Y
	C4591001 4444 44441911	Surgical and medical procedures	Prostatectomy	01SEP2016	01SEP2016	N
		Vascular disorders	Hypertension	01SEP1995		Y
	C4591001 4444 44441914	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	10OCT2015		Y
		Psychiatric disorders	Insomnia	12DEC2012		Y
	C4591001 4444 44441920	Vascular disorders	Hypertension	02MAR2016		Y
	C4591001 4444 44441922	Metabolism and nutrition disorders	Hypercholesterolaemia	05JUL2003		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leiomyosarcoma	07MAY2016	20JUN2016	N
		Reproductive system and breast disorders	Prostatitis	14JAN2015		Y
		Surgical and medical procedures	Cancer surgery	28JUN2016	28JUN2016	N
		Vascular disorders	Hypertension	03APR2003		Y
	C4591001 4444 44441926	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JAN2006		Y
		Vascular disorders	Varicose vein	01JAN2016		Y
	C4591001 4444 44441927	Gastrointestinal disorders	Gastritis	03MAR2014		Y
		Infections and infestations	Diverticulitis	03APR2014	05APR2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	03MAR2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Obesity	01JAN2015		Y
			Vitamin D deficiency	01FEB2010		Y
		Psychiatric disorders	Insomnia	01MAR2017		Y
		Surgical and medical procedures	Colectomy	05APR2014	05APR2014	N
		Vascular disorders	Hypertension	01FEB2016		Y
	C4591001 4444 44441930	Surgical and medical procedures	Hysterosalpingo-oophorectomy	01JUN2013		Y
		Vascular disorders	Hypertension	07SEP2010		Y
	C4591001 4444 44441936	Endocrine disorders	Hypothyroidism	01SEP2015		Y
	C4591001 4444 44441941	Metabolism and nutrition disorders	Hypercholesterolaemia	13SEP2010		Y
		Skin and subcutaneous tissue disorders	Psoriasis	02JUN1980		Y
	C4591001 4444 44441942	Endocrine disorders	Hypothyroidism	12SEP1980		Y
		Metabolism and nutrition disorders	Dyslipidaemia	12JAN2000		Y
		Musculoskeletal and connective tissue disorders	Osteoporosis	12JAN2010		Y
			Scoliosis	12FEB1980		Y
		Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	03MAR2020		Y
	C4591001 4444 44441947	Vascular disorders	Hypertension	10APR2018		Y
	C4591001 4444 44441948	Metabolism and nutrition disorders	Dyslipidaemia	01SEP2014		Y
	C4591001 4444 44441960	Musculoskeletal and connective tissue disorders	Osteoarthritis	01JUN2016	01JUL2016	N
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Laryngeal neoplasm	01JUN1993	01JUL1993	N
		Surgical and medical procedures	Hip arthroplasty	01JUL2006	02JUL2006	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
			Tumour excision	01JUL1993	02JUL1993	N
	C4591001 4444 44441978	Vascular disorders	Hypertension	01FEB2019		Y
	C4591001 4444 44441981	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01SEP2014		Y
	C4591001 4444 44441987	Endocrine disorders	Hypothyroidism	01SEP2010		Y
	C4591001 4444 44441989	Metabolism and nutrition disorders	Dyslipidaemia	01MAR2018		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	01MAR2005	01MAR2006	N
	C4591001 4444 44441993	Hepatobiliary disorders	Cholelithiasis	23JUN2020		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	03MAR2010		Y
	C4591001 4444 44441998	Metabolism and nutrition disorders	Dyslipidaemia	25SEP2010		Y
	C4591001 4444 44441999	Vascular disorders	Varicose vein	01JAN2012		Y
	C4591001 4444 44442010	Endocrine disorders	Hypothyroidism	01JUN1990		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01MAR2015		Y
	C4591001 4444 44442012	Metabolism and nutrition disorders	Hypercholesterolaemia	01JUN2016		Y
		Psychiatric disorders	Depression	01MAY2015		Y
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 4444 44442020	Gastrointestinal disorders	Haemorrhoids	01JUL2012		Y
	C4591001 4444 44442023	Metabolism and nutrition disorders	Dyslipidaemia	10FEB2020		Y
			Hypercholesterolaemia	01FEB2020		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442027	Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2013	02JAN2018	N
		Surgical and medical procedures	Hip arthroplasty	01JAN2018	02JAN2018	N
				01SEP2013	02SEP2013	N
	C4591001 4444 44442031	Endocrine disorders	Hypothyroidism	01JUN2018		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JAN2005		Y
		Vascular disorders	Hypertension	01JAN2020		Y
	C4591001 4444 44442036	Vascular disorders	Hypertension	03JAN2012		Y
	C4591001 4444 44442038	Nervous system disorders	Encephalopathy	15JUL1977		Y
		Surgical and medical procedures	Cholecystectomy	17JAN2018	17JAN2018	N
	C4591001 4444 44442057	Ear and labyrinth disorders	Otosclerosis	01JUN1985		Y
		Nervous system disorders	Migraine	01MAY1980		Y
	C4591001 4444 44442061	Vascular disorders	Hypertension	04FEB2015		Y
	C4591001 4444 44442063	Gastrointestinal disorders	Lumbar hernia	06JUL2015	02DEC2019	N
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	06JUL2015	02DEC2019	N
		Nervous system disorders	Carotid artery occlusion	02SEP2000		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01DEC2016	10JUL2018	N
		Surgical and medical procedures	Prostatectomy	10JUL2018	11JUL2018	N
			Spinal fusion surgery	02DEC2019	02DEC2019	N
		Vascular disorders	Hypertension	02JUN1991		Y
	C4591001 4444 44442067	Metabolism and nutrition disorders	Type 2 diabetes mellitus	01MAR2018		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Surgical and medical procedures	Radiotherapy to prostate	01MAR2016	01OCT2016	N
		Vascular disorders	Hypertension	04SEP2009		Y
	C4591001 4444 44442075	Psychiatric disorders	Anxiety disorder	01SEP1998		Y
	C4591001 4444 44442076	Cardiac disorders	Arteriosclerosis coronary artery	01FEB2007		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01FEB2017		Y
			Obesity	05OCT2015		Y
			Type 2 diabetes mellitus	01FEB2015		Y
		Psychiatric disorders	Anxiety disorder	01JAN2010		Y
		Surgical and medical procedures	Coronary arterial stent insertion	01FEB2007		Y
		Vascular disorders	Hypertension	01JAN1984		Y
	C4591001 4444 44442078	Metabolism and nutrition disorders	Dyslipidaemia	01JUL2020	31AUG2020	N
	C4591001 4444 44442079	Hepatobiliary disorders	Cholelithiasis	07JAN2020	10JAN2020	N
		Surgical and medical procedures	Cholecystectomy	07JAN2020	07JAN2020	N
		Vascular disorders	Hypertension	07OCT2014		Y
	C4591001 4444 44442083	Vascular disorders	Hypertension	01SEP2017		Y
	C4591001 4444 44442089	Vascular disorders	Hypertension	06DEC2019		Y
	C4591001 4444 44442092	Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 4444 44442096	Metabolism and nutrition disorders	Type 2 diabetes mellitus	10SEP2012		Y
		Vascular disorders	Hypertension	07AUG2008		Y
	C4591001 4444 44442098	Infections and infestations	Appendicitis	28JUN1970	28JUN1970	N

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Fibroadenoma of breast	03JUL1976	03OCT1976	N
		Surgical and medical procedures	Appendicectomy	28JUN1970	30JUN1970	N
			Breast conserving surgery	03OCT1993	09OCT1993	N
			Rhinoplasty	05JUL1978	05JUL1978	N
	C4591001 4444 44442103	Eye disorders	Glaucoma	01JUN1985		Y
		Metabolism and nutrition disorders	Type 2 diabetes mellitus	01JUN2013		Y
		Psychiatric disorders	Alcoholism	01JUN1980	12NOV2002	N
			Major depression	01JUN2019		Y
		Vascular disorders	Hypertension	01JUN1980		Y
	C4591001 4444 44442111	Vascular disorders	Hypertension	02OCT2018		Y
	C4591001 4444 44442112	Psychiatric disorders	Anxiety disorder	08FEB2015		Y
	C4591001 4444 44442120	Congenital, familial and genetic disorders	Thalassaemia	01JAN1990		Y
		Gastrointestinal disorders	Gastritis	01JAN1996		Y
			Inguinal hernia	01MAR1997	04SEP2008	N
				03SEP2008	04SEP2008	N
		Injury, poisoning and procedural complications	Meniscus injury	15AUG1990	05SEP1990	N
		Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	01JUN1965	10JUL1965	N
		Surgical and medical procedures	Meniscus operation	01SEP1990	05SEP1990	N
			Tonsillectomy	07JUL1965	10JUL1965	N
	C4591001 4444 44442121	Reproductive system and breast disorders	Benign prostatic hyperplasia	10MAY2018		Y
		Vascular disorders	Hypertension	07FEB2000		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442126	Endocrine disorders	Hypothyroidism	16SEP2015		Y
		Eye disorders	Cataract	10DEC2019	12FEB2020	N
		Surgical and medical procedures	Cataract operation	12FEB2020	12FEB2020	N
		Vascular disorders	Hypertension	09SEP2015		Y
	C4591001 4444 44442127	Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2019		Y
	C4591001 4444 44442128	Gastrointestinal disorders	Gastroesophageal reflux disease	01SEP2015		Y
		Hepatobiliary disorders	Non-alcoholic steatohepatitis	02SEP2003		Y
		Metabolism and nutrition disorders	Insulin resistance	01SEP2010		Y
		Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	01JAN2002		Y
		Vascular disorders	Hypertension	01SEP2003		Y
	C4591001 4444 44442130	Endocrine disorders	Hypothyroidism	01JAN2005		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2015		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01JAN2014		Y
	C4591001 4444 44442134	Metabolism and nutrition disorders	Obesity	01JAN2018		Y
		Musculoskeletal and connective tissue disorders	Osteopenia	01AUG2019		Y
		Psychiatric disorders	Anxiety	01JUN2001		Y
	C4591001 4444 44442136	Infections and infestations	Hepatitis A	01JUN1968	16JUN1968	N
	C4591001 4444 44442137	Endocrine disorders	Hypothyroidism	08SEP1979		Y
		Vascular disorders	Peripheral venous disease	01JAN2004		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442139	Vascular disorders	Hypertension	02APR2018		Y
	C4591001 4444 44442141	Metabolism and nutrition disorders	Hypercholesterolaemia	03MAY2019		Y
	C4591001 4444 44442143	Endocrine disorders	Hypothyroidism	05JUL2000		Y
		Psychiatric disorders	Insomnia	01JAN2010		Y
		Surgical and medical procedures	Lipectomy	02OCT1995	02OCT1995	N
			Metabolic surgery	09JAN2019	09JAN2019	N
	C4591001 4444 44442145	Cardiac disorders	Sinus tachycardia	01SEP2010		Y
	C4591001 4444 44442150	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neurilemmoma benign	01SEP2015	01OCT2015	N
		Surgical and medical procedures	Nervous system neoplasm surgery	01OCT2015	01OCT2015	N
		Vascular disorders	Hypertension	01JUN2012		Y
	C4591001 4444 44442153	Hepatobiliary disorders	Cholelithiasis	29OCT2019	20JAN2020	N
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2000		Y
		Musculoskeletal and connective tissue disorders	Lumbar spinal stenosis	01JAN1990	21MAR2015	N
		Vascular disorders	Hypertension	01JUN2000		Y
	C4591001 4444 44442164	Endocrine disorders	Hypothyroidism	01JAN2010		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
			Type 2 diabetes mellitus	01JAN2012		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	01JAN2004	01JAN2010	N
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 4444 44442166	Gastrointestinal disorders	Gastrooesophageal reflux disease	05JUL2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Musculoskeletal and connective tissue disorders	Osteopenia	12MAR2018		Y
		Vascular disorders	Hypertension	13MAY2000		Y
	C4591001 4444 44442169	Musculoskeletal and connective tissue disorders	Osteoarthritis	10AUG2015		Y
			Osteoporosis	10SEP2019		Y
	C4591001 4444 44442175	Gastrointestinal disorders	Inguinal hernia	10SEP1992	23SEP1992	N
		Infections and infestations	Hepatitis A	03SEP1982	23SEP1982	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01SEP2015		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of testis	16SEP1993	16DEC1993	N
		Reproductive system and breast disorders	Benign prostatic hyperplasia	03SEP2015		Y
		Surgical and medical procedures	Implantable defibrillator insertion	11SEP2014		Y
			Inguinal hernia repair	23SEP1992	26SEP1992	N
			Orchidectomy	16DEC1993	18DEC1993	N
	C4591001 4444 44442176	Musculoskeletal and connective tissue disorders	Back pain	19AUG2020	24AUG2020	N
		Surgical and medical procedures	Salpingo-oophorectomy unilateral	01MAR2001	01MAR2001	N
	C4591001 4444 44442179	Metabolism and nutrition disorders	Hypercholesterolaemia	25SEP2018		Y
		Vascular disorders	Hypertension	25SEP2018		Y
	C4591001 4444 44442183	Gastrointestinal disorders	Hiatus hernia	17OCT2010		Y
		Metabolism and nutrition disorders	Hypercholesterolaemia	07MAR2018		Y
	C4591001 4444 44442184	Endocrine disorders	Hypothyroidism	01JUN1977		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01JUN2019		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442187	Gastrointestinal disorders	Inguinal hernia	30SEP2015	01OCT2015	N
		Metabolism and nutrition disorders	Dyslipidaemia	25SEP2004		Y
		Surgical and medical procedures	Cholecystectomy	30SEP2015	01OCT2015	N
		Vascular disorders	Hypertension	27SEP2005		Y
			Infarction	16SEP2008	18SEP2008	N
	C4591001 4444 44442191	Metabolism and nutrition disorders	Dyslipidaemia	01JUN2000		Y
		Vascular disorders	Hypertension	01JUN2016		Y
	C4591001 4444 44442192	Metabolism and nutrition disorders	Dyslipidaemia	03JUN2013		Y
		Vascular disorders	Obesity	01JAN2015		Y
		Vascular disorders	Varicose vein	03MAY2007		Y
	C4591001 4444 44442204	Endocrine disorders	Hypothyroidism	01JUN2000		Y
		Respiratory, thoracic and mediastinal disorders	Asthma	11OCT1990		Y
	C4591001 4444 44442206	Metabolism and nutrition disorders	Obesity	01MAR2010		Y
		Musculoskeletal and connective tissue disorders	Osteoarthritis	01SEP2015		Y
			Spinal osteoarthritis	01SEP2015		Y
		Psychiatric disorders	Depression	01SEP2000		Y
	C4591001 4444 44442207	Gastrointestinal disorders	Hiatus hernia	05MAY2018		Y
		Nervous system disorders	Carpal tunnel syndrome	01JAN2018	31DEC2019	N
				01MAR2020		Y
		Surgical and medical procedures	Aneurysm repair	03MAY2011	03MAY2011	N
		Vascular disorders	Hypertension	04MAY1993		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442208	Gastrointestinal disorders	Irritable bowel syndrome	01MAY2010		Y
		Vascular disorders	Hypertension	01MAR2005		Y
	C4591001 4444 44442223	Hepatobiliary disorders	Cholelithiasis	01JUL2005	01SEP2005	N
		Injury, poisoning and procedural complications	Foot fracture	01APR2015	01APR2015	N
		Social circumstances	Tobacco user	01MAR1980		Y
		Surgical and medical procedures	Cholecystectomy	01SEP2005	01SEP2005	N
			Internal fixation of fracture	01APR2015	01APR2015	N
	C4591001 4444 44442225	Metabolism and nutrition disorders	Hypercholesterolaemia	01MAR2020		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01MAR2016	01MAR2018	N
		Vascular disorders	Hypertension	10MAY2017		Y
	C4591001 4444 44442228	Metabolism and nutrition disorders	Dyslipidaemia	01JAN2010		Y
		Vascular disorders	Hypertension	01MAY2005		Y
	C4591001 4444 44442239	Infections and infestations	Bronchitis	21SEP2017	30SEP2017	N
		Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	21SEP2017		Y
	C4591001 4444 44442240	Cardiac disorders	Arrhythmia	01DEC2001		Y
		Metabolism and nutrition disorders	Dyslipidaemia	01DEC2005		Y
		Vascular disorders	Hypertension	01MAR1996		Y
	C4591001 4444 44442243	Endocrine disorders	Hypothyroidism	15AUG2017		Y
	C4591001 4444 44442246	Reproductive system and breast disorders	Benign prostatic hyperplasia	01NOV2018		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Vascular disorders	Hypertension	01JAN2005		Y
	C4591001 4444 44442247	Cardiac disorders	Arrhythmia	16MAR2017	16NOV2018	N
		Ear and labyrinth disorders	Deafness bilateral	15MAY1998		Y
			Otosclerosis	10MAY1996		Y
		Endocrine disorders	Hypothyroidism	16JUN2017		Y
		Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	01DEC2012	28DEC2013	N
		Nervous system disorders	Tension headache	09AUG2019		Y
			Transient ischaemic attack	10JUL2013	17AUG2013	N
		Surgical and medical procedures	Hysterectomy	07JAN2013	07JAN2013	N
				28DEC2013	28DEC2013	N
		Vascular disorders	Hypertension	11JUL2013		Y
	C4591001 4444 44442259	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	03MAR2016	02AUG2016	N
		Surgical and medical procedures	Exeresis	09AUG2016	09AUG2016	N
	C4591001 4444 44442264	Metabolism and nutrition disorders	Obesity	06JUN2018		Y
	C4591001 4444 44442266	Respiratory, thoracic and mediastinal disorders	Asthma	01SEP2018		Y
		Vascular disorders	Hypertension	01SEP2010		Y
	C4591001 4444 44442267	Eye disorders	Cataract	01JUN2016	15DEC2020	N
	C4591001 4444 44442272	Congenital, familial and genetic disorders	Hereditary spherocytosis	20SEP2011		Y
		Gastrointestinal disorders	Gastrooesophageal reflux disease	30OCT2007		Y
			Hiatus hernia	03SEP2007		Y
		Metabolism and nutrition disorders	Dyslipidaemia	07JAN2013		Y
		Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	01MAY2010		Y



### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
		Psychiatric disorders	Insomnia	01APR2020		Y
		Respiratory, thoracic and mediastinal disorders	Cough	30OCT2007		Y
		Skin and subcutaneous tissue disorders	Lichen sclerosus	03OCT2014		Y
		Vascular disorders	Hypertension	01SEP2006		Y
	C4591001 4444 44442276	Endocrine disorders	Hypothyroidism	01SEP2010		Y
	C4591001 4444 44442282	Metabolism and nutrition disorders	Type 1 diabetes mellitus	01JUN1990		Y
	C4591001 4444 44442289	Reproductive system and breast disorders	Benign prostatic hyperplasia	01JUN2019		Y
	C4591001 4444 44442290	Cardiac disorders	Acute myocardial infarction	16AUG2010	16AUG2010	N
		Metabolism and nutrition disorders	Hypercholesterolaemia	01JAN2010		Y
		Musculoskeletal and connective tissue disorders	Arthralgia	01JAN2018		Y
		Reproductive system and breast disorders	Benign prostatic hyperplasia	01JAN2016		Y
		Vascular disorders	Hypertension	01JAN2010		Y
	C4591001 4444 44442295	Cardiac disorders	Atrial tachycardia	04SEP2015		Y
		Infections and infestations	Hepatitis B	26FEB2020	26FEB2020	N
	C4591001 4444 44442296	Renal and urinary disorders	Urinary bladder polyp	01JUN2013	06JUN2013	N
		Surgical and medical procedures	Bladder polypectomy	06JUN2013	06JUN2013	N
		Vascular disorders	Hypertension	01JUL2010		Y
	C4591001 4444 44442302	Metabolism and nutrition disorders	Metabolic syndrome	04AUG2015		Y
			Obesity	01JAN1995		Y
		Vascular disorders	Hypertension	01SEP2015		Y

### 16.2.5.4 Listing of Medical History – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	System Organ Class	Preferred Term	Start Date	End Date	Ongoing (Yes/No)
	C4591001 4444 44442309	Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	23MAR2018		Y
	C4591001 4444 44442320	Metabolism and nutrition disorders	Obesity	20FEB2010		Y

Note: MedDRA (v23.1) coding dictionary applied.

Note: † = Human immunodeficiency virus (HIV)-positive subject, ^ = Phase 1 subjects.

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